Study on the deployment of AI in healthcare

Final report

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1 Abstract

Present day healthcare systems face several complex challenges, including rising demand due to an aging population, increasing prevalence of chronic and complex conditions, rising costs, and shortages in the healthcare workforce. Artificial intelligence (AI) has the potential to address some of these by improving operational efficiency, reducing administrative burdens, and enhancing diagnosis and treatment pathways. Despite the promise and availability AI-based tools in the market, their deployment in clinical practice is slow.

Using a mixed methods approach, entailing a literature review and consultation activities, the study identifies a range of challenges to AI deployment in healthcare, spanning technological and data-related issues, legal and regulatory complexities, organisational and business challenges, and social and cultural barriers. It also highlights successful strategies (accelerators) employed by hospitals globally to overcome these common obstacles, offering valuable inspiration in the broader European Union (EU) context.

The EU is uniquely positioned to support the safe, effective, ethical and equitable scale-up of AI deployment in healthcare, balancing the need to nurture innovation with safeguarding the fundamental rights of patients. This report presents considerations for future action and proposes a monitoring and indicators framework that could enable progress to be tracked with the view of enabling the sustainable integration of AI into healthcare systems.

Abstrakt

Die heutigen Gesundheitssysteme stehen vor mehrerlei komplexen Herausforderungen, darunter die steigende Nachfrage aufgrund einer alternden Bevölkerung, die zunehmende Prävalenz chronischer und komplexer Erkrankungen, steigende Kosten und ein Mangel an Arbeitskräften im Gesundheitswesen. Künstliche Intelligenz (KI) hat das Potenzial, einige dieser Herausforderungen zu bewältigen, unter anderem durch die Verbesserung operativer Effizienz, die Einschränkung von Verwaltungslasten und die Fortentwicklung von Diagnosen- und Behandlungswegen. Trotz des vielversprechenden Potenzials und der Verfügbarkeit von KI-basierten Instrumenten auf dem Markt erfolgt der Einsatz von KI in der klinischen Praxis nur langsam.

Diese Studie stellt, anhand von einer Mischung aus Literaturrecherche und Konsultationstätigkeiten, eine Reihe von Herausforderungen für den Einsatz von KI im Gesundheitswesen dar. Diese Herausforderung umfassen, unter anderem, technologische und datenbezogene Aspekte, rechtliche und regulatorische Komplexität, organisatorische und geschäftliche Herausforderungen sowie soziale und kulturelle Barrieren. Darüber hinaus hebt die Studie erfolgreiche Strategien (Beschleuniger) hervor, die von Krankenhäusern weltweit eingesetzt werden, um diese Hindernisse zu überwinden, und die im breiteren Kontext der Europäischen Union (EU) wertvolle Inspiration anbieten.

Die EU ist in einer einzigartigen Position, um die sichere, wirksame, ethische und gerechte Einsatzverbreitung von KI im Gesundheitswesen zu unterstützen und dabei ein Gleichgewicht zwischen der Notwendigkeit, Innovationen zu fördern, und gleichermaßen das Grundrecht der Patienten zu schützen. Diese Studie liegt Überlegungen für künftige Maßnahmen hervor, sowohl auch als ein Überwachungs- und Indikatorrahmen, der es ermöglichen könnte, die Fortschritte zu verfolgen, um die nachhaltige Integration von KI in die Gesundheitssysteme zu ermöglichen.

Résumé

Les systèmes de santé en place sont confrontés à des défis complexes, parmi lesquels, l'augmentation de la demande de soins due au vieillissement de la population, la prévalence croissante des maladies chroniques et complexes, l'augmentation des coûts et la pénurie de main-d'œuvre dans le secteur des soins de santé. L'intelligence artificielle (IA) a le potentiel de répondre à certains de ces défis en améliorant l'efficacité opérationnelle, en réduisant les charges administratives et en améliorant les parcours de diagnostic et de traitement. Malgré les promesses et la disponibilité sur le marché d'outils basés sur l'IA, leur déploiement dans la pratique clinique est lent.

À l'aide d'une approche méthodologique mixte, composée d'une analyse documentaire et d'activités de consultation, l'étude identifie une série de défis liés au déploiement de l'IA dans les soins de santé, couvrant les questions technologiques, les questions liées aux données, les complexités juridiques et réglementaires, les défis organisationnels et commerciaux, et les barrières sociales et culturelles. L'étude met également en évidence les stratégies efficaces (accélérateurs) employées par les hôpitaux du monde entier pour surmonter ces obstacles communs, offrant ainsi une inspiration précieuse dans le contexte plus large de l'Union européenne (UE).

L'UE est particulièrement bien placée pour soutenir l'expansion sécurisée, efficace, éthique et équitable du déploiement de l'IA dans les soins de santé, en conciliant la nécessité de favoriser l'innovation et la sauvegarde des droits fondamentaux des patients. Ce rapport présente des considérations pour l'action future et propose un cadre de suivi et d'indicateurs susceptibles de permettre un suivi des progrès réalisés, en vue d'une possible intégration durable de l'IA dans les systèmes de soins de santé.

2 Introduction

It is widely accepted that European healthcare systems are currently grappling with significant challenges, raising concern over their long-term sustainability. The proportion of the population aged 65 and above has increased from 16% in 2000 to over 21% in 2023, with projections indicating a further rise to nearly 30% by 2050. Coupled with the consideration that 40% of EU citizens aged 65 and above live with at least two chronic conditions – this demographic shift is likely to translate into increasing demand for healthcare services[1]. The World Health Organisation (WHO) projects that the EU will experience a shortage of 4.1 million healthcare workers by 2030[2], translating into a constrained supply of healthcare. In addition to the abovementioned hurdles, inequalities in healthcare between EU countries and within EU countries persist with an estimated cost of 980 billion per year as a result of lower productivity and higher healthcare and welfare costs[3]. Innovative solutions are needed in order to improve healthcare delivery, optimise resource allocation, and enhance patient outcomes[4].

Artificial Intelligence (AI) has emerged as a promising tool to help address such challenges. An AI system, as defined in the EU AIA, refers to a machine-based system that is designed to operate with varying levels of autonomy and that may exhibit adaptiveness after deployment, and that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments[5]. It has the potential to transform various aspects of healthcare, from early diagnosis and personalised treatment plans to operational efficiencies and administrative support. AI applications may analyse vast amounts of data, speed up processes, and offer insights that could enhance clinical decision-making and streamline routine tasks, potentially helping healthcare systems manage resources more effectively and meet the needs of diverse patient populations. Despite the potential of AI solutions, there are various challenges and barriers hindering the effective deployment of AI tools in healthcare in the EU. Such challenges and barriers highlight the importance of a structured approach to AI deployment, addressing technological, social, legal, and organisational challenges.

The objective of the study was to identify the current and future needs in clinical practice that AI could address, the potential of AI to transform healthcare (with a particular focus on cancer and delivery of healthcare in remote areas) and assess the most prominent sector-specific challenges and accelerators, both present today as well as the ones that may emerge in the future, for the successful deployment of AI in healthcare. The study aimed to provide recommendations on how these gaps can be addressed, drawing inspiration from all EU 27 Member States and relevant third countries where the deployment of AI in healthcare is advanced, such as the USA, Israel and Japan.

3 Methodology

The methodological approach for this study on the deployment of AI in healthcare adopted a comprehensive and mixed-methods framework across several tasks to ensure a nuanced

1 OECD (2024) Health at a Glance: Europe 2024
2 Zapata T, Muscat N.A *et al* (2023) From Great Attrition to Great Attraction: Countering the Great Resignation of Health and Care Workers.
3 Forster T, Kentikelenis A *et al* (2018) Health Inequalities in Europe: Setting the Stage for Progressive Policy Action
4 EIT Health (2020) Transforming Healthcare with AI – The Impact on the Workforce and Organisations.
5 Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act)

and multi-dimensional analysis. A detailed description of the methodological approach across each of the tasks is described in the following sections.

3.1 Task 1: Literature review

Task 1 aimed to review existing literature on the deployment of AI in healthcare, identifying key challenges, barriers, and best practices. This process involved a structured search and screening strategy to ensure the inclusion of the most relevant and up-to-date sources for further analysis. As a first step, a **literature review** was conducted on the 3rd of June 2024 using multiple databases, including Google Scholar, PubMed, and Web of Science. The search aimed to identify relevant publications on the deployment of AI in healthcare, using the search terms described in Box 1.

Box 1: Search terms for the literature review

("artificial intelligence" OR "machine learning" OR "AI" OR "deep learning" OR "neural networks" OR "natural language processing" OR "language models" OR "chatbot") **AND** ("deploy*" OR "adopt*" OR "application*" OR "use") **AND** ("healthcare" OR "clinical practice" OR "hospital") **AND** ("challenge*" OR "barrier*" OR "obstacle*" OR "issue*" OR "best practice*" OR "success").

Source: Authors' elaboration

A total of 14,407 articles were retrieved. To refine the results and ensure only the most relevant literature were further analysed, the inclusion and exclusion criteria outlined in Table 1 were applied.

Table 1: Inclusion and exclusion criteria for literature review.

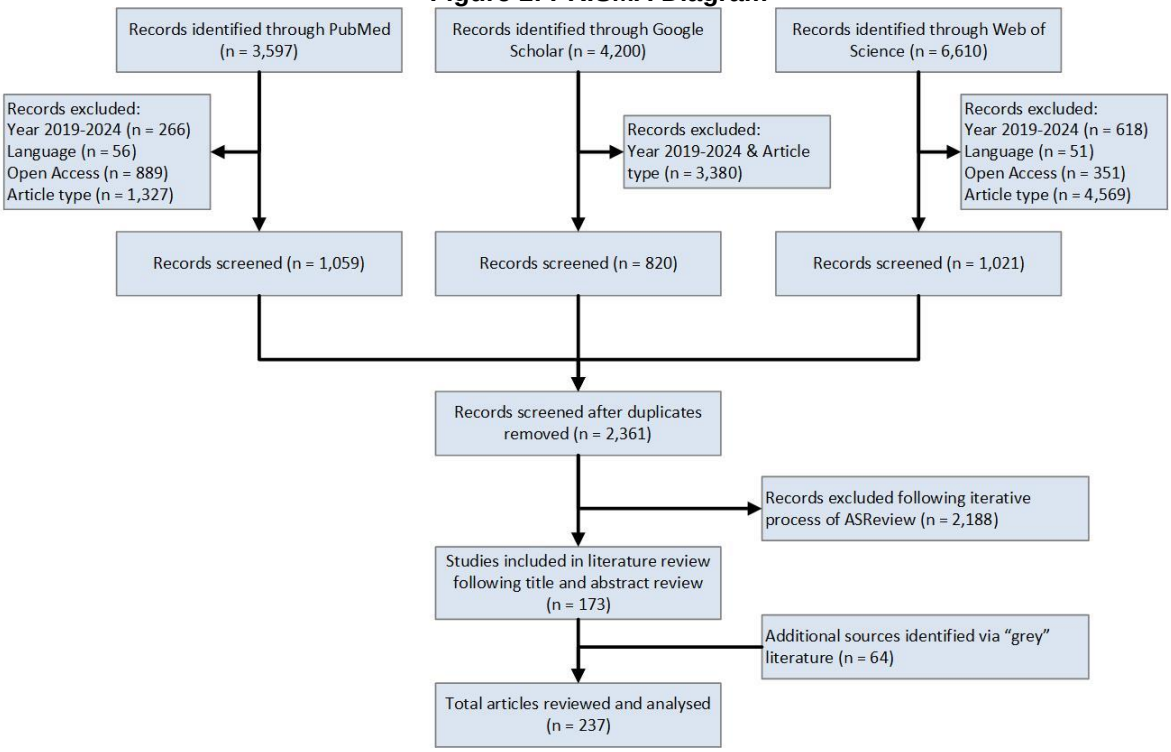
Criteria	Inclusion	Exclusion	Rationale
Type of publication	Review, Systematic review	Any other article type	Review articles provide a comprehensive summary of existing research, highlighting key concepts, findings, and gaps.
Publication year	Articles published between January 2019 and June 2024	Articles published prior to 2019	To ensure the validity of the content and gather information on the most recent and relevant challenges, barriers, and accelerators.
Language	English language	Any language other than English	English is the official language of research articles.
Accessibility	Open access, freely available	Articles behind a paywall	Searching for open access or freely available literature will ensure that the proposed methodology can be replicated in the future without any access issues.

Source: Author's elaboration

To further refine the search results, the titles and abstracts of the remaining articles were manually reviewed. This process was supported by the machine-learning software ASReview, which works by employing active learning by iteratively selecting the most informative documents for human review. This process helped prioritise documents that were most likely relevant to the research question, and reduced the time and effort required for manual screening.

To complement the review of academic and scientific literature, relevant "grey" literature sources[6] were identified via a traditional web search in Google using the possible combinations of keywords described above. We focused on sources published in the last 5 years (2019-2024) in consideration of recent technological advancements and the changing regulatory landscape to capture the most up-to-date perspective. The screening process is detailed in Figure 1.

Figure 1: PRISMA Diagram



Source: Author's elaboration

Following the screening process, information from the 237 sources was collected in a data extraction sheet structured along the study questions to ensure all relevant information were captured in a consistent and comparable manner. Between June 2024 and November 2024, additional relevant literature was identified, with 119 more sources reviewed and incorporated into the analysis, bringing the total number of sources to 356.

3.2 Task 2: Consultation Activities

Task 2 aimed to gather in-depth insights from stakeholders through exploratory interviews, targeted interviews, surveys, workshops, and case studies.

3.2.1 Exploratory interviews and workshop

Prior to conducting the literature review initial exploratory consultation activities were conducted with key stakeholders. The aim of these exploratory interviews was to improve the understanding of the study questions and context, to identify additional data sources and information, and to refine the methodological approach of the study. These activities formed an important complement to the desk research in recognition that the deployment

6 Grey literature is information produced outside of traditional publishing and distribution channels, and can include reports, policy literature, working papers, newsletters, government documents, speeches, white papers.

of AI in healthcare is a rapidly evolving topic, and as such many more recent and important concepts/accelerators/challenges may not be found in the published literature.

Three **exploratory interviews** were conducted between the 14th of March and the 9th of April with relevant stakeholders from Europe, the USA and Israel, covering the geographic scope of the study. The stakeholders were agreed upon with DG SANTE and included a hospital representative from Sweden, an Academic researcher in Medical AI from the USA and a hospital representative from Israel, all of which have deployed AI solutions in healthcare. In addition to the exploratory interviews, an **exploratory workshop** was held on the 29th of April 2024 with the overall objective to identify the sector specific challenges as well as accelerators for the effective and efficient deployment of AI in healthcare and clinical practice. The workshop focused on several key areas, including the current and future needs in healthcare that AI could address, areas with the greatest potential for AI transformation, discussion of the challenges to AI deployment, and identifying accelerators for effective AI integration. The workshop was attended by 11 stakeholders, all of which were from the EU, from a range of stakeholder categories, namely Healthcare Professionals, Patients, Regulatory Experts and AI Developers (See Table 2).

Table 2: Exploratory Workshop Stakeholders

Stakeholder Group	Description
Healthcare Professionals	Two EU-level Associations
Patients	Two EU-level Associations
Regulatory Experts	One EU level Industry Association
AI Developers	Three EU level Industry Associations

Source: Author's elaboration

3.2.2 Stakeholder Mapping

For this study, five key stakeholder groups were identified, and a tailored approach was taken to ensure that the insights extracted from each stakeholder group are tailored both to their unique expertise and experiences as illustrated below:

Patients and patient associations[7] - to gather information on the level of digital health literacy amongst patients and patient associations, the level of comfort in AI solutions being used in their care, the perceived impact of AI tools in healthcare, their concerns of AI being used in their care, and actions that could improve their digital health literacy and would make them more comfortable with AI being used in their care.

Healthcare professionals (HCP) and healthcare professional associations[8] **-** to gather information on the level of digital health literacy amongst HCP and HCP associations, the needs in healthcare that could be addressed by AI in the short term and long term, the perceived impact of AI tools in healthcare, the areas where AI tools are expected to have the most transformative potential, the AI tools they use, the challenges affecting the deployment of AI tools, any good practices to ensure the effective deployment of AI and improving digital health literacy, their level of knowledge on the EU AI Act, and any complementary actions that could facilitate the deployment process.

7 EU wide, national, and international patient associations across different medical conditions.
8 EU wide, national, and international HCP associations across different medical specialties.

Hospital representatives and hospital representative associations[9] - to gather information on the needs in healthcare that could be addressed by AI in the short term and long term, the perceived impact of AI tools in healthcare, the areas and medical specialties where AI tools are expected to have the most transformative potential, the AI tools currently deployed within their hospital, the challenges affecting the deployment of AI tools, any good practices they employed to ensure the effective deployment of AI, the impact of the regulatory landscape, and any complementary actions that could facilitate the deployment process.

AI developers and researchers and AI developer associations[10] - to gather information on the needs in healthcare that could be addressed by AI in the short term and long term, the areas where AI tools are expected to have the most transformative potential, the tools they develop and deploy and reasons for not deploying AI tools they have developed, the challenges affecting the deployment of AI tools, any good practices they employed to ensure the effective deployment of AI and the transferability of these good practices, and the impact of the regulatory landscape.

AI regulatory experts[11] - to gather information on the impact of the regulatory landscape including the EU AI Act (AIA), the Product Liability Directive (PLD), the European Health Data Space (EHDS), the Medical Devices Regulation (MDR) and the *In-Vitro* Diagnostic Medical Device Regulation (IVDR), the General Data Protection Regulation (GDPR), the Health Technology Assessment (HTA) Regulation on the deployment of AI in healthcare.

The organisation of consultation activities across stakeholder groups was based on their operational proximity to the AI deployment process, aiming to provide granular insights into the accelerators and challenges of AI deployment (
Table 3).

Table 3: The organisation of the consultation activities across the stakeholder groups

Stakeholder Group	Targeted Survey	Targeted Interview	Workshops[12]	Case Studies
Patient and Patient Representatives	X		X	
Healthcare Professionals	X	X	X	X
Hospital Representatives	X	X	X	X
AI Developers and Researchers	X	X	X	X
AI Regulatory Experts	X		X	

9 Hospital representatives include the decision makers within hospitals (e.g., Chief Information Officers (CIO), Chief Executive Officers (CEO), AI officers) and EU wide, national, and international hospital representative associations.
10 EU wide and international associations representing AI developers, and developers of AI solutions based in the EU and internationally.
11 Individuals that have published work on the impact of the regulatory landscape on AI in healthcare.
12 Exploratory Workshop, Regulatory Workshop and Workshop on the AI Deployment Journey

Source: Author's elaboration

3.2.3 Surveys

3.2.3.1 Survey design and distribution

The information collected from the literature review and exploratory activities informed the design of the surveys. This approach ensured that the questions within the survey were targeted and precise, allowing the survey respondents to indicate specific challenges and accelerators, allowing for actionable insights.

To complement this information, **five separate surveys** were developed, one for each of the following stakeholder groups: Hospital representatives; healthcare professionals; AI developers/researchers; Patients; and AI regulatory experts. The surveys were then coded into the EUSurvey platform and initially launched in English on June 10, 2024. Translated versions for the surveys for healthcare professionals, hospital representatives, and patients, available in all EU languages, followed on July 3, 2024. The survey closed on the 25th September 2025[13].

A total of 1,224 stakeholders were invited to participate directly in the survey (See Table 4)[14]. In addition, several relevant EU and international networks/associations distributed the surveys to their members. The table below presents the distribution of stakeholders contacted across the stakeholder groups in addition to the response rate achieved.

Table 4: Distribution of surveys across the five stakeholder groups

Stakeholder category	EU associations	National associations	Individuals	Stakeholders initially contacted	Total responded
Healthcare professionals	28	102	112	**242**	**83**
Hospital representatives	5	49	253	**307**	**35**
AI developers	9	34	392	**435**	**36**
Patients and patient representatives	55	80	0	**135**	**70**
EU regulatory experts	0	0	105	**105**	**14**
TOTAL	**97**	**265**	**862**	**1,224**	**238**

Source: Author's elaboration

The distribution of stakeholders that responded to the survey based upon whether they were based within the EU or outside of the EU (International) is presented in the figure below. When considering all stakeholder groups together, we received at least one response per Member State (with the exception of Slovakia). The most responses were received from the Netherlands (27), Latvia (21) and Spain (15).

13 It should be noted that the survey was conducted at a time where the final texts for EHDS (Jan 2025), new PLD (Oct 2024) were not yet adopted. The final text for AIA was only adopted 4-months prior to the workshop (May 2024)

14 We had initially proposed to invite at least 175 stakeholders to participate in the targeted surveys.

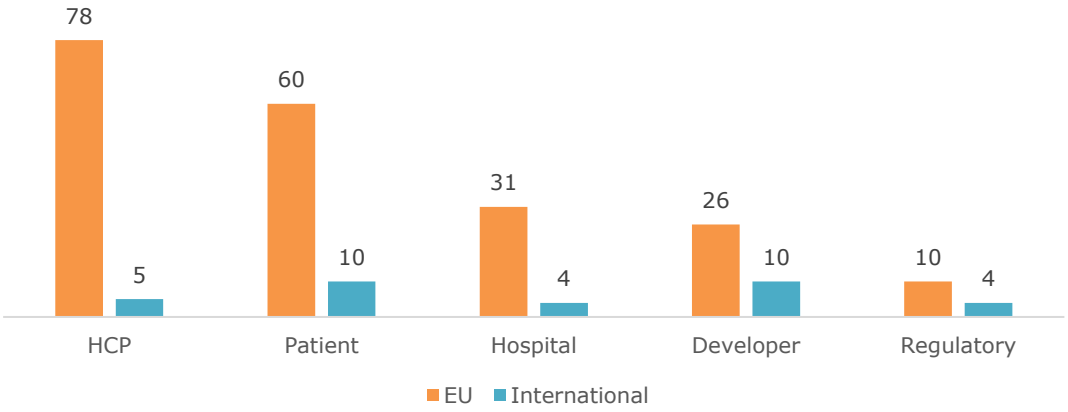


Figure 2: Geographical distribution of survey responses

Healthcare professionals and patients received different sets of questions according to their self-attributed level of awareness of AI (presented in the figure below). The surveys for patients and HCPs were organised so that participants with no, basic or solid knowledge were able to contribute through a distinct set of questions to those with solid and advanced knowledge who received more specific, granular and targeted surveys, presented in the Annex.

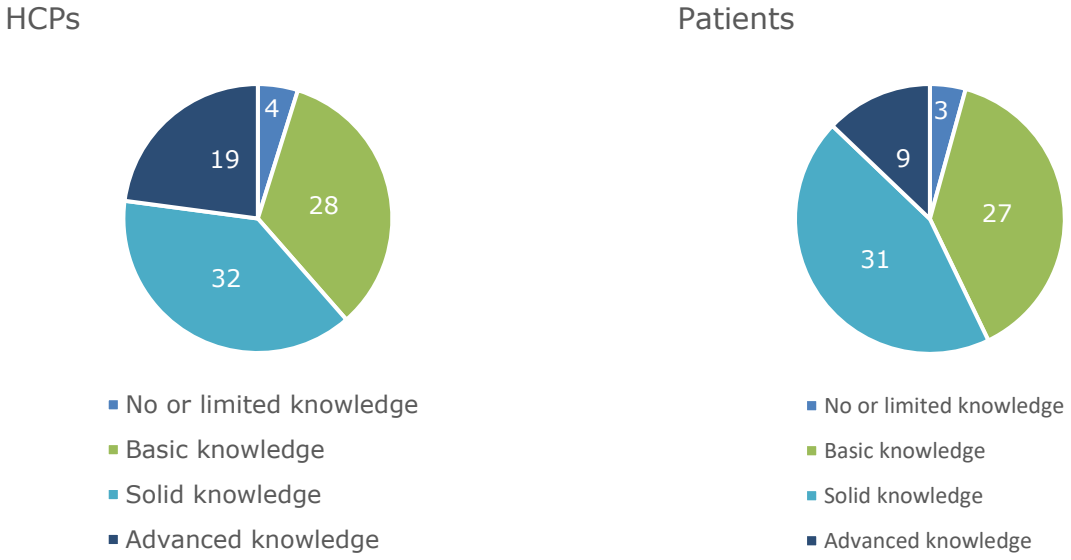


Figure 3: Self-reported level of knowledge for HCPs and Patients Survey

3.2.3.2 Survey analysis:

A total of 16 survey responses were excluded for the following reasons:

- 5 duplicate responses (1 in the hospital representative survey and 4 in the HCP survey). The most recent contribution from the respective stakeholders was included in the analysis.
- 11 responses due to geographic location

The cleaned and structured dataset was then subjected to quantitative and qualitative analysis. The specific analytical approach was determined according to the specific questions and the quantity/quality of the data collected. Quantitative analysis was conducted in Excel. For qualitative data analysis, in-house AI tools specifically designed

for qualitative data analysis, employing natural language processing techniques to extract meaningful insights from a diverse range of textual data (free text responses) were used. These tools enabled the identification of recurring themes, sentiments, and patterns within the qualitative data, providing a nuanced understanding of respondents' perspectives.

3.2.4 Interviews

A total of 26 **targeted interviews** were conducted with healthcare professionals, hospital representatives and AI developers within Europe (11 interviews) and regions outside of Europe (15 interviews). The interviews aimed to gather insights on the recent and expected future developments to the deployment of AI in clinical practice, the specific challenges affecting this deployment as well as good practices used to overcome the challenges, and considerations for future actions that may facilitate the deployment of AI in clinical practice. As one of the aims of the targeted interviews was to identify good practices to overcome the challenges affecting the deployment of AI in healthcare, the majority of stakeholders interviewed (57.7%) were from regions outside of the EU (international) where AI deployment could be considered advanced.

The content of the interview guides was informed by the literature review and the exploratory consultations (interviews and workshop) and was tailored towards the stakeholder expertise. The qualitative findings from the interviews were grouped into thematic areas according to converging and diverging perspectives presented. The table below shows an overview of the stakeholder distribution according to geographical location and type.

Table 5: Overview of the stakeholder distribution according to geographical location and type

Country	AI Developer	Hospital Rep/HCP
Austria		1
Belgium		1
Denmark		2
Germany	1	
Italy		2
Netherlands	1	1
Spain		1
EU level association		1
Total EU-level	2	9
Japan	1	1
South Korea		1
United Kingdom		4
United States of America	3	5
Total International	4	11
Total Interviewees	6	20

Source: Author's elaboration

3.2.5 Workshops (regulatory and hospital)

Two **workshops** were organised with relevant stakeholders to discuss specific themes in detail. The first workshop, held on July 17, 2024, titled "**EU Regulatory Environment**," aimed at evaluating the extent to which existing EU legal frameworks, including horizontal AI proposals and sector-specific regulations such as the AIA, PLD), MDR, and IVDR, address challenges and barriers affecting the deployment of AI in clinical practice[15]. Participants, consisting of six academic EU regulatory experts, discussed potential gaps in

15 It should be noted that the workshop was conducted at a time where the final texts for EHDS (Jan 2025), new PLD (Oct 2024) were not yet adopted. The final text for AIA was only adopted 2-months prior to the workshop (May 2024)

these regulations and identified complementary actions that may facilitate AI integration in clinical settings.

The second workshop, titled "**The AI Deployment Journey**," was held on September 23, 2024. This workshop was attended by six participants, primarily hospital representatives and healthcare professionals from the USA (3 participants), Israel (2 participants) and Europe (1 participant), who shared their hospital's experiences regarding the challenges, barriers, and accelerators associated with AI deployment in healthcare. The workshop emphasised perspectives from participants across different regions to allow for a "compare and contrast" approach, particularly examining the challenges unique to regional healthcare systems.

3.2.6 Case studies

To complement the findings from the literature review and the consultation activities, **four, in-depth case studies** were conducted to analyse AI tools deployed in clinical practice across different medical specialities, geographic areas, and applications. The objective of these case studies was to collect first-hand information from key relevant stakeholders on their experience with the deployment of a specific AI tool in clinical practice, the challenges and barriers experienced, how these challenges and barriers may differ across different regions, any good practices to address the described barriers, and the overall impact of the tool so far. When selecting AI tools for further analysis, we ensured that the criteria described below were fulfilled.

Criterion	Description
Medical specialty	We ensured that the following criteria are covered: • Oncology • General Hospital (covering administrative processes) And two of the following: • Cardiology • Anaesthesiology • Neurology
Type of application	We ensured that we have one case study addressing each of the following applications: • Administrative processes (e.g., Large Language Models, Natural Language Processing for clinical documentation, chatbots) • Triage • Diagnostic tools • Treatment and monitoring tools
Healthcare settings	We ensured that at least one of the AI tools selected covers the following: • Urban healthcare settings • Rural healthcare setting
Geographic region	We ensured each case study focuses on an AI tool developed in the EU, USA, Israel and Japan
Company size	We ensured that the AI tools selected are developed by both: • Large enterprises • Small-Medium enterprises (SMEs)
Approval pathway	We ensured that at least three of the four AI tools selected have regulatory approval between January 2021 and June 2023 by: • European Conformity (CE) Marking • FDA approval • Both

In line with the above-mentioned selection criteria, we conducted four case studies on the AI-based tools described in the table below.

Table 6: Selection of AI-based tools for case studies.

Case Study Name	Medical Speciality	Country Developed	Company Size	Regulatory approval pathway	Application	Health Setting
Cardiology - Triage	Cardiology	Israel	Large	Both	Triage	Rural, Urban
Administrative - Clinical Documentation	General Hospital	USA	Large	N/A	Administrative processes	Rural, Urban
Radiology - Diagnosis	Radiology	Japan	Large	N/A	Diagnostic purposes	Urban, Rural
Oncology - Treatment and Monitoring	Oncology	France	SME	Both	Treatment and Monitoring	Rural, Urban

Source: Authors' elaboration.

A maximum of five interviews per case study were conducted. Interviews with AI developers focused on gathering insights into the development process, industry trends, and challenges faced in bringing the AI tool into clinical practice. Interviews with hospital representatives and healthcare professionals focused on collecting information from those either impacted by or involved in the deployment of AI into clinical practice, the practical challenges, benefits, and concerns related to using the specified AI tool as well as their views on organisational priorities, financial considerations, and the strategic vision for implementing the AI tool in healthcare. The stakeholders interviewed for each of the case studies can be found in the specific case study summary reports in Interview Guide - Case studies. For two of the case studies, the AI developers declined to participate in the interview.

3.3 Task 3: Analysis

Task 3 involved a comprehensive analysis of all the qualitative and quantitative data gathered from Task 1 and Task 2. The findings from the literature review, surveys, interviews, workshops, and case studies were triangulated together as part of the analysis to identify common discussion points and themes. Task 3 also included a preliminary findings workshop where the initial findings of the study were presented, and a market analysis focused on the state of deployment AI in healthcare within the EU.

3.3.1 Preliminary findings workshop

The **preliminary findings workshop** was held online on November 14, 2024, with 36 participants representing various stakeholder groups (Table 7), including AI developers, healthcare professionals, hospital representatives, and patient associations[16]. The emerging findings of the study were presented, and additional insights were gathered from the stakeholders to test and refine the validity of the conclusions developed.

Table 7: Preliminary findings workshop participants

Stakeholder group	Number of EU participants	Number of international participants
AI Developer	4	5
Healthcare professional	8	3
Hospital representative	6	1
Patient representative	5	0
Regulatory expert	4	0

Source: Authors' elaboration.

16 The target number of workshop participants proposed was 30.

3.3.2 Market analysis

The **market analysis** aimed to provide an economic overview of the market of AI for clinical practice in the EU, including a detailed overview of the extent of current research, development, and deployment of AI for clinical practice across the EU, the analysis of key trends and differences across countries and medical specialities, as well as an outlook for the next five years.

The market analysis was based mainly on desk research complemented by findings from the consultation activities carried out as part of Task 2 (e.g. survey). We collected a variety of data from several sources including EU and US databases, institutional reports, and scientific articles. To estimate the level of deployment of AI-based medical devices we retrieved from the US Food & Drug Administration (FDA) Medical Device Database the number of FDA-approved AI-based medical devices[17]. Given the limitations (See Annex 6) on the data available in the European Database on Medical Devices (EUDAMED), to assess the level of deployment of CE-marked AI medical devices, the study team included information from the Radiology Health AI Register developed by researchers from Radboud University Medical Centre in the Netherlands[18]. The market analysis included available information on AI-based medical devices between January 2021 and June 2024.

3.4 Task 4: Monitoring framework

The monitoring framework was done in line with the Better Regulations Guidelines, in particular Tool #43. For the preliminary identification of indicators, a mapping was conducted of qualitative and quantitative data sources via desk research of available indicators and reporting requirements. The mapping was not successful in identifying a set of indicators. Hence, many of the proposed indicators are to be collected upon request, as there is a lack of available indicators to inform the effective implementation of the recommended considerations for future actions.

17 U.S. Food & Drug Administration, 2024. Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices.

18 The database can be accessed via the following link: www.radiology.healthairegister.com (Last accessed 10/10/2024).

3.5 Limitations of this study

There are several methodological limitations to the study design that should be carefully considered by the reader in their interpretation of the findings. Firstly, although the literature review[19] covered a broad range of topics, it may not cover all emerging trends and niche studies in the rapidly evolving field of AI in healthcare. Given the large volume and continuous publication of AI research, some recent developments may be underrepresented. In addition, the literature available may present more successful deployment cases whilst under-representing those that were unsuccessful or subject to significant obstacles – this study aimed to mitigate this bias within the consultation activities.

Secondly, whilst the consultation activities (surveys, interviews, and workshops) captured the perspective of a diverse range of stakeholders and geographic regions. The focus of the study required the targeted identification of stakeholders who have had exposure to deployment of AI, resulting in a potential bias of the results. Stakeholders whose knowledge and/or exposure to AI tools in healthcare delivery are likely to have contributed to a lesser extent to the findings of this study, as they may not have been sufficiently aware of the challenges and accelerators to deployment to answer the consultation.

The consultation phase of this study was conducted during, or shortly thereafter the final text of several key pieces of regulation relevant for this study were adopted including the EU's AIA (May 2024[20]), the EHDS (January 2025[21]) and the revised PLD (October 2024[22]). This should be carefully considered by the reader when reflecting upon the stakeholder perspectives and desk research presented in this report, and how they apply to the regulatory reality in present day. Similarly, some of the challenges raised by the stakeholders have been reported in this study regardless of whether the aforementioned regulatory frameworks shape them (directly or indirectly) to maintain the comprehensive nature of this report, and in consideration that a full regulatory assessment was not part of the scope of this study. The study therefore in reference to the accelerators and challenges provides a high-level overview of the EU regulatory framework which may potentially shape or influence (directly and indirectly) the findings reported.

The study's specific focus on advanced regions outside of the EU for accelerators and challenges that may not yet be experienced in Europe, means that some of the accelerators identified may not be fully transferable. The same limitation also applies to the reporting of the potential of AI use cases to address healthcare challenges, as several studies and publications were from authors outside of the EU. Nevertheless, these findings are important to report for future consideration – notwithstanding differences in healthcare system structures.

The market analysis conducted as part of this study was subject to several limitations regarding the availability of data on AI technologies. Further detailed elaboration of these limitations are described in detail within Annex 5 – Details on data sources and methodology for market analysis. The data availability limitations and lack of currently established reporting requirements also impacted the establishment of the monitoring framework, which is subject to several assumptions and considerations.

19 search conducted June 2024, and complemented by additional sources between June and November 2024
20 European Council (2024) AI act: Council gives final green light to the first worldwide rules on AI
21 European Council (2025) EHDS: Council adopts new regulation improving cross-border access to EU health data.
22 European Council (2024) EU brings product liability rules in line with digital age and circular economy

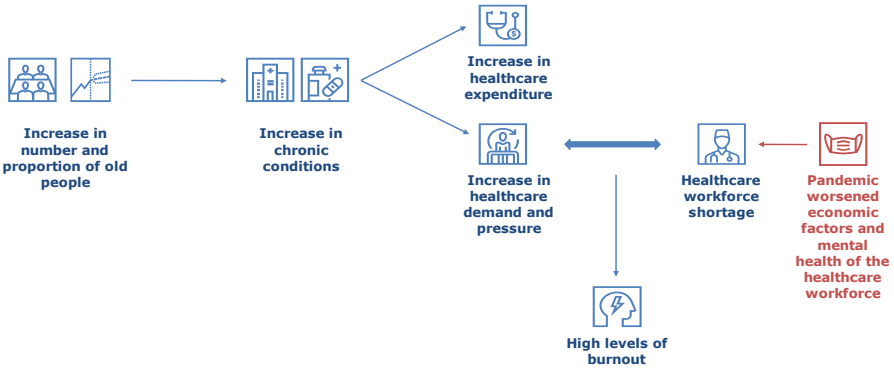
4 Potential of AI to address healthcare needs

Within the EU and globally, the sustainability of healthcare systems is facing a growing challenge. Over the past century, average life expectancy at birth has risen from less than 50 years to 78.9 years in the USA and 80.8 years on average in EU Member States, with some reaching 83 years[23]. By 2050, 1 in 6 people will be over the age of 65 – in Europe and North America, this will be 1 in 4. This demographic shift has led to a growing incidence of chronic and complex conditions. In 2014, people aged 60 and above accounted for 23% of the total global disease burden in terms of disability-adjusted life years, with the highest burden in high-income regions[24].

The rising prevalence of chronic conditions, particularly among aging populations, has increased the **demand on healthcare systems**, with **healthcare expenditure** becoming one of the largest government expenses—8.1% of Gross Domestic Product (GDP) in Europe (EU) and 18.3% in the United States of America (USA)[25,26]. Additionally, worsening shortages in the health workforce restricts the ability of healthcare systems to respond to demand, particularly in the EU, where disparities exist across Member States[27,28]. Twenty EU countries reported a shortage of doctors in 2022 and 2023, while fifteen countries reported a shortage of nurses. Based on minimum staffing thresholds for universal health coverage (UHC), EU countries had an estimated shortage of approximately 1.2 million doctors, nurses and midwives in 2022[29].

This shortage increases the **pressure on healthcare systems**, leading to **high levels of burnout** among HCPs [30]. In a study conducted by the European Employment Services (EURES), over 70% of HCPs reported poor mental health, with 40% experiencing depression and anxiety[31]. In USA, more than half of the doctors (53%) reported persistent burnout, with 62% experiencing burnout for over 13 months[32].

Figure 4: Summary of challenges leading to increased healthcare demand



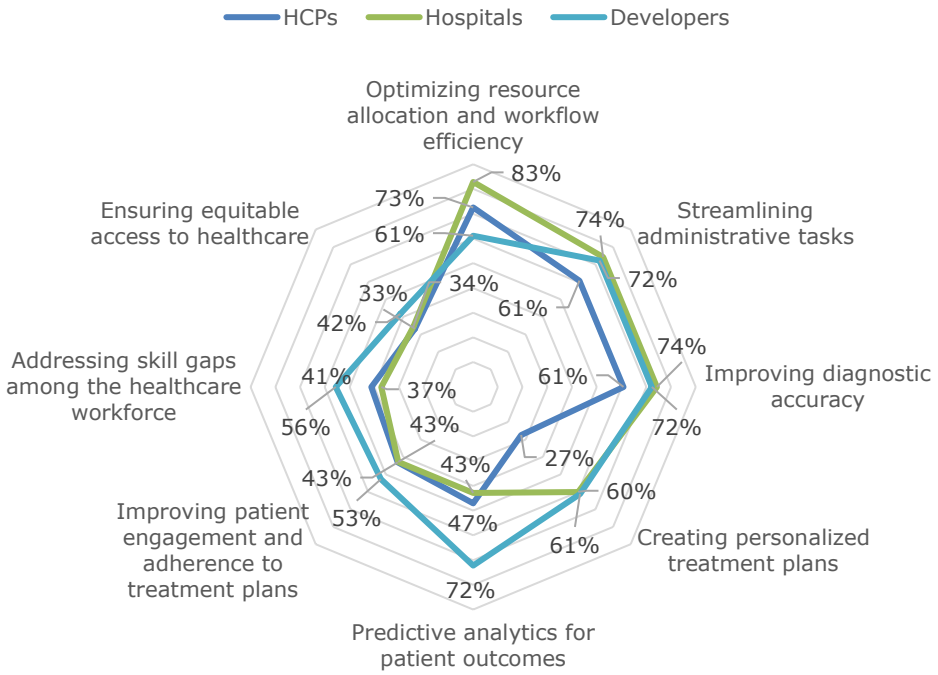
23 Eurostat, 2019. Life expectancy at birth.
24 Prince et al., 2015. The burden of disease in older people and implications for health policy and practice.
25 Eurostat, 2023. Sickness and healthcare expenditure down in 2022.
26 Peter G. Peterson Foundation, 2023. Healthcare spending in the United States remains high
27 Lehmann C, 2023. More physicians are experiencing burnout and depression.
28 Sipos, D et al., 2024. Addressing burnout in the healthcare workforce: current realities and mitigation strategies.
29 OECD (2024), Health at a Glance: Europe 2024
30 Sipos, D., Goyal, R. and Zapata, T., 2024. Addressing burnout in the healthcare workforce: current realities and mitigation strategies.
31 European University Hospital Alliance, 2024. Rethinking healthcare systems in Europe: A call for urgent, Europe-wide and EU-funded research and collaboration.
32 Lehmann C, 2023. More physicians are experiencing burnout and depression.

Source: Author's elaboration

Whilst not resolving the issues at their root, AI, including generative AI tools[33] such as Large Language Models (LLMs)[34], may relieve some of the strains experienced by global healthcare systems through their ability to rapidly process and analyse vast datasets reduce task-related fatigue and improve consistency in areas prone to human error[35]. In 2020, estimates suggested that AI could meet 20% of unmet clinical demand in the USA and save healthcare systems $150 billion annually by 2026[36].

Stakeholders consulted in this study highlighted that existing AI solutions ("low-hanging fruit"[37]) have the potential to address some of these challenges and healthcare needs by optimising resource allocation and workflow efficiency streamlining administrative tasks and improving diagnostic accuracy (see Figure 5).

Figure 5: Healthcare needs that can already be addressed by existing AI solutions according to HCPs, Hospital representatives, and AI developers[38].



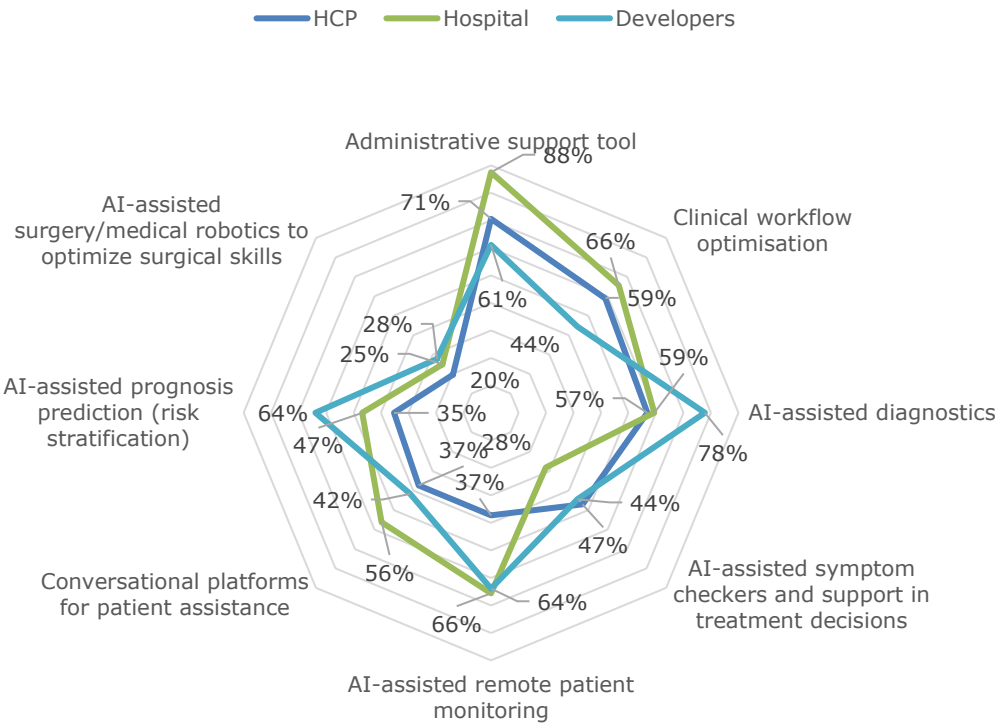
Source: Author's elaboration

They also identified opportunities for AI expected to have an impact in the mid- to long-term future ("high-hanging fruit"[39]) in personalised medicine, real-time decision-making, and predictive healthcare. In terms of AI applications expected to have the most transformative potential, these include administrative support tools, clinical workflow optimisation tools, and AI-assisted diagnostic tools according to the stakeholders consulted (Figure 6). These AI systems are both traditional AI systems such as machine

33 Generative AI refers to algorithms that are designed with the capability to generate outputs that can range from text and images. Such models operate by learning patterns and structures from given datasets, allowing them to produce outcomes based on the input they receive
34 Zhang and Kamel, 2023. Generative AI in Medicine and Healthcare: Promises, Opportunities and Challenges
35 Roppelt, J.S., Kanbach, D.K. and Kraus, S., 2024. Artificial intelligence in healthcare institutions: A systematic literature review on influencing factors.
36 Collier, M and Fu, Richard., 2020. Accenture - AI: Healthcare's new nervous system.
37 AI solutions that are already available and are expected to be deployed widely in the next 1 or 2 years.
38 Question was responded to by 36 AI developers, 51 HCPs and 35 hospital representatives
39 AI solutions that are expected to be available and deployed in the next 5 years.

learning models and generative AI systems such as LLMs. For example, LLMs have demonstrated promise for improving the efficiency and accuracy of healthcare delivery by extracting clinical information from electronic health records, summarising, structuring, or explaining medical texts, streamlining administrative tasks in clinical practice, enhancing medical research, quality control, and education, and supporting diagnosis or serving as prognostic models[40,41,42,43].

Figure 6: Areas where the use of AI is expected to have the most transformative potential according to HCPs, hospital representatives, and AI developers[44].



Source: Author's elaboration

4.1 Potential of AI to address challenges related to the increase in healthcare demand

AI tools have the potential to address the challenges posed by the increase in healthcare demand by enhancing **operational efficiency**, helping to alleviate the strain on healthcare systems. For example, at John Hopkins University Hospital in the USA, the use of AI tools that accompany medical personnel on patient rounds, analyse medical records, facilitate patient information retrieval, and schedule appointments reduced Emergency Room (ER) bed assignment times by 30%, operating room transfer delays by 70%, and ambulance response times by 63 minutes[45].

40 Yang et al., 2022. A large language model for electronic health records.
41 Tian et al., 2024. Opportunities and challenges for ChatGPT and large language models in biomedicine and health.
42 Adams et al., 2023. Leveraging GPT-4 for post hoc transformation of free-text radiology reports into structured reporting: a multilingual feasibility study.
43 McDuff et al., 2023. Towards accurate differential diagnosis with large language models.
44 Question was responded to by 36 AI developers, 51 HCPs and 35 hospital representatives. Categories of answers were extracted based upon free-text responses
45 Shiv Kumar et al., 2022. Real-world application, challenges and implication of artificial intelligence in healthcare: an essay.

Similarly, in the United Kingdom (UK), an AI tool pilot project at Mid and South Essex NHS Foundation Trust reduced patient non-attendances by 30% over six months, allowing an additional 1,910 patients to be seen and preventing 377 missed appointments. Co-designed by a frontline workers and clinical fellows, the tool used anonymised data to predict the likelihood of a missed appointment based upon factors such as weather, traffic, and patient's employment type and offered back-up bookings when the likelihood is high. It is estimated that the trust, which supports a population of 1.2 million people, could save £27.5 million a year by using the AI tool[46].

AI tools may also help predict **patient flow** and **service demand** by identifying patients likely to require intensive care or longer hospital stays, assisting in **efficient allocation** of staff, equipment, and beds to improve healthcare service delivery[47]. For example, an AI solution (utilising the Holistic Artificial Intelligence in Medicine framework) was developed in the USA that increased the accuracy of length of stay predictions from 8% to 20%, enhancing medical and economic decision-making and ensuring better care based on anticipated hospital duration. This framework also increased 48-hour mortality prediction rates from 11% to 33%, helping physicians identify patients who may benefit from immediate attention or intensive monitoring[48]. An AI tool currently in use at Vestre Viken hospitals in Norway has analysed 10,000 patients since its deployment in August 2023 and reduced patient waiting times, saving more than 100 days overall, eliminated the need for 15 doctor consultations per day and may even have the potential to analyse up to 39,000 patients annually, as reported by an HCP at the hospital[49]. In South Korea, a medical centre has deployed an AI solution that analyses the severity of pressure ulcers and identifies deep tissue damage from photos of the affected area while also recommending appropriate dressings. This tool may alleviate the workload of pressure ulcer specialists in a hospital where, on average, 200 patients—representing 10% of all inpatients—suffer from pressure ulcers at any given time[50].

AI tools may also reduce the growing pressure on the healthcare workforce by **assisting in patient triage**, which helps prioritise care, optimise resources, and improve efficiency. The use of chatbots and virtual assistants may enhance patient monitoring, facilitate communication, and improve the overall efficiency of healthcare systems. For instance, an AI-powered chatbot in the UK uses natural language processing (NLP) to assess patient symptoms and provide initial diagnoses. This can reduce the burden on primary care by triaging non-emergency cases and delivering health information quickly[51]. However, the deployment of the tool within the UK faced obstacles, related to its tailoring for specific medical needs and complex cases[52].

In Spain, Parc Taulí Hospital, a public hospital, collaborated with an AI software developer, to implement an AI-driven triage system and launch the Advanced Resolution Assistance Unit (ARA). The AI model redirects low-complexity patients, such as those with urinary tract infections or ankle sprains, to the ARA and away from the Emergency Department, which averages 130,000 visits per year. As a result, the model reduced waiting times and improved patient flow, streamlining operations and potentially lowering emergency room congestion[53]. While such tools may improve access to care and enable HCPs to focus on

46 NHS England, 2024. NHS AI expansion to help tackle missed appointments and improve waiting times.
47 Aung et al., 2021. The promise of artificial intelligence: a review of the opportunities and challenges of artificial intelligence in healthcare.
48 Soenksen et al., 2022. Integrated multimodal artificial intelligence framework for healthcare applications.
49 NRK, 2023. Har allereie spart 115 døgns ventetid for pasientar i Vestre Viken takka vere kunstig intelligens.
50 Hospital Management Asia, 2024. Samsung Medical Centre's path to smart healthcare.
51 Heaven, D., 2020. An algorithm that can spot cause and effect could supercharge medical AI.
52 Vermeulen, J., 2024. The fall of Babylon? Lessons for AI in the NHS
53 Barcelona Health Hub, 2024. Mediktor's AI integration at Parc Taulí sets a milestone in Spain's public health history

complex cases, concerns about trust may arise between patients and HCPs if AI systems are not well-calibrated or monitored. Poor calibration in chatbots can result in inaccurate recommendations and prevent access to care in a timely manner[54].

Another example of an AI tool used for triage is a model designed to assist in the management of pulmonary embolisms (PEs). This tool diagnoses, prioritises, and manages PEs by continuously analysing Computed Tomography (CT) scans and streamlining communication among multidisciplinary teams. This tool has improved time-sensitive outcomes, including reductions in turnaround time (TAT), time to treatment, and wait times across multiple hospitals. For instance, at the Region Halland Health System in Sweden, TAT decreased from 24.68 hours to 0.66 hours, while time to treatment dropped from 28.05 hours to 0.98 hours[55]. Similarly, the Cancer Institute in the Netherlands reported a reduction in TAT from 7,714 minutes to 87 minutes[56]. In the United States, the University of Alabama also observed improvements, with TAT reduced from 53.7 minutes to 45 minutes and wait times reduced from 22.8 minutes to 15.9 minutes[57].

4.2 Potential of AI to address challenges related to the growing administrative burden

> *"The least risk and most acceptable AI-based solutions will likely be in medical billing, improving workflow efficiency in documentation, and in overall resource allocation optimization. These are unlikely to cause patient harm and more positioned to improve clinic operations and clinic finances, which are a significant motivator."* – **AI developer from the USA.**

Hospitals are becoming increasingly digital and paperless, which has a number of benefits but also introduces some challenges. For example, the implementation of electronic health records (EHRs) in some instances has resulted in a growing administrative burden faced by HCPs globally. A study involving 200,081 HCPs across 396 organisations in the USA using an EHR system found that HCPs spend 5.8 hours out of 8 hours allocated for patient care actively working on the EHR[58]. Another study conducted at a university hospital in Switzerland found that nurses in an internal medicine unit spent 12.3% of their 12.5-hour shift on non-medical tasks activities, including logistic tasks[59]. These findings are consistent with the survey for this study where 61% of HCPs and 60% of hospital representatives reported that 20–60% of HCPs' time is consumed by clinical documentation. AI tools may have the potential to **reduce the administrative burden**, allowing HCPs to focus more on direct patient care. AI tools for administrative tasks, such as LLMs and Natural Language Processing (NLP), were reported as having the most transformative potential by 71% of HCPs (36 out of 51) and 87% of hospital representatives (28 out of 32) who responded to this question, along with 83% of patients (25 out of 30) who reported feeling comfortable with their use. Such tools may achieve quick, measurable benefits in hospital settings by assisting HCPs in non-clinical tasks such as documenting encounters, back-office functions, and patient scheduling.

54 Lucian Leape Institute, 2024. Patient safety and artificial intelligence: opportunities and challenges for care delivery. Boston: Institute for Healthcare Improvement
55 Wiklund et al., 2023. Use of a Deep Learning Algorithm for Detection and Triage of Cancer-associated Incidental Pulmonary Embolism
56 Topff L, Ranschaert ER, Bartels-Rutten A, et al. 2023, Artificial Intelligence Tool for Detection and Worklist Prioritization Reduces Time to Diagnosis of Incidental Pulmonary Embolism at CT
57 Rothenberg et al., 2023. Prospective Evaluation of AI Triage of Pulmonary Emboli on CT Pulmonary Angiograms
58 Holmgren, A.J. et al., 2024. National Comparison of Ambulatory Physician Electronic Health Record Use Across Specialties
59 Michel, O. et al., 2021. How do nurses spend their time? A time and motion analysis of nursing activities in an internal medicine unit

One example of such tools are digital scribes, which combine speech recognition with NLP to **automate clinical documentation and enhance data accuracy**[60]. A study conducted in 2023 at The Permanente Medical Group in USA demonstrated the potential of these AI tools to reduce the documentation burden of HCPs while producing high-quality clinical records. Among primary care physicians, the AI tool users experienced statistically significant reductions in the time spent on clinical documentation outside working hours and in the time spent in notes during appointments compared to non-users. Unadjusted analyses comparing metrics before and after implementation showed a decrease in mean time spent in notes from 5.3 to 4.8 minutes for the AI tool users and from 5.0 to 4.7 minutes for non-users. In terms of documentation quality, transcripts and encounter summaries generated by the digital scribes in the study at The Permanente Medical Group averaged a score 48 out of a possible 50 points. Ratings were particularly high (>4.95 out of 5 on average) in domains such as being free from bias, synthesis, internal consistency, and succinctness and slightly lower in domains like thoroughness, organisation, and accuracy (4.6 to 4.7). Hallucinations and missing details were reported but were infrequent, including errors like falsely reporting a prostate exam as performed or misinterpreting symptoms[61].

Similarly, in a study at Northwestern Medicine (USA), an ambient AI tool that generates clinical notes tailored to specific medical specialty from patient conversations led to a 24% reduction in time spent on notes and a 17% decrease in after-hours work, commonly referred to as "pyjama" time. Overlake Medical Center (USA) also reported an 81% reduction in cognitive burden, allowing more personal and family time, along with improvements in documentation quality when using the same tool, with 77% of HCPs reporting better documentation[62].

4.3 Potential of AI to address challenges related to delayed diagnoses and treatment

Healthcare systems also face unmet diagnostic and treatment needs, which may result in **delayed diagnosis**[63] which can result in **disease progression** and subsequently **reduce treatment effectiveness**. One such unmet need is the reduction of variability between HCPs responsible for interpreting diagnostic results (e.g. in diagnostic imaging), which based on a study conducted at 3 different hospitals in South Korea, can range from 75% to 88%[64]. A prospective observational study conducted in a university hospital in Switzerland found that one in nine patients admitted through the emergency room experience diagnostic discrepancies, which in turn were associated with increased in-hospital mortality[65].

Studies have shown that AI can **improve the speed and accuracy of diagnosis** in medical specialties such as radiology and digital pathology. From the stakeholders surveyed in this study, 78% of AI developers (28 out of 36), 59% of hospital representatives (19 out of 32) and 57% of HCPs (29 out of 51) anticipated that **AI-**

60 Pavuluri et al., 2024. Balancing act: the complex role of artificial intelligence in addressing burnout and healthcare workforce dynamics.
61 Tierney, A.A. et al., 2024. Ambient Artificial Intelligence Scribes to Alleviate the Burden of Clinical Documentation.
62 Microsoft, 2024. A year of DAX Copilot: Healthcare innovation that refocuses on the clinician-patient connection.
63 Young et al., 2023. The Role of Artificial Intelligence in Colorectal Cancer Screening: Lesion Detection and Lesion Characterization.
64 Kim et al., 2019. Interpretive Performance and Inter-Observer Agreement on Digital Mammography Test Sets.
65 Hautz, W.E. et al., Diagnostic error increases mortality and length of hospital stay in patients presenting through the emergency room

assisted diagnostics[66] will have the most transformative potential in healthcare. For example, in the USA, diagnostic errors cause 40,000 to 80,000 deaths annually[67]. Radiology, in particular, was referred to by stakeholders as among the most mature fields of AI utility, as highlighted in section 3.3.2. This may be attributed to the vast amounts of digital data accumulated over the years and through the widespread adoption of standards like DICOM (Digital Imaging and Communications in Medicine) and systems like PACS (Picture Archiving and Communication Systems). Hospital representatives from Austria, Denmark, Italy, the USA and UK highlighted that department specific AI tools may offer benefits such as improved diagnosis efficiency through requiring only one radiologist to validate results rather than two, and better prioritisation of urgent cases. However the stakeholders also highlighted that these tools may face challenges when applied beyond their training environment, and as such broader applications should be approached with caution

A study at a German university found that using an AI tool reduced the time taken to report findings in chest radiographs from 80 minutes to 35–50 minutes[68]. Another study conducted by the National Consortium of Intelligent Medical Imaging in Oxford (UK) revealed that an AI-assisted image analysis algorithm improved junior readers' proficiency in identifying pneumothoraxes on chest X-rays, achieving accuracy comparable to senior/consultant readers[69]. Additionally, in USA, an AI system that can prioritise intracranial haemorrhage reduced the waiting time from 16 min to 12 min per positive case[70].

However, not all AI algorithms showed improved performance in assessing radiographs compared to human readers. A recent study of 9 commercially available AI products in the UK (7 for lung nodule detection and 2 for bone age prediction) found that only 4 of the 7 AI algorithms for detecting lung nodules on chest radiographs showed improved performance compared to human readers. The remaining 5 algorithms showed no evidence of a difference in performance[71]. A hospital representative from Japan highlighted that the use of AI in diagnostic imaging could increase the workload of radiologists by requiring them to review an increased number of false positive results. Additionally, an HCP from the UK indicated that some diagnostic AI tools may slow down experienced HCPs by causing them to second-guess themselves.

In terms of treatment, AI algorithms in cardiology can analyse patient data, including medical history, genetic information, and lifestyle factors, supporting cardiologists to **tailor prevention and treatment strategies** to individual patients, thereby improving outcomes[72]. A study conducted at four stroke centres in Houston, in USA, assessed the impact of automated CT angiogram interpretation on in-hospital endovascular thrombectomy (EVT) workflows for stroke patients[73]. Prompt EVT can dramatically improve outcomes in patients with large vessel occlusion (LVO) acute ischemic stroke,

66 Not all stakeholders responded to this question
67 Rodziewicz, T.L. et al., 2024. Medical Error Reduction and Prevention.
68 Van Leeuwen et al., 2022. How does artificial intelligence in radiology improve efficiency and health outcomes
69 G Lip et al., 2024. Adoption, orchestration, and deployment of artificial intelligence within the National Health Service—facilitators and barriers: an expert roundtable discussion
70 O'Neill et al., 2020. Active reprioritization of the reading worklist using artificial intelligence has a beneficial effect on the turnaround time for interpretation of head CT with intracranial haemorrhage
71 G Lip et al., 2024. Adoption, orchestration, and deployment of artificial intelligence within the National Health Service—facilitators and barriers: an expert roundtable discussion
72 Stafie et al., 2023. Exploring the Intersection of Artificial Intelligence and Clinical Healthcare: A Multidisciplinary Review.
73 Endovascular thrombectomy, or EVT, is a minimally invasive surgical procedure used to treat acute ischemic stroke. EVT involves the removal of a blood clot from a blocked artery in the brain, which can restore blood flow and prevent further brain damage.

however its efficacy is time sensitive. The findings showed that AI-assisted LVO detection significantly decreased the door-to-intervention time by 11.2 minutes and the time from CT initiation to EVT start by 9.8 minutes in 243 LVO stroke patients, thus speeding up EVT treatment plans[74].

AI-driven robotic systems may also be used in surgical procedures to enhance precision and improve recovery times. These systems analyse preoperative imaging for surgical planning, guide instruments with precision, and predict complications, reducing surgical errors and improving outcomes[75,76]. A study conducted at Hyogo College of Medicine, in Japan, found that a deep learning model using surgical video from robot-assisted gastrectomy was capable of automatically segmenting loose connective tissue fibres to define a safe dissection plane and demonstrated a mean sensitivity score of 3.52/4.00, indicating good model performance for safe plane identification[77]. Additionally, another study conducted at the University of California Davis Medical Centre in USA found that an AI model was able to generate and overlay a heatmap of probable cancer location within the oral cavity to guide surgeons during cancer excision[78].

4.4 Potential of AI to improve cancer care

The application of AI in healthcare, particularly in cancer care, has increased in recent years. These tools may contribute to improving diagnostic accuracy, personalizing treatment approaches, and enhancing patient outcomes[79].

4.4.1 Screening, early detection and diagnosis

Early detection of cancer is important for improving survival rates and reducing treatment-related morbidity. Detecting cancer involves various methods depending on the type, location, and suspected stage of the tumour. These include imaging techniques (e.g., x-rays, mammography, ultrasound, CT scan, Magnetic Resonance Imaging (MRI) etc.), laboratory and blood tests, endoscopic procedures, biopsies, molecular genetic tests and physical examinations. The following section provides some examples of AI tools used in the early detection and diagnosis of certain cancers; however this is not a comprehensive picture of all the AI tools available for cancer detection across the different cancer types.

AI tools have been demonstrated effectiveness in developing advanced **screening and early detection techniques that improve sensitivity and specificity compared to traditional methods**. For example, AI algorithms are effective in analysing medical imaging, such as mammograms, CT scans, and MRIs, to detect cancerous lesions earlier than human radiologists[80,81,82]. For example, in a study in the USA, an AI tool used for cervical cancer screening achieved 91% accuracy, surpassing the 69% accuracy of human experts[83]. Similarly, in another study conducted in 2022 at the same clinic, the Intelligent Real-time Image Segmentation (IRS) algorithm improved the detection of abnormal pre-

74 Khalifa and Albadawy, 2024. AI in diagnostic imaging: Revolutionising accuracy and efficiency
75 Guni, A et al., 2024. Artificial Intelligence in Surgery: The Future is Now.
76 Reddy, K at al., 2023. Advancements in Robotic Surgery: A Comprehensive Overview of Current Utilizations and Upcoming Frontiers
77 Kumazu, Y. et al., 2021. Automated segmentation by deep learning of loose connective tissue fibres to define safe dissection planes in robot-assisted gastrectomy.
78 Marsden, M. et al., 2021. Intraoperative Margin Assessment in Oral and Oropharyngeal Cancer Using Label-Free Fluorescence Lifetime Imaging and Machine Learning.
79 Chua, I.S. et al., 2021. Artificial intelligence in oncology: Path to implementation.
80 Hwang and Park, 2020. Clinical Implementation of Deep Learning in Thoracic Radiology: Potential Applications and Challenges.
81 Ahn et al., 2023. Artificial Intelligence in Breast Cancer Diagnosis and Personalised Medicine.
82 Vobugari et al., 2022. Advancements in Oncology with Artificial Intelligence-A Review Article
83 Nagam VM, 2023. Diagnostic medical artificial intelligence: Futuristic prospects for implementation in healthcare settings.

cancerous cells (dysplasia) in Barrett's Oesophagus[84], identifying 100% of dysplastic areas compared to 76.9% with standard methods.

A prospective study at Capio Sankt Göran Hospital in Sweden involving 55,581 women demonstrated that double reading mammograms by one radiologist plus AI achieved a non-inferior cancer detection rate (0.5%) compared to standard double reading (0.4%) by two radiologists[85]. Moreover, a retrospective study in Norway conducted on 122,969 mammograms from 47,877 women found that an AI system detected 77.9% of all breast cancers, including 86.8% of screen-detected cancers, highlighting its potential to accurately detect true-positive cases and reduce radiologists' workload[86]. Furthermore, a study in the UK demonstrated that applying AI to interpret mammograms for breast cancer diagnosis reduced false positives by 5.7% and false negatives by 9.4%[87]. Lastly, in the USA, an AI-assisted cancer contouring tool using data from the University of California achieved a balanced accuracy of 84.7% in tumour delineation, outperforming manual methods (67.2%) by experienced radiologists and urologists [88].

AI tools are being used in endoscopy for early detection of certain cancers such as colorectal cancer. Most colorectal cancers develop from colorectal polyps, of which adenomas are the most common type. Early detection and treatment of adenomas by colonoscopy can therefore prevent colorectal cancer.. The Chinese University of Hong Kong's (CUHK) Faculty of Medicine (CU Medicine) introduced an AI system that can analyse endoscopic images real-time during colonoscopy to alert doctors to identify adenomas and tumours. A study conducted between 2021 and 2022, showed that junior endoscopists-in-training achieved an approximately 40% increase in adenoma detection rate with the use of AI tools[89]. Additionally, AI systems can assist in the diagnostic process by integrating data from diverse sources such as imaging, pathology slides, and genomic analyses. In a study using multiple datasets from China, USA, and Germany, an AI tool outperformed expert pathologists in diagnosing colorectal cancer, achieving an area under the curve[90] (AUC) of 0.988 surpassing that of pathologists (0.970)[91].

In Japan, an AI tool was developed to automate Temporal Subtraction (TS), a process that compares medical images taken at different times to diagnose new bone metastases. This tool helps radiologists quickly assess changes alongside CT scan series and is valuable due to the complexity and urgency of identifying bone metastases[92]. Studies found improved lesion-based sensitivity (46.1% with the AI tool vs 33.9% without the AI tool) without increasing interpretation time per each lesion found[93], shorter reading times compared to

84 Barrett's oesophagus is a condition in which the flat pink lining of the swallowing tube that connects the mouth to the stomach (oesophagus) becomes damaged by acid reflux, which causes the lining to thicken and become red. The condition is associated with an increased risk of developing oesophageal cancer.
85 Karin et al., 2023. Artificial intelligence for breast cancer detection in screening mammography in Sweden: a prospective, population-based, paired-reader, non-inferiority study.
86 Marthe Larsen et al., 2022. Artificial Intelligence Evaluation of 122 969 Mammography Examinations from a Population-based Screening Program.
87 Alowais et al., 2023. 'Revolutionizing healthcare: the role of artificial intelligence in clinical practice.
88 Mota, S. M. et al., 2024. Artificial Intelligence Improves the Ability of Physicians to Identify Prostate Cancer Extent
89 Lau et al., 2024. Effect of Real-Time Computer-Aided Polyp Detection System (ENDO-AID) on Adenoma Detection in Endoscopists-in-Training: A Randomised Trial.
90 A metric used to assess performance of AI tools, with a value closer to 1.0 indicating higher diagnostic accuracy.
91 Wang, K.S. et al., 2021. Accurate diagnosis of colorectal cancer based on histopathology images using artificial intelligence.
92 Iima M et al. 2023. The efficacy of CT temporal subtraction images for fibrodysplasia ossificans progressiva.
93 Onoue K, Yakami M, Nishio M, et al. 2021. Temporal subtraction CT with nonrigid image registration improves detection of bone metastases by radiologists: results of a large-scale observer study.

bone scintigraphy[94], and a 25% reduction in reading time for identifying new metastases using the TS AI tool[95].

4.4.2 Treatment planning and delivery

AI can play a role in **optimising cancer treatment**, from selecting appropriate therapies to enhancing precision in treatment delivery (AI personalised medicine). In the USA, a machine learning model from the National Cancer Data Base[96] (NCDB), developed to generate novel recurrence scores and identify high-risk patients who may benefit from adjuvant chemotherapy, achieved an AUC of 0.785 overall and an AUC of 0.817 for Hormone Receptor-positive (HR+/HER2-)[97] subtypes[98]. In China, in a study conducted at Fudan University Shanghai Cancer Centre, an AI model analysed key patient factors, such as weight, number of chemotherapy treatments, and metastases, and accurately predicted the optimal medication dose for metastatic positive breast cancer, enhancing precision and minimising side effects[99].

Additionally, in a retrospective study at the Netherlands Cancer Institute, an AI algorithm developed to identify patterns in medical images that could act as biomarkers for predicting treatment response was assessed. The AI tool analysed 1,055 cancer lesions from 203 patients with advanced melanoma and non-small-cell lung cancer (NSCLC) undergoing immunotherapy and achieved an AUC of 0.83 for NSCLC lesions and an AUC of 0.64 for melanoma lymph nodes. The AI tool then predicted immunotherapy response with an overall accuracy of 76%, which led to a 24% improvement in 1-year survival rates[100]. Lastly, in the USA, an AI tool predicted 30-day cardiotoxicity risk in 36,030 colorectal cancer patients undergoing chemotherapy by analysing key risk factors such as pre-existing cardiac conditions, recent surgery, and older age[101].

AI may also optimise treatment by enhancing radiotherapy planning, improving both precision and efficiency. A high-precision AI tool for automatic anatomical delineation on 3D cancer patient images reduced the time required for contour corrections. A study on head-and-neck cancers demonstrated a reduction in correction time to two minutes with the AI tool compared to 30 minutes for manual delineation—a 93%-time savings[102]. Another study evaluating deep learning solutions for CT image contouring found that the AI solution took less than two minutes to compute the segmentations, with all participating

94 Onoue K, Nishio M, Yakami M, et al. 2019. CT temporal subtraction improves early detection of bone metastases compared to SPECT.
95 Sakamoto R, Mori S, Miller MI, et al. 2014. Detection of time-varying structures by large deformation diffeomorphic metric mapping to aid reading of high-resolution CT images of the lung.
96 A nationally representative hospital-based registry covering approximately 70% of all new invasive cancer diagnoses in USA
97 HR+/HER2-: Hormone Receptor-positive (HR+) and Human Epidermal Growth Factor Receptor 2-negative (HER2-). HR+ refers to cancer cells that have receptors for hormones like oestrogen or progesterone, which can stimulate cancer growth. HER2- indicates the absence of excess HER2 protein on cancer cells. Together, HR+/HER2- is a common subtype of breast cancer that responds to hormonal therapies but not to treatments targeting HER2.
98 Zhao, F. et al., 2024. Predicting pathologic complete response to neoadjuvant chemotherapy in breast cancer using a machine learning approach.
99 Yu, Ze et al, 2022. Predicting Lapatinib Dose Regimen Using Machine Learning and Deep Learning Techniques Based on a Real-World Study.
100 Trebeschi S et al., 2019. Predicting response to cancer immunotherapy using non-invasive radiomic biomarkers.
101 Li, C.et al., 2022. Using Machine Learning Approaches to Predict Short-Term Risk of Cardiotoxicity Among Patients with Colorectal Cancer After Starting Fluoropyrimidine-Based Chemotherapy.
102 Grégoire V et al., 2020. Deep learning auto contouring of OAR for HN radiotherapy: a blinded evaluation by clinical experts.

physicians approving the AI-generated contours, which were comparable or superior to manual ones [103].

4.4.3 Clinical decision support

AI-powered clinical decision support systems (CDSS) can assist oncologists by **analysing vast datasets and offering evidence-based treatment recommendations**. A hospital in South Korea tested a CDSS developed to support hepatocellular carcinoma treatment using internal and external datasets from nine institutions (935 internal and 1,750 external patients). The system achieved an accuracy of up to 87.27% when tested on internal datasets and 86.06% on external datasets, and the integrated time-dependent AUC score for survival prediction was 0.89 and 0.86, respectively[104].

Additionally, a new AI-powered platform, developed by scientists at a hospital in USA demonstrated 94% accuracy in cancer detection across 15 datasets with 11 cancer types, achieving 96% accuracy in biopsy datasets and over 90% accuracy on surgically removed tumour slides. The tool also excelled in predicting molecular profiles, identifying genetic mutations linked to cancer growth, and accurately detecting mutations related to treatment response, such as 96% accuracy for a mutation in blood cancer. For predicting patient survival, the tool improved prediction accuracy by 8%, or 10% for advanced cancers, across 17 institutions. The AI tool also identified unique tumour patterns, such as immune cell presence in long-term survivors and abnormal cell characteristics in short-term survivors, offering insights into tumour aggressiveness[105].

4.4.4 Equity and access to care

AI tools may have the potential to bridge disparities in cancer care by making advanced diagnostic and therapeutic tools accessible to underserved populations. With its ability to enhance diagnoses, predict responses, and plan treatments, AI tools have the potential to **optimise resource allocation** and **make healthcare more inclusive and accessible**, **extending advancements to remote areas where resources are scarce**[106]. In Kenya, an AI tool achieved sensitivities of 95.7% and 100% for detecting cervical squamous cell atypia using digital and physical slides, with AUCs of 0.94 and 0.96[107]. In Ethiopia, an AI tool reduced leukaemia subtyping time from 30 minutes to under one minute while improving accuracy from 70% to 97%[108]. Similarly, in South Africa, six AI algorithms predicted colorectal cancer recurrence and survival with high accuracy, the best achieving 87.0% for recurrence and 82.0% for survival. These tools offer oncologists valuable insights for resource allocation and assist them in their informed decisions, optimising patient management in resource-limited areas[109].

103 Costea M, Zlate A, Serre AA, et al. 2023. Evaluation of different algorithms for automatic segmentation of head-and-neck lymph nodes on CT images.
104 Lee, Kyung Hwa et al., 2024. Machine learning-based clinical decision support system for treatment recommendation and overall survival prediction of hepatocellular carcinoma: a multi-center study.
105 The Harvard Gazette, 2024. New AI tool can diagnose cancer, guide treatment, predict patient survival
106 Garcia-Saiso, Sebastian et al., 2024. Artificial Intelligence as a Potential Catalyst to a More Equitable Cancer Care.
107 Holmström O et al., 2021 Point-of-Care Digital Cytology With Artificial Intelligence for Cervical Cancer Screening in a Resource-Limited Setting
108 K. Dese et al., 2021. Accurate Machine-Learning-Based classification of Leukaemia from Blood Smear Images
109 Achilonu, Okechinyere J et al., 2021. Predicting Colorectal Cancer Recurrence and Patient Survival Using Supervised Machine Learning Approach: A South African Population-Based Study

4.5 Potential of AI to harness large amounts of health data

There is a need for healthcare systems to **harness the vast amounts of data** generated by modern diagnostic systems[110]. It is estimated by the World Economic Forum that 97% of the health data assets are not utilised[111]. AI has the potential to unlock patient value and efficiently manage unused data assets (e.g., imaging, patient histories) to assist HCPs in diagnosing and optimising treatment for patients[112]. One example is an AI model that analyses vast genomic, molecular, and clinical data and predicts which DNA variations are likely to cause disease, facilitating faster diagnoses of rare disorders[113].

AI also has the potential to **cross reference diverse data sources** to improve clinical outcomes. For instance, AI can scan patient records alongside prescriptions and alert nurses to potential drug interactions or allergies. By streamlining the medication management process, nurses can focus more on patient care, delivering safer and more effective treatments to patients[114]. According to an association for AI developers based in Sweden, AI tools will have the potential to manage large amounts of health data for each patient through various applications across multiple medical fields. The stakeholder reflected that in radiology, these tools will rapidly and accurately evaluate vast amounts of imaging data to identify anomalies, such as tumours and fractures, with high precision, leading to faster diagnoses and improved patient outcomes. In oncology, the stakeholder explained that the need for personalised treatment plans is even more important, as therapies must be tailored to individual patients. According to the stakeholder, future AI tools will be able to analyse genomic, molecular, and clinical data to predict the most effective treatments based on a patient's unique genetic makeup, enhancing therapeutic efficacy while minimising side effects. Furthermore, in chronic conditions such as diabetes and in cardiology, future AI tools will leverage predictive analytics to assess the risk of cardiovascular events such as heart attacks and strokes. Those tools will analyse EHRs, lifestyle factors, and wearable device information and provide early warnings and facilitate prompt interventions, ultimately preventing serious health crises.

4.6 Potential of AI to address challenges related to the widening disparities and access to healthcare

Across Member States, there are widening disparities reflecting gaps in access, quality, and affordability of healthcare services[115]. AI tools have the potential to **reduce such healthcare disparities** by improving healthcare delivery, diagnostics, and operational efficiency that can help bridge healthcare access gaps, particularly for populations in rural and underserved areas[116]. In many rural areas, the scarcity of healthcare resources presents a barrier to providing comprehensive care. AI algorithms are increasingly used to optimise resource allocation, from staffing schedules to inventory management, enabling healthcare facilities to operate more efficiently (see section 4.1). Predictive AI models can forecast patient admission rates, enabling better preparation for seasonal fluctuations in healthcare demand, such as increased respiratory cases during winter

110 PwC. How artificial intelligence may improve quality and efficiency, whilst reducing healthcare costs in Europe.
111 Thomason, J, 2021. Big tech, big data and the new world of digital health.
112 Thomason, J, 2021. Big tech, big data and the new world of digital health.
113 MIT Technology Review. 2023. DeepMind's AlphaMissense AI can pinpoint causes of genetic disease.
114 Eggerth, A. et al., 2020. Medication management needs information and communications technology-based approaches, including telehealth and artificial intelligence.
115 European Commission, 2018. Inequalities in access to healthcare: A study of national policies 2018.
116 Cruickshank et al., 2024. How AI Could Help Reduce Inequities in Health Care

months[117]. Additionally, AI-driven supply chain management can prevent shortages of critical medications and medical supplies, reducing disruptions in patient care[118].

AI can also help **optimise the distribution of HCPs** across regions by analysing data on patient needs, available personnel, and transport logistics. For instance, a healthcare system could use AI to determine the optimal placement of mobile clinics or to schedule rotating specialists who can serve multiple remote communities[119]. By strategically managing resources with AI, healthcare facilities in underserved areas can maximize the utility of available assets, ensuring that patients in remote areas do not face excessive delays or shortages in critical healthcare services.

AI can also play an essential role in **upskilling local healthcare providers in remote areas**, where continuing medical education opportunities may be limited. Through virtual training modules, AI can simulate clinical scenarios, teach new diagnostic methods, and offer insights based on real-world data. This capability can help bridge knowledge gaps in rural settings where practitioners may not have the same level of access to specialty training as their urban counterparts. For example, AI-enabled training platforms use realistic simulations to help healthcare providers practice procedures, learn about new treatments, or refine diagnostic skills[120].

A primary advantage of AI in healthcare is its capacity to **enable rapid diagnostics and patient triage** (see sections 4.3 and 4.1), an area critical to remote and underserved populations with limited access to in-person medical consultations. AI-powered diagnostic tools, including those based on machine learning algorithms and image recognition, have been shown to provide accurate assessments for various conditions such as diabetic retinopathy, pneumonia, and certain cancers (see section 4.4). These systems can function remotely, often requiring only images or basic patient data, which allows patients to be screened and diagnosed without visiting a specialist. HCPs and hospital representatives consulted reported that AI can help bridge gaps in healthcare access by bringing advanced diagnostic tools to areas with fewer medical resources. For example, an app developed in Germany offers patients an AI-driven smartphone app that assesses symptoms, diagnoses various medical issues, and suggests personalised care. The app has outperformed human doctors in accurately diagnosing rheumatological disease, skin rashes, and the source of abdominal pain in emergency room visits[121]. Such AI-powered tools democratise access to a highly effective and scalable "pocket doctor," no matter how physically far patients find themselves from health care providers, which empowers patients in under-resourced areas to reliably triage themselves and subsequently seek health care through the most appropriate avenue.

The rise of wearable devices equipped with AI algorithms has allowed for **continuous remote patient monitoring**, a feature that is especially beneficial for individuals with chronic illnesses living far from healthcare facilities[122]. AI-powered remote monitoring tools can track vital signs, detect early warning signals, and predict potential health

117 Dixon et al., 2024. Unveiling the Influence of AI Predictive Analytics on Patient Outcomes: A Comprehensive Narrative Review
118 Kudrenko, 2024. Navigating the Future: AI-Driven Healthcare Supply Chains
119 World Economic Forum, 2022. How autonomous mobile clinics can transform healthcare in least developed countries.
120 Allan Hamilton, 2024. Artificial Intelligence and Healthcare Simulation: The Shifting Landscape of Medical Education.
121 Gräf et al., 2022. Comparison of physician and artificial intelligence-based symptom checker diagnostic accuracy; Berry et al., 2023. Online symptom checkers lack diagnostic accuracy for skin rashes; Faqar-Uz-Zaman et al., 2022. The Diagnostic Efficacy of an App-based Diagnostic Health Care Application in the Emergency Room: eRadaR-Trial. A prospective, Double-blinded, Observational Study.
122 Shajari et al., 2023. The Emergence of AI-Based Wearable Sensors for Digital Health Technology: A Review

complications. For instance, AI models can monitor patients with diabetes by analysing blood glucose levels, exercise patterns, and diet[123]. These systems provide alerts to both patients and healthcare providers if patterns indicate an elevated risk of complications, enabling timely medical intervention without the need for regular clinic visits. For healthcare systems in remote regions, this can reduce the need for frequent in-person consultations, lessen transportation costs for patients, and alleviate the demand on local clinics, thereby making healthcare resources more efficient and accessible.

Telemedicine and AI Chat-bots have emerged as an important tool in bridging healthcare gaps in rural areas, and AI has the potential to further enhance this service[124]. Through NLP, machine learning algorithms and AI-driven chatbots, telemedicine platforms can offer preliminary consultations, answer questions, and guide patients toward appropriate care pathways. AI-powered chatbots, for instance, can handle patient intake, conduct symptom checks, and even provide preliminary diagnostic suggestions, enabling healthcare providers to focus on more complex cases while maintaining consistent patient engagement. A study in the UK evaluating an AI-chatbot, alongside seven primary care physicians, revealed that while human doctors managed to identify 100% of conditions, the AI chatbot effectively recognised 99%, covering a wide array of areas, including obstetrics and mental health. Human doctors achieved a higher accuracy than the AI-chatbot (82% in comparison to 71%) but when used together provided safe advice 97% of the time, showcasing the potential of AI in enhancing healthcare delivery[125].

AI technologies offer transformative potential in addressing healthcare disparities across Europe, particularly in remote and underserved regions. From AI-driven diagnostics and remote monitoring to telemedicine enhancements and resource optimisation, AI tools can significantly improve healthcare access, reduce travel needs, and alleviate the burden on limited healthcare resources in rural areas.

4.7 Summary

In summary, healthcare systems today face a number of challenges. Challenges include a rise in the burden of chronic and complex conditions with an aging population, a global shortage of healthcare workforce, widening health disparities and access to care, inefficiencies in the delivery of healthcare, and a rise in the cost of healthcare. To address these challenges, it is important to prepare and transform healthcare systems, leveraging the large amount of health data available and using innovative solutions such as AI, to improve the overall efficiency, quality, and access to healthcare. The use of AI systems has the potential to transform the delivery of healthcare and are already deployed and used in several hospitals globally with a demonstrable impact. AI systems have proven to improve operational efficiency by optimising processes and assisting in patient triage, to automate manual and repetitive tasks (e.g., scheduling, clinical documentation) relieving HCPs from the growing administrative burden, and to directly improve patient outcomes by improving diagnosis, monitoring and the delivery of care. For example, AI tools have shown to improve the speed and accuracy of diagnosis, as well as tailoring treatment strategies to needs of individual patients.

123 Ahmed et al., 2023. Performance of artificial intelligence models in estimating blood glucose level among diabetic patients using non-invasive wearable device data
124 Sharma et al., 2023. Addressing the challenges of AI-based telemedicine: Best practices and lessons learned
125 Gilbert et al., 2020. How accurate are digital symptom assessment apps for suggesting conditions and urgency advice? A clinical vignettes comparison to GPs

5 Current EU regulatory landscape

To realise the transformative potential of AI in healthcare, its deployment must occur within a framework that not only promotes innovation, but also ensures safety, transparency, and fairness. Realising these opportunities requires alignment with existing regulations that balance innovation with ethical and societal safeguards. The EU regulatory landscape plays a pivotal role in shaping how AI technologies are designed, deployed, and used across healthcare systems, ensuring they address healthcare needs while upholding trust among patients, HCPs and other stakeholders. The below section presents a high-level informative overview of the regulatory frameworks that may directly or indirectly be relevant for the deployment of AI in healthcare.

5.1 Key EU regulatory frameworks for AI deployment in healthcare

The regulatory landscape for AI in healthcare within the EU is shaped by several frameworks, each addressing directly or indirectly specific aspects of AI development, deployment, and use. The landscape can be distinguished by both cross-sector and healthcare specific regulation.

5.1.1 Cross-Sector Regulations

Cross-Sector regulations provide a foundational framework for safety, transparency, and liability throughout the lifecycle of AI systems, but with different focal points:

- **The AI Act (AIA)** establishes a risk-based approach to AI governance, classifying AI systems into different risk categories (unacceptable risk, high risk, limited transparency risk, minimal to no risk) and subject these to different rules while ensuring safety, transparency, and fairness.
- **The Product Liability Directive (PLD):** The PLD focuses on liability for harm caused by defective products, including AI systems, regardless of fault. The PLD as amended[126] addresses the unique challenges posed by AI technologies, such as their complexity, opacity, and autonomous capabilities. The updated directive clarifies the liability rules for AI-related defects, ensuring that victims are compensated even in cases where a defect cannot be directly attributed to a specific fault. This reinforces the importance of robust safety and quality measures throughout an AI system's lifecycle.

5.1.2 Healthcare-specific legal acts

Healthcare-specific legal acts address the unique requirements of healthcare AI, emphasising patient safety, clinical effectiveness, and data governance across different lifecycle stages:

- **The Medical Device Regulation (MDR):** Encompasses the entire medical device lifecycle, with strong emphasis on clinical evidence, traceability, post-market surveillance and transparency. It mandates rigorous clinical evidence and continuous post-market surveillance for AI systems that qualify as medical devices (Medical Device Artificial Intelligence - MDAI). This ensures that systems maintain safety and performance standards throughout their lifecycle.
- **The *In Vitro* Diagnostic Medical Devices Regulation (IVDR):** Similar to the MDR, the IVDR spans the full lifecycle of diagnostic AI tools, with a particular focus on development and clinical evidence. The IVDR requires proof of both scientific

126 The revised PLD was adopted in November 2024, after the main analysis of this study had already been completed.

validity, analytical and clinical performance before market entry, ensuring that diagnostic AI tools are safe and performant. In addition to rigorous pre-market conformity assessments, post-market surveillance and reporting obligations also apply.

- The **Health Technology Assessment Regulation (HTAR)** provides a framework to support Member States to assess the relative effectiveness and relative safety of health technologies through joint-clinical assessments focusing on clinical value.

  The HTAR Includes in scope of joint clinical assessments high-risk medical devices of which devices incorporating software using AI. In addition the HTAR provides a voluntary mechanism for health technologies not in mandatory scope and assessment of non-clinical assessments domains.

- The **European Health Data Space (EHDS)[127]** aims at improving data standardisation, interoperability, and secure access to health data, creating a robust foundation for AI integration in healthcare. There are provisions in the EHDS both on primary and secondary uses of health data that could both aid AI integration in clinical practice. The EHDS will support data governance and interoperability across all stages, facilitating secure and standardised access to health data for AI research, deployment, and post-market use. The EHDS will promote secure data access for healthcare innovation, helping improve data accessibility and AI model accuracy while maintaining data privacy and security.

5.1.3 Artificial Intelligence Act (AIA)

The AIA (Regulation (EU) 2024/1689)[128] is a cornerstone of the EU's regulatory framework for governing AI systems, addressing risks associated with their design, deployment, and use. In line with the New Legislative Framework (NLF)[129] policy, the AI Act is conceived as safety legislation that will complement existing sectoral measures, such as the MDR/IVDR, by specifically targeting hazards posed by AI systems. With its risk-based approach, the AIA provides a robust foundation for ensuring the safety, transparency, and trustworthiness of AI technologies, particularly in critical sectors like healthcare. Notably, the AI Act and the sectoral legislation will apply jointly.

Most healthcare AI applications, such as diagnostic tools, clinical decision support systems, and patient monitoring systems, largely fall under the high-risk category. In the "health sector where the stakes for life and health are particularly high, increasingly sophisticated diagnostics systems and systems supporting human decisions should be reliable and accurate" (recital 47). Such systems would be largely classified as medical devices, which may present risks not addressed by the essential health and safety requirements set out in the relevant Union harmonised legislation. The AIA establishes strict requirements across the AI value chain to ensure safety, transparency, and accountability. Some of these requirements focus on providers—such as ensuring risk management, robustness, and compliance through conformity assessments—while others focus on deployers of AI systems who also bear critical responsibilities, particularly for high-risk

127 The EHDS was adopted in January 2025, after the main analysis of this study had been completed.
128 Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act)
129 EU Commission (2008) New legislative framework

applications[130,131,132,133]. The AIA defines a "**deployer**" as any natural or legal person, public authority, agency, or other body that uses an AI system under their authority within the EU, except where the AI system is used in the course of a personal non-professional activity. In healthcare, deployers typically include hospitals, healthcare organisations, and private practitioners adopting high-risk AI systems such as diagnostic tools, clinical decision support systems, or patient monitoring applications. Table 8 summarises the AIA risk categories and the requirements for deployers of AI systems under each category.

Table 8: Requirements for health-related AI systems in the EU AIA [134].

Risk categories	Examples	Deployer obligations
Unacceptable risk	• Social scoring of individuals for health benefits	The placing on the market, the putting into service and the use are prohibited (Article 5).
High-risk	• AI-based medical devices falling within the scope of Regulation (EU) 2017/745 and 2017/746 (e.g. AI Clinical Decision Support Systems); • AI for risk assessment and pricing for health insurance; • AI for evaluating and classifying emergency calls; AI for decisions on dispatching medical aid; • AI for emergency healthcare patient triage systems; • AI used by public authorities to evaluate eligibility for essential public assistance benefits and services, including healthcare services.	• AI literacy measures (Article 4) • Use systems in accordance with instructions (Article 26(1)) • Assign human oversight to qualified natural persons (Article 26(2)) • Ensure relevant and sufficiently representative input data (Article 26(4)) • Monitor the functioning and inform stakeholders of serious incidents (Article 26(5) and Article 72) • Keep automated logs (Article 26 (6)) • Registration obligations for certain deployers (Article 26(8) and Article 49) • Carry out data protection impact assessment (Article 26(9)) • Fundamental rights impact assessment (Article 27)
Transparency risk	• AI-chatbots providing advice on wellbeing; • AI-generated medical deepfakes (e.g. adding and eliminating tumours from medical images); • AI-based wandering detectors in long-term care homes; • AI-based food intake sensors in home care settings.	• AI literacy measures (Article 4); • Transparency obligations (Article 50).
Minimal to no risk	• AI used in pharmaceutical research and development; • AI-based systems used for administration in healthcare;	No requirements in the EU AIA.

According to the stakeholders consulted 86% of HCPs (26 out of 30) believe that the AIA references some of the challenges that their healthcare facilities are facing. However, 72% (18 out of 25) indicated that the AIA also exposes new challenges related to how the

130 Sandra Wachter., 2024. Limitations and Loopholes in the EU AI Act and AI Liability Directives: What This Means for the European Union, the United States, and Beyond
131 St John Lynch et al., 2024. Artificial Intelligence-Enabled Medical Device Standards: A Multidisciplinary Literature Review.
132 Busch et al. 2024. Navigating the European Union Artificial Intelligence Act for Healthcare
133 Van Kolfschooten, H. and van Oirschot, J., 2024. *The EU Artificial Intelligence Act: Implications for healthcare*.
134 Van Kolfschooten, H. and van Oirschot, J., 2024. *The EU Artificial Intelligence Act: Implications for healthcare*.

regulation should be implemented and complied with at hospital level. Examples provided by stakeholders include the additional training requirements for accountability standards and the need for more risk management protocols. In addition, only 26% (6 out of 25) of the hospital representatives that responded to the survey feel prepared for the obligations introduced by the AIA, expressing concerns about the financial and logistical burden of compliance, including difficulties in recruiting skilled personnel and the need for investments in infrastructure and training.

In contrast, among AI developers consulted, 47% (16 out of 34) are prepared for the implementation of the AIA and the associated obligations, especially those experienced with MDR/IVDR compliance, viewing the AIA as an extension of their current efforts. Some AI developers indicated they had already integrated transparency measures and ethical frameworks, though others remain in a transition phase, delaying new tool deployment until they fully understand the AIA.

Training and compliance support is a concern amongst the stakeholders consulted. HCPs suggested the implementation of short, accessible training programs that fit into their busy schedules and proposed the establishment of peer-to-peer support networks and collaboration with legal experts. Hospital representatives echoed the need for government-accredited auditors and increased access to training resources. AI developers who indicated they are prepared for the provisions of the AIA have started to create frameworks for early identification of AI risks and conducting workshops to educate teams on compliance**.**

5.1.4 Medical Device Regulation (MDR) and In-Vitro Diagnostic Medical Devices Regulation (IVDR)

The MDR (Regulation (EU) 2017/745)[135] and the IVDR (Regulation (EU) 2017/746)[136] establish safety and performance requirements for medical devices and *in-vitro* diagnostic medical devices, including those incorporating AI. The MDR applies to a broad range of medical devices, such as AI-powered diagnostic tools, while the IVDR focuses on *in-vitro* diagnostic devices (IVD). Both regulations employ a **risk-based classification** system with four classes, for MDR:

- **Class I -** low risk such as bandages,
- **Class IIa/IIb** - medium to higher risk such as diagnostic imaging software, and
- **Class III -** highest risk such as AI tools for direct clinical decision-making

Similarly, for IVDR the following risk classes apply:

- **Class A -** low risk such as specimen receptacles
- **Class B/C** – medium to high risk including self-testing pregnancy tests, and those used for the detection of infectious agent without a high risk of propagation
- **Class D-** highest risk such as those that are used to detect life-threatening transmissible agents with a high risk of propagation

High-risk devices in must undergo rigorous **conformity assessments** by independent notified bodies to ensure clinical safety, robust performance, and proven patient benefits. Key regulatory tools, including the Eudamed database and unique device identification (UDI) system, support traceability and post-market monitoring, ensuring ongoing oversight.

135 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

136 Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

The MDR and IVDR ensure that medical devices and in-vitro diagnostic medical devices meet stringent safety and performance requirements.

5.1.5 Product Liability Directive (PLD)

The new PLD, (Directive (EU) 2024/2853)[137], formally Directive 85/374/EEC, is a key EU framework aimed at ensuring liability and protecting individuals who suffer harm caused by defective products. The directive establishes strict liability, meaning that injured parties are not required to prove negligence but only that the product was defective and caused harm. This is particularly important in healthcare, where AI systems are increasingly integrated into critical medical devices and diagnostic tools. By holding manufacturers liable for defects, the PLD can indirectly incentivise for robust design, rigorous testing, and continuous monitoring of AI-powered healthcare solutions.

In healthcare, AI systems used for clinical decision support, diagnostics, or patient monitoring can have significant implications for patient safety. Under the current PLD framework, harm caused by a defective AI system—such as incorrect diagnoses or treatment recommendations—could result in liability for the manufacturer. Clarity of liability regimens protects patients and aids in clarifying the liability between healthcare providers and manufacturers as well as maintaining high standards for safety and reliability throughout the product lifecycle.

The complexity and opacity of AI systems, particularly those based on machine learning, presented challenges for traditional liability frameworks, such as attributing defects or proving causation. The new product liability directive (Directive (EU) 2024/2853) seeks to modernise liability rules to address challenges posed by AI and digital products. It explicitly includes digital products, such as standalone software and AI systems, under its scope to ensure that liability frameworks remain relevant in the evolving technological landscape. The revision also aims to address the complexity of proving causation in AI-related harm by introducing mechanisms for courts to request technical information from manufacturers, helping to balance transparency with innovation protection[138].

Recognising the dynamic nature of AI systems, the updated PLD proposes considerations for risks that may emerge over a product's lifecycle, such as those linked to learning and adaptation post-deployment. These updates reflect efforts to align liability rules with the unique characteristics of AI, while maintaining a balance between consumer protection and fostering innovation.

5.1.6 Health Technology Assessment Regulation (HTAR)

The HTA Regulation (Regulation (EU) 2021/2282)[139] establishes a framework for the coordinated clinical evaluation of health technologies across EU Member States, including pharmaceuticals and high-risk medical devices, and *in vitro* diagnostic medical devices. Its primary objective is to enable faster, more consistent clinical evaluation and reduce delays in patient access to innovative healthcare technologies. By a **Joint Clinical Assessment (JCA)** process, the HTAR ensures that new technologies are evaluated for their relative clinical effectiveness, safety, compared to existing alternatives in a harmonised manner.

137 Directive (EU) 2024/2853 of the European Parliament and of the Council of 23 October 2024 on liability for defective products and repealing Council Directive 85/374/EEC

138 European Parliamentary Research Service, 2023. The Artificial Intelligence Act: A step towards a comprehensive EU framework for AI

139 Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU

The HTAR represents a shift towards a unified approach to the clinical assessment of health technologies in the EU[140].

5.1.7 European Health Data Space (EHDS)

The EHDS (Regulation (EU) 2025/327)[141] establishes a unified and secure framework for health data exchange across EU Member States. Its overarching goal is to enhance healthcare delivery, improve patient access to their health data, and enable broader uses of health data for research, policymaking, and innovation, including the development and deployment of AI in healthcare. The EHDS addresses two key aspects of health data usage:

1 **Primary Use:** Facilitating individuals' access and control over their personal health data, allowing seamless sharing across borders. This includes interoperability standards for electronic health records and health information systems to ensure consistent data exchange across EU Member States.

2 **Secondary Use:** Enabling those interested in using data (data users) such as individuals, researchers, public health authorities and AI developers to access health data for innovation, regulatory, and policy purposes. Strict privacy and security standards govern this access, ensuring sensitive information is protected.

The proposed framework includes provisions for a secure, interoperable digital infrastructure that supports health data accessibility and cross-border collaboration. For example, the European electronic health record exchange format seeks to facilitate the cross-border interoperability of EHRs in the EU. It delineates a set of principles that should govern this exchange and a process for further development, monitoring and review. It also lays down set of common technical specifications for the cross-border exchange of data. Additionally, specifically, for AI deployment in healthcare, the EHDS is expected to provide a valuable foundation that could incentivise the establishment of high-quality datasets essential for training, performance testing, and monitoring AI systems[142]. This will help address challenges related to data availability, quality, and fragmentation, which often hinder the scalability of AI solutions. The EHDS also emphasises trust through privacy safeguards, data anonymisation, and secure access protocols.

5.2 EU regulatory ecosystem and the path to AI deployment in healthcare

The aforementioned frameworks collectively shape key aspects such as safety, performance, data quality and interoperability, and clinical evidence. While these regulations lay the groundwork for innovation and adoption, the actual deployment of AI in healthcare involves navigating diverse clinical environments, addressing implementation challenges, and meeting the unique needs of healthcare systems.

140 European Commission, 2023. Factsheet - Implementing the EU Health Technology Assessment Regulation.
141 Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847.
142 for example see Data quality and utility label requirements under Article 56 EHDS

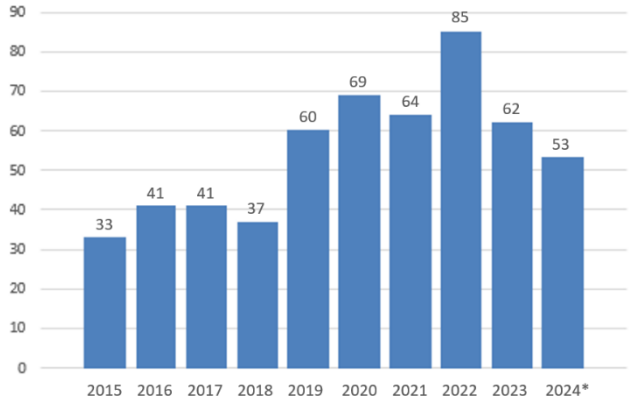
6 Current state of deployment of AI in healthcare in the EU

This section presents an overview of the current market of AI/ML-enabled medical devices in clinical practice within the EU, and to provide a future outlook on their level of deployment. The section is organised into three sections, one analysing the trends in research, the second focused upon AI development and the last focusing on deployment in clinical practice. More details on the methodology and data sources used can be found in Annex 5 – Details on data sources and methodology for market analysis.

6.1 Research of AI/ML-enabled medical devices in clinical practice

AI applications in healthcare are rapidly expanding and gaining increasing interest, with data showing numerous companies, universities, and research institutes both in Europe and internationally investing in the research of these technologies[143]. To assess the level of research on AI in the healthcare sector, various data sources were consulted[144]. According to the CORDIS database[145], there were a total of 553 funded research projects over the past 10 years on the topic of "AI in healthcare". The majority were initiated from 2019 onwards, beginning with 33 projects in 2015 and peaking at 85 projects in 2022[146]. Specifically, the number increased consistently from 2019 to 2022, **indicating a sustained momentum for AI research in healthcare** during those years.

Figure 7: Number of EU-funded research projects on AI in healthcare initiated each year (2015-2024)



* The number of approvals in 2024 is based on data last accessed on 13/11/2024. Additionally, the 553 projects include 8 that are scheduled to start in 2025.

Source: Authors' elaboration based on CORDIS database.

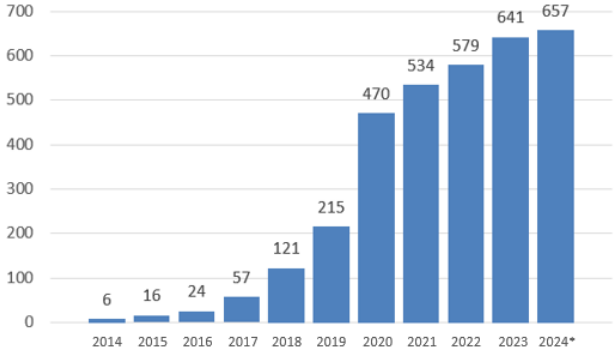
The number of EU-funded projects slowed down in the last two years, however this may be an artefact of the period between the completion of previously funded projects and launch of follow-up calls. The total budget of the research projects considered above between 2015 and 2024 amounted to **approximately EUR 3.53 billion**, with an average budget per project of EUR 6.73 million. It should be noted that at the time of writing this report, the Commission recently launched a call as part of the EU4Health Programme

143 Secinaro et al., 2021. The role of artificial intelligence in healthcare: a structured literature review.
144 details on these data sources are provided in Annex 5 – Details on data sources and methodology for market analysis
145 CORDIS is the European Commission's primary source of results from the projects funded by the EU's framework programmes for research and innovation. It has a structured public repository with all project information held by the European Commission such as project factsheets, participants, reports, deliverables and links to open-access publications
146 The number of projects is indicative and is based upon extracting projects from CORDIS using the search string "(Artificial Intelligence) AND (Healthcare). It is possible that relevant projects that did not include these terms within their description were excluded. Please see the Annex 6 for more details.

aiming at supporting the deployment of AI in the healthcare sector[147] with an estimated budget of **EUR 4.5 million.**

In addition to EU-funded research projects, the rapid technological advancements in AI are evident from the sharp rise in **patenting activity**. In the medical field, in particular, patent data underscores a strong and growing trend in AI-related inventions[148]. Data from the platform Espacenet from the European Patent Office (EPO) includes 675 patents of AI in healthcare, with the majority of patents being filled from 2019 onward. There was a significant increase from 22 patents in 2017 to 118 in 2023 (representing a five-fold increase). Research in AI can also be estimated by the **number of clinical trials** on AI/ML-enabled medical devices. The data from the WHO International Clinical Trials Registry Platform (WHO ICTRP)[149] on clinical trials involving AI or ML-enabled medical devices provided a total of 3,320 results between 2014 and 2024, showing a stark increase from 6 trials in 2015 to 657 trials in 2024. The number increased consistently over the 10-year span, **highlighting growing progress in the development of AI/ML-based solutions in healthcare.** A significant increase was particularly evident from 2020, when numbers doubled compared to the previous year. Although no clear causal relationship has been established, this increase may be related to the rise in research funding following the implementation of the EU4Health programme in response to the COVID-19 pandemic, along with the new priorities emerging and recent advancements in the field of AI.

Figure 8: Number of clinical trials on AI/ML-based interventions started each year (2014-2024)*



* The number of clinical trials started in 2024 is based on data last accessed on 19/11/2024. The total number for the full year 2024 is expected to be higher.

6.2 Development of AI/ML-enabled medical devices in clinical practice

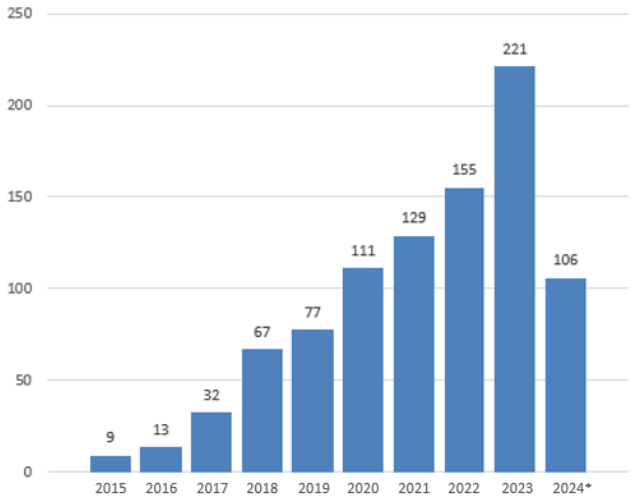
In this section we provide an in-depth analysis of the list published by the Food and Drug Administration (FDA) of the US in August 2024 of the approved AI/ML-enabled medical devices[150]. More information on the database and data limitations with respect to information on CE-marked AI/ML-enabled medical devices can be found in Annex 5 – Details on data sources and methodology for market analysis.

The FDA list contains **950 AI/ML-enabled medical devices approved by the FDA** up to June 2024[151]. According to Muehlematter *et al*, prior to 2021, the number of FDA approved devices was low but was following an upward trend. In fact, **the number of**

147 For more information on the call, please refer to the following link: here
148 Aboy et al., 2023. Mapping the patent landscape of medical machine learning.
149 The WHO ICTRP provides a searchable database containing the trial registration data sets made available by data providers around the world meeting criteria for content and quality control. It compiles data from national and regional clinical trial registries worldwide, including ClinicalTrials.gov (USA), the EU Clinical Trials Register, the Chinese Clinical Trial Registry, and the Japan Primary Registries Network.
150 While the exact criteria for inclusion in the FDA list were not specified, the FDA website defined artificial intelligence as "a device or product that can imitate intelligent behaviour or mimic human learning and reasoning"
151 U.S. Food & Drug Administration, 2024. Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices.

FDA approved devices had more than a 12-fold increase between 2015 and 2020, from 9 devices listed in 2015, up to 77 in 2019 and 111 in 2020[152]. Between January 2021 to June 2024, **611 AI/ML-based medical devices had been approved by the FDA**. As it can be observed in Figure 9, there's been a steady increase in recent years in the number of approved devices, with a 71% increase between 2021 (129 devices) and 2023 (221 devices).

Figure 9: Number of FDA approvals of AI/ML-enabled medical devices between 2015 and 2024 (per year)



*Number of approvals in year 2024 only includes approvals between January and June. Assuming that the number of approvals remains constant throughout the year, 212 AI-ML-based medical devices would be approved in the whole year 2024.

Source: Authors' elaboration based on FDA database.

According to the data retrieved from January 2021 to June 2024, 598 (98%) of 611 AI/ML-based medical devices were approved through the 510(k) pathway[153], indicating that almost every device on the market presents a low risk or was preceded by a similar product that had already been legally placed on the market. Each device was assigned one lead medical specialty review panel. As exhibited in Figure 10, **the most common medical specialty assigned for the approved FDA AI/ML medical devices was radiology with 81% of entries** (492 out of 611). The second most common medical specialty related to cardiovascular devices with 56 (9.2%), followed by neurological devices with 20 (3.3%), and gastroenterology-urology with 11 devices (1.8%).

As Figure 10 shows, the number of AI products for radiology has **rapidly expanded over the past years**, and the sector is perceived to be leading the way with the implementation of AI/ML-based solutions for worldwide applied image reading software[154]. Most AI/ML-based medical devices are approved for radiological use, substantially more so than other medical specialties. One contributing factor to this trend could be the exponential growth of **radiological imaging data** compared to the number of available trained readers[155].

152 Muehlematter et al., 2021. Approval of artificial intelligence and machine learning-based medical devices in the USA and Europe (2015–20): a comparative analysis.

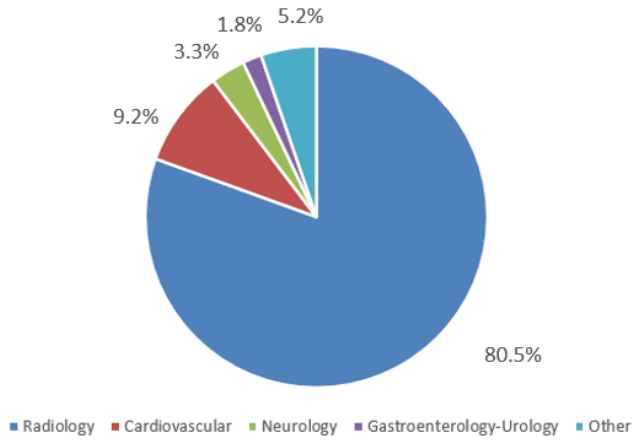
153 Before medical hardware or software can be legally introduced to the US market, the parent company must submit it to the FDA for evaluation. Depending on the devices' risks, the FDA centrally approves medical devices through three pathways: the premarket approval pathway (the most rigorous review for high-risk devices), the de novo premarket review (for low and moderate-risk devices), and the 510(k) pathway, each of which needs specific criteria to be fulfilled to be granted to be granted. For simplicity, we use "approval" to denote the clearance of these devices.

154 Benjamens et al., 2020. The state of artificial intelligence-based FDA-approved medical devices and algorithms: an online database.

155 Hosny et al., 2018. Artificial intelligence in radiology.

The routine collection of imaging data during clinical practice has resulted in the **availability of large datasets**, which are valuable resources for scientific and medical exploration. Moreover, the adoption of AI technologies may further be driven by the **shortage of radiologists**, as these AI devices have the potential to reduce the time required for radiologists to interpret large volumes of medical images. Consequently, the number of approved AI/ML-based medical devices in radiology has risen since 2015, suggesting a continued increase in such devices related to radiology in the future[156]. However, **clinical implementation remains limited**[157,158,159], and the available evidence for commercially available AI software is still scarce[160].

Figure 10: Number of FDA approvals of AI/ML-enabled medical devices per lead medical specialty review panel



Source: Authors' elaboration based on FDA database

6.3 Deployment of AI/ML-enabled medical devices in clinical practice

In multiple studies, healthcare emerges as one of the most prominent sectors for AI deployment, alongside industries such as ICT, financial services, and education[161,162]. Based on the insights into research and development discussed above, the deployment of AI technologies in clinical practice could be expected to follow a similar upward trend. Despite these increasing shares and encouraging data, there is a **large disconnect between the amount of research and development on AI medical devices and their adoption in clinical practice**.

A limited body of literature attempts to estimate the level of AI deployment in clinical practice due to the **lack of comprehensive and complete databases** on actual deployment of AI in general terms, and on AI medical devices in clinical practice in particular. To overcome these data limitations, two main methodological approaches were identified in the literature. The first, used in a study by Goldfarb et al provides evidence on a **slow adoption of AI in healthcare in the US**[163]. The study analysed data from

156 Muehlematter et al., 2021. Approval of artificial intelligence and machine learning-based medical devices in the USA and Europe (2015–20): a comparative analysis.
157 Huisman et al., 2020. Implementation of artificial intelligence: is the community ready? An international survey of 1,041 radiologists and residents.
158 Strohm et al., 2020. Implementation of artificial intelligence (AI) applications in radiology: hindering and facilitating factors.
159 Wichmann et al., 2020. Artificial intelligence and machine learning in radiology: current state and considerations for routine clinical implementation.
160 Van Leeuwen et al., 2021. Artificial intelligence in radiology: 100 commercially available products and their scientific evidence.
161 O'Reilly, 2021. AI Adoption in the Enterprise 2021.
162 PwC Netherlands, 2017. Adoption of artificial intelligence in healthcare.
163 Goldfarb et al., 2020. Artificial Intelligence in Health Care? Evidence from Online Job Postings

online job postings in the US between 2015 and 2018 and inferred that based upon open positions in healthcare roles related to machine learning and AI that **fewer than 5% of healthcare organisations have adopted AI tools**[164]. Specifically, the study found that **less than 3% of hospitals** posted any jobs requiring AI expertise. It should be noted that the interpretation of these results is subject to potential biases as some research has demonstrated that some companies may publish job advertisements requiring AI capabilities with the purpose of positively influencing investor perceptions and company valuations[165]. Equally, job advertisements may be anticipatory of future deployment, rather than current deployment activities.

The other common approach to estimate the deployment of AI in clinical practice relates to the use of surveys. For instance, in 2020 the Commission conducted the European enterprise survey on the use of technologies based on AI[166]. According to the results, **47% of respondents working in the human health services sector claimed to be using at least one AI tool**, while 19% had plans to use AI tools in the future. Earlier this year, in February 2024, a group of researchers also conducted an online survey across general practitioners in the UK on their use of generative AI[167]. A total of 1,006 general practitioners responded to the survey, of which **20%** (205 out of 1,006) **reported to be using AI tools in clinical practice**. Those who claimed to be using generative AI were asked a follow-up question on the tasks they were using it for. Out of the 205 respondents, 47 claimed to be using the tools to generate documentation after patient appointments (29%), and 45 for the use of differential diagnosis (28%).

Similarly, there are several papers that analyse data on **surveys conducted specifically among radiologists**, as they are one of the groups of medical professionals who are expected to make the most use of AI tools. A 2024 survey conducted by the European Society of Radiology among its members showed that **48% of respondents (274 out of 572) claimed to be currently using AI systems in their clinical practice**, 27% were not using any, and 25% were not using any but were planning to do so in the future[168]. Similarly, the American College of Radiology Data Science Institute also conducted a survey among its members[169]. Their results show that approximately **35% of total respondents** (493 out of 1,427) claimed to be **currently using AI as part of their clinical practice**. The percentage of radiologists claiming to be using AI tools in their clinical practice is therefore higher compared to the data for healthcare professionals in general terms.

However, surveys may lead to overly optimistic estimations of AI deployment in healthcare since participants are usually more familiar with these technologies than the average healthcare professional, potentially skewing responses toward a more favourable perception. Moreover, respondents may conflate traditional rule-based or knowledge-based systems – such as clinical decision support tools – with more recent deep learning-based AI, which only remains in the early stages of deployment in clinical workflows. Additionally, methodological limitations, such as unclear phrasing of survey questions or a lack of transparency regarding respondent selection, may further affect the reliability of these findings.

164 Johns Hopkins University – Hopkins Business of Health Initiative, 2022. AI in healthcare is here, but uptake is slow.
165 Elder, 2024. If you want your company's stock to go up, hire worker IT people.
166 European Commission, 2020. European enterprise survey on the use of technologies based on Artificial Intelligence.
167 Blease et al., 2024. Generative artificial intelligence in primary care: an online survey of UK general practitioners.
168 European Society of Radiology, 2022. Current practical experience with artificial intelligence in clinical radiology: a survey of the European Society of Radiology.
169 Allen et al., 2021. 2020 ACR Data Science Institute Artificial Intelligence Survey.

Conversely, several other studies indicate that medical AI device adoption remains in its early stages, with usage concentrated around a few leading devices. Moreover, the overall utilisation of medical AI products is still limited, primarily applied to a select number of procedures[170]. Further research suggests that AI integration into clinical practice will remain modest in the coming years, as many AI healthcare products are still in the design and development phase[171,172,173].

The **survey conducted as part of this study[174]** also collected information on whether surveyed healthcare professionals and hospital representatives claimed to be using AI medical devices in their clinical practice, and whether AI developers had deployed their AI applications.

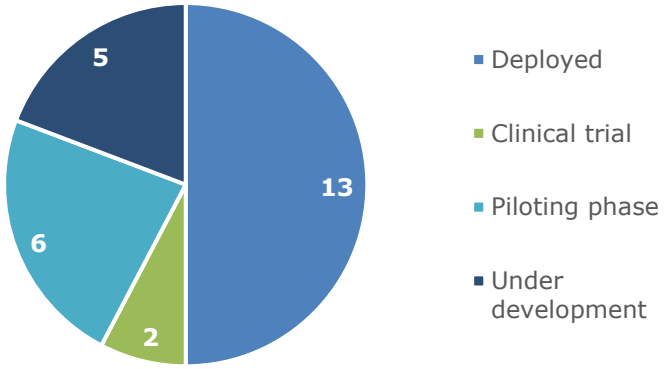
For **HCPs and HCP associations**, the question on the use of AI tools was only asked to those respondents who **previously indicated to have a good knowledge of AI usage**. In addition, in order to gather granular insights on deployment in practice, HCPs from technologically advanced hospitals were consulted. The responses collected may therefore be positively biased, than if the opinion of all healthcare professionals had been considered. From the 51 responses collected, **63% of respondents** (32 out of 51) **stated to have used or to be currently using AI tools in clinical practice** against 31% (16 out of 51) who claimed not to be using them. For EU-based respondents, the responses stayed similar, with 63% of respondents (29 out of 46) claiming to use AI tools compared to 30% who claimed not to be using them. It should be noted, however, that from the HCPs that claimed to be using AI tools in their clinical practice, **five did not provide further information on the AI tools while four of them mentioned the use of ChatGPT**. In one of these cases, the HCP claimed that they were testing the use of ChatGPT with bad outcomes so far. Considering that only 20 out of the 46 respondents (43%) provided evidence on the actual use of AI/ML-enabled medical devices the **survey results be interpreted with caution, as they may provide biased estimations**. Additionally, the results show that there is a higher percentage of healthcare professionals based in urban areas who have deployed AI in their clinical practice compared to professionals in rural areas. Notably, 31 respondents stated to be based on a large city or metropolitan area of which 58% claimed to have adopted AI. On the other hand, three of the respondents were based in small towns, of which only one (33%) had deployed AI in their institution.

In the case of **hospital representatives**, of the 35 hospital representatives responding to the survey, **20 claimed to be currently piloting an AI solution (57%),** 19 had already purchased and deployed a commercially available solution (54%), and 11 had developed and deployed an in-house AI solution (31%). Only two hospital representatives mentioned not to have yet adopted AI. Thus, the percentage of hospital representatives who claimed to have deployed AI medical devices was lower than in the case of healthcare professionals. This may be due to hospital representatives not considering the use of general-purpose AI tools when replying to this question. From the responses collected, three respondents mentioned to be from a hospital in a small town with none of them having deployed AI in their institution. On the other hand, 6 out of the 11 respondents (55%) from large or metropolitan areas; and 7 out of 10 (70%) from medium cities claimed to have deployed AI. These results suggest that the adoption of AI tools remains more prevalent in urban compared to rural regions.

170 Wu et al., 2024. Characterizing the clinical adoption of medical AI devices through US insurance claims.
171 Davenport et al., 2019. The potential for artificial intelligence in healthcare.
172 Apell et al., 2023. Artificial intelligence (AI) healthcare technology innovations: the current state and challenges from a life science industry perspective.
173 Bajwa et al., 2021. Artificial intelligence in healthcare: transforming the practice of medicine.
174 Subject to the same limitations discussed above for surveys

In terms of the responses collected by 36 **AI developers and researchers,** a total of 25 respondents (69%) claimed to have developed or to be developing AI tools for healthcare use – including 16 EU respondents and 9 international respondents. It should be noted, however, that when AI developers were asked on the specific state of deployment of their developed AI medical devices there was a significant number of respondents who mentioned that their tool **was in testing and/or piloting phases.** In the case of EU developers, 10 out of the 12 respondents who said they had deployed AI tools provided more information on their tools. In total, they provided information for **28 developed tools**, of which **five were still under development** and therefore not actually deployed. From the 28 AI tools they provided information, **46% (13 out of 28) had been deployed**, while 21% (6 out of 28) were in a piloting phase and 7% in clinical trial phase. In the case of international respondents, AI developers provided information for 16 AI tools they had developed of which 12 have been deployed (75%) while 4 were in a piloting phase (33%). Hence, although the broader question on deployment may have hinted to an overall fair level of deployment; **the actual level of deployment was lower when respondents provided further details**.

Figure 11: State of deployment of AI tools by EU developers identified in the survey

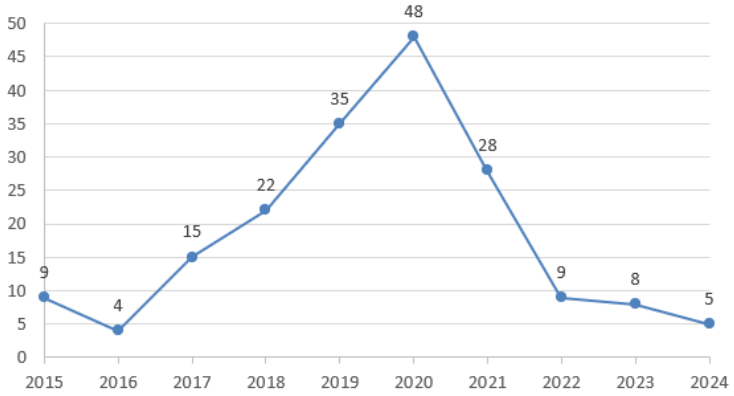


Source: Authors' elaboration based on survey results

Further assessment on the deployment of AI in the EU was conducted based on the data available in the **Radiology Health AI Register**[175]. As of October 2024, the Register included information for **214 CE-marked AI products in the field of radiology**. The Register provides information on the date that the AI medical devices listed have been on the market since. This information was available for 202 devices, of which 183 (90%) had been on the market since 2015. In the figure below we include the annual number of AI medical devices in the Register which have been deployed between 2015 and 2024 (up to June).

175 An online overview of CE-marked AI products based on vendor-supplied product specifications created by a research team from the Department of Medical Imaging at the Radboud University Medical Center (The Netherlands). The database can be accessed via the following link: www.radiology.healthairegister.com (Last accessed 29/11/2024).

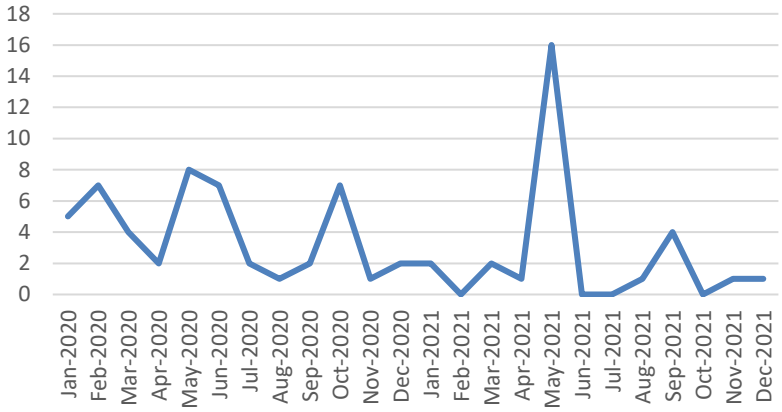
Figure 12: Annual number of AI medical devices in radiology in the EU market



Source: Authors' elaboration based on the Radiology Health AI Register

As it can be observed, the number of medical devices that entered the EU market followed an **upward trend until 2020**. Since 2021, the number of AI radiology devices on the market has considerably diminished, which could be inferred as being a result of market saturation, or the changing regulatory landscape (MDR/IVDR). It should be noted that the data on market entry dates collected by the Register also shows that there was a peak in May 2021 on the number of AI medical devices entering the market, prior to the entry into force of the MDR/IVDR. As exhibited in Figure 13, in May 2021 there were 16 AI radiology devices entering the market. For the following months of June and July 2021 the number of products that entered the market was zero. A similar trend could not be identified in the data analysed on FDA-approved medical devices (see Figure 13 Annex 5 – Details on data sources and methodology for market analysis).

Figure 13: Monthly entries in the market of AI devices in radiology between 2020 and 2021



Source: Authors' elaboration based on the Radiology Health AI Register

To ensure the comparability with the previous analysis conducted on FDA approved medical devices, the project team analysed the data on medical devices which had been CE-marked between January 2021 and June 2024. Between these dates, **a total of 50 new AI software for clinical radiology** were launched on the EU market and marked with CE conformity.

Regarding the modalities, we observe that products are distributed over Computed Tomography (CT) (34%, 17 out of 50 devices), followed by MR and X-ray (each of them accounting for 13 devices, 26%), ultrasound (4 devices, 8%), and mammography (3 devices, 6%). These figures are in line with the results of a 2024 survey among members of the European Society of Radiology, whereby AI impact was predominantly expected on

breast and oncologic imaging, primarily involving CT, mammography, and MRI[176]. The extensive use of AI tools for CT is justified by the high volume of imaging data it generates and its critical role in diagnosing complex conditions, making it ideal for leveraging AI to enhance accuracy and efficiency[177]. **Additionally, half of the products (25 out of 50) were marked with IIa risk class, that is products with low and medium risk levels**[178]. Such result is also in line with the analysis conducted on FDA approved medical devices, which also showed a higher percentage of low-risk devices. In terms of tasks performed, the main ones are **diagnostic tasks** (39 devices, 78%), AI-assisted prognosis prediction and risk stratification (18%, 9 out of 50 devices), and AI-assisted symptom checker and support in treatment decisions (4%, 2 out of 50 devices). AI devices, in this regard, are particularly helpful for diagnostic tasks as they excel at analysing complex imaging data to detect abnormalities with high accuracy[179].

The Register also includes information on the **type of deployment** of the AI medical devices for four pre-defined options: locally on dedicated hardware; locally virtualised (virtual machine, docker); cloud-based; and hybrid solution. Data was available for 47 out of the 50 analysed AI medical devices: the majority of analysed devices were deployed cloud-based (77%, 36 out of 47) or locally on dedicated hardware (72%, 34 out of 47). It should be noted that the majority of AI medical devices offered more than one type of deployment. In this regard, those that usually only offered one form of deployment were the ones being cloud-based – 7 out of the 36 solutions (19%) which could be deployed via cloud services only had that option for deployment. This analysis therefore **evidences the importance of cloud services for the deployment of AI medical devices**, particularly in the field of radiology. This is in particular the case for small/rural hospitals which may lack the infrastructure to deploy AI medical devices and may therefore need to rely on cloud-services.

Hence, the information provided above clearly shows that the **breadth of applications has continuously and rapidly increased in the last few years and, it is not anticipated to decelerate in the near future**[180]. This is evident when examining both the **research** phase of AI technologies in healthcare, the **development** of AI-based tools for clinical use and the actual **deployment** of AI/ML-enabled medical devices in clinical practice. All indicators mentioned above point to a clear upward trend:

- In terms of **research**, the number of EU-funded research projects on AI in healthcare initiated annually tripled, rising from 33 in 2015 to 85 in 2022.[181] The number of patents on AI in healthcare published annually experienced a 20-fold increased, rising from 6 in 2016 to 122 in 2024[182]. The number of clinical trials on AI/ML-based interventions initiated annually increased approximately by 109-fold, growing from 6 in 2014 to 657 in 2024.

176 Zanardo et al., 2024. Impact of AI on radiology: a EuroAIM/EuSoMII 2024 survey among members of the European Society of Radiology.
177 Mello-Thoms and Mello, 2023. AI in imaging and therapy: innovations, ethics, and impact: review article.
178 According to the MDR, there are four different classes of medical devices depending on the risk level of the product (described in detail in section 6.1.2): class I low risk, class IIa low/medium risk, class IIb medium/high risk, and class III high risk. Whereas a class I CE mark is obtained through self-certification, classes II and III necessitate an external evaluation by a notified body, which entails a more complex process that also includes the review of results.
179 Mello-Thoms and Mello, 2023. AI in imaging and therapy: innovations, ethics, and impact: review article.
180 U.S. Food & Drug Administration, 2024. Artificial Intelligence Program: Research on AI/ML-Based Medical Devices.
181 The number of projects is indicative and is based upon extracting projects from CORDIS using the search string "(Artificial Intelligence) AND (Healthcare). It is possible that relevant projects that did not include these terms within their description were excluded. Please see the Annex 6 for more details.
182 Please note it cannot be inferred that these patented products derived from EU funded initiatives/research

- In terms of **development**, the number of FDA approvals for AI/ML-enabled medical devices has a 25-fold increase, going from 9 in 2015 to 221 in 2023.
- Lastly, in terms of **deployment** in clinical practice, when looking at the number of AI-based medical devices in radiology available in the EU market, this also had a 12-fold increase, growing from 4 in 2016 to 48 in 2020.

Despite the clear upward trend in terms of research and development of AI/ML-enabled medical devices, their **market presence is however still proportionally limited**. In particular, our research shows that even for radiology, that is the medical field which is expected to leverage the most on AI tools in the future, the number of medical devices in use is limited. Moreover, our research shows that **relying on survey results might provide biased estimations** given that either those participating in surveys may be those most familiar with AI technologies; or that their responses may not be fully accurate (e.g. they may be considering the use of general AI application such as ChatGPT). Another interesting result of our analysis is the fact that **most AI/ML-enabled devices are still products with a medium/low risk**, indicating that the human component is still predominant in higher risk clinical operations and interventions.

Given the limitations in terms of data needed to assess the level of deployment, it becomes even more challenging to provide a **future outlook**. Nevertheless, it can be assumed that, as research and development on AI progresses, and AI enabled medical devices access the market, a corresponding **rise in clinical deployment** will follow, albeit this might be at a **slower pace.** In Table 9, we provide three different scenarios of the future outlook of deployment of AI/ML-enabled medical devices in clinical practice in the EU.

Table 9. Three different scenarios of future outlook of deployment of AI/ML-enabled medical devices in clinical practice.

Scenario	Level of deployment in clinical practice (%)	Description
Baseline scenario – slow adoption	5%	Under the baseline scenario, we assume that AI deployment in clinical practice will progress more slowly than the trends observed in research and development, resulting in levels of clinical adoption comparable to the estimates provided by Goldfarb et al. (2020).
Best-case scenario – rapid adoption	48%	Under the best-case scenario, we assume that AI deployment in clinical practice will align with those reported by radiologists who have been identified as the group of medical professionals using the most AI/ML-enabled medical devices.
Average scenario	27%	Under the average scenario, we assume that the level of AI deployment in clinical practice will reach a midpoint between the slower adoption trends projected under the baseline scenario and the higher adoption levels anticipated in the best-case scenario.

Source: Authors' elaboration

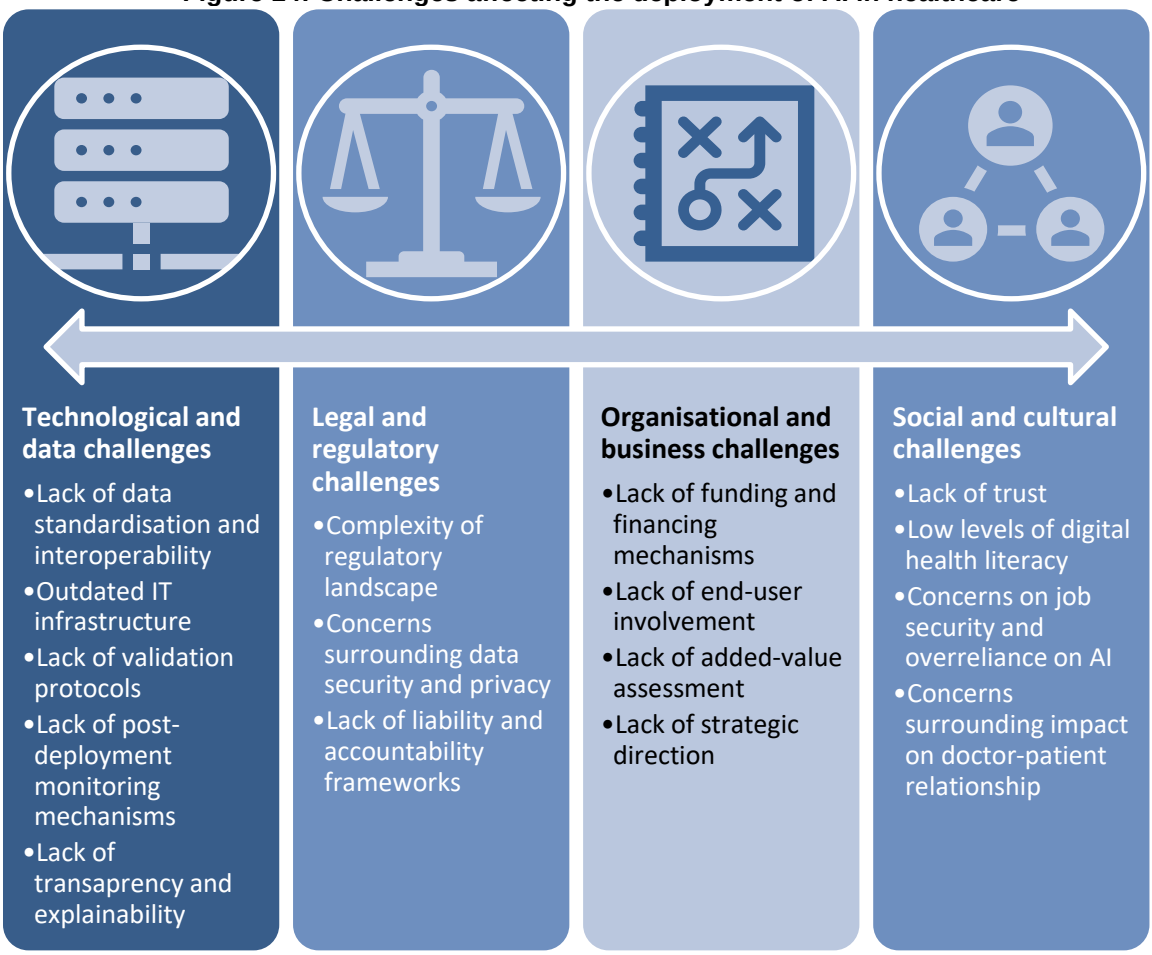
Reliable forecasts for the deployment of AI/ML-enabled medical devices, however, are significantly undermined by the **lack of robust data on their actual use in clinical practice**. This highlights a **crucial gap between official databases and the real-world deployment of these tools**. Existing official databases and market indicators are insufficient for tracking the true extent of these technologies' adoption[183].

183 Alderucci et al., 2019. Quantifying the impact of AI on productivity and labour demand: evidence from U.S. census microdata.

7 Challenges and accelerators to AI deployment and use in healthcare

AI tools have the potential to address several needs that healthcare systems face today (see section 4). However, despite the number of tools on the market today, deployment remains limited (see section 6.3). The findings of this study extracted several challenges faced by both developers and deployers of AI solutions that impact the effective and efficient deployment of AI tools in healthcare. For the scope of this study, these challenges are grouped into four categories as described in Figure 14. In the following sections we elaborate on each of these challenges and present the identified accelerators for the effective deployment of AI tools in clinical practice based on information collected via the desk research and the consultation activities. Where relevant, the existing regulatory frameworks directly and indirectly relevant to the challenges identified is also presented.

Figure 14: Challenges affecting the deployment of AI in healthcare



Source: Authors' elaboration

7.1 Technological and data challenges and accelerators

The technological and data challenges affecting the deployment of AI in healthcare identified in this study can be grouped into five categories presented in the sections below.

7.1.1 Data standardisation and interoperability

7.1.1.1 Challenges

> *"The lack of interoperability of AI solutions with existing IT solutions is the single most common challenge cited by customers. Transferring data from system to system is highly tedious, laborious, and can bring mistakes too easily."* – **AI developer from the USA.**

According to the literature, **data heterogeneity** is a common challenge that hinders the deployment of AI tools as it complicates the **integration and interoperability** of various data sources[184,185]. Data heterogeneity refers to differences in data types (e.g., text, images, audio, or video), data structures (e.g., structured, semi-structured, and unstructured data) and formats across different sources or systems[186]. According to hospital representatives consulted, such differences exist between different healthcare systems, and in some instances between different departments within the same healthcare institution. The **lack of standardised data structures** was described as a significant challenge affecting the deployment of AI in healthcare by 61% of HCPs (30 out of 49), 62% of hospital representatives (16 out of 26), and 70% of AI developers (24 out of 34) that responded to the survey question. When integrating an AI system with an EHR, compatibility challenges may arise due to differences in data formats, structures, and communication protocols. For instance, an AI system might use JSON[187] for data exchange, while the EHR system uses Health Level 7 (HL7) Fast Healthcare Interoperability Resources (FHIR) standard, leading to discrepancies in data interpretation. An example in the literature highlights the integration of an AI tool in oncology, where data transformation tools had to be developed to convert the oncology-specific data from the AI solution into a format that the relevant EHR system could process accurately[188]. Data heterogeneity hinders AI's ability to analyse and aggregate data effectively across various systems and requires complex mapping and conversion processes to ensure interoperability between systems. In addition, according to an AI developer consulted, the lack of standardised data structures impacts the availability of large and diverse datasets which could be used to train, refine, and test AI algorithms that would subsequently improve their overall performance and result in more widescale deployment of AI tools.

Interoperability is defined by the Healthcare Information and Management Systems Society (HIMSS) as "the ability of different information systems, devices and applications (systems) to access, exchange, integrate and cooperatively use data in a coordinated manner, within and across organisational, regional and national boundaries, to provide timely and seamless portability of information and optimise the health of individuals and populations globally"[189]. The **lack of interoperable systems** was described as a significant challenge affecting the deployment of AI in healthcare by 49% of HCPs (24 out of 49), 68% of hospital representatives (19 out of 26), and 74% of AI developers (25 out of 34) that responded to the survey question. According to the HCPs and hospital representatives consulted, **the lack of standardised data structures** and

184 Ahmed et al., 2023. A Systematic Review of the Barriers to the Implementation of Artificial Intelligence in Healthcare
185 Roppelt et al., 2024. Artificial intelligence in healthcare institutions: A systematic literature review on influencing factors
186 Gala et al., 2024. The Role of Artificial Intelligence in Improving Patient Outcomes and Future of Healthcare Delivery in Cardiology: A Narrative Review of the Literature
187 JSON is an open standard file format and data interchange format that uses human-readable text to store and transmit data objects consisting of attribute–value pairs and arrays.
188 Gao et al., 2024. Artificial Intelligence Applications in Smart Healthcare: A Survey.
189 Li et al., 2022. The impact of electronic health record interoperability on safety and quality of care in high-income countries: systematic review.

interoperable systems increases **operational complexity**, creates **workflow inefficiencies** and subsequently **reduces user adoption**. Non-interoperable systems can lead to manual handling of data (e.g. printing the result of AI and carrying it further through the existing workflow), which is inefficient and often results in errors. According to an AI developer from Israel, interoperability is lacking between advanced AI solutions and existing hospital systems and is often attributed to the incomplete implementation of EHRs and the fragmented digital health infrastructure across the region. This creates obstacles to seamless integration and data sharing, forcing HCPs to switch between multiple platforms, which disrupts their workflow and increases cognitive load. In addition, the lack of interoperability is a major barrier to scaling AI tools across different healthcare settings according to AI developers.

7.1.1.2 Accelerators

For AI solutions to be effectively deployed and used within clinical practice, it is important for AI tools **operate seamlessly within existing digital platforms** such as an EHR already familiar to users. They should be **readily accessible**, **require minimal or no manual data entry** by HCPs, and reduce clerical tasks or additional work generated by their use (e.g., extra clicks, menu navigation, more documentation), thereby minimising **disruptions to the clinical workflow**[190,191].Establishment of data sharing policies, standardisation of data collection processes, and promotion of interoperability was highlighted as a good practice to facilitate the deployment of AI in clinical practice by 71% of the HCPs who answered the survey question (36 out of 51). Overall, the workflow, existing practice, current roles, and functions should be minimally impacted to accommodate the AI system[192]. Non-disruptiveness is often perceived as safer for patients and increases the likelihood of successful implementation.

To address the feasibility of interoperability, it was highlighted by stakeholders interviewed that AI developers should **conduct an internal screening of relevant information systems** deployed in the hospital and workflows related to the identified problem (e.g., how are they currently solving the problem, what integrations with other systems and supporting infrastructure will be needed). Collaboration between AI developers and deployers early on in the deployment process has proven to be effective in ensuring that AI solutions are interoperable within the existing hospital infrastructure and allowing for seamless integration according to an HCP from the USA. Ensuring that AI tools are developed with compatibility in mind supports integration of AI solutions within existing IT infrastructure and clinical workflows, facilitating cross-regional deployment, particularly in rural or remote areas. In addition, healthcare organisations might need to **invest in custom middleware solutions** such as application programming interfaces (APIs) to bridge the data format differences and ensure seamless data flow between the AI system and the EHR system, as carried out by the **Mayo Clinic**[193].

Siloing of data and **cumbersome data access approval processes** involving multiple data custodians may be **replaced by efficient, standardised processes for accessing and sharing data from EHR** and other sources which is rendered interoperable using data exchange standards. According to an interviewed hospital representative from Israel and an AI developer from Germany, radiology provides valuable lessons on the importance

190 Scott et al., 2024. Achieving large-scale clinical adoption of AI-enabled decision support
191 This was evident across the four case studies described in Interview Guide - Case studies.
192 Davis et al., 2020. Machine Learning and Improved Quality Metrics in Acute Intracranial Haemorrhage by Non-Contrast Computed Tomography.
193 N'gbesso, Y. 2020. Integration of Artificial Intelligence in electronic health records: Impacts and challenges.

of data standardisation and system interoperability, particularly through the widespread adoption of standards like DICOM (Digital Imaging and Communications in Medicine) and systems like PACS (Picture Archiving and Communication Systems). DICOM ensures a universal format for medical images, enabling compatibility across various imaging devices and software, while PACS facilitates the storage, retrieval, and sharing of these images. These systems exemplify how standardised data, and interoperable frameworks allow for seamless integration with broader healthcare systems, such as EHR and Radiology Information Systems (RIS). This integration enhances workflow efficiency and ensures that imaging data is readily accessible to healthcare providers within a unified digital ecosystem, paving the way for smoother AI deployment in clinical practice. Outside of the field of radiology, there are several standards available to achieve data integration and interoperability:

1. The Artificial Intelligence Modern Data Platform (AIMDP) **integrates the core features of the modern data platform with data science capabilities** to handle various data types. In practice, this platform can manage both structured data (e.g., EHR) and unstructured data (e.g., medical images). For instance, in a large healthcare institution, AIMDP can integrate data from different departments, such as laboratory results, patient monitoring data, and clinical notes. By utilizing its experimentation and knowledge extraction modules, the platform helps clinicians extract valuable insights from integrated data, thereby optimising patient treatment plans[194].

2. **Transform available data into data with similar properties and structure**. This can be achieved by developing a **data harmonisation pipeline** that adheres to the common FHIR data standard. The process includes querying data from the hospital database, performing FHIR mapping, conducting syntactic validation, transferring harmonised data into a patient-model database, and exporting data in an AI-friendly format. The FHIR uses a set of resources and APIs to enable interoperability, allowing healthcare data to be accessed, exchanged, and integrated across different systems. It is widely adopted by recognised leaders in the healthcare industry such as the Mayo clinic[195]. For example, in diabetes management, a hospital can consolidate patient blood glucose data, weight, and dietary records from various sources into a unified FHIR standard. This ensures that the data can be consistently used across different medical applications, enhancing the personalisation and accuracy of treatment[196]. The advantage of this method is that it ensures **data consistency and standardisation**, which facilitates interoperability between different systems and applications. However, it requires rigorous **data validation and transformation processes**, with a substantial initial workload.

3. **Use health data content modelling and exchange standards.** This includes the use of HL7 FHIR or the Observational Medical Outcomes Partnership (OMOP) and other agreed-upon international standards as a health data content modelling and exchange standard. This involves extracting health data from various sources, converting them into a standardised FHIR format, and **ensuring data consistency and interoperability**. For example, in a cross-regional healthcare network, hospitals can share patient medical records using the FHIR standard, facilitating seamless information exchange. Such standards have already been used in a hospital in Belgium to improve interoperability between system. For example, a publicly accessible

194 Ortega-Calvo et al., 2023. An artificial intelligence modern data platform. use case for Spanish national health service data silo.
195 Learn about HL7 international, 2024. Health Level Seven International - Homepage
196 Williams et al., 2023. A Standardised Clinical Data Harmonization Pipeline for Scalable AI Application Deployment (FHIR-DHP): Validation and Usability Study.

foundation model pretrained on longitudinal, structured medical records from 2.7 million patients from **Stanford Medicine** that is compatible with the widely adopted OMOP Common Data Model (CDM) can be shared and built upon across hospitals. Using **standardised data structures** allows for adapting such models to new tasks that significantly **reduces the amount of training labels** needed, thereby lowering label acquisition costs and speeding up the deployment of new applications[197]. In addition, **pre-training on a larger and more diverse patient population** improves the **adaptability of the foundation model** across healthcare settings (a single external foundation model consistently achieved strong performance across both a Canadian paediatric cohort and an American adult ICU-based cohort). In Europe, the European Health Data and Evidence Network (EHDEN), an Innovative Health Europe funded study, supported data partners in transforming data into the OMOP CDM, as well as launching the EHDEN Portal – a gateway to the EHDEN ecosystem with a Database Catalogue of 210 databases, over 359M patient records, and 1,300 registered researchers[198]. Another example is in cancer treatment, where genetic information, treatment history, and current clinical data can be integrated through FHIR standards, allowing specialists across different hospitals to access comprehensive patient information on a unified platform and devise the best treatment plans[199]. The benefits of such a method include widespread adoption and support, promoting collaborative care and treatment planning. For example, the Scottish Breast Screening Service transitioned to a fully paperless allowing for seamless HL7 (international standards for transfer of clinical and administrative data between software applications used by various healthcare providers) integration, electronic messaging and commands between systems[200]. However, it demands significant effort to convert and maintain data in the FHIR format and ensure consistent implementation across different systems[201].

In addition to the above-mentioned data standards allowing for data integration and interoperability, according to a hospital representative from Israel and AI developers from the Israel and the UK, establishing a single platform within which AI solutions can be integrated, trialled, adopted, and evaluated would also ensure that AI tools can be seamlessly deployed into clinical workflows. Many AI developers are developing niche algorithms for specific tasks, meaning that hospitals must procure and integrate multiple point solutions with often limited IT resources. Using such platforms, hospitals can ensure that AI tools will already be configured within the enterprise AI platform, acting as the AI interoperability layer, with all the contracting and deployment built into the system. Such a platform could allow healthcare providers to evaluate and implement AI tools more effectively and efficiently without adding to the hospital IT burden.

197 Guo et al., 2024. A multi-center study on the adaptability of a shared foundation model for electronic health records.
198 van Bochove et al., 2020. EHDEN - D4.5 - Roadmap for interoperability solutions; Oja et al., 2023. Transforming Estonian health data to the Observational Medical Outcomes Partnership (OMOP) Common Data Model: lessons learned
199 Sinaci et al., 2023. A Data Transformation Methodology to Create Findable, Accessible, Interoperable, and Reusable Health Data: Software Design, Development, and Evaluation Study.
200 Lip et al., 2024. Adoption, orchestration, and deployment of artificial intelligence within the National Health Service—facilitators and barriers: an expert roundtable discussion.
201 Setyawan et al., 2021. Data integration and interoperability problems of HL7 FHIR implementation and potential solutions: A systematic literature review.

7.1.2 IT infrastructure

7.1.2.1 Challenges

The successful deployment and continuous use of AI solutions in clinical practice relies upon having the **right IT infrastructure** in place. **Outdated IT infrastructure** is a significant issue[202], especially in Europe where hospitals in rural or underfunded regions face even greater challenges in updating their systems. Many healthcare facilities do not have digital EHRs and still operate on legacy systems that are not designed to support the advanced computational requirements of AI technologies[203]. These systems often lack the necessary processing power, storage capabilities, and network bandwidth needed for AI applications, leading to slow performance and inefficiencies. Such varying levels of digital maturity can also exacerbate the **issue of interoperability** previously described. Outdated IT infrastructure was described as a significant challenge affecting the deployment of AI in healthcare by 59% of HCPs (29 out of 49) , 68% of hospital representatives (19 out of 28), and 53% of AI developers (18 out of 34) that responded to the survey question. According to an HCP from Italy, some hospitals are not aware of the infrastructure requirements they should have in place, resulting in improper deployment of AI solutions.

> *"The deployment of AI tools requires a base level of digital and physical infrastructure to be effective. However, many hospitals in Europe still have limited digitalisation requiring more investment in basic digital and physical infrastructure prior to deploying AI tools. Indeed, physical infrastructure is also essential for supporting AI, making sure that digital services are dependable, safe, and accessible to healthcare professionals in each hospital."* – **Hospital representative association based in Belgium.**

7.1.2.2 Accelerators

Defining the minimum IT standards to facilitate widespread deployment across hospitals in the EU was highlighted as a good practice by 55% of the HCPs surveyed (28 out of 51[204]). Investing in the appropriate IT infrastructure prior to adoption may allow for **interoperable systems** and a more **seamless integration of AI tools** in the clinical workflow according to consulted stakeholders (hospital representatives from France and Italy, an HCP from the USA, and an HCP from the UK). Upgrading IT infrastructure improves hospital operations by reducing the need for manual tasks, which can save time and improve the integrity of the data by minimising the risk of errors. To support the computational demands of AI, **robust IT infrastructure** that includes high-performance computing (HPC) clusters, advanced data storage solutions, high-speed networks, and resilient systems was indicated by stakeholders as important (Figure 15)[205]. A total of 63% of hospital representatives who responded to the survey question (15 out of 24) indicated that they invested in upgrading and modernising their IT infrastructure prior to deployment to support the implementation of AI solutions. For example, the Mayo Clinic updated its IT infrastructure to include **HPC clusters and advanced data storage solutions** that can handle the large data volumes required for AI analysis as part of its "big data" platform (see section 4.5). The robust IT infrastructure enables **real-time processing and analysis**, providing HCPs with timely insights that improve patient outcomes. Such investments, allow for AI solutions to not only be deployed within healthcare settings, but to also be scaled effectively. According to an AI developer from the USA, an effective

202 Hospital Management Asia. 2024. Samsung Medical Centre's path to smart healthcare.
203 European Commission: Directorate-General for Communications Networks, Content and Technology, Page, M., Winkel, R., Behrooz, A. and Bussink, R. 2024. 2024 digital decade ehealth indicator study.
204 For this survey question 32 HCPs did not respond.
205 Noorbakhsh-Sabet et al., 2019. Artificial intelligence transforms the future of health care.

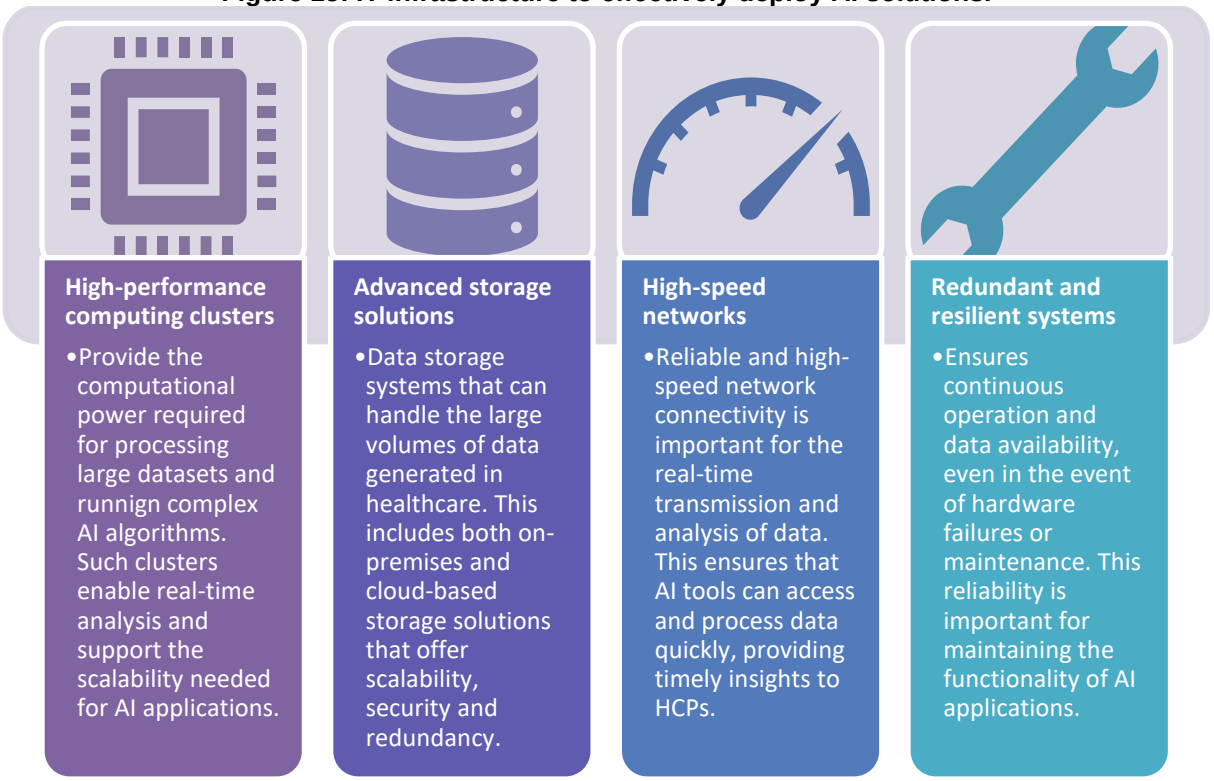
strategy for updating the IT infrastructure is to use a **bottom-up approach** where a specific use-case is selected and the necessary infrastructure and data requirements for integrating the use-case are identified. Such an approach ensures that deployed AI solutions are tailored to specific needs rather than trying to fit existing infrastructure into new technologies.

In the healthcare field, **scalability** presents a significant challenge for deploying AI solutions. While AI applications may perform optimally in small-scale clinical evaluations with a limited data pool, they may face substantial difficulties in maintaining accuracy and operational speed when the scope expands to a national healthcare framework. For example, AI systems may struggle with handling large volumes of inpatient data due to the vast amount of patient information, the diversity of medical conditions, and the need for seamless integration with various healthcare information technology systems. To address this challenge, hospitals and healthcare institutions need to **implement effective data processing strategies** and **sophisticated system architectures** to ensure the integrity and effectiveness of AI applications at scale[206].

The **use of modular architecture** is one solution for achieving scalability in AI applications. Such architecture supports parallel processing, which enhances speed and efficiency, especially when dealing with extensive patient data. For instance, in a healthcare AI application, the architecture might include separate modules for processing patient data, performing predictive analytics, and generating reports. Each module operates independently and concurrently, which improves overall performance[207]**.** For example, the Modular Health Information System at **Mount Sinai** hospital in the USA integrates various **specialised modules to handle tasks like patient monitoring, data analysis and reporting** which enables effective management of large volumes of patient data and flexibility to adapt to evolving needs without extensive system modifications[208].

206 Barmer et al., 2021. Scalable AI.
207 Cohen et al., 2021. A Methodology for a Scalable, Collaborative, and Resource-Efficient Platform to Facilitate Healthcare AI Research.
208 Gao et al., 2024. Artificial Intelligence Applications in Smart Healthcare: A Survey.

Figure 15: IT infrastructure to effectively deploy AI solutions.



Source: Authors' elaboration.

Cloud computing also offers a solution for achieving scalability as it provides scalable computing resources and storage capabilities that adjust dynamically to meet the demands of AI workloads without the need for on-premises infrastructure. Cloud services also offer scalable storage systems that are essential for managing large amounts of medical data that can be used to train, test, optimise, and monitor AI models. Cloud computing services **enable efficient scaling of computational power and storage**, maintaining system stability and performance during high demand periods[209]. For example, smaller hospitals in rural or remote areas, which often lack the infrastructure to manage large data volumes, increasingly rely on cloud computing services to store their data. According to a hospital representative from Israel that took the strategic decision to migrate all its processes to the cloud, the use of cloud services improves reliability, flexibility, and agility compared to on-premises solutions, which also made the deployment of cloud-based AI solutions smoother and more streamlined. The establishment of a "Cloud Committee" within the hospital, whose role is to approve and certify all cloud-based solutions before they are deployed, made the deployment process easier.

Although cloud computing offers dynamic scalability and cost efficiency by adjusting resources in real time, there are concerns about **data security** (see section 7.2.2.1) and **reliance on external service providers**[210]. Such concerns were mentioned by a hospital representative from Denmark. The transmission of patient data to cloud-based services is often subject to internal approval processes defined by the healthcare organisation, which may involve the Data Protection Officer (DPO) or data security team—particularly when the processing involves international data transfers under the GDPR[211]. In addition,

209 Wittig et al., 2023. Amazon Web Services in Action: An In-Depth Guide to AWS.
210 Amajuoyi et al., 2024. Transforming business scalability and operational flexibility with advanced cloud computing technologies.
211 In this context see Penzkofer T. 2024. Prostate MRI: what to consider when shopping for AI tools.

different countries and sometimes different regions have different guidelines and regulations regarding the use of cloud services for medical data, which may complicate the standardisation of AI deployment across different sites. In most data protection legislations, processing of health data has additional requirements since health data is considered sensitive. According to an AI developer interviewed from the USA, most healthcare organisations in Europe **prefer on-premises AI systems over cloud-based solutions**. Three AI developers from the USA and the hospital representative from South Korea indicated that the reluctance of healthcare providers to use **cloud-based solutions is a barrier to scaling AI solutions** within healthcare. According to an AI developer from the USA, **cloud-based solutions facilitate data sharing** allowing for **more efficient post-deployment monitoring** (see section 7.1.4.2) and help overcome any limitations with on-premises data storage and computational power.

7.1.3 Local AI performance

7.1.3.1 Challenges

In some instances, there is a **lack of real-world evidence**, to indicate the effectiveness of AI use in real-life settings[212]. AI platforms are limited by the quality of the data inputs they receive, implying that the algorithm is only as good as the data source "teaching" it[213]. The local performance of AI tools is often evaluated and validated using a **different set of evaluation criteria** or **small datasets** leading to **difficulty in comparing algorithms** and **variations in performance** that may occur within the same healthcare settings, across different healthcare settings and across medical specialties. This issue is compounded when applied to the wide variety of predictive AI models from disease detection to clinical intervention **that need performance testing** and **ongoing monitoring** for algorithmic effectiveness across demographic and social determinants such as race and ethnicity, gender, age, geography, and income[214]. The **accuracy and quality of AI tools** within specific healthcare settings are some of the main contributors to adoption hesitance amongst HCPs according to HCPs and hospital representatives consulted. A **lack of an agreed standard and benchmark for accuracy** (e.g., how accurate does an AI tool need to be before it is approved for clinical practice) is an impediment to implementation, and subsequently, adoption[215]. The **lack of accuracy of AI outputs** could pose a potential risk of harm by both HCPs and patients, for example false negative results may provide an incorrect sense of reassurance and cause a delay in treatment[216]. The **lack of protocols for local performance testing** to assess variations in performance across healthcare settings for existing AI solutions was described as a significant challenge affecting the deployment of AI in healthcare by 55% of HCPs (18 out of 49), 39% of hospital representatives (9 out of 26), and 56% of AI developers (13 out of 34) that responded to the survey question. It is also important to consider that AI tools do not only fail because of how the algorithm was trained, but may also fail because of **variability in human behaviour**, both by HCPs and patients. For example, a hospital representative from Israel stated that variations in performance may arise due to differences in HCPs preferences, workflows, and the types of cases handled (in-patients

212 Liu et al., 2019. A comparison of deep learning performance against health-care professionals in detecting diseases from medical imaging: a systematic review and meta-analysis.
213 Singh et al., 2020. Current challenges and barriers to real-world artificial intelligence adoption for the healthcare system, provider, and the patient.
214 Shah et al., 2023. A Nationwide Network of Health AI Assurance Laboratories.
215 Morrison K, 2021. Artificial intelligence and the NHS: a qualitative exploration of the factors influencing adoption.
216 Mlodzinski et al., 2023. Assessing barriers to implementation of machine learning and artificial intelligence-based tools in critical care: web-based survey study.

versus out-patients). If appropriate standards and benchmarks are established, it could provide rationale for the accuracy of such AI tools.

7.1.3.2 Accelerators

Training on diverse datasets to account for local performance variation was highlighted as an important good practice by 67% of the HCPs who answered the survey question (34 out of 51). According to a stakeholder consulted from the USA, there is a need for well designed, multi-site, multi-centre (ideally heterogenous population) **local performance testing** using standardised methodologies to understand the real-world impacts of AI in healthcare and explore robustness, interpretability, and trust of data within specific healthcare settings. Under regulatory frameworks pre-market conformity assessments to ensures that AI systems meet predefined safety and performance standards. However, pre-market conformity assessments alone may not guarantee that the AI performs optimally in all healthcare settings, as differences in demographics, clinical practices, and healthcare infrastructure can impact outcomes. Additionally, AI tools not within the regulatory oversight (for example some administrative use cases) may not be subject to the same framework.

Local performance testing examines whether AI tools (including AI Medical Devices) maintain consistent performance when applied in different regions or clinical environments - such as determining whether an AI based medical device developed and tested in the US or Germany and performs equally well in Cyprus.

Unlike pre-market conformity assessments, local performance testing is not explicitly required by regulation and can be carried out by the developer, the deployer, or both in collaboration. Incorporating local performance testing as a standard practice could potentially improve trust and ensure consistent AI performance across diverse healthcare settings. Local performance testing has the added benefit of involving a subset of future users of an AI tool prior to wide-spread deployment, which may help to alleviate resistance to change, by allowing HCPs to explore first-hand the performance of an AI solution against their own data.

AI systems **should be tested on analogous datasets** so that performance can be assessed and compared using standardised high-quality data to produce reports on model performance that can be widely shared. A total of 54% of the hospital representatives surveyed (13 out of 24) indicated that they conducted local performance tests of the AI solutions prior to deployment to address any concerns on variations in performance. Forming partnerships between the relevant stakeholders including other hospitals, and AI developers allow for the formation of collaborative data infrastructures that facilitates such local performance studies, ensuring that AI tools are suitable for local use[217]. This was supported by a number of different stakeholders consulted from both Europe and the USA. For example, an AI developer from the USA highlighted that the **establish partnerships with clinic healthcare centres and research institutes** to perform such local performance studies and **address variations in performance**, while an HCP from Denmark reported that a **central entity for data collection and storage** is being investigated that will allow for such performance studies to be conducted effectively. Should local performance be suboptimal, AI models **should be retrained to ensure they perform as required** within the given healthcare setting[218].

217 Lip et al., 2024. Adoption, orchestration, and deployment of artificial intelligence within the National Health Service—facilitators and barriers: an expert roundtable discussion.
218 Scott et al., 2024. Achieving large-scale clinical adoption of AI-enabled decision support.

A digitally advanced hospital in the USA has established a **distributed data network**, in which partners contribute their unique data in an agreed-upon standard (see section 7.1.1.2), while each organisation maintains strict control over their own data within the confines of their organisational IT infrastructure and cybersecurity boundaries[219]. This model relies upon a unique **collaborative design philosophy with technical and administrative controls** that **ensure privacy and confidentiality**. While network controls vary from partner to partner, two overarching principles ensure consistency and promote trust:

- **Data de-identification:** users cannot see or interact with identifiable data and cannot export, co-mingle, or attempt to reidentify individual de-identified records. Depending on the data owner's jurisdiction, the system uses a variety of techniques to accomplish de-identification or its equivalent.
- **Secure, federated architecture:** Data and intellectual property remain under the control of each respective partner or model developer and are only viewed or used as authorised.

> *"If AI is going to be used as a clinical tool (diagnostic or otherwise), then it should be subjected to the same level of scrutiny that any new clinical tool is subjected to when coming to market. Given that this particular tool constantly improves, there is need for constant monitoring on deployment and oversight by medical professionals to ensure that it does what is intended." –* ***HCP from Ireland.***

Users can view and analyse data in a federated manner across the network when they use the data to develop, train, and **test algorithms**. During performance testing, data and models remain with their respective owners. In some cases, a model developer may agree to securely transmit their model to the platform for testing. The model is never visible to the owners of the platform, as it remains encrypted. In all local performance testing use cases, a report detailing model performance is securely transmitted back to the user and the platform securely disposes of any models in its possession once testing is complete.

Additionally, **single platforms within which AI solutions** can be integrated and procured, may both enable seamless integration and interoperability (see section 7.1.1.2) and allow hospitals to test AI products using anonymised data to evaluate the tool's performance in a standardised way, acting as an 'AI sandbox'. An EU-level association and a hospital representative from Israel consulted highlighted that having a single platform where deployment teams can **analyse and locally test AI-solutions on high-quality and anonymised data** could accelerate deployment. Such single platforms could:

- **Accelerate sales cycles with real-world validation:** demonstrate performance in healthcare settings to streamline decision-making and improving go-to-market success.
- **Unique performance insights:** on how the AI tool performs in varying conditions and demographics.
- **Market adaption:** evaluate the AI tool in new markets, getting local evidence and helping the AI developer to understand and adapt to local healthcare practices.
- **Build collaborations:** new strategic partnerships or collaborative research opportunities by working closely with the owners of the enterprise platform and healthcare providers during evaluations.

A **network of assurance laboratories,** consisting of hospitals with large datasets and interested in deploying AI solutions, could serve as a shared resource for developers to **locally test** the performance of AI models across different healthcare setting and populations. This approach could accelerate the pace of development and innovation,

219 Mayo Clinic Platform. Data Behind Glass.

responsive and safe AI deployment, and successful market adoption, including in low-resource settings that may lack the capability of deployment and performance testing of AI tools[220]. Such **laboratories could provide different levels of performance testing**, ranging from **a technical evaluation of model performance** and **bias** for a specific use case, to an **interpretation of its performance** for stratified subgroups of patients, to a **prospective evaluation of usability** and adoption via human-machine teaming and **pre-deployment simulation of the consequences** of using the model's output considering specific policies and work capacity constraints. Additionally, these laboratories **could partner with model developers** to help **remediate specific areas for improved performance** and adherence to best practices. **Independent third-party testing of AI models**—irrespective of the source of the model—may provide a path for adhering to assurance standards agreed on via a community consensus and would greatly facilitate governance decisions at health systems about which algorithms are trustworthy. A blueprint for trustworthy AI implementation guidance and assurance for healthcare in the form of assurance laboratories as a place to evaluate and validate AI models via an agreed-on set of community best practices was recently published by such a community[221].

7.1.4 Post-deployment monitoring and maintenance

7.1.4.1 Challenges

The deployment of AI tools is an ongoing process involving continuous monitoring and adaptation to ensure that AI tools continue to perform as expected. The **performance of AI models can decline** over time due to shifts in local input data, changes to infrastructure or protocols, software updates, or naturally occurring changes in patient populations and demographics[222]. Without effective monitoring frameworks to detect and address these drifts, healthcare providers may be hesitant to trust AI tools for critical decision-making as undetected performance degradation could have significant impact on patient safety and care. Therefore, as the use of AI becomes more prevalent and diverse, institutions using AI should establish **ongoing performance oversight** as one function of a local AI governance process[223]. Strategies for real-world monitoring of AI in clinical practice should be tailored according to the AI tool and the corresponding risk to patient safety if model performance declines. The inclusion of a **defined baseline input data characteristic** at the time of initial acceptance of the AI tool will allow the system to monitor for data drift against the baseline[224]. By monitoring for individual components of data drift, institutions could trigger **re-evaluation of model performance** depending on timing and severity of changes and initiate appropriate steps to safeguard patient care.

Post-deployment monitoring mechanisms differ from post-market surveillance required under regulatory approval processes. While post-market surveillance focuses on compliance, safety reporting, and addressing adverse events to meet regulatory standards, post-deployment monitoring emphasises the continuous evaluation of an AI tool's performance and use in real-world settings. This includes detecting performance drifts, ensuring alignment with evolving clinical workflows, and maintaining accuracy over time. Unlike regulatory surveillance, which is typically episodic and compliance-driven, post-deployment monitoring requires ongoing, proactive oversight tailored to the dynamic nature of AI systems and their operational environments. This distinction highlights the

220 Shah et al., 2023. A Nationwide Network of Health AI Assurance.
221 Coalition for Health AI (CHAI), 2022. Blueprint for trustworthy AI implementation guidance and assurance for healthcare.
222 Pianykh et al., 2020. Continuous learning AI in radiology: implementation principles and early applications.
223 Daye et al., 2022. Implementation of Clinical Artificial Intelligence in Radiology: Who Decides and How?
224 Geis, JR. 2023. Drifting away: When you're A+ decision-making AI machine falls to average… or worse.

need for dedicated frameworks that go beyond regulatory obligations to support the sustained and effective use of AI in healthcare.

7.1.4.2 Accelerators

Post-deployment monitoring of AI tools used in clinical practice is an important driver for safe implementation, and sustained use of AI tools. **Post-deployment monitoring** and **performance assessment** was highlighted as an important accelerator for AI deployment by 80% of HCPs surveyed (41 out of 51). The assurance laboratories (described in section 7.1.3.2) and the enterprise level platforms (described in section 7.1.1.2) could monitor the ongoing performance of AI models to ensure their intended objectives are achieved. This would support hospitals to verify the **long-term appropriateness** of AI models and provide credible verification of information for the use of such AI tools. Post-deployment monitoring also allows hospitals to identify when the AI algorithms do not work as well in a given population and can continually test AI systems against historical data (according to an HCP from the UK). Post-deployment monitoring mechanisms to assess the performance of AI systems were employed by 35% (8 out of 23) of the hospital representatives who responded to this survey question. According to a hospital representative in the USA, the hospital developed an AI Hub to track every **AI 'transaction'**, including both inputs and outputs, as well as their own in-house solutions to ensure internal monitoring and performance with set thresholds to ensure sustainable impact. The information collected supports the creation of quality assurance plans to assess the model's performance over time which is shared with the AI developer to make the necessary adjustments to the model should they be necessary, ensuring that AI tools remain effective and reliable. According to a hospital representative consulted, in Portugal, the hospital collects and analyses post-deployment data to evaluate the impact and ongoing effectiveness of AI tools. This helps in making data-driven decisions for further improvements and ensuring that AI solutions continue to meet clinical needs.

> *"Providing clear, understandable explanations for AI model predictions helps clinicians and patients trust the AI system. When users can see and understand the rationale behind the AI's recommendations or decisions, they are more likely to rely on and accept these tools."* – **AI developer from France.**

Sustaining the use of AI tools within healthcare settings can be reinforced by **creating a support system after the deployment process**[225]. Suitable strategies to reinforce this support system is the **organisation of information sharing meetings between hospital representatives and AI developers.** These meetings can be utilised in order to facilitate "check-ups" on the AI tool deployed in terms of its functioning and identify future possibilities. Collaboration between hospitals and developers of AI tools to monitor performance of AI systems post-deployment was highlighted by a number of hospital representatives consulted. Such an approach, already employed by a hospital in Sweden, allows the developer of the AI solution to update the AI algorithm when necessary and ensure it effectively meets the hospital's specific needs and positively impacts patient outcomes. An AI developer from the USA stated that they **meet with HCPs on a weekly basis immediately post-deployment** which allows for early detection of performance issues or model degradation. In addition to this meeting, the AI Developer reflected that **an internal service desk handling deviation reports and answering questions** and a **dedicated contact person from the AI developer side** who could be contacted any time was a valuable bridge to support HCPs. Another strategy implemented by a hospital representative from the USA is to establish **a cross-functional governance committee**

225 Nair et al., 2024. A comprehensive overview of barriers and strategies for AI implementation in healthcare: Mixed-method design.

for AI implementation, which is recommended to meet monthly. Such committees include professionals from the closest to the patient (HCPs) to innovation managers and leaders of the organisation. The committee's goals could include AI's usage promotion, training new users in terms of application and workflow, tracking effectiveness and compliance, reporting, and planning financial sustainability for continuing using the AI system in the organisation. The agenda of such a committee could also include reviewing individual patient cases where the treatment had failed to increase learning.

Effective post-deployment monitoring also allows deployers to monitor how end-users interact with the AI solution over time. An approach described by a hospital representative from Canada allows the identification of low or inadequate use of deployed AI tools. This information can be used to follow-up with end-users on the reasoning behind the low/inadequate utility and inform approaches to encourage engagement and future tool improvements. Additional post-deployment monitoring mechanisms already employed by hospitals in Canada and the USA include running surveys with HCPs using or affected by deployed AI solutions to monitor the impact of the tool on their clinical practice, as well as integrating patient satisfaction, where relevant, as an additional key performance indicator to monitor the impact of the AI tool.

7.1.5 Transparency and explainability

7.1.5.1 Challenges

The term "black box" refers to a phenomenon whereby an AI algorithm reaches a conclusion without users being able to understand the basis or 'see inside' the system[226]. The **difficulty in interpreting and tracing the techniques** used by some AI models and the lack of explainability could in certain instances erect barriers to AI deployment. The **lack of transparency and explainability** could in some instances be argued to contradict evidence-based medicine, which relies on HCPs understanding both the scientific and clinical bases of the recommendations provided by AI and high standards of explainability to confidently validate and apply the decision[227]. The lack of transparency and explainability of AI tools was described as a challenge affecting the deployment of AI in healthcare by 41% of HCPs (20 out of 49), 58% of hospital representatives (15 out of 26), and 38% of AI developers (13 out of 34) that responded to the survey question. In addition, 59% of patients and patient associations that responded to the survey (41 out of 70) expressed concerns regarding the lack of information on how decisions are made by AI systems. This lack of HCP oversight could lead to errors in clinical settings. One example is the study from **Mount Sinai Hospital**, where an AI model's predictive performance relied on data from specific x-ray machines rather than clinically relevant data. This misinterpretation was uncovered through explainability methods, emphasising the need for robust transparency measures[228]. The degree of explainability however, may vary according to the use case in question. For example, greater explainability may be warranted for high stakes, nuanced, decision-making such as choosing the right antibiotic in a septic, immunosuppressed patient or determining organ donor and recipient matches[229]. A hospital representative from Israel highlighted that HCPs do not necessarily need to understand the complex computational processes behind AI algorithms but should be able to understand what specific features resulted in the AI algorithms decision. Such an approach fosters trust, promotes responsible usage, and establishes a common understanding between AI developers and HCPs.

226 Poon et al., 2021. Opening the black box of AI-Medicine.
227 Morrison K, 2021. Artificial intelligence and the NHS: a qualitative exploration of the factors influencing adoption.
228 Amann et al., 2020. Explainability for artificial intelligence in healthcare: a multidisciplinary perspective
229 Scott et al., 2024. Achieving large-scale clinical adoption of AI-enabled decision support.

Despite the importance of explainability, there is a trade-off when it comes to accuracy. This is particularly relevant in consideration that full explainability in some instances is neither possible nor necessary for HCP and patient acceptance[230]. In a study conducted in the UK, citizen jurors **favoured accuracy over explainability** of AI tools because of the potential for harm from inaccurate predictions and the potential of accurate tools to increase the efficiency of, and access to, care[231]. In addition, the value to HCPs of any explanation will vary according to the specific model and its use case and the expertise (i.e., level of AI or domain knowledge), preferences for accuracy relative to explainability and other contextual values of the user[232].

The lack of transparency and explainability could result in a **lack of trust amongst HCPs and patients**, and subsequently could **negatively impact the doctor-patient relationship** (see section 7.4.4). There is an overall lack of agreement on the different levels of explainability, no clear guidance on how to choose among different explainability methods and an absence of standardised methods for evaluating explainability[233]. Explainability methods may present plausible but misleading explanations and may subsequently affect the human ability to detect model mistakes, resulting in decreased vigilance and auditing of AI tools and over-reliance on their outputs[234].

7.1.5.2 Accelerators

There is a need to improve transparency and explainability of AI tools to build trust of deployers, facilitating acceptability and the adoption of such tools[235]. Short and concise guidelines on how the AI model works to ensure transparency, interpretability and explainability was highlighted as a good practice to facilitate AI deployment by 67% of HCPs surveyed (34 out of 51). According to HCPs consulted, this could be achieved by creating a user-friendly interface of the AI tool with input from experts in the field. This would subsequently reduce the complexity and ensure that HCPs can efficiently and accurately interpret model decisions without having to have extensive technical knowledge of the tool to interpret confidence scores, visualise hidden layers, and conduct sensitivity analyses. This can be achieved by the **creation of clear and comprehensive guidelines** addressing the following points:

1. Having mechanisms in place to **support HCPs in case of disagreements** on decisions due to a lack of transparency and explainability[236].
2. **Revealing the process** of how the algorithm was developed, who was involved in the development process, whether clinicians were consulted, and how the data was processed[237].

230 Van der Veer et al., 2021. Trading off accuracy and explainability in AI decision-making: findings from 2 citizens' juries.
231 Van der Veer et al., 2021. Trading off accuracy and explainability in AI decision-making: findings from 2 citizens' juries.
232 Bienefeld et al., 2023. Solving the explainable AI conundrum by bridging clinicians' needs and developers' goals.
233 Ghassemi et al., 2021. The false hope of current approaches to explainable artificial intelligence in healthcare.
234 Tonekaboni et al., 2019. What clinicians want: contextualizing explainable machine learning for clinical end use.
235 Watson et al., 2020. Overcoming barriers to the adoption and implementation of predictive modelling and machine learning in clinical care: what can we learn from US academic medical centers?
236 Li et al., 2021. Digital technology, tele-medicine and artificial intelligence in ophthalmology: a global perspective.
237 Sangers et al., 2021. Views on mobile health apps for skin cancer screening in the general population: an in-depth qualitative exploration of perceived barriers and facilitators.

3. **Informing HCPs** about what the AI takes as input, how the input is processed, and what the AI produces as output[238].
4. Producing **user-friendly visualisations of output** that are readily understood and clinically actionable[239] (HCPs prefer graphical or numerical displays of probabilities or alert thresholds for a diagnosis, confidence scores for these outputs and links to relevant, consistent recommendations for tests or treatments[240]).
5. **Clearly presenting information about the indications and contraindications** of the AI model, demonstrating awareness of its strengths and weaknesses (e.g., in the form of model report cards that are regularly updated, see section 7.1.3.2, or model facts label, see Box 2).
6. Using **established explainable AI methods** that strike a balance between explainability and high accuracy.

Additionally, according to the patients/patient associations surveyed, 55% of respondents (39 out of 70) reported that clear communication from HCPs on how the AI model works and comes to its decisions would make them more comfortable with AI being used in their healthcare.

Box 2: The "Model Facts" label developed by the FDA[241].

- Defined by the United States Food and Drug Administration (FDA) as "the term of art used for situations when people need good information to make sound choices".
- The "Model Facts" label was designed by an interdisciplinary team including developers, clinicians, and regulatory experts.
- The target audience are HCPs who make decisions supported by an AI model.
- The purpose is to collate relevant, actionable information in 1-page to ensure that HCPs know how, when, how not, and when not to incorporate model output into clinical decisions.
- The label also contains important information about the model, such as the demographic representation of training and evaluation data.
- The "Model Facts" label needs to be localized and needs to be updated over time. "Model Facts" labels include information about model performance within the local population. If a model is adopted in a new setting, a new "Model Facts" label needs to be generated and distributed to clinical end users.
- The target population of model use is also specified in both the "Uses and directions" and "Validation and performance" sections.
- The version of the "Model Facts" label is documented and version control with documentation of changes should be accessible to all end users.

7.1.6 High-level overview of the EU regulatory landscape

The current EU regulatory framework may both directly and indirectly in shape some of the technological and data challenges affecting the deployment of AI in healthcare. The section below presents a high-level non-exhaustive summary overview of key regulation to be considered in the view of the challenges identified and should be reflected in line with the limitations of this study identified in section 3.5.

238 Hassan et al., 2024. Barriers to and facilitators of Artificial Intelligence adoption in health care: Scoping review.
239 Scott et al., 2024. Achieving large-scale clinical adoption of AI-enabled decision support.
240 Tschandl et al., 2020. Human-computer collaboration for skin cancer recognition.
241 Sendak et al., 2020. Presenting machine learning model information to clinical end users with model facts labels.

At the outset and as a foundation, the **GDPR** (Regulation (EU) 2016/679)[242] ensures that personal **data** is processed lawfully, securely, and transparently, protecting individuals' rights while enabling responsible data use. This minimises risks associated with data misuse and fosters public confidence in AI-driven healthcare solutions. Frameworks like the **EHDS**[243] promote some level of **data standardisation, data quality** (primary use), **interoperability** and secure access, particularly to electronic health data for secondary use (see also section 5.1.7).

The measures on interoperability for primary uses of electronic health data could aid AI integration into clinical practice. Under the **EHDS**, the Commission shall establish a central interoperability platform for digital health ('MyHealth@EU') to provide services to support and facilitate the exchange of personal electronic health data for primary use between the national contact points for digital health of the Member States (Article 23 EHDS). Also of relevance are the obligation in the EHDS providing that EHR systems shall include a European interoperability software component for EHR systems and a European logging software component for EHR systems (the 'harmonised software components of EHR systems'), in accordance with the provisions laid therein (Art. 25 EHDS). In addition, manufacturers of medical devices or *in vitro* diagnostic medical devices, that claim interoperability of those medical devices or *in vitro* diagnostic medical devices with the harmonised software components of EHR systems shall prove compliance with the essential requirements on the European interoperability software component for EHR systems and the European logging software component for EHR systems, laid down in Section 2 of Annex II to the EHDS (Article 27 EHDS).

The provisions in the EHDS on secondary uses of data are also of relevance as they provide the possibility to access diverse health data for defined purposes including training, testing and evaluation of algorithms. In this respect, there are measures on health data quality and utility for secondary use (see dataset description and dataset catalogue (Art. 77 EHDS), data quality and utility label (Art. 78 EHDS), EU dataset catalogue (Art. 79 EHDS), minimum specifications for datasets of high impact (Art. 80 EHDS).

The **AIA**[244] sets standards for, among others, high-risk AI systems (see section 5.1.3 for the different risk categories covered by the AIA), ensuring **transparency**, **robust risk management**, and **accountability throughout the AI lifecycle.** The AIA lays down a uniform legal framework in particular for the development, the placing on the market, the putting into service and the use of artificial intelligence systems (AI systems) in the Union, in accordance with Union values, to promote the uptake of human centric and trustworthy artificial intelligence while ensuring a high level of protection of health, safety, fundamental rights (recital 1 AIA).

The AIA mandates that high-risk AI systems shall be designed and developed in such a way as to ensure that their operation is sufficiently transparent to enable deployers to interpret a system's output and use it appropriately (Art. 13 AIA). Additionally high-risk AI systems shall be designed and developed in such a way that they achieve an "appropriate level of accuracy, robustness, and cybersecurity, and that they perform consistently in those respects throughout their lifecycle" (Art. 15 AIA). As noted in the

242 Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)).
243 Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847.
244 Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act)

recitals of the AIA (see recital 71 AIA) "*having comprehensible information on how high-risk AI systems have been developed and how they perform throughout their lifetime is essential to enable traceability of those systems, verify compliance with the requirements under the AIA as well as monitoring of their operations and post market monitoring. Consequently, there are requirements on keeping records and the availability of technical documentation, containing information which is necessary to assess the compliance of the AI system with the relevant requirements and facilitate post market monitoring*". Additional transparency obligations for providers and deployers of certain AI systems are presented within Art. 50.

The MDR[245] and IVDR[246] subjects AI Medical Devices (MDAI) to vigorous requirements through clinical investigation/clinical performance studies and conformity assessment (Chapter VI of the MDR and Chapter VI of the IVDR). Additionally, manufacturers must maintain robust clinical evidence and technical documentation (MDR Art. 10, and IVDR Art. 10).

The AIA places distinct obligations on providers of high-risk AI systems, including pre-market conformity assessment procedures (Articles 24, 43, 47, and 48 AIA). High-risk AI systems which make use of techniques involving the training of AI models with data to be developed on the basis of training, validation and testing data sets that meet the quality criteria referred to therein (Art. 10 AIA), providers of high-risk AI systems shall put a quality management system in place that ensures compliance with the AIA including examination, test and validation procedures to be carried out before, during and after the development of the high-risk AI system, and the frequency with which they have to be carried out (Art. 17 AIA); transparency and provision of information to deployers also encompassing the level of accuracy, including its metrics, robustness and cybersecurity against which the high-risk AI system has been tested and validated and which can be expected, and any known and foreseeable circumstances that may have an impact on that expected level of accuracy, robustness and cybersecurity (Art. 13). For AI systems classified as medical devices, the **MDR** (Chapter VII) and **IVDR** (Chapter VII) enforce rigorous **post-market surveillance requirements**.

While the **AIA, MDR** and **IVDR post-monitoring** primarily focus upon safety, technical performance, and compliance — findings from our study suggest that complementary forms of post-deployment monitoring mechanisms may help foster trust and adoption of AI in healthcare. Beyond technical oversight, deployers and stakeholders in healthcare environments may benefit from post-deployment evaluations that capture qualitative insights, **such as user satisfaction, physician and patient feedback, and alignment with clinical workflows**. For instance, some initiatives highlight the value of holistic monitoring approaches that go beyond technical metrics to assess whether AI systems effectively address local needs, improve patient outcomes, and enhance healthcare efficiency. These broader monitoring practices complement existing regulatory obligations by providing a more comprehensive understanding of AI's real-world impact, ultimately supporting continuous improvement and increasing stakeholder confidence in AI tools. This underscores the importance of integrating both technical and qualitative post-monitoring measures into deployment strategies. During the workshop conducted with EU regulatory experts, the variation in AI performance across healthcare settings and populations, as well as the importance of conducting local performance studies, was discussed. Experts acknowledged that frameworks like **the MDR and IVDR** and **AIA** aim

245 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

246 Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

to ensure robust performance. However, concerns were raised about the need for additional complementary actions to assess AI performance in specific local contexts. Experts highlighted that addressing these variations—through local performance testing processes (see sections 7.1.3 and 7.1.4)—could mitigate risks of healthcare disparities and ensure equitable access to AI benefits.

7.1.7 Summary

The deployment of AI in healthcare faces several technological and data challenges. Data heterogeneity complicates AI integration due to differences in data types, structures, and formats across systems, limiting interoperability and requiring complex data conversion processes. The lack of interoperable systems further exacerbates this issue, increasing operational inefficiencies and creating workflow disruptions that hinder AI adoption. Additionally, outdated IT infrastructure in many healthcare facilities, particularly in underfunded regions, limits the computational capabilities necessary for AI deployment. The absence of standardised local performance testing protocols also affects AI deployment, as AI performance varies across healthcare settings and medical specialties, and there is a lack of clear benchmarks for accuracy and effectiveness. Post-deployment monitoring is another important challenge, as AI models require continuous oversight to detect performance drifts and maintain reliability in real-world settings. Furthermore, the "black box" nature of many AI models raises concerns about transparency and explainability, leading to trust issues among HCPs and patients. Addressing these challenges is important for ensuring the seamless integration, scalability, and responsible use of AI in healthcare.

To overcome technological and data challenges in AI deployment in healthcare, several accelerators have been identified. Ensuring **data standardisation and interoperability** through seamless integration with existing hospital IT systems, early collaboration between AI developers and deployers, and adopting common data standards like FHIR and OMOP can facilitate data exchange. Investing in **modern IT infrastructure**, including high-performance computing, cloud storage, and modular architecture, is important for AI scalability, though security and regulatory concerns impact cloud adoption. Establishing **robust performance testing protocols** through multi-site local performance studies, federated data-sharing networks, and AI sandboxes can enhance real-world AI performance assessments and address variations in performance across diverse healthcare settings. **Post-deployment monitoring** frameworks, such as AI hubs and governance committees, ensure AI tools maintain effectiveness and compliance over time. Additionally, improving **transparency and explainability** with user-friendly visualisations, confidence scores, and standardised reporting can build trust among healthcare professionals and patients. Implementing such strategies could enhance AI adoption, ensuring safe, effective, and scalable integration into clinical workflows.

7.2 Legal and regulatory challenges and accelerators

There are a number of different legal and regulatory challenges affecting the deployment of AI in healthcare that can be grouped into three categories presented in the section below.

7.2.1 Complex regulatory landscape

7.2.1.1 Challenges

The healthcare sector is highly regulated, and obtaining approval for AI applications can be a lengthy process, which can limit the ability of these innovations to reach the market (see section 5). The complexity of the regulatory approval process for AI product commercialisation was described as a significant challenge to AI deployment according to

47% of HCPs (23 out of 47), 56% of hospital representatives (14 out of 25), and 62% of AI developers (21 out of 32) that responded to the survey question. Regulatory experts during the workshop highlighted that the administrative burden of ensuring compliance with these regulations, coupled with the need for extensive documentation, may deter healthcare institutions from adopting AI tools, particularly those with limited resources or technical expertise. Sustained use of AI tools may be further complicated by the need for post-market surveillance obligations. This may require robust infrastructure, technical capacity, and interdisciplinary collaboration, which are often challenging to maintain over time.

The uncertainty surrounding regulatory interpretations[247] also impacts deployment. Healthcare stakeholders, including HCPs and hospital representatives, may struggle to understand the nuanced requirements for using AI in clinical settings leading to delays in adoption as organisations seek legal or technical guidance to ensure compliance, or avoid AI altogether due to fear of non-compliance and associated liabilities. In addition, the complex regulatory landscape and associated procedures (e.g., thorough clinical evaluations, risk management procedures, and post-market surveillance to ensure the safety and performance of medical devices) can sometimes prolong the time it takes for AI tools to reach the market. This subsequently **delays the deployment** of AI-based medical devices into clinical practice and increase the cost of deploying the AI solution in Europe. In the USA, where regulatory approval processes are shorter, the cost of AI solutions is often lower according to an AI developer from Israel.

7.2.1.2 Accelerators

Regulatory guidance and clarification of roles throughout the deployment process was highlighted as a good practice by 67% of HCPs surveyed (34 out of 51). To address the above-mentioned challenges, hospital representatives consulted from Italy, Israel and the USA, have established a legal support at hospital level with knowledge of the regulatory landscape impacting the deployment of AI solutions from the perspective of the deployers. Another effective strategy employed by two hospitals in the USA is the establishment of interdisciplinary AI governance committees comprising HCPs, IT specialists, legal experts, data scientists, and compliance officers. These committees are responsible for assessing potential AI tools, ensuring alignment with regulatory requirements, and overseeing the integration of these tools into clinical workflows. According to hospital representatives who answered the survey question, 61% (13 out of 21) have implemented dedicated compliance teams to oversee the process of AI deployment from the regulatory perspective. By centralising decision-making within hospitals and fostering cross-functional collaboration, hospitals can navigate the regulatory landscape more efficiently and mitigate risks associated with non-compliance.

7.2.2 Data security and privacy

7.2.2.1 Challenges

Concerns surrounding data privacy and data protection was described as a significant challenge to AI deployment according to 49% of HCPs (23 out of 47), 56% of hospital representatives (14 out of 26), and 44% of AI developers (14 out of 32) that responded to the survey. In addition, 54% of the patients and patient associations that responded to the survey (38 out of 70) expressed concerns about data privacy, confidentiality and security. A primary concern shared by hospital representatives from Europe, Japan and the USA is the uncertainty about where and how the data processed by AI solutions is stored. Many AI tools, particularly those relying on cloud-based platforms, may require

247 See limitations section of this report with regard to the timing of the analysis conducted in this study and the evolving regulatory environment.

data to be transferred and stored across different jurisdictions, potentially outside the EU. This raises concerns about compliance with the GDPR and the risk of unauthorised access, especially in regions with weaker data protection standards, a concern raised by a hospital representative from Belgium. Healthcare providers hesitate to adopt AI solutions without robust assurances that data storage and processing comply with local and international privacy regulations.

In addition, another concern involves the potential misuse of data collected by AI tools. Consulted stakeholders highlighted concern that sensitive health data, initially used for specific diagnostic or therapeutic purposes, could be repurposed for secondary uses, such as commercial profiling or research, without a proper legal basis. This is exacerbated by a lack of transparency in how some AI solutions handle data after deployment, creating challenges in maintaining patient trust.

Concerns surrounding **cybersecurity and vulnerability of data to breaches** was described by 38% of HCPs (18 out of 47), 52% of hospital representatives (13 out of 25), and 48% of AI developers (15 out of 31). The sensitive nature of medical data makes it a prime target for malicious activities, and the integration of AI introduces additional vulnerabilities, such as insecure APIs, model inversion attacks, or adversarial exploitation of algorithms [248]. A breach involving an AI system not only jeopardises patient confidentiality but also undermines trust in the technology, prompting regulators and providers to adopt stricter data protection measures. These measures, while essential, can increase the cost and complexity of deploying AI solutions, further discouraging adoption.

7.2.2.2 Accelerators

To address the concerns surrounding data privacy and security, there is a need for comprehensive data governance framework clarifying the role of all stakeholders in data processing. Policies and guidance on information access and sharing within healthcare facilities was highlighted as a good practice by 61% of HCPs surveyed (28 out of 51). As a foundational step, these frameworks should establish clear governance protocols that outline responsibilities, accountability, and processes for data oversight. They must define protocols for data storage, access, and processing by AI solutions, ensuring compliance with regulations like GDPR and the EHDS. A key practice identified in this study is the employment local data storage solutions as described by a hospital representative from South Korea or using certified cloud providers that adhere to stringent data protection standards, as described by hospital representatives from Israel and Canada. By keeping data within jurisdictions with robust privacy laws, healthcare providers may mitigate concerns about unauthorised access or misuse. Employing advanced encryption methods ensures that patient information remains secure, even in the event of unauthorized access. This includes de-identifying data for data stored on local or cloud servers, an approach employed by several hospitals in the USA and Israel. In addition, according to an AI developer from the USA, integrating privacy-by-design technologies into AI solutions that incorporate advanced data protection features helps address some of the challenges related to data privacy [249].

In addition, prior to deploying AI solutions, it is important to assess them to ensure they comply with data security and privacy standards. Clarification on how privacy and data protection rules apply to AI is a good practice employed by 61% of the hospital representative surveyed (13 out of 21). A number of hospital representatives consulted (42% of hospital representatives surveyed Hospital representatives from Israel referenced

248 Ahmad et al., 2020. Barriers and pitfalls for artificial intelligence in gastroenterology: ethical and regulatory issues.
249 Wolf et al., 2021. Success factors of artificial intelligence implementation in healthcare.

a dedicated internal review board responsible for reviewing and assessing ethical and regulatory considerations for each new AI tool prior to deployment. Other hospital representatives in the USA, had implemented a rigorous review process for all third-party vendors and strategic partners, ensuring they meet stringent security standards to protect patient data used by these AI solutions and prevent potential data breaches. According to the patients/patient associations surveyed, 44% (31 out of 70)of respondents reported that clear communication of data protection measures when using AI would make them more comfortable with AI being used in their healthcare.

Informed consent protocols to maintain patient autonomy and data privacy was highlighted as a good practice by 61% (31 out of 51) of the HCPs surveyed. A hospital in the USA has implemented a policy requiring verbal or written informed consent prior to deploying AI solutions in patient care. This required the establishment of clear and coherent communication mechanisms for patients impacted using such AI solutions. However, the hospital outlines that there is a lack of guidance on when patient consent should be obtained, for what types of AI applications, and what specific information needs to be provided to the patients. According to the patients/patient associations surveyed, 53% of respondents (37 out of 70) reported that informed consent on the use of AI in the delivery of care would make them more comfortable with AI being used in their healthcare.

7.2.3 Liability

7.2.3.1 Challenges

There are growing concerns amongst hospital representatives and HCPs as to who is liable or responsible for a bad outcome where decision-making was guided, or in some instances even entirely devolved, to AI tools[250,251]. Additionally questions regarding the extent to which an HCP should follow the advice of an AI tool, and their liability in the event that AI advice is ignored and later shown to have caused harm. **Lack of clarity in liability** was described as a significant challenge to AI deployment according to 43% of HCPs (20 out of 47), 40% of hospital representatives (10 out of 25), 22% of AI developers (7 out of 32) who responded to this survey question. In addition 57% of patients/patient associations (40 out of 70) that responded to the survey also flagged concerns regarding liability. Such concerns may lead to slow uptake or lack of use altogether of AI tools. Additionally, during interviews, hospital representatives and HCPs highlighted the need for clear guidance for hospitals on which AI applications require consent when used for some clinical tasks and what specific information should be communicated to patients.

7.2.3.2 Accelerators

Regulatory guidance to define user responsibilities and liabilities concerning AI models was highlighted as a good practice to address the abovementioned challenge by 80% of the HCPs surveyed (41 out of 51). According to the patients/patient associations surveyed, 70% of respondents (49 out of 70) reported that clear information related to liability in case of errors or adverse outcomes caused by AI systems would make them more comfortable with AI being used in their healthcare. For example, a hospital representative from Portugal highlighted that they are establishing clear liability framework to define the responsibilities of all parties involved in AI deployment.

A step is to also avoid grouping all AI applications together, as the potential AI use cases in healthcare vary widely-from image analysis to precision medicine-with some tools being

250 Ho et al., 2019. Governance of automated image analysis and artificial intelligence analytics in healthcare.
251 The timing of the analysis (prior to the updated PLD) should be carefully considered in reflection of the findings presented.

riskier than others. A policy brief from Stanford University[252] described a framework for establishing liability that conceptualises risk as a function of four major factors and recommends calibrating adoption decisions and post-deployment safety monitoring based on these risk indicators:

- The likelihood and nature of errors (based on the AI model, its training data, its task design, and how it is integrated into clinical workflow).
- The likelihood that humans or another system will detect errors before they harm patients (which depends in part on how much time with and visibility into the AI tool humans have).
- The potential harm if errors are not caught (especially for tools that perform critical clinical functions or are used in caring for patients with serious health conditions).
- The likelihood that injuries would garner compensation in the tort system (which turns on, among other things, the severity of the injury, the ease of proving negligence, and the causal relationship between the AI tool and the injury).

In addition to the above, having clearly defined mechanisms to assess and monitor risk, test the performance of AI systems prior to widespread deployment (see section 7.1.3.2), and monitoring the performance of AI systems post-deployment are effective mechanisms to address concerns regarding liability. Deployers of AI systems can also use indemnification clauses[253] to establish who is responsible for paying in the case of a claim (e.g., requiring that developers pay for errors in the model's output while hospitals pay for errors arising from poor deployment or misuse of the AI technology). Regulators, policymakers, and deployers could also establish guidelines for informing patients when AI is used in diagnostic or treatment decisions to provide a basis for informed consent, addressing some of the liability concerns of HCPs.

7.2.4 High-level overview of the EU regulatory landscape

The section below presents a high-level non-exhaustive summary overview of key regulation to be considered in the view of the challenges identified and should be reflected in line with the limitations of this study identified in section 3.5.

The AIA[254] and the **MDR[255]/IVDR[256]** present obligations on the development and, to some extent, the deployment of AI systems in healthcare. These include requirements related to transparency, cybersecurity, risk management, pre-market assessments, and post-market surveillance. Together, these frameworks provide guidance to support the safe, effective, and ethical development and deployment of AI systems in healthcare. However, deployers must navigate compliance processes which can be complex. This

253 Provisions in contracts that require one party to compensate or reimburse another party for losses, damages, liabilities, or costs that arise from certain actions or events specified in the agreement
254 Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act)
255 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
256 Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

underscores the importance of fostering coordination among these frameworks, ensuring that AI deployers have clear pathways to meet their obligations without uncertainty.

When addressing data privacy and security concerns, the **GDPR**[257] remains the cornerstone of data protection in the EU. It sets clear obligations for entities processing personal data of individuals within the EU, ensuring robust safeguards for individual rights. For organisations deploying AI in healthcare, GDPR compliance is critical, particularly in managing sensitive health data, ensuring lawful processing, and addressing principles such as data minimisation and purpose limitation. Additionally, **the AIA** includes provisions on cybersecurity which state that high-risk AI systems shall be designed and developed in such a way that they achieve an appropriate level of cybersecurity, and that they perform consistently in those respects throughout their lifecycle (Article 15 AIA).

Regarding liability, **the recently updated PLD**[258] includes software, AI systems, and digital services within its scope. This ensures that AI systems are clearly recognised as products under EU liability law, addressing previous ambiguities and enhancing the legal framework for liability in AI-driven healthcare solutions. The updated PLD by introducing measures to ease the burden of proof in liability claims involving AI systems, aids to address some of the unique challenges associated with these technologies. In a product liability case, the claimant (plaintiff) is required to prove the defectiveness of the product, the damage suffered and the causal link between that defectiveness and that damage.

As regards product liability cases, the updated PLD provides presumptions concerning causation that will aid in dealing with the issue of causation. The updated PLD provides that the causal link between the defectiveness of the product and the damage shall be presumed where it has been established that the product is defective and that the damage caused is of a kind typically consistent with the defect in question (Article 10 PLD). A national court shall presume the defectiveness of the product or the causal link between its defectiveness and the damage, or both, where, despite the disclosure of evidence as required in the updated PLD and considering all the relevant circumstances of the case. Specifically when (a) the claimant faces excessive difficulties, in particular due to technical or scientific complexity, in proving the defectiveness of the product or the causal link between its defectiveness and the damage, or both; and (b) the claimant demonstrates that it is likely that the product is defective or that there is a causal link between the defectiveness of the product and the damage, or both. (Article 10 PLD). The updated PLD also provides that the defendant shall have the right to rebut some of these presumptions. (Article 10 PLD).

The transparency provisions in the AIA may also enhance clarity in the usage of AI systems in healthcare and therefore enhance the trust of HCP as well as a step in aiding to clarify the liability of HCPs in using AI systems. Article 13 provides that high-risk AI systems shall be designed and developed in such a way as to ensure that their operation is sufficiently transparent to enable deployers to interpret a system's output and use it appropriately. Additionally, the provisions in the AIA on human oversight could provide further clarity to the interaction between HCP and AI. Article 14 AIA provides that high-risk AI systems shall be designed and developed in such a way, including with appropriate human-machine interface tools, that they can be effectively overseen by natural persons during the period in which they are in use. The aim of human oversight shall be to prevent or minimise the risks to health, safety or fundamental rights that may emerge when a high-risk AI system

257 Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)).
258 Directive (EU) 2024/2853 of the European Parliament and of the Council of 23 October 2024 on liability for defective products and repealing Council Directive 85/374/EEC

is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse, in particular where such risks persist despite the application of other requirements set out therein. Moreover, Article 14 AIA provides that the oversight measures shall be commensurate with the risks, level of autonomy and context of use of the high-risk AI system and shall be ensured through different types of measures set therein. Finally, the obligations on deployers of high-risk AI systems (Art. 26) provide further clarity in the how AI systems should be used.

Accountability is also enhanced by the AIA with different obligations such as the obligation to draw up a technical documentation of a high-risk AI system before that system is placed on the market or put into service and be kept up-to date (Article 11 AIA).

As far as issues of regulatory complexity are concerned, the AIA includes provisions to aid in simplifying the regulatory landscape. Some of these measures, include AI sandboxes for testing (Art. 58) and guidelines on the practical implementation of the AIA that are being developed by the commission; the harmonised standards to be developed across the EU will also provide further clarity (Art. 40). In the context of standards, the Commission issued a **standardisation request** to the European Committee for Standardisation and the European Committee for Electrotechnical Standardisation in support of Union policy on artificial intelligence. This request includes European standard(s) and/or European standardisation deliverable(s) for example on human oversight of AI systems[259]. Moreover, the Commission sets course for Europe's AI leadership with an ambitious AI Continent Action Plan. The AI Act raises citizens' trust in technology and provides investors and entrepreneurs with the legal certainty they need to scale up and deploy AI throughout Europe. In this regard, the Commission will launch the **AI Act Service Desk**, to help businesses comply with the AI Act. It will **serve as the central point of contact and hub for information and guidance on the AI Act[260]**.

It was highlighted during the regulatory workshop with stakeholder, there are nuances in practical implementation—such as localised challenges in aligning diverse frameworks and the need for more granular guidance on addressing specific concerns like contextual bias, operational performance in varied settings, and inter-regulatory interactions. This highlights the importance of continuous dialogue and exploration of complementary measures to support the effective deployment of AI systems in healthcare. Such efforts can help ensure that AI solutions align not only with technical and regulatory requirements but also with the broader societal and clinical contexts in which they operate.

7.2.5 Summary

The deployment of AI in healthcare faces several legal and regulatory challenges. As developers and deployers they may need to comply with multiple frameworks such as the AIA, GDPR, MDR/IVDR, and upcoming EHDS complexities may occur in the navigation of this landscape. **Data security and privacy** concerns, particularly regarding cross-border data storage and cybersecurity threats, create some concerns to the stakeholders consulted and this may lead to a hesitation in adopting AI without robust data protection assurances. **Liability** issues may also raise challenges, for example, concerning the liability of healthcare professionals using AI systems.

To address challenges in AI deployment in healthcare, several accelerators have been identified. For example, at clinical setting, to navigate the **complex regulatory**

259 Commission implementing Decision of 22.5.2023 on a standardisation request to the European Committee for Standardisation and the European Committee for Electrotechnical Standardisation in support of Union policy on artificial intelligence Brussels, 22.5.2023 C(2023) 3215 final

260 EU Commission (2025) Commission sets course for Europe’s AI leadership with an ambitious AI Continent Action Plan.

landscape, some stakeholders indicated that interdisciplinary AI governance committees can be established to oversee compliance and streamline decision-making. **Data security and privacy** concerns may be addressed through comprehensive data governance frameworks, robust data storage policies, encryption methods, and privacy-by-design technologies. To clarify **liability,** some healthcare institutions are defining clear frameworks, differentiating AI risk levels, and implementing risk assessment mechanisms. Such strategies collectively promote regulatory clarity, data security, and trust in AI adoption within healthcare.

7.3 Organisational and business challenges and accelerators

There are a number of different organisational and business challenges affecting the deployment of AI in healthcare that can be grouped into four categories presented in the section below.

7.3.1 Financing mechanisms

7.3.1.1 Challenges

The deployment and maintenance of AI solutions in healthcare can be costly and is often associated with uncertainty regarding the return on investment for healthcare providers[261]. They entail significant investment in personnel, infrastructure and technology to test, validate, implement, and improve AI tools[262]. Underinvestment in the required infrastructure within healthcare settings can be a barrier to the sustained use of AI tools as it creates problems for interoperability with other systems or increases demand for human resources (e.g., due to manual data entries together with digital ones)[263]. The high financial costs of effectively deploying AI solutions, when taken together with the lack of funding and clear reimbursement mechanisms limits the potential to scale AI deployment. AI innovations may fall outside the scope of EU Member State reimbursement frameworks and as a result, stakeholders remarked that direct reimbursement remains sparse or almost non-existent across mainland Europe. Stakeholders highlighted that they perceive this is primarily a result the difficulty to demonstrate improved outcomes for patients. In addition, there is a **lack of published evidence of the value** of some types of AI systems which hinders attracting funding or introducing reimbursement frameworks for effectively deploying AI solutions[264].

The **lack of funding, investment and financial incentives** to deploy AI in clinical practice was described as a significant challenge affecting the deployment of AI by 62% of HCPs (29 out of 47), 50% of hospital representatives (13 out of 26), and 61% of AI developers (19 out of 31) that responded to the survey. Restricted budgets, primarily in public healthcare systems, often make it hard to justify the financial investments in AI tools, a sentiment shared by stakeholders from Spain, Denmark, the UK, the USA, Germany and Austria. According to an HCP from the UK, existing funding is often used only on implementing AI, without considering the broader needs like education, policy development, and the creation of necessary platforms to ensure effective AI integration in the healthcare system. The stakeholder emphasised that due to the abovementioned financial constraints, deployment of AI solutions is often limited to large University hospitals with the financial means and access to research grants to fund the deployment

261 Bongurala et al., 2024. Transforming healthcare with Artificial Intelligence (AI): Redefining Medical Documentation.
262 Scott et al., 2024. Achieving large-scale clinical adoption of AI-enabled decision support.
263 Wijnhoven F., 2021. Organisational learning for intelligence amplification adoption: lessons from a clinical decision support system adoption project.
264 Strohm et al., 2020. Implementation of artificial intelligence (AI) applications in radiology: hindering and facilitating factors.

of innovative AI solutions, putting smaller hospitals and those found in remote or rural areas at a disadvantage. In addition, the high licencing costs of AI solutions, in some cases, limits the deployment of AI solutions to only a small number of HCPs that are deemed to make the most of the solution and not readily accessible to all potential users.

7.3.1.2 Accelerators

The greatest benefits from AI deployment can only be realised if AI solutions are deployed at scale within entire healthcare systems rather than specific point-solutions in niche areas according to hospital representatives from the USA and Belgium. Improving affordability through funding, capital investment and financial incentives was highlighted as good practice for AI deployment by 47% of the HCPs surveyed (24 out of 51).

In the USA, **health-insurance programs already reimburse hospitals** for the use of certain AI devices, making them economic appealing as health institutions may be inclined to adopt AI tools that promise cost savings, even if they do not necessarily improve patient care[265].

In Europe, an analysis of assessment frameworks for digital medical devices (DMDs) reveals the existence of five distinct clusters[266]. As of today, Germany, Belgium and France are the three EU countries with national statutory frameworks for DMDs that integrate both regulatory and reimbursement pathways with Finland, Spain, the Netherlands and Estonia, characterised as fast followers that have swiftly introduced robust assessment frameworks. However, as of now, these frameworks either are not directly linked to reimbursement decisions, lack a unified centralised approach, or are in the process of consolidation.

Japan has also introduced reimbursement frameworks for certain AI tools, accessible to approximately 50 hospitals across Japan. To be eligible for reimbursement of AI tools, hospitals need to comply with guidelines established by related academic societies (e.g., Japanese Society of Radiological Medicine) and having a certain amount of full-time equivalent HCPs working in the specific department of the healthcare facility. This framework has encouraged hospitals to deploy and use AI tools across different medical specialties. However, this reimbursement framework is challenging for smaller hospitals in rural settings, which often do not fulfil the requirements for reimbursement. Hospitals in such healthcare settings are those where the use of AI tools is expected to be the most beneficial, as they often have a shortage of specialised HCPs and lack the necessary expertise.

Beyond the reimbursement of AI solutions, several deployers of AI solutions reported that establishing clear budget allocations for AI deployment and flexible financing options offered by developers (e.g., where deployers can chose to pay a fixed flat rate or pay-per-scan depending on the needs of the healthcare institution), has also proven to be beneficial in addressing the financial constraints limiting AI deployment. **Budgeting recruitment** and the **involvement of several roles** to actively engage in AI deployment during the planning of AI implementation has been reported as a strategy that contributes to successful implementation. Healthcare leaders should plan to recruit and involve trusted HCPs and innovation managers that are qualified to work cross-functionally with HCPs and other stakeholders during the deployment phase[267]. Financial sustainability of the AI use and continuous maintenance and improvement of the model could be resolved through

265 Lenharo M. 2024. The testing of AI in medicine is a mess. Here's how it should be done.
266 Tarricone et al., 2024. Towards harmonizing assessment and reimbursement of digital medical devices in the EU through mutual learning.
267 Nair et al., 2024. A comprehensive overview of barriers and strategies for AI implementation in healthcare: Mixed-method design

fundraising or through public-private partnerships that have been proven to be a sustainable model to ensure financing[268]. For example, the AI in Health and Care Award in the UK ran from 2020 to 2024 and was part of the NHS AI Lab, a Department of Health and Social Care initiative included in the Government Major Projects Portfolio. It allocated more than 100 million GBP to support the design, development and deployment of promising AI technologies. The AI Award was structured into 4 'phases' based on how ready products were for real-world implementation and the evidence available to support wider adoption.

Additionally, given the high cost of deployment, some hospitals in the USA monitor the usage of AI solutions across users (e.g., in terms of number of hours per week spent on the AI application) and reallocate the available licenses of the AI tools accordingly should there be users not making the most of the available tools. However, it is expected that as more AI solutions are developed and available on the market, the cost of deploying such solutions will inevitably decrease.

7.3.2 End-user involvement

7.3.2.1 Challenges

The **lack of involvement of end-users** in the development, testing and deployment of AI tools was described as a significant challenge affecting the deployment of AI tools by 55% of HCPs (26 out of 47), 50% of hospital representatives (13 out of 26), and 45% of AI developers (14 out of 31) that responded to the survey. The lack of end-user involvement in the deployment process of AI in healthcare creates significant challenges, undermining the effectiveness and acceptance of these technologies. End-users, such as clinicians, nurses, and administrative staff, are the ones interacting with AI tools in their daily workflows. Without ensuring adequate engagement and buy-in from these stakeholders, even the best AI tools are unlikely to be accepted and integrated into clinical practice and will be unable to improve clinical outcomes. This sentiment was shared by a number of hospital representatives and HCPs consulted. The lack of end-user involvement often results in AI solutions that are not aligned with the clinical needs that need to be addressed, systems that fail to integrate seamlessly into existing clinical workflows and processes. This can lead to inefficiencies, increased cognitive workload, and user frustration, ultimately diminishing the value AI is meant to bring. For example, a diagnostic AI tool that doesn't align with clinicians' decision-making workflows or provides outputs in a non-intuitive format may face resistance, regardless of its technical accuracy.

Additionally, the lack of end-user involvement hinders trust and liability, both important factors to the successful deployment of AI in healthcare. Without their involvement, end-users feel alienated, perceiving AI as a "black box" technology imposed upon them rather than a tool designed to enhance their capabilities. This perception exacerbates fears of job displacement and raises ethical concerns about decision-making authority (see section 7.4.3.1). Furthermore, end-user feedback during deployment is essential for identifying practical issues, such as errors in real-world data interpretation or gaps in the tool's functionality. When such insights are not captured early in the deployment process, it leads to suboptimal systems that require costly and time-consuming adaptations, delaying widespread adoption and negatively impacting confidence in the potential of the AI solution.

268 Romero-Brufau et al., 2020. Implementation of artificial intelligence based clinical decision support to reduce hospital readmissions at a regional hospital.

7.3.2.2 Accelerators

To ensure buy-in from end-users and those impacted by AI tools, it is important to **incorporate relevant stakeholders** such as HCPs, potential users of AI, hospital leaders, IT departments, and patients early in the development and deployment lifecycle of AI tools, especially during the testing phase with the application of a user-centred designed and testing approaches[269]. Early engagement of end-users to ensure relevance and usability of AI solutions was highlighted as a good practice by 75% of the HCPs surveyed (38 out of 51). It has been demonstrated that the buy-in from the leadership and managers within healthcare institutions creates conditions for the buy-in from HCPs. Of the hospital representatives that replied to the survey question, 83% (20 out of 24) highlighted that they explored partnerships with AI vendors to access different AI solutions to ensure usability, while 67% created opportunities for staff involvement in AI implementation projects (16 out of 24).

Multidisciplinary collaboration to ensure integration into clinical workflow was also highlighted as a good practice by 71% of the HCPs surveyed (36 out of 51). Establishing multidisciplinary teams (including IT experts, data engineers, HCPs, financial analysts, etc.) that are involved throughout the deployment process has proven to be an effective strategy to ensure the effective deployment and use of AI solutions as evident by digitally advanced healthcare institutions such as the Mayo Clinic and Duke Health. Such an approach was also employed by a hospital in Israel and the USA consulted. Multidisciplinary teams may also facilitate the deployment process by providing on-site support to ensure seamless integration into clinical workflows, and by facilitating explainability, interpretability and the overall understanding of AI tools, encouraging inter-professional learning. According to AI developers, **multidisciplinary collaboration** and **inclusive design and testing processes** that involve end-users early in the development process fosters greater acceptance and trust by HCPs. For example, the Cleveland Clinic established a Center for Artificial Intelligence and Data Science (CAIDS) consisting of a dedicated AI team focusing on advancing research and applications in AI and data science. CAIDS serves as a hub for innovation and collaboration, driving interdisciplinary efforts to address complex challenges. Another example described by a hospital representative from the USA is the introduction of fellowship programs within the hospital Data Science Institute which aim to onboard a balanced cohort of 50% medical doctors engaged in research and 50% of data and computer scientists, fostering collaboration between these stakeholders and improving AI integration into clinical practice.

The establishment of multidisciplinary teams is further enhanced by the introduction of new roles within healthcare settings, such as "AI champions" and Clinical Information Officers (CIOs). According to hospital representatives from the USA and Japan, CIOs are often individuals with clinical backgrounds tasked with driving AI deployment, ensuring AI tools align closely with clinical needs. On the other hand, "AI champions" are transitioning into technology-focused roles and operate within specific departments, are involved in the end-to-end process of deployment, have in-depth knowledge of AI and are serving as the technology leads in any deployment processes. According to a hospital representative from the USA, these "champions" should not only be "tech-savvy" but also deeply involved in their respective fields, which best positions them to understand and identify specific healthcare needs and workflows that AI tools can address. To support this approach, a hospital in the USA has introduced a new financial strategy that compensates clinical "AI champions" with an additional 10–70% of their salary for their role in deploying AI, all while they continue their clinical duties. A hospital representative from Israel indicated

269 Moorman LP, 2021. Principles for real-world implementation of bedside predictive analytics monitoring.

that such "AI champions" could be appointed at the specific department level to promote collaboration with AI developers and the use of AI tools among colleagues. For example, the Mayo Clinic appointed a **'local AI champion'** to oversee bridging the gap between developers and the end-users. The AI champion identified the need for further guidance on how to talk to patients about the algorithm's findings and developed recommendations to include bullets points with important information to communicate to the patient. Conditions for a strong buy-in are created when the request for developing an AI solution is initiated by local HCPs. Feeling the local importance of the problem and the necessity to solve it creates better chances that HCPs could achieve buy-in and promote the AI project and system to their peers[270]. This **co-design approach** also ensures that AI tools developed are interoperable with existing digital solutions ensuring seamless integration into the clinical workflow, have a user-friendly design informed by end-users that interact with the AI tool, and providing minimal to no disruption to the workflow, existing practice, roles and functions.

Communication is another important factor for ensuring buy-in by the end-users during the deployment phase of AI solutions. Effective communication increases awareness amongst the impacted healthcare workforce about the upcoming change due to the AI system and its potential impact on processes[271]. To ensure buy-in, the communication needs to be adjusted and address value that is meaningful to different types of stakeholders[272]. It is important to tailor the amount and type of information based on relevance when communicating about the model. For example, patient outcomes are of most interest to HCPs, while numbers and statistics are more interesting to administrative staff and managers. The communication should focus on a vision for change that needs to be communicated to all relevant stakeholders in the form of periodic meetings and/or newsletters. In addition, the formation of partnerships between hospitals and AI developers and the promotion of informal communication between these stakeholders during the deployment phase helps create trust in AI and helps HCPs understand the value of outputs better[273]. By dedicating time prior to the deployment phase to build communication channels and clear feedback mechanisms, allows for the strengthening of the relationship between the relevant stakeholders and contributes to a more effective and efficient deployment process in the longer term. Clear communication and education of the benefits of using AI in healthcare and clear communication from HCPs on how AI is used in the delivery of care would make patients more comfortable with AI being used in their healthcare according to 64% and 60% of patients/patient associations surveyed respectively. For example, a hospital in the USA has a representative on the healthcare advisory board of an AI developer, with additional representatives from other healthcare facilities, providing feedback on desired features of the AI solution and addressing any challenges. This collaborative approach supports continuous improvement and ensures alignment with healthcare needs. To ensure sustained use of AI tools amongst HCPs, performance-based incentive schemes or gamification strategies have been introduced within hospital settings to create a sense of competition and potential rewards for using an AI system[274].

270 Sendak et al., 2020. Real-world integration of a sepsis deep learning technology into routine clinical care: implementation study.
271 Gonçalves et al., 2020. Implementation of an artificial intelligence algorithm for sepsis detection.
272 Sendak et al., 2020. "The human body is a black box" supporting clinical decision-making with deep learning.
273 Sendak et al., 2020. Real-world integration of a sepsis deep learning technology into routine clinical care: implementation study.
274 Chong et al., 2021. Development and implementation of venous thromboembolism stewardship across a hospital network.

7.3.3 Local Added Value Assessment (real-world local added value)

7.3.3.1 Challenges

The deployment of AI in healthcare faces significant challenges due to the lack of comprehensive assessments of its added value compared to existing clinical solutions/currently employed approaches. A **lack of assessment of the added value at hospital level** of integrating AI tools in clinical practice was described as a significant challenge affecting the deployment of AI by 53% of HCPs (25 out of 47), 54% of hospital representatives (14 out of 26), and 42% of AI developers (13 out of 31) that answered the survey question. How local (hospital level) added value is assessed also varies across regions, with some hospitals balancing different elements.

Evaluating the clinical value of AI tools is important to determine whether they truly improve patient outcomes, diagnostic accuracy, or treatment efficacy beyond what current methods provide at local level. For example, AI tools must enhance decision-making for commonly encountered scenarios where current clinical judgement is suboptimal such as early detection of sepsis[275] and timely diagnosis of stroke[276], resulting in improved patient care[277]. Tools used in such instances do not have to be perfectly accurate, as a modestly accurate tool substantially better than current clinical judgement will be favoured over a highly accurate tool no better than current judgement[278]. AI tools must also perform better than current well-accepted, high-performing but simpler decision rules.

In addition, HCPs **need to know if deployed AI tools will improve patient care** and outcomes to an extent they and their patients would regard as clinically relevant, irrespective of the statistical significance of reported results. Whether an effect is clinically important depends on the nature of the condition, the effect, and the context such as patient population and clinical setting. Based upon findings from the literature, **prospective impact studies of clinically deployed tools are few and incomplete**. In one review, only one-third of 51 studies examined patient outcomes, with mixed results (8 positive effects, 6 no change)[279]. In a more recent review of 32 studies, only 8 (25%), 10 (31%) and 12 (38%) assessed effects on decision-making, care delivery and patient outcomes, respectively, in all cases reporting mixed results[280].

Without robust evidence demonstrating tangible benefits, healthcare providers and decision-makers are reluctant to invest in and integrate these technologies. This lack of clarity can lead to scepticism, as stakeholders may view AI as a costly and unproven innovation rather than a transformative tool for healthcare improvement. Stakeholders emphasised that AI developers, in collaboration with HCPs, must first deeply **understand the clinical task** and the datasets being targeted, their amenability to AI, current clinical decisional performance, end-user needs and the primary goals to be achieved. The **goals should be expressed in measurable targets** in improved clinical processes and outcomes, patient and professional experience, economic and efficiency gains or greater equity and sustainability in care delivery. The absence of such evaluations hampers the ability to prioritise resources effectively, potentially diverting funding and effort toward tools that offer limited practical benefits. For example, in many healthcare settings,

275 Barket et al., 2023. Recognition and management of hospital-acquired sepsis among general medical inpatients in Queensland public hospitals.
276 Tarnutzer et al., 2017. ED misdiagnosis of cerebrovascular events in the era of modern neuroimaging: a meta-analysis.
277 Gunda et al., 2022. Improved stroke care in a primary stroke centre using AI decision support.
278 Sanders et al., 2015. A systematic review of studies comparing diagnostic clinical prediction rules with clinical judgment.
279 Yin et al., 2021. Role of artificial intelligence tools in real-life clinical practice: systematic review.
280 Susanto et al., 2023. Effects of machine learning-based clinical decision support systems on decision-making, care delivery, and patient outcomes: a scoping review.

individual department heads or chief quality or medical information officers face complex decisions about medical AI without support from expert interdisciplinary committees, potentially selecting AI tools instead based on pragmatic considerations (e.g., models from current vendors may be preferred over models that would require new contracts, security and compliance reviews)[281].

Beyond clinical outcomes, the operational and financial value of AI tools also requires thorough assessment to ensure their adoption aligns with healthcare system goals. AI solutions often promise to streamline workflows, reduce costs, or enhance resource allocation, but these claims must be validated through real-world evidence. According to hospital representatives consulted, without clear metrics for operational efficiency and financial returns, healthcare organisations cannot justify the significant upfront costs of implementation and training. Moreover, failure to assess these aspects risks introducing tools that may inadvertently increase workloads or create inefficiencies.

The lack of standardised approaches and performance metrics to assess the clinical, operational, and financial added value of AI solutions, when taken together with the fragmentation of AI tools and vendors, makes selecting and effectively deploying the most appropriate AI solutions very difficult. It is not feasible for hospitals to test and pilot every available AI solution prior to deployment to determine which one would work in the specific healthcare setting. This issue is further exacerbated by the lack of endorsement of specific AI developers and tools by professional societies and associations, often leaving healthcare providers uncertain about which AI tools to deploy and thereby slowing down the deployment process. These issues were highlighted by several stakeholders consulted from Israel, Italy and the USA.

7.3.3.2 Accelerators

Comprehensive evaluations that quantify AI's added value across clinical, operational, and financial dimensions are essential for gaining stakeholder confidence, informing policy and reimbursement decisions, and ensuring the sustainable deployment of AI in healthcare systems. Tools to assess and evaluate the local/hospital level added value of deploying an AI solution in clinical practice compared to existing solutions was highlighted as a good practice to facilitate the deployment of AI by 73% of the HCPs who answered this survey question (37 out of 51). To develop a comprehensive value proposition, according to an AI developer from the USA, it is important to consider the following:

1. **Define and measure** the tool's impact across three criteria: clinical value (improvement in patient outcomes), operational efficiency (enhancements in workflow and time savings), and financial impact (economic benefits and cost-effectiveness).
2. Conduct **value proposition research** by using frameworks to quantify and communicate the tool's benefits, such as time savings in operational contexts or adherence to clinical guidelines.
3. Provide **real-world evidence and case studies** demonstrating the tool's effectiveness and impact, including publications and comparisons with similar health systems.
4. Tailor the **metrics and value propositions** to the specific medical specialty and domain to ensure relevance and accuracy.

281 Price et al., 2023. Enabling collaborative governance of medical AI.

This approach can be facilitated by conducting pilot studies on AI tools that aim to address a specific healthcare need within specific healthcare settings with a small number of end-users to ensure that the AI model performs as described by the developers (see section 7.1.3.2), but also to assess the widespread impact of AI solutions in terms of measurable outcomes and indicators on their clinical value, operational efficiency gains, and potential financial impact and Return on Investment (ROI). Such pilot studies clearly outline the specific needs that AI solutions will address and highlight the potential impact to both HCPs and patients, assisting the hospital leadership in their decision-making process, a statement supported by a hospital representative from Germany. It is important to ensure that pilot studies are timely, and that pre-defined Key Performance Indicators (KPIs) are reported and presented appropriately. In addition, pilot studies could be conducted comparing the performance of multiple AI solutions from different vendors, considering any necessary modifications to the existing infrastructure and workflows.

Of the hospital representatives surveyed, 38% (10 out of 26) have developed tools to assess and evaluate the added value of deploying an AI solution in clinical practice compared to existing solutions. At **Michigan Medicine and Duke Health, an assessment of added value is carried out by teams** combining technical, clinical, and operational experts[282]. Evaluation involves analysing model performance, generalisability to local settings, transparency, bias, workflow integration, and total ownership cost. Often, there is no universally best AI system; for instance, Duke Health implemented the Sepsis Watch system differently across two hospitals due to varying workflows. Selected models are rigorously tested on controlled local EHR data, with local performance compared to reported outcomes to ensure clinical utility. Successful integration into clinical workflows is followed by continuous monitoring to detect and address changes in performance due to factors like patient population shifts or workflow modifications. This process relies on close collaboration between technical and clinical teams to maintain model reliability and efficacy post-deployment.

A hospital representative from Belgium highlighted that they are developing a comprehensive model to assess the operational efficiency gains as a result of deploying AI solutions. According to this model, value is determined by outcomes that matter to patients divided by the cost. To assess the value of the AI solution, the hospital is focusing on various metrics, including the time required for accurate diagnosis, improvements in hospital capacity, reductions in staff working hours, enhanced availability of services, and the speed of diagnosis. By using these indicators, the hospital aims to quantify how the AI solution contributes to patient outcomes and operational efficiency, thereby providing a comprehensive evaluation of its impact and justifying its integration into clinical practice. On the other hand, a hospital representative from Japan highlighted that they conduct simulations of AI deployment to assess their impact on workload and efficiency, such as working hours and financial expenditure, allowing for informed decision-making prior to widespread adoption.

The few economic evaluations of AI tools assessing the added financial value of deploying AI solutions are of limited quality, mostly cost minimisation analyses of specific cost elements within single-use cases over short time horizons[283]. For HCPs to effectively conduct economic evaluations, a key consideration is **estimating**, for the outcome being predicted, the number of patients the tool flags as being positive, thereby incurring costs of preventive or therapeutic interventions, versus the number of true positives[284]. This equation and the estimated costs will vary according to what clinicians perceive as the

282 Price et al., 2023. Enabling collaborative governance of medical AI.
283 Voets et al., 2022. Systematic review of health economic evaluations focused on artificial intelligence in healthcare: the tortoise and the cheetah.
284 Liu et al., 2019. The number needed to benefit estimating the value of predictive analytics in healthcare.

most clinically appropriate sensitivity and specificity thresholds or cut-off points for the tool which, using simulation methods, determine the net monetary benefit[285]. According to AI developers consulted, failing to evaluate the economic value of AI tools (through methods such as ROI) will make it harder to prioritise investments in financially constrained or low-resource environments and justify the high up-front costs of AI tools [286].

There are **challenges in defining and quantifying the ROI**, as such a metric is **highly dependent on the healthcare system (e.g.** public, private, not for profit) which results in complexities in terms of how it can be evaluated, as supported by a hospital representative from the USA. **Past implementations should be taken into consideration** when calculating ROI according to hospital representatives from the USA and Italy. To maximize ROI from AI projects, hospitals could **divide initiatives into smaller, impactful use cases** that deliver quick returns with minimal infrastructure investment according to an AI developer from the USA. A **two-phased approach** is highlighted, focusing on immediate financial gains—such as increased efficiency and reduced labour—while also considering foundational investments in data infrastructure and systems integration needed for sustainable deployment. To justify the operational efficiency gains of the AI tool, an AI developer proposed **demonstrating performance gains from retrospective studies** in the short term, before large-scale prospective trials.

To address the challenge posed by the fragmented AI landscape and facilitate the hospital/local-level added-value assessment, the **NHSX published "A Buyer's Guide to AI in Health and Care"**, which sets out 10 questions that Healthcare Trusts in the NHS need to consider to make well-informed procurement decisions[287]. These cover problem identification, product assessment, implementation considerations, and procurement and delivery. Establishing a **feasibility checklist** to assess whether AI solutions could be adapted and/or integrated into internal hospital frameworks and creating a **catalogue of AI vendors** with **specific key performance indicators on which hospitals can assess their local added value** could be an effective strategy according to a hospital representative from Italy. This could also be achieved through enterprise platforms provided by local vendors (see section 7.1.3.2), within which various AI solutions can be piloted and purchased, all integrated into the same platform for ease of integration.

7.3.4 AI strategy

7.3.4.1 Challenges

The absence of a clear AI strategy from hospital leadership poses a challenge to the successful deployment of AI in healthcare. Lack of strategic direction to promote AI in healthcare was described as a significant challenge affecting the deployment of AI in healthcare by 53% of HCPs (25 out of 47), 44% of hospital representatives (11 out of 25) and 39% of AI developers (12 out of 31) that responded to the survey question. Without a cohesive hospital-level vision, hospitals often struggle to align AI initiatives with their overarching clinical and operational goals which can result in fragmented efforts and AI tools adopted in isolated departments without system-wide integration. The absence of strategic oversight may also lead to inefficiencies in resource allocation, with hospitals investing in AI projects that may not deliver meaningful value or that fail to address high-

285 Parsons et al., 2023. Integrating economic considerations into cut point selection may help align clinical decision support toward value-based healthcare.
286 Brat et al., 2024. Cutting through the hype: the true economic impact and ROI of AI in radiology.
287 NHSX. 2020. A Buyer's Guide to AI in Health and Care – 10 questions for making well-informed procurement decisions about products that use AI.

priority challenges. For example, several hospital representatives and HCPs consulted reported that delays in AI deployment arise due to the lack of central coordination, **redundant projects** and **poorly allocated resources**.

A clear AI strategy is also important for fostering organisational buy-in and addressing cultural resistance to change. When hospital leadership does not articulate the hospital level vision for AI in improving care delivery, healthcare professionals may view these technologies with scepticism or fear of disruption to established workflows leading to a lack of engagement from end-users, who are critical to the successful implementation and sustained use. In addition, an unclear strategy may result in inconsistent policies around training, data governance, and ethical considerations, creating additional barriers to deployment.

In addition, the **absence of coordinated efforts** at the national and regional level further exacerbates these issues, as healthcare providers lack the necessary guidance and support to navigate the complexities of AI deployment. This often results in highly **variable strategic directions**, as described by AI developers from the USA. This challenge was also raised by a recent report by the Standing Committee of European Doctors where European doctors stressed the importance of publicly coordinated efforts to establish knowledge environments of sufficient scale and clinical expertise within national settings[288]. The lack of strategic direction is perceived by HCPs in Denmark and the UK to be most prevalent in countries with fragmented healthcare systems.

7.3.4.2 Accelerators

Strategic planning should involve **setting clear objectives**, **allocating resources**, and **establishing a roadmap** for AI deployment[289,290]. A clearly defined strategy for AI deployment in clinical practice was highlighted as a good practice for AI deployment by 55% of the HCPs surveyed (28 out of 51). To effectively deploy, ensure use, and scale AI solutions in clinical practice stakeholders emphasised that it is important to have a **comprehensive "top-down strategy" in place** that includes the organisation's goals and resource distribution for AI implementation. Engaging stakeholders from different departments and creating cross-functional teams can ensure a coordinated approach to AI implementation[291].

According to hospital representatives surveyed, 48% (10 out of 21) have developed a strategy or action plan for the efficient and effective deployment of AI in healthcare. For example, a hospital representative from the USA reported that they developed a **'playbook'** describing the experiences of early adopters from which late adopters can learn from. In addition, as part of the AI strategy, the same hospital **encourages department leaders to identify AI use cases** which are then centrally evaluated through a business case process to ensure alignment with the operational capabilities of the hospital. When deploying AI tools, **senior leadership** (e.g., hospital managers with both clinical and IT background) should **employ their formal power to establish follow-up procedures** (e.g., weekly meetings) on the utilisation of the AI tool[292]. A recent paper based on the NHS in the UK highlighted six critical challenges that an AI in healthcare strategy should prioritise, together with some of the actions needed to address

288 The Standing Committee of European Doctors – CPME, 2024. Deployment of artificial intelligence in healthcare.
289 Roppelt et al., 2024. Artificial intelligence in healthcare institutions: A systematic literature review on influencing factors
290 DNV. Adoption of AI in healthcare.
291 Mennella et al., 2024. 'Ethical and regulatory challenges of AI technologies in healthcare: A narrative review
292 Sun TQ., 2021. Adopting artificial intelligence in public healthcare: the effect of social power and learning algorithms.

them in order to harness the potential of AI in healthcare[293]. To effectively develop an AI strategy, the integration of AI in healthcare should be guided by the perspectives and needs of patients, the public, and healthcare professionals. It is important to build a deep understanding of how different stakeholders perceive AI-driven health technologies to ensure they are both effective and widely accepted. Mechanisms for engagement should be established to enable patients, the public, and healthcare staff to participate in discussions on emerging issues and inform strategic decision-making. In addition, involving these groups in the co-design of AI solutions can maximise the potential of AI in a way that aligns with their expectations and priorities.

Healthcare leaders could focus AI development and deployment on addressing critical challenges in the sector. While encouraging local innovation and experimentation, it is important to identify certain high-priority areas where AI can provide the greatest impact. Demonstrating, testing, and scaling successful AI tools requires a well-defined strategy that includes proactive horizon scanning and opportunities for healthcare staff and organisations to highlight areas where AI could have the most benefit. Finally, equipping the healthcare workforce with the skills and knowledge needed to leverage AI is critical. Comprehensive plans should focus on training both current and future professionals, developing specialised career pathways in AI, and empowering staff to shape the evolution of their roles in light of technological advancements.

An indicative example of an strategy is that of **Northwestern University Hospital**, where in 2022 it institutionalised the **Collaborative AI in Healthcare Initiative into the Centre for Collaborative AI in Healthcare** as a means to promote the use AI in healthcare (for details see Box 3)[294]. The lessons learned from this initiative include:

- **Early and ongoing engagement with a wide range of stakeholders**, including clinicians, scientists, administrators, and industry partners, enriched the centre's understanding of diverse needs and perspectives. This inclusivity has been instrumental in designing resources and programs such as AI4H clinics and NM Healthcare AI Forum that are both comprehensive and targeted.
- **Treating the centre's offerings as products** meant adopting a mindset focused on the end-user—whether a clinician, researcher, or educator. This shift emphasised the importance of understanding user needs, preferences, and challenges, leading to the development of more accessible, intuitive, and valuable resources.
- Embracing a **product development approach** encouraged the adoption of iterative cycles, where resources and programs are continuously refined based on user feedback and performance metrics. This process ensures that the centre's offerings remain at the cutting edge of utility and effectiveness.
- **Designing with scalability in mind**, the centre has focused on creating resources and programs that can grow and evolve (e.g., partnering with the health system, the schools of engineering and art and science when launching NM Healthcare AI Forum). This foresight has been critical for ensuring long-term sustainability, allowing the centre to adjust its strategies in response to changing demands and new opportunities.

293 Thornton, N. 2024. Priorities for an AI in healthcare strategy.
294 Luo et al., 2024. Northwestern University resource and education development initiatives to advance collaborative artificial intelligence across the learning health system. Learning Health Systems.

Box 3: Northwestern University strategy to promote the use AI in healthcare

Governance and oversight framework

- Established a governance framework that includes an Executive Steering Committee and an Advisory Board, while leveraging the Community Engagement Panel from Northwestern University Clinical and Translational Science Institute (NUCATS) for community outreach.
- The 12 members of the Advisory Board bring expertise from core AI techniques applied to multimodal health data (e.g., imaging, clinical notes, multi-omics), health equity, ethics and patient engagement, various clinical specialties (e.g., from general internal medicine to cardiovascular and pulmonary care), basic science powered translational medicine, as well as education innovation and knowledge management.
- This governance structure not only ensures strategic alignment and ethical integrity but also facilitates broad stakeholder engagement, drawing on a wealth of expertise to create an inclusive and collaborative ecosystem.

Disseminating collaborative education resources

- AI for Health (AI4H) Clinic, aimed at providing practical guidance and support to the approximately 4000 practicing clinicians within the faculty.
- The AI4H clinic sessions serve as a platform where clinicians interested in AI for healthcare can discuss their clinical challenges and ideas.
- Clinicians, alongside AI and data scientists, bring forth clinical, research, or operational problems to explore AI/ML-based solutions through brainstorming, consultation, and iterative solution development. This process not only leads to pilot projects, prototype systems, and academic publications but also deepens the appreciation of the nuances of clinical data among AI professionals.
- The clinic has empowered clinicians, especially those previously lacking resources, to develop and deploy AI models with the support of AI scientists and informatics trainees.
- Clinicians are paired with AI trainees, creating a mentorship dynamic where both parties could learn from each other.
- These collaborative efforts have led to the development of AI models tackling critical clinical challenges.
- The Northwestern Medicine Healthcare AI Forum was established in 2023 to expand AI literacy and foster patient-centred innovation. This pioneering biweekly forum is uniquely inclusive, inviting not only faculty and students from Northwestern University but also healthcare professionals, patients, and the broader community within the Greater Chicago area.
- The sessions are designed to break down the complexities of AI in healthcare, presenting the latest advancements in a manner that is accessible and engaging to everyone, including patients and their advocates.
- Each forum features multiple succinct and modular presentations that distill complex research and technological innovations into intuitive, easily understandable insights. These 10–15 min segments avoid technical jargon, opting instead for plain English explanations that invite questions, stimulate open discussion, and encourage participation from all attendees.

Democratizing access to unstructured health information

- Developed bulk natural language processing (NLP) and data harmonization pipelines to systematically extract structured information from unstructured clinical notes, and stored processing results in interoperable data marts to power augmented intelligence in clinical practice.
- The outputs are mapped to the Unified Medical Language System and the relations and concepts are stored in OMOP Common Data Model tables to ensure interoperability across the 12 hospitals in the adult health system, the pediatric hospital and clinics, and with external health systems.
- To disseminate the use of this state-of-the-art language model, they developed easy-to-follow tutorial with a simplified version of TextGCN and introduced it into classroom teaching so that trainees can run a graph deep learning model on their laptop within 10 min.
- To ensure broad use of the data and tools, tutorials and educational resources (e.g., case studies, consulting sessions, currently available to approved Northwestern Medicine Enterprise Data Warehouse [NMEDW] users) were created for the data marts produced by the bulk NLP pipelines.
- Validation studies demonstrated a significant enhancement in model performance when incorporating information extracted through the NLP pipelines when compared to predictive models based on structured data alone.

Establishing a roadmap for AI adoption and implementation has also proven to be an effective strategy to facilitate the deployment of AI technologies as evidenced by the first full-scale deep learning technology deployed into routine clinical care[295]. The Mayo Clinic

295 Sendak et al., 2020. Real-World Integration of a Sepsis Deep Learning Technology Into Routine Clinical Care: Implementation Study.

has also developed a roadmap for AI adoption known as the wheel of AI, which aligns with the AI lifecycle proposed by Coalition on Health AI (CHAI) in its assurance standards guide. The following steps are outlined to effectively develop a roadmap for AI deployment:

1. **Define problem and plan:** Identify the problem, understand stakeholder needs, evaluate feasibility, and decide whether to build, buy, or partner.
2. **Design the AI system:** Capture technical requirements, design system workflow, and plan deployment strategy.
3. **Engineer the AI solution:** Develop and validate the AI model, prepare data, and plan for operational deployment.
4. **Assess:** Conduct local validation, establish a risk management plan, train end users, and ensure compliance.
5. **Pilot:** Implement a small-scale pilot, monitor real-world impact, and update risk management. An HCP from the USA highlighted the importance of conducting a **limited rollout** of the AI tool to evaluate its seamless integration into the clinical workflow.
6. **Deploy and monitor:** Deploy the AI solution at scale, conduct ongoing monitoring, and maintain quality assurance.

Across all steps in the roadmap for AI deployment, it is important to consider several core principles that includes:

1. **Usefulness, usability and efficacy:** AI solutions should be beneficial, reliable, and improve user experience. They must solve specific problems and show clear benefits for patients and healthcare providers, such as better clinical outcomes and patient satisfaction. Usability means the AI should be easy to use and fit well into existing workflows. Efficacy ensures the AI achieves its goals and continues to perform well through ongoing testing and monitoring.

2. **Fairness, equity and bias management:** AI solutions must be fair and work equally well for all demographic groups. Fairness means the AI's performance should be consistent across different groups, and outcomes should not depend on protected attributes like race or gender. Equity involves ensuring that AI solutions help reduce health disparities. Bias management includes regularly checking and correcting any biases in the data or AI system to promote fairness and equity.

3. **Safety and reliability:** AI solutions should not harm patients or healthcare providers. This involves thorough testing and risk assessments before implementation, and continuous monitoring to detect and address any safety issues. Clear liability and governance structures must be in place to ensure the AI system remains safe and reliable throughout its use.

4. **Transparency, intelligibility and liability:** Stakeholders need clear and understandable information about AI systems and their outputs. Transparency involves sharing how the AI system works and its limitations. Intelligibility ensures stakeholders can understand the AI's decision-making processes. Liability means being responsible for minimising harm and addressing any negative impacts of the AI system.

5. **Security and privacy:** AI systems must protect data confidentiality and integrity with strong security measures. This includes preventing unauthorised access and data breaches, and ensuring personal data is handled in compliance with privacy regulations. Organisations should have protocols for monitoring security and privacy, and for addressing any incidents, to keep data safe and maintain trust.

A recent study from the UK presented the strategy and structured approach to AI deployment through a comprehensive case study of a hospital in Southwest London, resulting in widespread deployment and use of an AI solution[296].

Artificial intelligence (AI) implementation within the National Health Service (NHS): the Southwest London (SWL) AI Working Group experience.

1. Aspiration for AI adoption and shared learning that aligns with the wider NHS long-term workforce plan for "new ways of working by harnessing digital innovations."
2. Establishment of an AI Work Group following early buy-in from senior management.
3. Development of a robust AI strategy
    a. Collaboration: every radiology department within the 5 NHS hospitals making up the SWL Imaging Network were contacted, and any interested members of staff from any background were encouraged to join.
    b. Data driven decisions: adopting a data-centric mindset to foster better decisions for patient care from objective outcome measures and actionable insights
    c. Engagement with AI vendors for clinical evaluation: assess viability and efficacy of AI in a real-world healthcare setting allowing a pipeline of implementation to be set.
    d. Scalability for future sustainability: understanding that offerings from AI vendors are likely to grow in the future, with adoption of greater tools and post-deployment evaluation being a continual process and foresight in how to fund, maintain, and expand AI integration beyond single, narrow applications or single-site deployment for the widest-possible patient benefit.
4. 'First project' based on a problem-led solution so that improvements in clinical care can be evaluated. The AI Group agreed upon the clinical problem to be tackled and started exploring various AI tools available on the market.
5. Application of Kotter's 8-step model and the BS30550 structure to guide the AI implementation plan across three stages: pre-implementation, implementation, and post-implementation.
6. Development of an 'AI implementation team' to instigate the change ensuring a shared sense of belonging and ownership of the project, as well as a common understanding of the challenges and solutions. The team consisted of expertise from 4 key domains:
    a. Management: clinical lead, divisional directors, finance, and procurement
    b. Clinical: patient advocates, clinical stakeholders, research lead
    c. Governance: legal, compliance, and information governance
    d. Technical: IT, PACS, integration leads
7. Development of a comprehensive score sheet for AI product selection based on existing guidelines to be used by all core AI team members, with different members playing a greater role in evaluating certain aspects of the AI product and vendor.
8. In-depth market research for all AI vendors with suitable tools for the specific use-case. Invitation of all identified vendors to provide written information about their product and attend a virtual meeting with the AI team for a live demonstration of the product. One score sheet was used per product with a point system used to aid and differentiate between products.
9. Short-listing and tool selection based on scoring across the different criteria.
10. Retrospective analysis on local healthcare data for comparison with published evidence from the AI vendor.
11. Collaboration between the AI vendor and the IT department to develop a local virtual server to act as the portal between the local PACS and the cloud-based servers of the vendor, allowing for information exchange and interoperability.
12. Agreement between the AI core team and the AI vendor to conduct a probationary 6–8-month prospective service evaluation project to evaluate the accuracy of the tool, improvements in patient care, issues with any technical integration, and canvas staff opinions at regular intervals during implementation, with a view to building a business case based on several key performance indices that would result from this evaluation project. These would help build a case for future formal funding and longer-term adoption, should improvements in care be demonstrated.

296 Shelmerdine et al., 2024. Artificial intelligence (AI) implementation within the National Health Service (NHS): the Southwest London AI Working Group experience.

7.3.5 High-level overview of the EU regulatory landscape

The current EU regulatory framework may both directly and indirectly in shape some of the organisational and business challenges affecting the deployment of AI in healthcare. The section below presents a high-level non-exhaustive summary overview of key regulation to be considered in the view of the challenges identified and should be reflected in line with the limitations of this study identified in section 3.5.

The **HTAR**[297] supports organisational decision-making at national level by providing **evidence-based clinical assessments**. These assessments can guide healthcare providers in understanding the clinical added value of AI tools, helping align AI deployments with healthcare needs and system priorities. The HTAR specifies that some high-risk medical devices including those incorporating software using AI (Art. 7) can be subject to joint clinical assessment. In addition, Art. 23 provides a voluntary mechanism for health technologies not in mandatory scope and assessment of non-clinical assessments domains such as cost-effectiveness and organisational impact.

The **AIA**[298] lays down harmonised rules on AI needed to "foster the development, use and uptake of AI in the internal market that at the same time meets a high level of protection of public interests, such as health and safety" and the protection of fundamental rights as recognised and protected by Union law (recital 8 AIA). To achieve these objectives, there are rules regulating the placing on the market, the putting into service and the use of certain AI systems. Moreover, the AIA provides clarity on risk categorisation, compliance obligations, and governance mechanisms, which can aid healthcare organisations in developing robust **AI strategies**. In the context of financing challenges, the AI sandboxes (Art. 58) under the AIA, may indirectly support innovation and reduce initial testing costs.

In the context of involvement of end-users, the AIA transparency provisions of high-risk AI systems and provision of information to deployers (Art. 13), helps aligning system functionality with practical use, despite that this provision does not require end-user involvement in the design phase. As regards challenges around the local added value assessment of AI systems in real-world clinical practice, the AIA does not mandate added-value assessments but does require transparency and documentation of system capabilities (Art. 13), which aids deployers in understanding system effectiveness and potential alignment with workflows.

As regards helpful elements for aiding in formulating an AI strategy, the AIA's provisions on Governance (Ch. VII) can be valuable. Specifically, these elements in the AIA include: the Commission to develop Union expertise and capabilities in the field of AI through the AI Office; the establishment of a European Artificial Intelligence Board (the 'Board'); the establishment of an advisory forum to provide technical expertise and advise the Board and the Commission, and to contribute to their tasks under this Regulation and the establishment of a scientific panel of independent experts (the 'scientific panel') intended to support the enforcement activities under the AIA.

297 Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU

298 Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act)

7.3.6 Summary

The deployment of AI in healthcare faces several organisational and business challenges. The **high costs** of implementation, infrastructure, and licensing, combined with unclear reimbursement mechanisms, limit AI adoption, especially in smaller or rural hospitals. **Lack of end-user involvement** in AI development and deployment leads to misalignment with clinical needs, clinical workflows, resistance to adoption, and concerns over trust and liability. **Inadequate assessment of AI's added value complementary to regulatory provisions** — both clinically and operationally—creates uncertainty about its benefits, making decision-makers hesitant to invest in AI tools. Additionally, **the absence of a clear AI strategy** from hospital leadership results in fragmented deployment efforts, inefficient resource allocation, and a lack of long-term vision, particularly in public healthcare institutions. Without strategic coordination at institutional, national, and regional levels, AI deployment remains inconsistent, limiting its full potential in improving healthcare delivery.

To address organisational and business challenges in AI deployment in healthcare, several accelerators have been identified. **Financing mechanisms** can be improved through value-based reimbursement models, clear budget allocations, and flexible financing options. Public-private partnerships and structured funding initiatives, such as the NHS AI Lab, have also been effective in supporting AI deployment. **End-user involvement** is important for successful integration, and this can be achieved through early stakeholder engagement, multidisciplinary teams, and dedicated roles like AI champions and Clinical Information Officers to facilitate adoption. **Added-value assessment**s focusing on demonstrating AI's clinical, operational, and financial benefits using real-world evidence, key performance indicators, and structured pilot studies have proven to be effective. Additionally, economic evaluations, including ROI assessments, help justify AI investments. **AI strategy** development is also important, requiring clear objectives, resource allocation, and structured implementation roadmaps. Engaging stakeholders, aligning AI initiatives with healthcare priorities, and ongoing monitoring ensure effective and scalable AI deployment. These accelerators collectively support AI's integration into healthcare.

7.4 Social and cultural challenges and accelerators

There are a number of different societal and cultural challenges affecting the deployment of AI in healthcare that can be grouped into five categories presented in the section below.

7.4.1 Trust

7.4.1.1 Challenges

Trust is important in the adoption and long-term use of AI solutions and is multifaceted in its root causes. Concerns regarding a lack of trust in AI tools were raised as a significant challenge by 28% of HCPs (13 out of 47), 50% of hospital representatives (13 out of 26) and 59% of AI Developers (17 out of 29). In addition 51% of patients and patient associations (36 out of 70) that responded to the survey reported concerns related to lack of trust in the accuracy of decisions made by AI systems. These apprehensions may be further exacerbated when AI tools are introduced without adequate communication or education about their benefits and limitations. Building trust requires transparent communication, patient-centred design, and rigorous performance testing of AI tools to ensure that they are perceived as reliable, equitable, and beneficial by all stakeholders.

The "black box" nature of many AI systems, where decision-making processes are not easily explainable, is one of the main contributors to the lack of trust amongst HCPs who are accustomed to evidence-based, transparent methodologies (see section 7.1.5.1). This was echoed by HCPs and AI developers consulted, indicating that a lack of trust in AI is often compounded when it differs from conventional human decision-making. HCPs are also wary of potential biases embedded in AI algorithms, which could lead to incorrect diagnoses or disparities in treatment recommendations. If AI tools do not undergo rigorous evaluation prior to their introduction and use in real-world settings (see section 7.1.3), they could lead to significant patient harm, irreversible loss of confidence amongst the medical profession, and inaccurate conclusions being made at the population level[299].

According to stakeholders consulted, amongst HCPs, there is often a generational divide in attitudes towards AI where younger HCPs are generally more open to incorporating AI solutions into their practice, while more senior HCPs could be more resistant to change. This was reported by hospital representatives from Germany, Japan and the USA. In addition, there are also concerns related the level of scrutiny that AI solutions undergo prior to their release into the clinical environment[300].

Patients, too, are often wary of AI tools, further complicating their deployment in healthcare settings with 51% of patients and patient associations (36 out of 70) that responded to the survey having concerns and lack of trust in the accuracy of decisions made by AI systems. Based on free text responses provided, this lack of trust arises from concerns about privacy, data security, and the potential for impersonal or dehumanized care. Patients ad patients representatives consulted question whether AI systems can fully understand their unique medical conditions or prioritize their well-being over operational efficiency. The lack of trust is most prevalent when AI solutions are used for tasks that are traditionally performed by highly trained medical professionals. Building trust requires transparent communication, patient-centred design, and rigorous validation of AI tools to ensure that they are perceived as reliable, equitable, and beneficial by all stakeholders.

7.4.1.2 Accelerators

Development of a consistent narrative of the benefits of AI for patients, HCPs, and organisations to improve trust was highlighted as a good practice to facilitate the deployment of AI in clinical practice by 57% of the HCPs (29 out of 51) surveyed. In this regard, the results of robust local level performance testing could be transparently shared to all stakeholders including end-users to foster confidence in the technology's reliability (see sections 7.1.3.2 and 7.1.5.2). Clear communication channels have been identified as a key factor in gaining trust, as reported by hospital representatives from Japan and the UK, alongside insights from an EU level HCP association and an AI developer in the USA. Transparent communication involves articulating the AI tool's goals, benefits for both patients and HCPs, and any operational changes required for its integration. Sharing lessons learned from deployment experiences, such as successes, errors, and areas for improvement, also provides valuable guidance for other institutions looking to adopt similar technologies. Of the hospital representatives surveyed, 62% (13 out of 21) promoted open and transparent communication about the utilisation of the AI tool and the risks and benefits associated with it.

299 Ahmad et al., 2020. Barriers and pitfalls for artificial intelligence in gastroenterology: ethical and regulatory issues.
300 He et al., 2019. The practical implementation of artificial intelligence technologies in medicine.

According to stakeholders consulted, in Swedish hospitals, the use of standardised notes by radiologists to explain the purpose and functionality of AI tools to patients has proven to be an effective strategy to improve trust. This approach has helped to demystify the technology, addressing common concerns about dehumanisation and data privacy. First-hand interaction with AI tools also plays a pivotal role in building trust; allowing healthcare professionals to test and observe these systems in real-world conditions fosters familiarity and confidence in their capabilities. For instance, according to a hospital representative from Japan live demonstrations by AI developers, tailored to specific departments, are instrumental in showcasing the tool's capabilities and fostering trust among end-users. AI developers can also enhance trust by prioritising transparency, offering clear explanations of how their tools operate, and using visual markers or analogies to make complex processes more comprehensible. Educating end-users about the limitations and risks of AI, including the likelihood and potential impact of errors, further promotes a balanced understanding and supports the responsible adoption of AI in healthcare.

The presence of younger healthcare professionals (HCPs) within healthcare facilities has emerged as a key accelerator for the adoption and sustained use of AI tools. In a hospital in Germany, for example, younger doctors have demonstrated strong advocacy for AI, playing a pivotal role in showcasing its value to their more senior colleagues according to a hospital representative. Their familiarity with technology and enthusiasm for innovation make them effective ambassadors for AI, bridging the generational gap and fostering a culture of acceptance. By involving younger HCPs in demonstrating the tangible benefits of AI, such as improved diagnostics or streamlined workflows, hospitals can build credibility and trust among their broader medical staff, ensuring a smoother deployment process.

Another driver of trust reported by stakeholders is the use of real-world evidence and testimonials from institutions that have successfully deployed AI solutions. Decision-makers within healthcare facilities are more likely to embrace AI tools when they see tangible proof of their effectiveness and hear feedback from peer institutions. Highlighting the number of facilities that have already adopted the technology and presenting evidence of added clinical or operational value provides reassurance about its reliability and utility.

> *"By incorporating AI and related technologies into medical education, you prepare future healthcare professionals not only to understand and effectively use AI tools in their practice, but most importantly to accept them. This approach helps overcome resistance due to unfamiliarity or fear of AI by embedding technological literacy from the start of their careers. Likewise, when all stakeholders understand how AI can improve patient outcomes, reduce workload, and enhance decision-making, it reduces fear and resistance. If we would like to prepare members of the health and care workforce for todays and tomorrow's challenges and opportunities – investing in skills is a must by updating university curricula, offering training programmes."* – **HCP association based in Belgium.**

7.4.2 Digital health literacy

7.4.2.1 Challenges

Detailed knowledge regarding the potential and workings of AI in the medical community remains rudimentary and considerable AI education and training will be needed[301]. Many HCPs lack the foundational knowledge and skills needed to effectively engage with AI tools, including understanding how these systems function, their potential applications, and their limitations. The **low level of digital health literacy among healthcare providers** and the public was described as a significant challenge affecting the deployment of AI in healthcare by 43% of HCPs (20 out of 47), 58% of hospital

301 Paranjape et al., 2021. The value of artificial intelligence in laboratory medicine.

representatives (15 out of 26) and 27% of AI developers (8 out of 30) that responded to the survey question. In addition, 59% of patients and patient associations (41 out of 70) expressed concerns about the lack of competence amongst HCPs, which is related to the lack of digital health literacy. This gap can lead to resistance or hesitation in adopting AI, as clinicians may feel unprepared to use the technology responsibly or may distrust its outputs. Without a basic understanding of AI concepts, such as machine learning, data-driven decision-making, or the interpretation of algorithmic results, healthcare professionals are less likely to integrate these tools into their clinical workflows. This lack of familiarity can also impede their ability to critically evaluate AI recommendations, potentially reducing the quality of care and undermining the benefits AI is designed to deliver. This was described as a very important issue that needs to be addressed by a hospital representative from Israel. The hospital representative explained that using AI without adequate training not only limits the value extracted from these technologies but also poses potential risks to patient safety. This is further exacerbated by the lack of structured training programs available to HCPs.

The absence of digital health literacy also affects the ability of HCPs to communicate effectively with patients about AI-enabled care. Patients increasingly expect clear and informed explanations of how AI tools influence their diagnoses or treatments, a sentiment shared by 54% of the patients/patient associations (39 out of 70) that responded to the survey. When HCPs lack confidence or understanding of the technology, they may struggle to provide such explanations, potentially eroding patient trust. In addition, low levels of digital literacy can hinder collaboration between HCPs and AI developers, as HCPs may be unable to articulate their needs or provide meaningful feedback during the design and deployment of AI tools. Today's **medical education system is lacking** in AI training, representing a significant barrier in both the medium and long-term. There are limited individuals in medical faculties who are AI competent and capable of teaching the relevance and importance of AI in the healthcare setting[302]. The barrier resulting from a lack of education also extends beyond clinical staff, as **specific technical expertise** and **mathematical knowledge is required** to develop and use AI tools and proficiency is still rare within healthcare settings.

7.4.2.2 Accelerators

Addressing the issue of digital health literacy requires comprehensive educational programs, ongoing professional development, and the inclusion of digital health literacy as a core competency in healthcare training curricula to ensure that clinicians are well-equipped to engage with and benefit from AI technologies. Healthcare providers will need to develop **training programmes specifically targeted at HCPs** required to use AI systems and designed to ameliorate the multiple concerns resulting from unfamiliar technology (Box 4), a good practice highlighted by 65% of HCPs (33 out of 51) surveyed. Such training programs can be conducted by a quality improvement team, an innovation team, AI developer, or through combined efforts between the hospital and the AI developer, with different stakeholders included in creating the training materials[303]. The focus of the training should be on how to understand the outputs of the AI system and how to act in the new workflows, which will help make decisions regarding the workflow, and better understand the needs for staff recruitment in using the AI system. According to 50% of the hospital representatives surveyed, training programs were conducted for the staff and management programs were tailored accordingly. For example, the Mayo Clinic College of Medicine and Science launched a new initiative called **Advanced Digital**

302 Singh et al., 2020. Current challenges and barriers to real-world artificial intelligence adoption for the healthcare system, provider, and the patient.
303 Sun TQ., 2021. Adopting artificial intelligence in public healthcare: the effect of social power and learning algorithms.

Education to oversee and advance digital technology and AI education across the organisation. This team aims to develop a comprehensive strategy for integrating digital tools and AI into education at Mayo Clinic and equip HCPs with the knowledge and skills to effectively and responsibly utilise these technologies[304]. Another successful approach to improving digital health literacy amongst the healthcare workforce and the public is via **more informal communications**, such as social media communication or in-person communication. IT staff and AI experts could then leverage these communication channels to disseminate AI-related knowledge to HCPs[305]. According to HCPs surveyed, digital health literacy could also be improved by providing clear communication and education of the benefits of using AI in healthcare (66% of respondents, 21 out of 32), by providing clear communication form healthcare facilities/AI developers on how the AI model works and comes to its decisions (59% of respondents, 19 out of 32), or by providing clear communication from the healthcare facility/AI developer on how AI is used in delivery of care (53% of respondents, 17 out of 32).

Several countries have adopted innovative practices to equip HCPs with the skills needed to effectively use AI in clinical settings. These initiatives emphasise tailored training, interdisciplinary collaboration, and accessible resources, reflecting a global commitment to fostering AI literacy across healthcare roles. In the UK, efforts to integrate AI into healthcare have focused on comprehensive education programs. A year-long AI fellowship program trains doctors in clinical AI applications, initially targeting junior doctors before expanding to early and mid-career professionals across various disciplines. A tiered education model ensures that foundational AI literacy is accessible to all HCPs, while specialised training is available for those involved in deploying AI technologies. Leaders and executives receive targeted education to help them understand AI's strategic implications, enabling informed decision-making at all levels. The UK has also explored integrating AI awareness into medical school curricula and postgraduate training, ensuring future healthcare providers are well-prepared. Resources like webinars, including those from the British Institute of Radiology, provide accessible learning opportunities for radiologists and other professionals. A hospital in Israel, is developing and implementing a course on machine learning and AI in medicine, which will be available to all medical staff within the hospital.

In the USA, collaborative programs between HCPs and AI experts foster hands-on learning. The AI Scholars Program pairs HCPs with data scientists to work on real-world AI development projects, combining theoretical education with practical experience. Educational resources include playbooks, offering self-guided tutorials and lessons distilled from the experiences of early adopters to support late adopters in navigating AI integration. Fellowship programs through data science institutes recruit both medical and technical professionals to advance AI-driven research and innovation. In Canada, a hospital integrated a multifaceted education strategy which includes gate checks every two months where HCPs participate in 30-minutes calls, with 5 minutes dedicated to data presentation and the remaining 25 minutes focused upon informal peer discussions on AI deployment and use. These initiatives emphasise experiential learning, equipping healthcare teams to contribute to AI development and deployment actively.

Italy has addressed the need to educate nurses, who are frontline users of healthcare AI but often lack access to professional development opportunities compared to physicians. Courses specifically tailored to nurses aim to bridge this gap, ensuring a more inclusive and well-rounded approach to AI adoption within healthcare teams. Japan has taken a

304 Mayo Clinic College of Medicine and Science, 2024. New Advanced Digital Education Team to Coordinate Digital and AI Education for Mayo Clinic Learners

305 Sendak et al., 2020. Real-world integration of a sepsis deep learning technology into routine clinical care: implementation study.

forward-looking approach with its "Medical Professionals 2030" training project, focusing on providing healthcare providers with the AI literacy and tools needed to integrate AI into their practices. This long-term initiative highlights the importance of preparing healthcare systems for future challenges and innovations. These practices demonstrate the importance of structured and accessible AI education, targeted to various roles within healthcare systems. By offering hands-on learning opportunities, interdisciplinary collaboration, and tiered training programs, countries are paving the way for HCPs to harness the full potential of AI technologies, ensuring better patient outcomes and operational efficiency.

In addition, future medical undergraduate and postgraduate curricula should be updated to include a basic understanding of AI methodology and limitations and include advanced statistical and computational skills[306]. An HCP from the UK stated that there is a growing consideration for **integrating AI training into medical curricula at both the undergraduate and postgraduate levels**. This was also highlighted as a good practice by 73% of the HCPs surveyed (37 out of 51). Such courses would include mandatory AI awareness training alongside existing modules like information governance and data protection. For example, **at Northwestern University, a mandatory curriculum in digital health and data science** has been instituted for all medical students, equipping future doctors with essential AI/ML competencies required for modern healthcare practice[307]. In Europe, **EIT Health established Digital Health Transformation courses** allowing HCPs to deepen their knowledge of key aspects and apply them in real case examples. The course aims to equip students with a foundational knowledge of AI and its practical applications in the healthcare sector. Understanding AI is critical for innovating and improving patient safety measures and decision-makers involved in procuring and implementing AI-based systems in healthcare settings.

Improvements in digital health literacy are not only needed amongst the healthcare workforce, but also for those impacted by the use of AI, patients. A study conducted in the USA on 2,675 responses where minoritised populations were oversampled indicated that 52.9% of respondents chose a human doctor, with 47.1% choosing an AI clinic. Older and black respondents were less likely to choose AI. However, for each unit increase in education, the odds are 1.1 greater for selecting an AI provider indicating that while many patients appear resistant to the use of AI, accuracy information, nudges and a listening patient experience may help increase acceptance[308].

Box 4: NHS AI Lab and HEE: Developing healthcare workers' confidence in AI.

Aim: inform how educational and training providers and educators of healthcare workers plan, resource, develop and deliver educational offerings to equip the workforce with necessary knowledge, skills and capabilities to develop healthcare workers' confidence in AI.

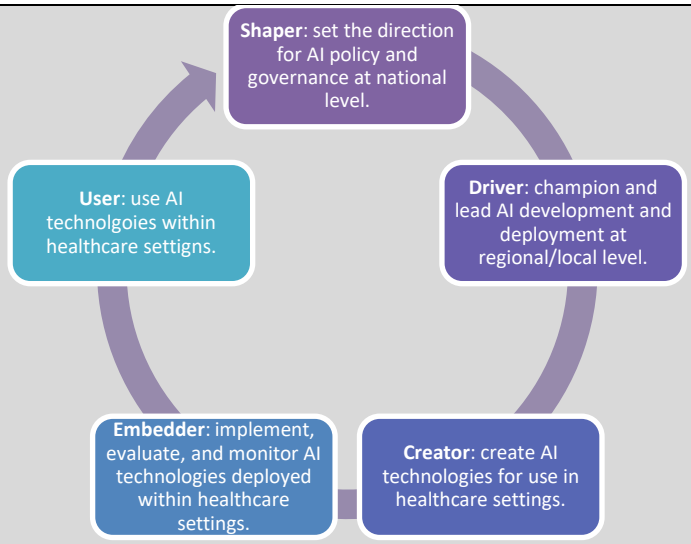
Details:

- Definition of 5 archetypes where each has different knowledge and skill requirements to confidently develop, implement or use AI technologies, and hence specific educational needs.

306 Ahmad et al., 2020. Barriers and pitfalls for artificial intelligence in gastroenterology: ethical and regulatory issues.

307 Luo et al., 2024. Northwestern University resource and education development initiatives to advance collaborative artificial intelligence across the learning health system. Learning Health Systems.

308 Robertson et al., 2023. Diverse patients' attitudes towards Artificial Intelligence (AI) in diagnosis.



- Educational priorities:
  - Produce foundational AI educational content across the whole healthcare workforce, including basic AI literacy and awareness of the limitations and risks of using AI technologies.
  - Advanced AI education that is specific to the workforce archetypes, including development of skills and capabilities that could be available through a centralised online learning hub.
  - Product-specific training for users of each AI technology during its deployment.
- Proposed workforce transformation to support AI-related education.

Supply	▪ Establish clear job roles and career pathways for digital, data and technology specialists ▪ Expand the specialist, digital, data and technology (DDaT) data family professions and clinical informatics workforce through targeted recruitment, increased education and training opportunities, competitive renumeration and flexible equivalence pathways for those with skills from experience outside the NHS ▪ Support professionalisation and accreditation of the DDaT data family professions and clinical informatics workforce through recognised and trustworthy national bodies
Upskilling	▪ Maximise the potential of the workforce through recognised and accredited digital career and education pathways ▪ Support ongoing CPD (Continuing Professional Development) frameworks for development and validation of digital professionals ▪ Provide protected education time for digital skill development supported by flexible hybrid training pathways for digital specialist clinicians ▪ Provide equitable access to training and support, including special efforts to engage and support the digitally unengaged or unconvinced
New roles	▪ Identify gaps that may be filled by development or implementation of new roles
New ways of working	▪ Establish and support AI multi-disciplinary teams (MDTs) involving clinical and technical roles to lead the evaluation, deployment and product-specific user training for AI technologies. A diverse team and a flat organisational structure should be encouraged to avoid hierarchy and minimise bias ▪ Through innovative placements and recruitment, promote an integrated workforce that creates new relationships and networks and a working environment that embraces intrapreneurship and collaboration
Leadership	▪ Develop a new cadre of digital leadership roles with recognition of the value of specialist skills at a senior level for individuals with DDaT data family and clinical informatics skills ▪ Set out clear training pathways and career trajectories to achieve a specific set of competencies required for digital leadership.

- Existing initiatives that address aspects of the workforce development cycle include the Health Education England Data Science Program, the Informatics Skills Development Networks, the 'Data Saves Lives' strategy, the NHSE Digital Workforce Program, the National Competency Framework for Data Professionals in Health and Care.

7.4.3 Job security and overreliance on AI

7.4.3.1 Challenges

Some HCPs may have concerns about job displacement or radically changed job plans as a result of AI adoption, a sentiment shared by hospital representatives and HCPs from Japan and the USA. The level of concern regarding AI use varies between HCPs, which

may be derived from concerns regarding job security in clinical specialties where investigations and results can be readily digitised and interpreted by autonomous AI systems (e.g., ophthalmology, cardiology, pathology, and radiology)[309]. For example, those in the emergency department may be more eager to use the AI tool for decision-making (e.g., discharging patients based on AI evaluations before a radiologist reviews the study), whereas other groups such as radiologists may be more cautious. This is brought upon by concerns that AI tools will ultimately become decision-makers in the clinical care pathway rather than assistive tools. However, "whether AI systems will eventually replace radiologists is the wrong question, the more apt question to be asked is will radiologists who use AI replace radiologists who don't"[310]. However, it should be noted that only 10% of HCPs (5 out of 47) and 12% of hospital representatives (3 out of 26) indicated concerns surrounding job security as a significant challenge to deployment of AI in clinical practice.

Additionally, as deployment and adoption of AI solutions in healthcare becomes more widespread, there are concerns that overreliance on such technologies can lead to decreased critical thinking amongst HCPs[311]. Of the patients and patient associations that responded to the survey, 59% (41 out of 70) expressed concerns about over-reliance on technology and the lack of human oversight. **Overreliance on AI could lead to automation bias** and overshadow human expertise, particularly among younger clinicians, who may become too reliant or trusting of AI tools. Such concerns were raised by HCPs, hospital representatives and AI developers from Israel, France, the UK, Austria and Germany. As clinicians increasingly depend on AI for diagnostics and treatment recommendations, there is a tangible risk that their clinical skills may deteriorate. This dependency could impair HCPs' abilities to make independent, critical decisions, especially in situations where AI systems are unavailable, malfunction or yield erroneous results[312]. Moreover, the **dynamic nature of healthcare employment, where professionals often transition between diverse clinical settings**, exacerbates this risk[313]. This variability across workplaces underscores the urgency of sustaining and enhancing clinical skills in tandem with AI utilisation.

7.4.3.2 Accelerators

To address such issues, it is important to **establish clear communication when AI solutions are used as supportive tools with the output evaluated by trained professionals**, maintaining an element of **human oversight**. HCPs have the clinical knowledge needed to make sure AI tools are well designed for the task required and then tested using large amounts of clinical data that needs to be tagged manually. Once AI systems are integrated into routine healthcare, they will need **human oversight introducing a new role** for HCPs to provide the ongoing oversight of such systems. In addition, there will also be **new roles at executive level to manage** the implementation of AI in hospitals and healthcare systems. Such new positions are already becoming more common with the **introduction of roles such as the Chief AI officer**. Such roles are pioneered by hospitals in the USA, where many individual hospitals or healthcare networks are developing their own AI systems. Although the number of such positions is still relatively small, HCPs have already been appointed to them, such as the **Mayo Clinic in Arizona and University of California San Diego Health.** Finally, it is important to consider that unlike many other professions, the human and personal aspects of medicine

309 Brady et al., 2020. Artificial intelligence in radiology-ethical considerations.
310 Laglotz, 2019. Will artificial intelligence replace radiologists?
311 Cabitza et al., 2017. Unintended consequences of machine learning in medicine.
312 Choudhury et al., 2024. Large Language Models and User Trust: Consequence of Self-Referential Learning Loop and the Deskilling of Health Care Professionals.
313 Sparrow et al., 2019. The promise and perils of AI in medicine.

is important and cannot be replaced with AI. For the abovementioned reasons, AI in the future could reduce mental tasks, improve treatments, and free up clinician time for human interactions rather than replace them[314]. Overall, concerns surrounding job security and overreliance on AI can be addressed by improving the digital health literacy of the healthcare workforce and the public (see section 7.4.2.2).

7.4.4 Doctor-patient relationship

The patient-doctor relationship is an important aspect of healthcare, characterised by mutual trust, effective communication, and collaboration. A trustworthy doctor-patient relationship is foundational for successful medical care - involving open communication, empathy, and a shared understanding of the patient's concerns, values, and treatment preferences[315]. Patients place trust in the expertise of their healthcare providers, relying on their guidance for accurate diagnoses and effective treatments. At the same time, healthcare providers trust in the information shared by patients to make informed decisions about their care.

Widespread integration of AI in healthcare could intensify feelings of alienation between patients and healthcare workers. As AI assumes greater responsibilities, the essential **human touch in patient care might become less prevalent**, potentially diminishing patient satisfaction and trust[316]. Of the patients and patient associations that responded to the survey, 56% (39 out of 70) expressed concerns about the loss of the doctor-patient relationship with the use of AI. In addition, patients arriving with AI-informed information, be it accurate or misleading, could complicate collaborative decision-making with the doctor. This could result in adherence to AI-driven advice without considering individual medical history or difficulties for physicians attempting to reconcile their expertise with AI suggestions. This not only risks eroding the HCP's role but also could reshape the doctor-patient relationship into a consumer-provider model[317]. To effectively ensure that AI has a positive impact on the doctor-patient relationship, it is important to **promote realistic and aligned expectations regarding AI via education** for HCPs and patients before implementing AI tools (see section 7.4.2.2).

7.4.5 High-level overview of the EU regulatory landscape

The current EU regulatory framework may both directly and indirectly in shape some of the social and cultural challenges affecting the deployment of AI in healthcare. The section below presents a high-level non-exhaustive summary overview of key regulation to be considered in the view of the challenges identified and should be reflected in line with the limitations of this study identified in section 3.5.

As regards trust, **the AIA**[318], as explained throughout this study, is central to fostering trust. The requirements on high-risk AI systems enhance trust of AI systems in healthcare. For example, the requirements for human oversight (Art. 14) ensure that clinicians remain integral to decision-making processes, mitigating concerns about the absence of a human touch in patient care. Additionally, the requirements on transparency and provision of information to deployers (Art. 13 AIA), aid to ensure healthcare professionals remain central to AI-assisted care.

314 Dobbs, T. 2024. Will artificial intelligence lead to new jobs in healthcare?
315 Mennella, C. et al., 2024. Ethical and regulatory challenges of AI technologies in healthcare: A narrative review.
316 Sauerbrei et al., 2023. The impact of artificial intelligence on the person-centred, doctor-patient relationship: some problems and solutions.
317 Allen et al., 2024. Navigating the doctor-patient-AI relationship - a mixed-methods study of physician attitudes toward artificial intelligence in primary care.
318

Ethical considerations, such as preventing **discrimination** and **bias**, are critical to ensuring trust and equitable outcomes during the deployment of AI systems in healthcare. In this regard, the provision in Article 10 AIA on data and data governance requires that high-risk AI systems to be developed on the basis of training, validation and testing data sets that meet quality criteria set therein. Such provisions aim to ensure that deployed systems make decisions that are unbiased and equitable, regardless of patient demographics or socio-economic factors, and effectively address the needs of diverse populations. **The EHDS**[319] facilitates equitable access to health datasets (Chapter IV EHDS – Secondary use). Such access can ensure that deployed AI tools are trained and validated on comprehensive data, reducing the risk of bias in their outputs.

The AIA also acknowledges that AI, can also be misused and provide novel and powerful tools for manipulative, exploitative and social control practices. Such practices are particularly harmful and abusive, and the AIA prohibits them because they contradict Union values of respect for human dignity, freedom, equality, democracy and the rule of law and fundamental rights enshrined in the Charter, including the right to non-discrimination, to data protection and to privacy and the rights of the child[320]. The European Commission has recently issued guidelines detailing AI practices prohibited under the AI Act, aiming to safeguard European values and fundamental rights[321].

The PLD[322] may indirectly reinforce trust by ensuring liability, holding providers liable for defective AI products. The PLD, particularly in its revised form, addresses trust by ensuring that patients and healthcare providers have clear recourse in the event of harm caused by defective AI systems. Its strict liability provisions create accountability for manufacturers, reinforcing confidence in the safety and reliability of AI technologies. The HTAR[323] may indirectly enhance trust by contributing to assessing the clinical value of some high-risk medical devices including those using AI based software (Art. 7), allowing healthcare institutions to validate AI tools based on clinical evidence, which can be shared with HCPs and patients to increase confidence.

As regards digital and health literacy, **the AIA** also tackles **digital literacy** challenges by requiring providers (such as developers) and deployers of AI systems to take measures to ensure a sufficient level of AI literacy of their staff and other persons dealing with the operation and use of AI systems on their behalf, taking into account their technical knowledge, experience, education and training and the context the AI systems are to be used in, and considering the persons or groups of persons on whom the AI systems are to be used (Article 4). This provision helps bridge knowledge gaps and empowers healthcare providers to effectively integrate AI into their workflows.

The **EHDS**, may also play a role in improving **digital literacy** by facilitating access to structured data, which can support educational efforts to enhance the digital health literacy of healthcare providers and stakeholders. This may improve understanding and acceptance of AI solutions, fostering trust and collaboration in their deployment. Additionally, the EHDS specifies that the Commission shall support the sharing of best practices and expertise to build capacity within Member States to strengthen digital health

319 Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847
320 See recital 28 and chapter II AIA
321 Commission Guidelines on prohibited artificial intelligence practices established by Regulation (EU) 2024/1689 (AI Act), 04 February 2025
322 Directive (EU) 2024/2853 of the European Parliament and of the Council of 23 October 2024 on liability for defective products and repealing Council Directive 85/374/EEC
323 Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU

systems for primary use and secondary use considering the specific circumstances of the different categories of stakeholders involved. To support that capacity building, the Commission shall in close cooperation and consultation with Member States establish indicators for self-assessment for primary use and secondary use (Article 82 EHDS); Art. 83 EHDS requires accessible training for health professionals, and Art. 84 EHDS calls for campaigns to improve patients' digital literacy regarding their rights and benefits.

As regards doctor-patient relationship, the AIA supports the doctor-patient relationship by promoting human oversight (Art. 14) and transparency (Art. 13), ensuring healthcare professionals remain central to AI-assisted care.

7.4.6 Summary

The deployment of AI in healthcare faces several social and cultural challenges. **Trust issues** among HCPs and patients hinder adoption, with concerns about AI transparency, potential biases, and the "black box" nature of decision-making. Resistance is more common among senior clinicians, while patients fear AI may lead to impersonal care. **Low digital health literacy** among HCPs and patients further complicates adoption, as many lack the necessary training to understand, interpret, and effectively use AI tools. This knowledge gap also affects communication, reducing patient confidence in AI-assisted care. **Job security concerns** are prevalent, particularly in specialties like radiology and pathology, where AI could automate tasks, while overreliance on AI raises fears of diminished critical thinking and clinical skills among HCPs. Lastly, **the doctor-patient relationship** may be strained by AI deployment, with patients fearing reduced human interaction and HCPs struggling to reconcile AI-driven recommendations with traditional expertise.

To address social and cultural challenges in AI deployment, several accelerators have been identified. **Building trust** requires transparent communication about AI's functionality, performance testing processes, and real-world benefits. Hospitals have successfully improved trust by involving younger HCPs as AI advocates, using standardised explanations for patients, and showcasing AI's effectiveness through real-world evidence. **Enhancing digital health literacy** is important for both HCPs and patients, achieved through structured AI training programs, interdisciplinary collaborations, and curriculum updates in medical education. Countries like the UK, USA, and Japan have implemented tailored AI literacy initiatives, ensuring HCPs are equipped to engage with AI effectively. **Addressing job security concerns** involves clearly defining AI as a supportive tool rather than a replacement for HCPs, with new roles such as Chief AI Officers emerging to oversee AI integration. Lastly, **preserving the doctor-patient relationship** requires balancing AI's efficiencies with human-centred care, ensuring AI supports rather than replaces clinician-patient interactions. These accelerators collectively promote AI acceptance, responsible usage, and integration into healthcare workflows.

7.5 Challenges faced by generative AI systems

The deployment of generative AI in healthcare introduces some unique challenges in addition to all of the abovementioned challenges relevant to both traditional and generative AI systems. A recent systematic review highlighted the limitations of LLMs that can broadly be categorised into design limitations and output related limitations that affect the deployment of such tools[324]. Trust and performance testing are essential to generative AI's adoption success in healthcare. The 'unpredictability' of generative AI tools is the main barrier to adoption success, as we do not know when it is going to return a good answer

324 Busch et al., 2025. Current applications and challenges in large language models for patient care: a systematic review.

and when its answers are going to be wrong or misleading, or in other words, when to trust generative AI and when not to trust it, especially when the user is not sufficiently qualified to assess the quality (accuracy and completeness) of a given response. This is particularly relevant given that some generative AI tools are known to make stuff up, termed generative AI "hallucinations". The issue of "hallucinations" was highlighted by HCPs and hospital representatives consulted, given that such generative AI models lack the long-standing reliability mechanisms found in more traditional machine learning models. To address this issue, it is important to have generative AI models that have been specifically and comprehensively trained using a large amount of quality evidence-based medical texts that sufficiently cover a given medical specialty.

The rapid evolution of generative AI models, such as LLMs, introduces an additional challenge regarding their clinical evaluation, regulation, and certification. Generative AI continuously evolves, adapting its outputs based on new data inputs. This dynamic nature necessitates ongoing performance testing to confirm that the AI remains accurate and reliable over time[325,326]. However, clinical evaluation and certification are processes that traditionally take a relatively long time to complete, so there is always the risk that by the time an evaluation is completed, the evaluated AI has already changed substantially with the release of a new version requiring a new evaluation. Generative AI models bring new challenges compared with already regulated AI-based technologies and will therefore require additional regulatory adaptations[327].

Generative AI models often contain billions of parameters that require significant computational power to generate accurate responses. As a result, resource-limited labs or healthcare providers may be compelled to rely on external, third-party digital tools for computational support. However, there are ethical, regulatory, and patient privacy concerns with using third-party generative AI tools. Before sensitive data are uploaded into these tools, potential users must conduct a thorough legal and data privacy review, which itself is resource intensive. Concerns surrounding data privacy and protection were raised by HCPs and hospital representatives consulted, with HCPs stating that generative AI models may struggle with privacy concerns, particularly in cases where models are trained on limited or sensitive data. One approach to address this issue is by using localised architecture with fewer parameters that can run on local networks or mobile devices, are optimised for specific tasks, and can be trained in less time than larger models, using a combination of model compression and higher-quality training data. Using generative AI models locally lessens privacy risks, as the data never leave the secure local network or device[328]. Using federated learning, where multiple actors collaboratively train a model by exchanging model updates without sharing patient data, is another approach that can be used to maintain data privacy and keep patient data local but enable HCPs to benefit from models trained on more patient records.

Overall, most stakeholders consulted as part of this study where not aware of specific accelerators to facilitate the deployment of generative AI tools in clinical practice. Those who were aware focused on **avoiding the inclusion of personal identifiable information in software outside the EHR system** and on **training and fine-tuning generative AI models with specific medical contexts** to improve their relevance in clinical settings.

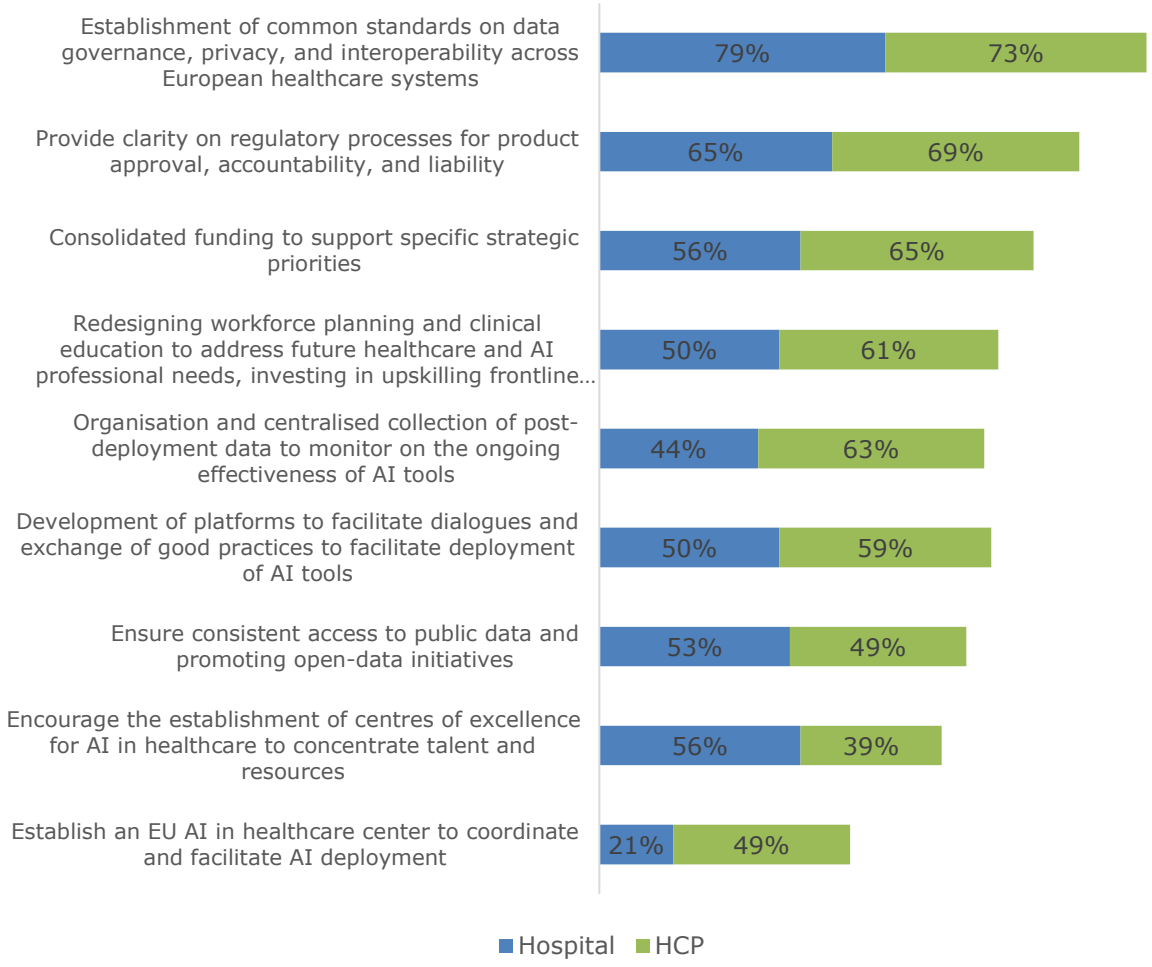
325 Hwang and Park, 2020. "Clinical Implementation of Deep Learning in Thoracic Radiology."
326 Reddy, S., 2024. Generative AI in healthcare: an implementation science informed translational path on application, integration and governance. 15 March
327 Mesko et al., 2023. The imperative for regulatory oversight of large language models (or generative AI) in healthcare.
328 Zou et al., 2023. Universal and transferable adversarial attacks on aligned language models.

8 Future Considerations

8.1 Considerations to facilitate the deployment of AI in healthcare

The successful deployment of AI in healthcare requires a multifaceted strategy that addresses the various challenges described in the previous sections while leveraging identified accelerators. A recent publication indicated the need for a comprehensive approach that includes consolidating funding, creating a level playing field, clarifying regulations, supporting centres of excellence, promoting trustworthy AI, fostering coordinated efforts, and implementing monitoring and assessment mechanisms to ensure safe and effective deployment of AI into clinical practice[329]. The stakeholders consulted during this study identified specific considerations for future actions, both regulatory and non-regulatory, that could be implemented at the EU level to support the deployment of AI tools in healthcare (Figure 16).

Figure 16: Considerations for future actions to facilitate the deployment of AI in healthcare according to hospital representatives (34 responses) and HCPs (51 responses).



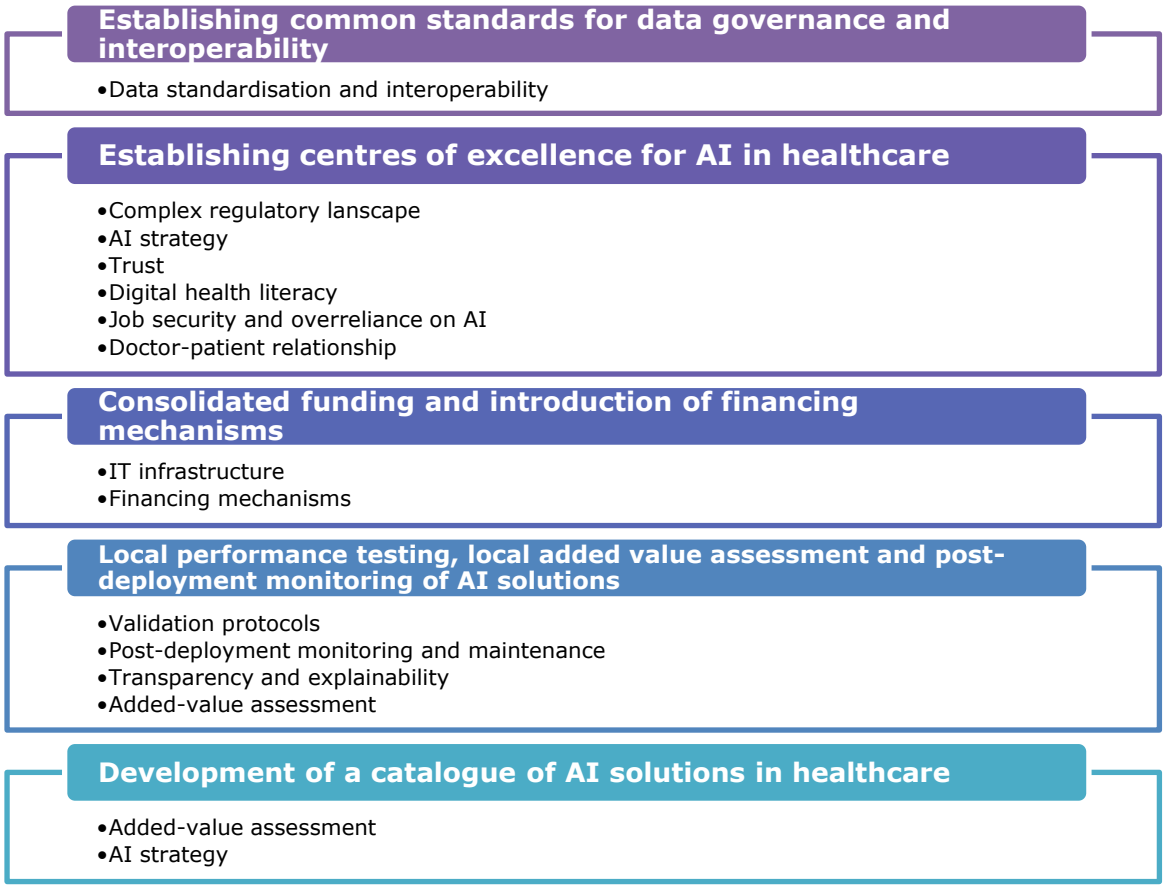
Source: Authors' elaboration

The sections below present considerations identified by the activities conducted that could be considered to facilitate the effective and efficient deployment of AI in healthcare by addressing the abovementioned challenges (Figure 17 describes the challenges addressed

329 EIT Health, 2020. Transforming healthcare with AI: The impact on the workforce and organisations.

by each of the considerations for future action). They are presented without any specific order or prioritisation.

Figure 17: Challenges addressed by the proposed considerations for future action.



Source: Authors' elaboration.

8.1.1 Establishing common standards for data governance and interoperability

The first action focuses upon the **establishment of common standards for data governance and interoperability** across European healthcare systems (see section 7.1.1)[330]. Such an action was identified by 73% of HCPs (37 out of 51) and 79% of hospital representatives (27 out of 34) surveyed. Common standards have the potential to support the **integration** of AI across different healthcare systems within the EU. Establishing these standards could address hurdles related to data governance and the interoperability of systems, facilitating **more effective data exchange** that is required to effectively use and scale AI solutions. By establishing rules for data access, and cross-border exchanges, the EHDS aligns closely with the need for common standards that facilitate AI deployment (see section 5.1.7). While the EHDS lays an important foundation, its eventual success depends on complementary actions to fully realise the potential of AI in healthcare. The EHDS enables AI innovation through access to richer and more diverse datasets. In addition, the EHDS framework could aid in testing and validating AI models across healthcare systems, facilitating compliance with EU regulations while ensuring that AI

330 The CEN-CENELEC Joint Technical Committee 21. responsible for the development and adoption of standards for AI and related data, as well as provide guidance to other Technical Committees concerned with AI, could be leveraged to provide such standards for the field of healthcare.

applications perform reliably across different demographic and clinical settings (see section 8.1.4).

Adherence to international interoperability standards reinforced, such as those described in section 7.1.1.2, to ensure uniform data exchanges and establish a certification program for AI developers and healthcare systems to validate compliance with these standards. A certification program could be used to assess the technical readiness and compliance with the standards. In addition, an open-source projects could be promoted that develop tools for data standardisation, integration, and exchange tailored to healthcare environments, an action highlighted by 53% of hospital representatives (18 out of 26) and 49% of HCPs (25 out of 51) surveyed. Such tools could include interoperable APIs and middleware that integrate with existing healthcare systems (see section 7.1.1.2). Financial incentives could accelerate the transition to a standardised data environment and interoperable systems that would facilitate the deployment of AI tools in healthcare.

8.1.2 Establishing centres of excellence for AI in healthcare

The study suggests that the establishment of Centres of Excellence for AI in healthcare, which could serve as hubs for concentrating talent and resources to develop playbooks for AI deployment, advance digital health literacy, foster collaboration between developers and deployers, digitally advanced with less advanced countries, and disseminate best practices across Member States. The establishment of such centres and community of experts was proposed by 56% of hospital representatives (19 out of 34) and 39% of HCPs (20 out of 51) surveyed.

These Centres of Excellence could:

1. **Provide advanced training programs for the healthcare workforce:** a function of these Centres of Excellence could be to develop and deliver training programs tailored for HCPs, focusing on AI fundamentals, practical applications, ethics, and data governance, an action highlighted as important by 50% of hospital representatives (17 out of 34) and 61% of HCPs surveyed (31 out of 51) in the context of workforce redesign. Such programs could be designed for clinicians, healthcare administrators, and IT staff, covering topics from understanding AI-generated insights to safely integrating AI tools into clinical workflows.. To accommodate various needs across the workforce, these centres could offer programs at different levels—from introductory courses for non-technical staff to in-depth training for healthcare practitioners and data scientists working directly with AI technologies (see section 7.4.2.2). Certification programs and continuing education credits could be awarded to encourage participation, with the centres partnering with universities, research institutions, and AI companies to provide current, high-quality training resources. These programs could ensure that healthcare providers across the EU are equipped to use and understand AI tools confidently, maximising their effectiveness in clinical settings. One example of such an initiative is the TRANSiTION (Digital Transition And Digital Resilience In Oncology) study already implemented at EU level that aims to develop training on digital skills for the health workforce.
2. **Provide public education and digital health literacy initiatives:** to build a well-informed public that can engage with AI-driven healthcare, the Centres of Excellence could also deliver digital health literacy programs for the general public. These initiatives would aim to demystify AI in healthcare, helping individuals understand how these technologies are used in diagnostics, treatment, and preventative care. Educational campaigns could focus on common uses of AI, patient data privacy, and ways to interpret AI-driven insights responsibly. These

programs could empower citizens to make informed choices and engage actively with their healthcare, fostering a sense of trust and transparency. The centres could achieve this through accessible online courses, interactive workshops, and public seminars, tailored to different age groups and levels of digital literacy. Partnerships with public health agencies, patient advocacy groups, and educational institutions could further amplify outreach, ensuring wide engagement across diverse demographics.

3. **Create a collaborative environment for knowledge and best practice sharing:** the Centres of Excellence could serve as collaborative hubs where researchers, clinicians, AI developers, and policymakers come together to share knowledge and best practices. Such collaborations and exchange of best practices was highlighted as an important action by 50% of hospital representatives (17 out of 34) and 59% of HCPs (30 out of 51) surveyed. They could facilitate cross-border collaboration and provide a structured environment for piloting AI technologies, running clinical trials, and developing guidelines. Regular workshops, conferences, and hackathons could foster innovation, while shared repositories of case studies, model documentation, and regulatory resources could support consistent standards across the EU. By centralising best practices and success stories, these centres may help standardise safe, ethical AI deployment in healthcare. Moreover, such collaboration could accelerate regulatory alignment, enabling Member States to learn from each other's experiences and address common challenges more effectively.

The collaborative environment in these Centres of Excellence could facilitate the development of AI playbooks, such as those developed in the UK (BS 30440:2023[331]) and the USA (the Coalition for Health AI assurance standards guide[332]), that could guide the effective deployment of AI solutions in healthcare, outlining a clear and structured roadmap for deployment at various levels of the healthcare system. These playbooks could also provide clear regulatory guidelines for AI deployment, highlighted as an important action by 65% of hospital representatives (22 out of 34) and 69% of HCPs (35 out of 51) surveyed. They could build on the provisions of the EU AIA and bridge **the gap between the requirements of the AIA and the practical implementation of AI solutions in healthcare**.

8.1.3 Consolidated funding and introduction of financing mechanisms

Consolidated funding or financing mechanisms could support specific strategic priorities. This was highlighted by 56% of hospital representatives (19 out of 34) and 65% of HCPs (33 out of 51) surveyed. This approach may accelerate both the development and deployment of promising AI applications and overcome some of the obstacles to deployment by setting the overall **strategy**. This could also support Member States, and in turn healthcare organisations align their own strategic objectives related to AI deployment in healthcare (see section 7.3.4).

Dedicated funding streams, grants, and subsidies could support healthcare institutions to pilot and deploy AI solutions across different strategic areas. Given the significant administrative tasks often associated with securing funding, deployers (particularly smaller hospital in remote areas) could be supported by connecting them with expert consultants who understand what is needed to secure, for example, EU funding.

331 BSI Knowledge, 2023. Validation framework for the use of artificial intelligence (AI) within healthcare.
332 Coalition for Health AI, 2024. CHAI Assurance Standards Guide.

Guidelines for reimbursement of AI tools in healthcare (through case studies and practice sharing). The framework could establish example reimbursement criteria for AI tools, focusing on clinical efficacy, safety, and patient outcomes. By providing clear guidelines, developers could be encouraged to focus on meeting these standards, thereby fostering the creation of high-quality, clinically assessed AI applications.

8.1.4 Local performance testing; local real-world added-value assessment and post-deployment monitoring

AI deployment could be facilitated by introducing local added-value assessments (see section 7.3.3), local performance tests (see section 7.1.3), and post-deployment monitoring of AI tools (see section 7.1.4), as highlighted by 24% of hospital representatives (8 out of 34) and 49% of HCPs (25 out of 51) surveyed. **Assurance laboratories could be established to evaluate the local performance** (does the solution perform as in my local setting) and local **added value** of AI tools already on the market for healthcare (see section 7.1.3.2). The assurance laboratories could be strategically located in leading university hospitals across EU Member States with access to high-quality real-world evidence, that could collaborate with each other and serve as "AI sandboxes". This network could build on the existing work of the Testing and Experimentation Facility for Health AI and Robotics (TEF-Health), a project supported by the European Commission and national funding agencies, where 51 academic and private partners from 9 European countries have come together to facilitate medical devices that incorporate AI to fulfil their regulatory obligations. This allows AI developers and healthcare providers to locally test the performance of models in a secure environment using anonymised, ethically sourced data from across the EU to ensure there are no variations in performance across healthcare settings. Additionally, the performance of AI systems in real world settings could be assessed on factors such as clinical workflows, local infrastructures, clinical guidelines and explainability of AI systems. Such a setup could ensure diverse and representative pre-deployment performance testing, capturing nuances across different patient demographics and healthcare contexts, and ensuring that AI tools perform accurately and safely across different healthcare settings before being integrated into clinical workflows.

A standardised model could be developed to evaluate the real-world local added value of AI solutions at hospital or regional level by focusing on three core dimensions: clinical value, operational efficiency, and financial impact. This model would provide a robust framework to present the impact of AI tools across several dimensions (performance benchmarks) such as clinical (e.g. reductions in adverse events), operational (e.g. time saving) and financial domains (e.g. ROI). Once local performance testing has completed, AI tools could be issued a "Model Report Card" or "Model Fact Label" summarising the tool's strengths, limitations, and validated use cases, offering HCPs, patients, and regulators a transparent overview of the model's performance and intended applications. This transparency may help healthcare providers make informed decisions about deploying AI tools, while also fostering trust among patients by clearly communicating the AI's capabilities and boundaries. Each assurance laboratory could then contribute insights and AI performance data to the centralised catalogue for AI tools proposed in section 8.1.5.

Assurance laboratories could also play an important role in conducting post-deployment monitoring of AI tools, ensuring their sustained performance and safety after deployment into clinical practice. The organisation and centralised collection of post-deployment data to monitor on the ongoing effectiveness of AI tools was highlighted as important by 63% (32 out of 51) of HCPs and 44% (15 out of 34) of hospital representatives surveyed. Assurance laboratories could establish a systematic framework

to periodically assess AI tools in real-world settings. This ongoing monitoring could verify that the AI models continue to meet predefined performance benchmarks, adapt to evolving healthcare needs and maintain consistency across diverse clinical environments. Such evaluations may focus on aspects like model drift (where AI performance may degrade over time due to changes in underlying data distributions) and the robustness of AI outputs when faced with new, unanticipated scenarios. The results of these periodic assessments could be shared with healthcare providers and end-users, fostering confidence in the AI's continued use.

In addition to monitoring the technical performance of AI tools, the assurance laboratories could evaluate the interaction between end-users, such as HCPs, and the AI systems, as well as the impact on patient experiences. This may involve gathering qualitative and quantitative feedback from users, analysing how effectively the tools integrate into clinical workflows, and identifying potential issues such as misuse, over-reliance, or resistance among healthcare providers. Similarly, patient interaction with AI-assisted care could be assessed to ensure tools are used in ways that enhance, rather than compromise, the quality of care and trust in healthcare systems. By incorporating this human-centred perspective, the labs could provide a holistic understanding of the AI tools' effectiveness, usability, and impact.

8.1.5 Development of a catalogue of AI solutions in healthcare

Stakeholders interviewed highlighted that the abundance of AI solutions available results in challenges to the identification of the most appropriate tool for their setting and objective. **A centralised catalogue of AI solutions for healthcare** could serve as a centralised repository of AI tools available across all medical specialities and application types.

This catalogue could act as a one-stop platform where healthcare providers, HCPs, and other stakeholders are able to access detailed information about AI solutions tailored to their needs. It could provide a structured database that categorises AI tools by functionality (e.g., diagnostic imaging, predictive analytics, patient triage), medical specialty (e.g., cardiology, oncology), and operational context (e.g., primary care, emergency settings). Such a platform may enhance transparency and accessibility, ensuring that stakeholders can make informed choices based on the specific requirements of their clinical environments.

A feature of the AI Tool Catalogue could be the inclusion of detailed performance metrics for each listed AI tool. These metrics, verified through the assurance labs (see section 7.1.3.2), could cover dimensions such as accuracy, sensitivity, specificity, robustness, generalisability, and adherence to ethical standards. The "AI catalogue" could also integrate user reviews and feedback mechanisms, enabling end-users to share their experiences with specific tools post-deployment. This feature may provide a dynamic layer of evaluation, capturing real-world insights into how AI tools perform under various clinical conditions and complementing the technical performance data provided by assurance labs. Additionally, the platform could include resources such as user guides, case studies, and tutorials to help healthcare providers understand and implement AI solutions effectively. By **facilitating peer-to-peer knowledge exchange** and continuous learning, the catalogue could support a community-driven approach to AI adoption in healthcare.

To ensure the catalogue remains up-to-date and relevant, a governance framework could be established to oversee its operations. This framework could involve regular updates to reflect new AI solutions, performance re-assessments of existing tools, and adaptations to emerging healthcare needs or regulatory changes. Partnerships with AI developers, healthcare institutions, and Member States would be important to maintaining the

platform's accuracy and comprehensiveness. By serving as a curated, trustworthy repository of healthcare AI tools, the catalogue may accelerate the safe and equitable integration of AI into healthcare systems across the EU, driving innovation while safeguarding public health interests.

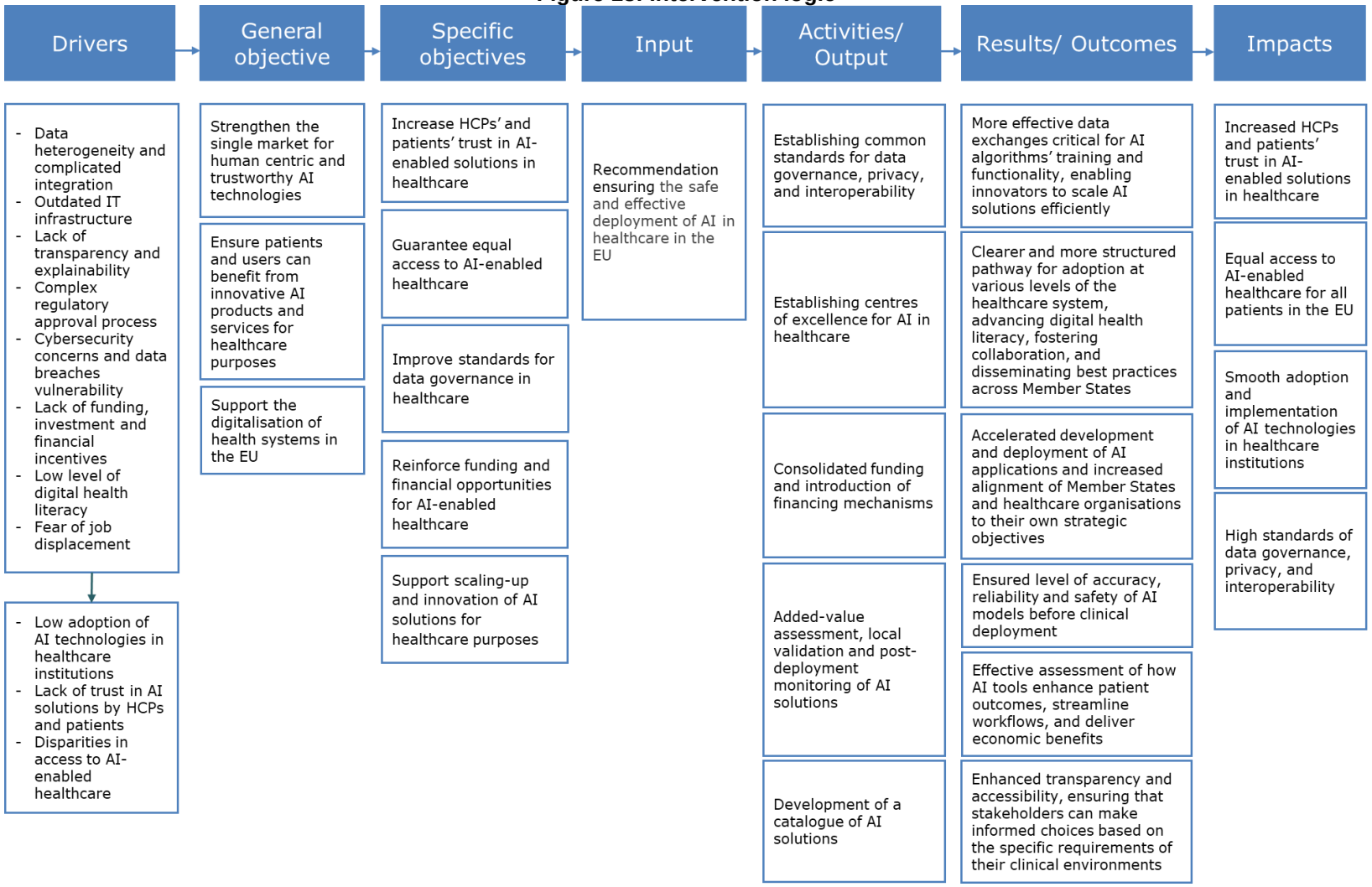
8.1.6 Summary

In summary, several considerations for future actions are presented to facilitate AI deployment in healthcare. First, establishing common standards for data governance and interoperability across European healthcare systems would enable seamless AI integration, support secure cross-border data exchange, and facilitate compliance with regulations. Secondly, the creation of Centres of Excellence would help address skills gaps, provide advanced training for healthcare workers, promote public digital health literacy, and foster collaboration on AI innovations. Thirdly, consolidated funding and financing mechanisms could support AI projects and ensure equitable access to AI tools across healthcare systems. Additionally, added-value assessment, local performance tests/studies through assurance labs and conducting post-deployment monitoring of AI tools could ensure their effectiveness, safety, and compliance. Finally, developing an AI Catalogue would create a central repository of AI solutions available, enabling healthcare providers to make informed decisions and driving innovation across the EU.

8.2 Monitoring framework for considerations for future actions.

As established by the Better Regulation Guidelines (Tool #43), the first step to design a monitoring framework for potential EU interventions is to define the scope of such interventions. To do so, we have assessed what are the objectives of the abovementioned considerations for future action, the problems they want to address, and the results and impacts they aim for. This assessment takes the form of an **intervention logic** which lay downs the links between the drivers, problems and the objectives of a given intervention by analysing intertwined inputs, outputs, outcomes and impacts. Below we include the intervention logic we have developed for the considerations for future actions identified in the previous sub-sections.

Figure 18: Intervention logic



Source: Authors' elaboration.

Once the intervention logic has been established, the second step is to conduct a **mapping of indicators** which could feed the monitoring framework to assess the level of achievement of the objectives in terms of the input, output, outcome and impacts of the intervention. The selection of indicators is to be done based on the RACER principles outlined in the Better Regulation Guidelines (Tool #43). The selected indicators should be **relevant** (i.e. linked to the objectives to be achieved), **acceptable** (i.e. are to be accepted by the Commission and other relevant stakeholders), **credible** (i.e. accessible to non-experts, unambiguous and easy to interpret), **easy to monitor** (i.e. feasible to monitor at a reasonable cost and administrative burden), and **robust** (i.e. difficult to manipulate).

To make this exercise easier, we have drawn specific actions for each of the considerations for future action actions (i.e. activities/output in the intervention logic). These specific actions were mentioned in the main text explaining the steps to be taken for each recommended action through the previous sub-sections. In the table in Annex 7, we provide the list of specific actions for each consideration for future action.

Following the Better Regulation guidelines, the study team has tried to rely as much as possible on existing reporting requirements for the development of the monitoring framework. However, this has encountered some limitations as there is a lack of data available which could inform the monitoring framework[333]. Secondly, the monitoring framework is developed for potential considerations for future action that the Commission could recommend or implement, and not actual implemented interventions. This makes the possibility of using existing reporting requirements more difficult. Given the overall data gaps on indicators that could be used, it remains challenging to suggest measures on the effectiveness of the actions taken by the Commission without creating a significant burden in reporting requirements.

As a result of the above, the framework relies primarily on desk research and information that can be only retrieved upon specific request, which constrains its practical application. At the same time, the entry into force of key databases, such as EUDAMED, will represent a significant step forward, as such databases might facilitate the identification and adoption of more practical indicators, enhancing the operationalisation of the monitoring framework.

In Annex 8 of this document we provide some data collection and reporting guidelines and include the full monitoring framework for the proposed considerations for future actions at EU level.

9 Conclusions

AI has the potential to transform the healthcare sector, addressing challenges that healthcare systems are facing today such as workforce shortages, diagnostic and treatment inefficiencies, and disparities in access to care. However, despite significant progress in AI research and its demonstrated benefits across several medical specialties and operational tasks, the level of adoption across healthcare systems, remains slow, and limited. This underlines the need to address existing challenges to deployment, build on lessons from diverse healthcare systems, and implement actionable strategies to facilitate equitable and impactful AI deployment across Europe.

There are a number of challenges that need to be overcome to allow for the effective and efficient deployment of AI across healthcare systems. Technological and data challenges such as data fragmentation remain a persistent issue, with healthcare systems struggling

333 In Annex 5 – Details on data sources and methodology for market analysis, we provide more details on the limitations in terms of data sources to assess the level of deployment of AI/ML-enabled medical devices in clinical practice.

to standardise formats and ensure interoperability across platforms. This lack of uniformity limits the ability of AI tools to be seamlessly integrated into clinical workflows to process and analyse data effectively, diminishing their overall utility. Additionally, many healthcare systems rely on outdated IT infrastructure, which is insufficient to support modern AI applications, creating an additional barrier to adoption. The lack of standardised local performance testing protocols to address variations in performance across health care systems, show the added value of deploying AI systems in clinical practice, as well as the lack of post-deployment monitoring mechanisms to assess the long-term performance of AI tools and how end-users interact with them is another barrier to adoption as it often results in a lack of trust and confidence amongst HCPs. This is further compounded by the lack of transparency and explainability of AI solutions, often referred to as the "black box" phenomenon.

The regulatory environment governing AI in healthcare, while robust, presents complexities that may contribute to hesitancy in AI deployment. The interplay of multiple regulations also raises challenges to deployers to navigate. Concerns surrounding data privacy, security, and liability further complicate the terrain.

Organisational and financial challenges also hinder the deployment of AI solutions. The absence of clear financing mechanisms and reimbursement frameworks for AI-based systems makes it difficult for healthcare providers to justify investments in these technologies. Inadequate end-user engagement during the development of AI solutions can lead to tools that misalign with the practical needs of healthcare professionals or patients. Additionally, a lack of standardised models for assessing the local added value of AI tools limits deployers' ability to evaluate solutions in terms of hospital level performance and potential benefits.. Obstacles on assessing the local-added value is often compounded by unclear of strategic direction and clear AI deployment roadmap in some healthcare systems, which undermines efforts to integrate AI effectively.

Social and cultural factors also play an important role in delaying AI adoption. The level of trust among HCPs and patients regarding the reliability and ethical implications of AI is a key factor, which is often exacerbated by concerns surrounding job-security and overreliance on technology, as well as its impact on the doctor-patient relationship. One of the drivers of the lack of trust and concerns shared by HCPs and patients is digital health literacy and technological competence to understand how AI tools operate, their potential and limitations, and their use as supportive tools in the provision of care.

In addition to the EU, countries that have advanced in the deployment of AI in healthcare, such as the USA, Israel, and Japan provide valuable insights into addressing these challenges.. Healthcare systems/providers in these regions have employed various good practices (accelerators) that may address a range of these challenges, which could further be investigated within the European context to support the scale-up of deployment.

Widespread AI deployment in healthcare is complex, but the potential rewards are transformative. By addressing the challenges affecting the deployment of AI in healthcare and implementing targeted strategies, it is possible to encourage and facilitate healthcare systems in the EU to adopt AI solutions to deliver high-quality, accessible, and sustainable healthcare. A collaborative effort involving policymakers, healthcare providers, developers, and patients is important to realise this vision, ensuring that AI becomes an integral part of the healthcare landscape in Europe. Through strategic action and a commitment to overcome deployment challenges, the EU can position itself as a global leader in AI-driven healthcare innovation.

10 Annexes

10.1 Annex 1 – Analytical framework

The analytical framework illustrated in the table below presents the study questions provided within the terms of reference, the framework served to guide the investigation and analysis toward the overall objectives and scope.

Study questions	Sub-questions
1. What are the current needs in clinical practice that AI could address? How are the needs expected to evolve in the next 5 years?	1.1 What are the present-day needs in clinical practice that currently available AI technology could address? 1.2 What are the needs in clinical practice that could be addressed by advancements in AI technology in the next 5-years (i.e. GenAI)?
2. Among those unmet needs, what are the areas where the use of AI in healthcare has the greatest potential to transform healthcare including clinicians' daily practice and individuals'/patients' diagnosis, treatments, and management?	2.1 In what medical specialties or areas do AI technologies have the greatest potential? 2.2 In what medical specialities or areas have AI technologies already been adopted?
3. What are the specific challenges of using AI in healthcare? - What are the specific challenges of using generative AI in healthcare? - Are there ethical issues emerging due to the use of AI in healthcare? If so, what are they? - Are there data protection and/or IP issues involved? If so, what are they? - Are there patient specific concerns in the use of AI? - Are there particular transparency issues when deploying AI in healthcare? - Are there clinicians' liability/standard of care issues when using AI systems?	What are the specific challenges of using AI in healthcare, related to: 3.1 Healthcare professionals that interact with AI tools, for example resistance to change/digital literacy 3.2 Ethical issues (that are not resolved by the AI Act) 3.3 Patient Data protection (that are not resolved by GDPR compliance and the upcoming EHDS regulation) 3.4 Patient specific concerns/hesitancy towards use of AI in their care 3.5 Related to transparency issues (that are not resolved by the obligations of the AI Act) 3.6 Related to clinicians' liability/standard of care issues (that are not resolved by the obligations of the AI Act and the PLD) 3.7 What are the challenges posed by the specific use of generative AI in healthcare that may not be considered in the broad scope of the AI act?
4. How many AI-based medical devices have been CE marked in the EU and how many FDA approved in the US? In what medical domains?	4.1. How many AI-based medical devices have been CE marked in the EU? And what medical domains do they cover? 4.2. How many AI-based medical devices have been FDA approved in the US? And what medical domains do they cover? 4.3. Are there any other relevant AI-based medical devices deployed in the EU and US which are not CE marked or FDA approved?

5. What is the current state of deployment of AI in clinical practice? Provide a mapping distinguishing the deployment of AI in clinical practice per Member State and relevant third countries as well as drawing a distinction between rural and urban areas as well as between medical specialties. Are there some patterns developing (e.g., geographical, regional, medical specialty related)? If so, what could be possible explanations? Is the deployment of AI benefiting patients equally?	5.1. What is the extent of AI deployment in clinical practice across Member States and relevant third countries (e.g., USA, Israel, Japan)? 5.2. What is the difference of AI deployment in healthcare between urban and rural areas? 5.3. What are the differences of AI deployment across medical specialties? 5.4. What are the factors explaining these differences in AI deployment? 5.5. To what extent is AI deployment in healthcare benefitting patients equally?
6. How does AI impact/transform clinical practice? Among others, how does the deployment of AI impact clinical workflows, clinical guidelines, healthcare system transformation, clinicians' collaborations, healthcare workers working time, patients, doctor-patient relationships, standard of care?	6.1. How does AI impact clinical workflows? 6.2. How does AI impact the application of clinical guidelines? 6.3. How does AI impact healthcare systems? 6.4. How does AI impact collaboration amongst clinicians? 6.5. How does AI impact the healthcare workforce working time? 6.6. How does AI impact the relationship between healthcare professionals and patients? 6.7. How does AI impact the standard and quality of care?
7. What are the <u>challenges and barriers in the EU and relevant third counties</u> – including technical, operational, budgetary, administrative, legal, ethical, educational, data protection, privacy, social, cultural, and other – to the effective and efficient deployment of AI in clinical practice? - How do these barriers compare in terms of significance? - Do the same or similar AI systems perform differently in diverse environments? If so, what are the factors that lead to this diverse performance beyond those attributed to the technical development of an AI system and data used for training/validating the algorithm (e.g., how is AI used in different environments (e.g., urban v rural hospitals etc.), by different clinicians (GPs, specialists etc.), within different specialties etc.)? - How could AI be deployed in healthcare settings in a way that is acceptable for and trusted by patients? What makes patients distrust or reject AI healthcare settings?	7.1. To what extent do technological and data challenges (e.g., IT infrastructure) impact the effective and efficient deployment of AI in clinical practice? 7.2. To what extent do legal and regulatory challenges (e.g., data protection, privacy) impact the effective and efficient deployment of AI in clinical practice? 7.3. To what extent do organisational and business challenges (e.g., operational, budgetary, administrative) impact the effective and efficient deployment of AI in clinical practice? List specific challenges. 7.4. To what extent do social and cultural challenges (e.g., digital health literacy, lack of trust in AI) impact the effective and efficient deployment of AI in clinical practice? List specific challenges. 7.5. To what extent and how do certain factors (e.g., the healthcare setting, the healthcare professional, the medical specialty) impact the performance of AI technologies in clinical practice? 7.6. How can the barriers described above be addressed at EU level to ensure AI is deployed in healthcare settings in a way that is acceptable for and trusted by patients?

8. What are the existing favouring conditions and practices - including technical, operational, budgetary, administrative, legal, ethical, educational, social, cultural, and other – to the effective and efficient deployment of AI in clinical practice? - Indicate best (good) AI deployment practices in the EU as well as in third countries based on the conditions and practices identified. - Why are these conditions and practices successful? To what extent can they be transferred or adapted in diverse settings (e.g., university v non-university hospital, rural v urban hospital, size of hospital and expertise of clinicians etc.)?	7.1. To what extent do good practices addressing **technological and data challenges** (e.g., ethical challenges) ensure the effective and efficient deployment of AI in clinical practice? List specific favouring conditions and good practices and describe why they are successful. 7.2. To what extent do good practices addressing **legal and regulatory challenges** (e.g., data protection, privacy) ensure the effective and efficient deployment of AI in clinical practice. List specific favouring conditions and good practices and describe why they are successful. 7.3. To what extent do good practices addressing **organisational and business challenges** (e.g., operational, budgetary, administrative) ensure the effective and efficient deployment of AI in clinical practice? List specific favouring conditions and good practices and describe why they are successful. 7.4. To what extent do good practices addressing **social and cultural challenges** (e.g., educational, social, cultural) ensure the effective and efficient deployment of AI in clinical practice? List specific favouring conditions and good practices and describe why they are successful. 7.5. Specify other favouring conditions and good practices can ensure the effective and efficient deployment of AI in clinical practice and describe to what extent. 7.6. To what extent are each of the above favouring conditions and good practices transferable across healthcare settings and regions?
9. Do the existing legal frameworks (e.g., HTA, MDR/IVDR), horizontal AI proposals (e.g., AIA, PLD, AILD) and sector specific initiatives (e.g., EHDS) address some of the barriers and accelerators in deploying AI in clinical practice? Are there gaps in these legislations/complementary needed actions related specifically to deployment of AI in clinical practice? - What is the impact of the "human oversight" provisions in the AIA on a clinical setting (Art. 14)? - Is there an impact, and if so what, of the "transparency and provision of information to users" under the AIA on clinical practice (Art 13)? - What is the impact of the "obligations of users of high-risk AI systems" under the AIA on clinicians, hospitals etc (Article 26 AIA)? - Are there implications on the development of a "risk	9.1. To what extent does the HTAR address the barriers in deploying AI in clinical practice (consider at which stage in the life cycle of a health technology would AI have the greatest potential to support joint work through evidence generation such as for horizon scanning of emerging health technologies, joint scientific consultations, joint clinical assessments, and post-marketing)? What are the gaps? 9.2. To what extent does the MDR/IVDR address the barriers in deploying AI in clinical practice (consider how the requirements under these Regulations could be applicable for AI-based solutions in terms of health, safety, and innovation in practice)? What are the gaps? 9.3. To what extent does the AIA address the barriers in deploying AI in clinical practice (consider the impact of the "human oversight" provisions in the AIA on a clinical setting (Art. 14), the impact of the "transparency and provision of information to users under the AIA on clinical practice (Art 13), the impact of the "obligations of users of high-risk AI systems" under the AIA on clinicians, hospitals (Art 29), and the implications on the development of a "risk

management system" in the AIA in clinical practice beyond the manufacturers' obligations (Article 9)? - How should "causation" in the proposed product liability directive (PLD) be better interpreted for AI in healthcare? Especially as regards generative AI systems used in clinical practice. - As regards the Health Technology Assessment Regulation (HTAR), at which stage in the life cycle of a health technology would AI have the greatest potential to support joint work through evidence generation such as for horizon scanning of emerging health technologies, joint scientific consultations, joint clinical assessments, and post-marketing? - As regards the MDR and IVDR, how the requirements under these Regulations could be applicable for AI-based solutions in terms of health, safety, and innovation in practice?	management system" in the AIA in clinical practice beyond the manufacturers' obligations (Art 9)) ? What are the gaps? 9.4. To what extent does the PLD address the barriers in deploying AI in clinical practice (consider how "causation" be better interpreted for the use of generative AI systems in clinical practice)? What are the gaps? 9.5. To what extent does the AILD address the barriers in deploying AI in clinical practice? What are the gaps? 9.6. To what extent does the EHDS address the barriers in deploying AI in clinical practice? What are the gaps? 9.7. Are additional actions needed to address the barriers for the deployment of AI in clinical practice?
10. What complementary actions (EU, national etc. as well as regulatory/non-regulatory etc.) might still be required to ensure the safe and effective deployment of AI in light of the challenges and accelerators identified? What would be their advantages and limitations? - Among others, what complementary actions could contribute to enhancing trust and acceptability of AI in clinical practice, as well as transparency and explainability? - In addition, how can equal access for patients to the use of AI in clinical practice be ensured?	10.1 What complementary actions (regulatory/non-regulatory) are still required to ensure the safe and effective deployment of AI in clinical practice? 10.2 What complementary actions are required to enhance trust, acceptability, transparency and explainability of AI in clinical practice with respect to deployment? 10.3 What complementary actions are required to ensure equal access for patients to the use of AI in clinical practice?
11. How could the recommended actions identified in this study be empirically assessed in real world scenarios (e.g., pilot projects etc.)? What indicators would allow to monitor the effectiveness and efficiency of the recommended actions?	11.1. What are real-world scenarios where the recommended actions can be assessed? 11.2. What are the existing indicators and data sources to monitor the effectiveness and efficiency of the recommended actions? 11.3. What indicators and data sources are missing to measure the effectiveness and efficiency of the recommended actions?

10.2 Annex 2 – Survey questionnaires

A mapping of the study questions addressed to each stakeholder category can be found in the table below.

10.2.1 Patient Survey

1. How would you rate your knowledge about the use of artificial intelligence in healthcare[334]? *(single answer)* • Advanced knowledge • Solid knowledge • Basic knowledge • No or limited knowledge		
	Advanced/Solid	Basic/No/ Limited
2. What factors contribute to your current level of knowledge about AI in healthcare? *(multiple answer)* • Limited exposure to information and/or educational resources • Lack of interest in technology or healthcare advancements • Lack of trust in new technologies • Complexity of AI concepts and terminology • Difficulty understanding the potential applications of AI in healthcare • Limited discussions or explanations from healthcare providers • Fear of technology or apprehension about AI replacing human healthcare providers • Other (please specify) • None of the above		X
3. What methods do you believe would be effective in improving your knowledge about artificial intelligence in healthcare? *(multiple answer)* • Clear communication and education of the benefits of using AI in healthcare • Clear communication from the healthcare professional on how AI is used in delivery of care • Clear communication from the healthcare professional on how the AI model works and comes to its decisions • Other (please specify) • I do not know	X	
4. How do you feel about the idea of the following types of AI being used in your healthcare *(Options: Very comfortable, somewhat comfortable, neutral, somewhat uncomfortable, very uncomfortable, I do not know)*		X

334 Patients were asked specific sets of questions dependent upon their level of knowledge of AI. This is indicated by "X"

• Assisting healthcare professionals with diagnosis • Assisting healthcare professionals with your treatment • Assisting healthcare professionals with remote monitoring of your health • Assisting healthcare professionals with administrative tasks • Optimisation of clinical workflows (e.g., optimize the allocation of medical staff, equipment, and rooms based on patient load and predicted demand, ensuring efficient use of resources and reducing wait times) • Conversational platforms ("chatbots") for patient assistance		
5. In your opinion, what impact will the use of artificial intelligence have on healthcare settings in the coming years? *(Options: Significantly improve, slightly improve, no impact, slightly worsen, significantly worsen, I do not know)* • Speed and accuracy of diagnosis of medical conditions • Personalised treatment plans tailored to my individual needs • Access to healthcare services, especially in rural or underserved areas • Efficiency in healthcare delivery, reducing waiting times • Management of chronic conditions through remote monitoring and proactive interventions • Cost saving on healthcare expenses • Communication and coordination among healthcare providers • Other (please specify) *If worsen or slightly worsen was selected:* Why do you feel uncomfortable with artificial intelligence tools being used in your healthcare or believe that artificial intelligence will have a negative impact on the standard and quality of care in the coming years? *(multiple answer)* • AI algorithms are not reliable or accurate enough to positively impact the standard and quality of care • Increased reliance on AI in healthcare will lead to a loss of the human touch in medical care, potentially worsening patient experiences and outcomes • The use of AI in healthcare could compromise patient privacy or result in data breaches, leading to negative consequences for patient outcomes • Increasing use of AI in healthcare could lead to job loss for healthcare professionals, potentially affecting the quality of patient care and outcomes • Negative experiences with technology in the past made me sceptical about the benefits of AI in healthcare and its potential impact on the standard and quality of care	X	

• Concerns that AI algorithms may be biased or unfair, leading to disparities in healthcare outcomes for certain patient populations • Concerns about the lack of regulation and oversight surrounding the use of AI in healthcare, as well as ethical implications related to issues such as consent and transparency • Other (please specify) • I do not have sufficient knowledge to respond		
6. What concerns, if any, do you have about the use of AI in healthcare? *(multiple answer)* • Concerns about data privacy, confidentiality, and security • Lack of trust in accuracy of decisions made by AI and technical malfunctions resulting in misdiagnosis • Lack of information on how decisions are made by AI models • Over-reliance on technology and lack of human oversight • Concerns about the lack of AI competence amongst healthcare professionals • Loss of patient-doctor relationship • Unclear liability and accountability structure in case of errors or adverse outcomes caused by AI solutions • Other (please specify) • I do not have any concerns • I do not have sufficient knowledge to respond	X	X
7. Which of the following factors, if any, would make you more comfortable with artificial intelligence being used in your healthcare? *(multiple answer)* • Clear communication and education of the benefits of using artificial intelligence in healthcare • Clear communication from the healthcare professional on how artificial intelligence is used in delivery of care • Clear communication from the healthcare professional on how the artificial intelligence model works and comes to its decisions • Informed consent on the use of artificial intelligence in delivery of care • Human oversight over artificial intelligence decisions • Clear communication of data protection measures when using artificial intelligence • Clear liability and accountability in case of errors or adverse outcomes caused by artificial intelligence solutions • Clear communication on how the artificial intelligence model is regulated • Other (please specify) • None of the above	X	X

• I do not have sufficient knowledge to respond		
8. In your opinion, does the use of artificial intelligence-based tools in the delivery of healthcare to vulnerable groups require additional measures beyond those you described above? • Yes (please specify) • No • I do not know	X	

10.2.2 Healthcare Professional Survey

1. Please indicate your medical speciality or the medical speciality your association represents *(single answer)*: • Radiology • Pathology • Oncology • Cardiology • Neurology • Orthopaedics • Psychiatry • Ophthalmology • Pulmonology • Endocrinology • Nephrology • Rheumatology • Other (please specify)		
2. How would you rate your knowledge about the use of artificial intelligence in healthcare? *(single answer)*[335] • Advanced knowledge • Solid knowledge • Basic knowledge • No or limited knowledge		
	Advanced/Solid	Basic/Limited
3. What is the reason for your lack of knowledge of artificial intelligence tools and their use in healthcare? *(multiple answer)* • Limited exposure to information and/or educational resources • Lack of interest in technology or healthcare advancements		X

335 Healthcare Professionals were asked specific sets of questions dependent upon their level of knowledge of AI. This is indicated by "X"

• Lack of trust in new technologies • Lack of interpretability and transparency of AI tools in giving a case-specific decision • Concerns about the quality and robustness of AI tools • Lack of empirical evidence demonstrating the potential transformative effect of applications of AI in healthcare • Lack of education and training on this topic at the healthcare facility, and unsure where to seek relevant training • Fear of technology or apprehension about AI replacing human healthcare providers • Other (please specify) • None of the above (please specify		
4. What methods do you believe would be effective in improving your knowledge about artificial intelligence in healthcare? *(multiple answer)* • Clear communication and education of the benefits of using AI in healthcare • Clear communication from the healthcare facility/AI developer on how AI is used in delivery of care • Clear communication from the healthcare facility/AI developer on how the AI model works and comes to its decisions • Other (please specify)		X
5. In your opinion, what impact will the use of artificial intelligence have on healthcare settings in the coming years? *(Options: Significantly Improve, Slightly Improve, No Impact, Slightly Worsen, Significantly Worsen, I do not know)* • Speed and accuracy of diagnosis of medical conditions • Personalised treatment plans tailored to my individual needs • Access to healthcare services, especially in rural or underserved areas • Efficiency in healthcare delivery, reducing waiting times • Management of chronic conditions through remote monitoring and proactive interventions • Cost saving on healthcare expenses • Communication and coordination among healthcare providers • Other (please specify)		X
6. In your medical specialty, what are the current healthcare needs that existing artificial intelligence technologies have the potential to already address now? *(multiple answer)* • Optimizing resource allocation and workflow efficiency • Streamlining administrative tasks Improving diagnostic accuracy • Creating personalized treatment plans	X	

• Predictive analytics for patient outcomes • Improving patient engagement and adherence to treatment plans • Addressing skill gaps among the healthcare workforce • Ensuring equitable access to healthcare • Other (Please specify) • I do not know		
7. If applicable, what percentage of time do you or healthcare professionals in general spend in carrying out administrative tasks related to the provision of healthcare but that are not strictly medical tasks? *(Sliding scale)*	X	X
8. In your opinion, what are the needs in healthcare that artificial intelligence advances could address in the next 5 years (needs that cannot be addressed by existing AI technologies)? *(Free text)*	X	
9. In your opinion, to what extent do the following applications have the potential to provide concrete added value to the existing delivery of healthcare in your medical specialty? *(Options: Large Extent, Moderate Extent, Small Extent, I do not know, Not applicable)* • AI-assisted diagnostics • AI-assisted surgery/medical robotics to optimize surgical skills • AI-assisted remote patient monitoring • AI-assisted symptom checkers and support in treatment decisions (e.g. surgical indications, use and dosage of medications, and complication management) • Administrative support tool (e.g., EHR management, for clinical documentation) • Clinical workflow optimisation (e.g., predicting patient admissions, bed occupancy) • Conversational platforms for patient assistance (e.g., chatbots, virtual assistants) • AI-assisted prognosis prediction (risk stratification) • Other (please specify)	X	
10. Have you used or are you currently using artificial intelligence technologies in your clinical practice? *(Single answer)* • Yes (Please specify tools and state of deployment) • No • I don't know	X	
11. Have you used or are you aware of any generative AI tools used in the healthcare facility within which you work? *(Single answer)* • Yes (Please specify tools and state of deployment) • No	X	

12. Based on your knowledge, to what extent do the following **technological and data challenges** impact the effective and efficient deployment of artificial intelligence tools in the healthcare facility within which you work? *(For each option, impact was rated significant, moderate, no or I do not know. The responders were also asked for the relevance of the challenge for in house developed tools, commercially available tools or both)* • Outdated IT infrastructure • Lack of interoperability of AI solutions with existing IT solutions • Lack of standardised data structures • Variations in performance across healthcare settings and populations • Quality concerns amongst end-users • Lack of transparency and explainability of AI tools • Lack of validation protocols for existing AI solutions • Other (Please specify)	X	
13. Based on your knowledge, to what extent did the following **legal and regulatory challenges and barriers** impact the effective and efficient deployment of artificial intelligence tools in the healthcare facility within which you work? *(For each option, impact was rated significant, moderate, no or I do not know. The responders were also asked for the relevance of the challenge for in house developed tools, commercially available tools or both)* • Lack of accountability and liability structure for errors by AI • Cybersecurity issues and vulnerability of data-to-data breaches • Complexity of regulatory approval process for AI product commercialisation • Lack of guidance on compliance of AI tools with current legislation • Concerns surrounding data privacy and data protection • Other (Please specify)	X	
14. Based on your knowledge, to what extent did the following organizational and business challenges and barriers impact the effective and efficient deployment of artificial intelligence tools in the healthcare facility within which you work? *(For each option, impact was rated significant, moderate, no or I do not know. The responders were also asked for the relevance of the challenge for in house developed tools, commercially available tools or both)* • Lack of strategic direction to promote AI in healthcare • Lack of technological skills and knowledge amongst healthcare professionals to use AI tools effectively	X	

• Lack of involvement of end-users in the development, validation and deployment of AI tools • Lack of cost-benefit analysis of AI tools versus existing clinical solutions • Lack of funding, investment and financial incentives to deploy AI in clinical practice • Other (please specify)		
15. Based on your knowledge, to what extent do the following social and cultural challenges and barriers impact the effective and efficient deployment of artificial intelligence tools in the healthcare facility within which you work? *(For each option, impact was rated significant, moderate, no or I do not know. The responders were also asked for the relevance of the challenge for in house developed tools, commercially available tools or both)* • Concerns among healthcare professionals on job security • Low level of digital health literacy among healthcare providers and the general public • Concerns about AI's impact on the personal relationship between doctor and patient • Concerns about patient autonomy and consent in the use of AI tools for their care • Lack of trust in AI tools • Concerns about skill shift to remain competitive in the job market • Concerns about overreliance on AI • Other (please specify)	X	
16. Are there any other challenge and barriers not described above affecting the effective and efficient deployment of artificial intelligence in healthcare? *(Single answer)* • Yes (Please specify) • No	X	
17. Are you aware of specific challenges affecting the deployment of generative AI models in clinical practice? *(Single answer)* • Yes (Please specify) • No	X	
18. Which of the following practices could address technological and data challenges in the healthcare facility within which you work and improve the uptake of artificial intelligence tools? *(Multiple answer)* • Early engagement of end users, such as yourself, to ensure relevance and usability • Short and concise guidelines on how the AI model works to ensure transparency, interpretability and explainability • Definition of minimum IT standards to facilitate widespread deployment and promotion of interoperability	X	

• Testing and pilot studies to ensure safety, efficacy and interoperability • Training and validation on diverse datasets to account for performance variation • Post-deployment monitoring mechanism to assess the performance of AI systems in real and diverse clinical settings • Human oversight over AI model decisions • Other (Please Specify) • Not applicable • I do not know		
19. Which of the following practices could be implemented within the healthcare facility within which you work to address legal and regulatory challenges and improve the uptake of artificial intelligence tools? *(Multiple answer)* • Legal guidance and clarification of roles • Policies and guidance on information access and sharing within your healthcare facility • Regulatory guidance to define user responsibilities and liabilities concerning AI models • Informed consent protocols to maintain patient autonomy and data privacy • Other (Please Specify) • Not applicable • I do not know	X	
20. Which of the following practices could address organizational and business challenges in the healthcare facility within which you work and improve uptake of artificial intelligence tools? *(Multiple answer)* • Tools to assess and evaluate the added value of deploying an AI solution in clinical practice compared to existing solutions • Multidisciplinary collaboration to ensure integration into clinical workflow • Renewing reimbursement models to align with value-based care • Involvement of all stakeholders in decision-making processes • Validation of the system by healthcare professionals before deployment • New talent acquisition to ensure workflow readiness and expertise • Clearly defined strategy for AI deployment in clinical practice • Improving affordability through funding, capital investment and financial incentives • Other (Please Specify) • Not applicable • I do not know		

21. Which of the following practices could address social and cultural challenges in the healthcare facility within which you work and improve uptake of artificial intelligence tools? *(Multiple answer)* • Integration of technology into medical curricula • Promoting continuous learning to keep up with the advancements • Targeted training programs to upskill workforce • Development of a consistent narrative of the benefits of AI for patients, practitioners, and organizations to improve trust • Other (Please Specify) • Not applicable • I do not know	X	
22. Are you aware of specific good practices for the deployment of generative AI models in clinical practice? *(Single answer)* • Yes (Please specify) • No	X	
23. Are you aware of the EU AI Act? *(Single answer)* • Yes • No	X	
24. Does the AI Act address any of the challenges you highlighted above affecting the effective and efficient deployment of AI in healthcare? *(Single answer)* • Yes (Please specify) • No • I do not know	X	
25. Do any of the deployer (user) obligations under the AI Act described above introduce new or additional challenges to healthcare professionals such as yourself? • Yes (Please specify) • No • I do not know	X	
26. What additional support could be provided to healthcare professionals such as yourself to address the challenges introduced by the AI Act?	X	
27. In your opinion, what action could support healthcare institutions to efficiently and effectively deploy artificial intelligence tools in clinical practice? • Consolidated funding to support specific strategic priorities	X	

• Establishment of common standards on data governance, privacy, and interoperability • Ensure consistent access to public data and promoting open-data initiatives • Organisation and centralised collection of post-deployment data to monitor on the ongoing effectiveness of AI tools • Provide clarity on regulatory processes for product approval, accountability, and liability • Encourage the establishment of centres of excellence for AI in healthcare to concentrate talent and resources • Establish an EU AI in healthcare centre to coordinate and facilitate AI deployment • Redesigning workforce planning and clinical education to address future healthcare and AI professional needs, investing in upskilling frontline staff. • Development of platforms to facilitate dialogues and exchange of good practices to facilitate deployment of AI tools • Other (please specify) • I do not know • None of the above		

10.2.3 Hospital Representative Survey

2. What of the following best represents the location of the healthcare facility you represent? *(single answer)*: • Small town (less than 50,000 inhabitants) • Medium-sized city (50,000-250,000 inhabitants) • Large city (250,000-1,000,000 inhabitants) • Metropolitan area (over 1,000,000 inhabitants) • Other (please specify)
3. The healthcare facility I represent is a *(single answer)*: • Public healthcare facility • Private healthcare facility • I work at both a private and public healthcare facility • Other (please specify)
4. What are the top 3 challenges in your healthcare facility that hinder productivity, efficiency, and effectiveness in diagnosing, treating, and managing patients? *(Free text)*
5. What are the current needs in your healthcare facility that existing artificial intelligence technologies have the potential to already address now? *(multiple answer)*

- Optimizing resource allocation and workflow efficiency
- Streamlining administrative tasks Improving diagnostic accuracy
- Creating personalized treatment plans
- Predictive analytics for patient outcomes
- Improving patient engagement and adherence to treatment plans
- Addressing skill gaps among the healthcare workforce
- Ensuring equitable access to healthcare
- Other (Please specify)
- I do not know

6. If applicable, what percentage of time do you or healthcare professionals in general spend in carrying out administrative tasks related to the provision of healthcare but that are not strictly medical tasks? *(sliding scale)*

7. In your opinion, what are the needs in healthcare that artificial intelligence advances could address in the next 5 years (needs that cannot be addressed by existing AI technologies)? *(Free text)*

8. In your opinion, to what extent do the following applications have the potential to provide concrete added value to the existing delivery of healthcare in your medical specialty?
   (Options: Large Extent, Moderate Extent, Small Extent, I do not know, Not applicable)
   - AI-assisted diagnostics
   - AI-assisted surgery/medical robotics to optimize surgical skills
   - AI-assisted remote patient monitoring
   - AI-assisted symptom checkers and support in treatment decisions (e.g. surgical indications, use and dosage of medications, and complication management)
   - Administrative support tool (e.g., EHR management, for clinical documentation)
   - Clinical workflow optimisation (e.g., predicting patient admissions, bed occupancy)
   - Conversational platforms for patient assistance (e.g., chatbots, virtual assistants)
   - AI-assisted prognosis prediction (risk stratification)
   - Other (please specify)

9. In your opinion, in which medical specialties does the use of artificial intelligence have the biggest transformative potential? *(single answer)*
   - Radiology
   - Pathology
   - Oncology
   - Neurology
   - Cardiology
   - Primary care
   - Psychiatry

- Triage
- General hospital administration
- Other (please specify)
- I do not know

10. Which of the following best describes your experience with development and/or deployment of artificial intelligence tools in healthcare? *(Multiple answer)*
    - Developed (in house) an AI solution and deployed it
    - Purchased a commercially available AI solution and deployed it
    - Developed (in house) an AI solution but not deployed it
    - Purchase a commercially available AI solution but has not deployed it yet
    - Piloting an AI solution
    - In the process of purchasing/developing an AI solution that we intent to deploy
    - Is not developing and has not purchased any AI solutions, and has not deployed any AI solutions (please elaborate)
    - None of the above
11. Please list the names of the artificial intelligence tools you use or intend to use in clinical practice in your healthcare facility *(Specify tool and current state of deployment. Options: early deployment in the absence of formal processes and policies; pilot phase; advanced deployment including widespread and ongoing use)*
12. Do you use specific indicators to monitor the effectiveness of artificial intelligence tools in clinical practice?
    - Yes
    - No
13. Do you use specific indicators to monitor the efficiency of artificial intelligence tools in clinical practice?
    - Yes
    - No
14. If applicable, what are the reasons why some of the artificial intelligence tools you developed and/or purchased have not yet been deployed in clinical practice? *(Multiple answer)*
    - The AI tool is undergoing regulatory approval processes
    - The AI tool is undergoing testing and validation to ensure its accuracy, reliability, and safety before deployment in real-world healthcare settings
    - Limited access to high-quality healthcare data for training and testing the AI tool
    - Lack of interoperability and compatibility with electronic health records (EHRs), medical devices, and other existing IT infrastructure
    - Lack of funding or resources to support deployment
    - Unfavourable market conditions for effective deployment
    - Concerns about usability, workflow integration, and training
    - Concerns surrounding data privacy, liability, and patient consent
    - Technical limitations related to scalability and computational resources required for effective deployment

- Considerations regarding the competitive market landscape
- Other (please specify)
- None of the above
- Not applicable

15. Have you deployed any generative AI solutions in your healthcare facility?
    - Yes *(Specify tool and transformative potential of tool. Options: high, moderate, low, I do not know)*
    - No

16. Based on your knowledge, to what extent do the following **technological and data challenges** impact the effective and efficient deployment of artificial intelligence tools in the healthcare facility within which you work?
    (For each option, impact was rated significant, moderate, no or I do not know. The responders were also asked for the relevance of the challenge for in house developed tools, commercially available tools or both)
    - Outdated IT infrastructure
    - Lack of interoperability of AI solutions with existing IT solutions
    - Lack of standardised data structures
    - Variations in performance across healthcare settings and populations
    - Quality concerns amongst end-users
    - Lack of transparency and explainability of AI tools
    - Lack of validation protocols for existing AI solutions
    - Other (Please specify)

17. Based on your knowledge, to what extent did the following **legal and regulatory challenges and barriers** impact the effective and efficient deployment of artificial intelligence tools in the healthcare facility within which you work?
    (For each option, impact was rated significant, moderate, no or I do not know. The responders were also asked for the relevance of the challenge for in house developed tools, commercially available tools or both)
    - Lack of accountability and liability structure for errors by AI
    - Cybersecurity issues and vulnerability of data-to-data breaches
    - Complexity of regulatory approval process for AI product commercialisation
    - Lack of guidance on compliance of AI tools with current legislation
    - Concerns surrounding data privacy and data protection
    - Other (Please specify)

18. Based on your knowledge, to what extent did the following organizational and business challenges and barriers impact the effective and efficient deployment of artificial intelligence tools in the healthcare facility within which you work?
    (For each option, impact was rated significant, moderate, no or I do not know. The responders were also asked for the relevance of the challenge for in house developed tools, commercially available tools or both)
    - Lack of strategic direction to promote AI in healthcare
    - Lack of technological skills and knowledge amongst healthcare professionals to use AI tools effectively
    - Lack of involvement of end-users in the development, validation and deployment of AI tools

- Lack of cost-benefit analysis of AI tools versus existing clinical solutions
- Lack of funding, investment and financial incentives to deploy AI in clinical practice
- Other (please specify)

19. Based on your knowledge, to what extent do the following social and cultural challenges and barriers impact the effective and efficient deployment of artificial intelligence tools in the healthcare facility within which you work?
(For each option, impact was rated significant, moderate, no or I do not know. The responders were also asked for the relevance of the challenge for in house developed tools, commercially available tools or both)
    - Concerns among healthcare professionals on job security
    - Low level of digital health literacy among healthcare providers and the general public
    - Concerns about AI's impact on the personal relationship between doctor and patient
    - Concerns about patient autonomy and consent in the use of AI tools for their care
    - Lack of trust in AI tools
    - Concerns about skill shift to remain competitive in the job market
    - Concerns about overreliance on AI
    - Other (please specify)
20. Are there any other challenge and barriers not described above affecting the effective and efficient deployment of artificial intelligence in healthcare? *(Single answer)*
    - Yes (Please specify)
    - No
2. Are you aware of specific challenges affecting the deployment of generative AI models in clinical practice? *(Single answer)*
    - Yes (Please specify)
    - No
21. Which approach do you believe facilitated a more seamless deployment of artificial intelligence tools into the clinical workflow at your healthcare facility?
    - Purchasing a commercially available AI tool
    - Developing an AI tool in-house
    - No difference
    - I do not know, we only deployed commercially available AI tools
    - I do not know, we only deployed in-house developed AI tools
    - I do not know; we have not deployed any AI tools
22. What good practices did your healthcare facility implement to address technological and data challenges affecting the deployment of artificial intelligence in healthcare? *(Multiple answer)*
    - Invested in upgrading and modernizing our IT infrastructure prior to the deployment to support the AI implementation
    - Conducted validation tests of the AI algorithms and models
    - Implemented data governance frameworks to ensure the quality and integrity of the AI data
    - Explored partnerships with the AI vendors to access different AI solutions

- Guidance on transparency, interpretability and explainability of AI solutions to ensure trust in outcomes
- Post-deployment monitoring mechanism to assess the performance of AI systems
- Collection of post-deployment data to evaluate impact and ongoing effectiveness of AI tools
- Other (please specify)

23. What good practices did your healthcare facility implement to address legal and regulatory challenges affecting the deployment of artificial intelligence in healthcare? *(Multiple answer)*
    - Clarification on how privacy and data protection rules apply to AI
    - Regulatory clarification and guidance on secondary use of health data
    - Policies and guidance around the ethical use of AI in healthcare
    - Accountability and liability rules for manufacturers, deployers and users applicable to AI systems in health care
    - A dedicated compliance team to oversee the process of AI deployment
    - Regular reviewing of AI usage policies to remain up to date with any changes
    - Regular audits to monitor compliance
    - Collaboration with regulatory bodies to share best practices
    - Other (please specify)
24. What good practices did your healthcare facility implement to address organisational and business challenges affecting the deployment of artificial intelligence in healthcare? *(Multiple answer)*
    - Tools to assess and evaluate the added value of deploying an AI solution in clinical practice compared to existing solutions
    - Developed a strategy or action plan for the efficient and effective deployment of AI in healthcare
    - A comprehensive implementation plan was developed with defined roles and responsibilities for all the staff
    - Sufficient resources and budget were planned and allocated for the deployment
    - Training programs were conducted for the staff and management programs were tailored accordingly
    - Clear metrics and benchmarks were established to measure the impact of AI deployment and look for areas for improvement
    - Other (please specify)
25. What good practices did your healthcare facility implement to address social and cultural challenges affecting the deployment of artificial intelligence in healthcare? *(Multiple answer)*
    - Communicated openly with stakeholders to address any concerns and gather regular feedback
    - Promoted open and transparent communication about the utilization of the AI tool and the risks and benefits associated with it
    - Conducted community outreach and education campaigns
    - Gradually introduced the AI tool encouraging experimentation and learning, and rewarded creative initiatives that drove positive change
    - Other (please specify)
26. What steps did your healthcare facility take to prepare the workforce for artificial intelligence tool deployment?

For each option specify implemented (yes/no) and transferability of practice (highly transferable, moderately transferable, limited transferability, I do not know or not applicable) • Provided comprehensive training on AI tool usage and best practices. • Fostered a culture of lifelong learning and skill development • Created opportunities for staff involvement in AI implementation projects • Offered support services and resources to address staff concerns and challenges • Other (please specify)
27. Are you aware of specific good practices for the deployment of generative AI models in clinical practice? • Yes (please specify) • No
28. Are you aware of the EU AI Act? *(Single answer)* • Yes • No
29. Are you prepared for the implementation of the AI Act and the associated obligations within it on deployers of high-risk AI systems? *(Single answer)* • Yes (if yes, please elaborate on the steps taken to comply with deployer obligations) • No (if no, please explain) • I do not know
30. Does the AI Act address any of the challenges you highlighted above affecting the effective and efficient deployment of AI in healthcare? *(Single answer)* • Yes (Please specify) • No • I do not know
31. Do any of the deployer (user) obligations under the AI Act described above introduce new or additional challenges to hospitals? • Yes (Please specify) • No • I do not know
32. What additional support could be provided to hospitals to address the challenges introduced by the AI Act? *(Free text)*
33. Are you aware of the European Health Data Space? *(Single answer)* • Yes • No
34. Does the EHDS address any of the challenges you highlighted above affecting the effective and efficient deployment of artificial intelligence in healthcare? *(Single answer)* • Yes (Please specify) • No • I do not know

35. In your opinion, what action could support healthcare institutions to efficiently and effectively deploy artificial intelligence tools in clinical practice?
    - Consolidated funding to support specific strategic priorities
    - Establishment of common standards on data governance, privacy, and interoperability
    - Ensure consistent access to public data and promoting open-data initiatives
    - Organisation and centralised collection of post-deployment data to monitor on the ongoing effectiveness of AI tools
    - Provide clarity on regulatory processes for product approval, accountability, and liability
    - Encourage the establishment of centres of excellence for AI in healthcare to concentrate talent and resources
    - Establish an EU AI in healthcare centre to coordinate and facilitate AI deployment
    - Redesigning workforce planning and clinical education to address future healthcare and AI professional needs, investing in upskilling frontline staff.
    - Development of platforms to facilitate dialogues and exchange of good practices to facilitate deployment of AI tools
    - Other (please specify)
    - I do not know
    - None of the above

10.2.4 AI Developer Survey

1. Please indicate the number of employees in the organisation you work for. *(Single answer)*
    - Less than 250 employees
    - More than 250 employees
    - I do not know
    - Not applicable

2. What are the top 3 challenges that hinder productivity, efficiency, and effectiveness in diagnosing, treating, and managing patients? *(Free text)*

36. What are the current needs in your healthcare facility that existing artificial intelligence technologies have the potential to already address now? *(multiple answer)*
    - Optimizing resource allocation and workflow efficiency
    - Streamlining administrative tasks Improving diagnostic accuracy
    - Creating personalized treatment plans
    - Predictive analytics for patient outcomes
    - Improving patient engagement and adherence to treatment plans
    - Addressing skill gaps among the healthcare workforce

3. In your opinion, what are the needs in healthcare that artificial intelligence advances could address in the next 5 years (needs that cannot be addressed by existing artificial intelligence technologies)? *(Free text)*

28. In your opinion, to what extent do the following applications have the potential to provide concrete added value to the existing delivery of healthcare in your medical specialty?
(Options: Large Extent, Moderate Extent, Small Extent, I do not know, Not applicable)
    - AI-assisted diagnostics
    - AI-assisted surgery/medical robotics to optimize surgical skills
    - AI-assisted remote patient monitoring
    - AI-assisted symptom checkers and support in treatment decisions (e.g. surgical indications, use and dosage of medications, and complication management)
    - Administrative support tool (e.g., EHR management, for clinical documentation)
    - Clinical workflow optimisation (e.g., predicting patient admissions, bed occupancy)
    - Conversational platforms for patient assistance (e.g., chatbots, virtual assistants)
    - AI-assisted prognosis prediction (risk stratification)
    - Other (please specify)

4. Have you developed or are you developing an artificial intelligence tool to be used in healthcare? *(Single answer)*
    - Yes (If yes, specify name, current state of deployment and countries deployed in)
    - No
    - Not applicable

5. For the tools you have developed and have already been deployed, do you offer any post-deployment assistance? *(Single answer)*
    - Yes (Please specify)
    - No
    - Not applicable

6. If applicable, what are the reasons why some of the artificial intelligence tools you developed have not yet been deployed in clinical practice? *(multiple answer)*
    - The AI tool is undergoing testing and validation to ensure its accuracy, reliability, and safety before deployment in real-world healthcare settings
    - The AI tool is undergoing regulatory approval processes
    - Limited access to high-quality healthcare data for training and testing the AI tool
    - Lack of interoperability and compatibility with electronic health records (EHRs), medical devices, and other existing IT infrastructure
    - Lack of funding or resources to support deployment
    - Unfavourable market conditions for effective deployment (e.g., waiting to identify suitable pilot sites or establishing partnerships with healthcare organisations before deploying the AI tool)
    - User concerns about usability, workflow integration, and training

- User concerns surrounding data privacy, liability, and patient consent
- Technical limitations related to scalability and computational resources required for effective deployment
- Considerations regarding the competitive market landscape (this includes evaluating the presence and performance of competing AI solutions, market demand, and strategic business decisions)
- Other (please specify)
- None of the above
- Not applicable

7. Have you developed or are you developing generative AI tools to be used in healthcare? *(Single answer)*
   - Yes (Please specify)
   - No
   - Not applicable

8. Have you deployed a generative AI tool that you have developed in healthcare? *(Single answer)*
   - Yes
   - No

9. Based on your knowledge, to what extent do the following **technological and data challenges** impact the effective and efficient deployment of artificial intelligence tools in the healthcare facility within which you work?
   (For each option, impact was rated significant, moderate, no or I do not know. The responders were also asked for the relevance of the challenge for in house developed tools, commercially available tools or both)
   - Outdated IT infrastructure
   - Lack of interoperability of AI solutions with existing IT solutions
   - Lack of standardised data structures
   - Variations in performance across healthcare settings and populations
   - Quality concerns amongst end-users
   - Lack of transparency and explainability of AI tools
   - Lack of validation protocols for existing AI solutions
   - Other (Please specify)

10. Do these technological and data challenges differ between regions (e.g., between EU Member States, between EU countries and non-EU countries)? *(Single answer)*
    - Yes (please specify)
    - No
    - I don’t know

11. Based on your knowledge, to what extent did the following **legal and regulatory challenges and barriers** impact the effective and efficient deployment of artificial intelligence tools in the healthcare facility within which you work?
    (For each option, impact was rated significant, moderate, no or I do not know. The responders were also asked for the relevance of the challenge for in house developed tools, commercially available tools or both)
    - Lack of accountability and liability structure for errors by AI

- Cybersecurity issues and vulnerability of data-to-data breaches
- Complexity of regulatory approval process for AI product commercialisation
- Lack of guidance on compliance of AI tools with current legislation
- Concerns surrounding data privacy and data protection
- Other (Please specify)

12. Based on your knowledge, to what extent did the following organizational and business challenges and barriers impact the effective and efficient deployment of artificial intelligence tools in the healthcare facility within which you work?
(For each option, impact was rated significant, moderate, no or I do not know. The responders were also asked for the relevance of the challenge for in house developed tools, commercially available tools or both)
    - Lack of strategic direction to promote AI in healthcare
    - Lack of technological skills and knowledge amongst healthcare professionals to use AI tools effectively
    - Lack of involvement of end-users in the development, validation and deployment of AI tools
    - Lack of cost-benefit analysis of AI tools versus existing clinical solutions
    - Lack of funding, investment and financial incentives to deploy AI in clinical practice
    - Other (please specify)
13. Do these organisational and business challenges differ between regions (e.g., between EU Member States, between EU countries and non-EU countries)? *(Single answer)*
    - Yes (please specify)
    - No
    - I don't know
14. Based on your knowledge, to what extent do the following social and cultural challenges and barriers impact the effective and efficient deployment of artificial intelligence tools in the healthcare facility within which you work?
(For each option, impact was rated significant, moderate, no or I do not know. The responders were also asked for the relevance of the challenge for in house developed tools, commercially available tools or both)
    - Concerns among healthcare professionals on job security
    - Low level of digital health literacy among healthcare providers and the general public
    - Concerns about AI's impact on the personal relationship between doctor and patient
    - Concerns about patient autonomy and consent in the use of AI tools for their care
    - Lack of trust in AI tools
    - Concerns about skill shift to remain competitive in the job market
    - Concerns about overreliance on AI
    - Other (please specify)
15. Do these social and cultural challenges differ between regions (e.g., between EU Member States, between EU countries and non-EU countries)? *(Single answer)*
    - Yes (please specify)
    - No

- I don’t know

16. Are there any other challenge and barriers not described above affecting the effective and efficient deployment of artificial intelligence in healthcare? *(Single answer)*
    - Yes (Please specify)
    - No

17. Do the challenges associated with deploying a generative artificial intelligence tool in healthcare differ from those of traditional AI tools?
    - Yes (Please specify)
    - No
    - I don’t know

18. To what extent do the following good practices addressing technological and data challenges contribute to the effective and efficient deployment of artificial intelligence in healthcare and clinical practice?
    For each option specify impact (significant, moderate, no, not applicable) and transferability of practice (highly transferable, moderately transferable, limited transferability, I do not know or not applicable)
    - Ensure that the training data used to develop the AI algorithms are diverse and representative of the population the model will serve
    - Generate explanations for AI model predictions
    - Develop AI tools with visualization tools for model inputs and outputs as well as case specific decisions
    - Develop and deploy low complexity models with sufficient performance
    - Train healthcare professionals to recognize model limitations, interpret confidence scores, visualize hidden layers as well as conduct sensitivity analyses to ensure they know how to interpret model decisions

19. To what extent do the following good practices addressing legal and regulatory challenges contribute to the effective and efficient deployment of artificial intelligence in healthcare and clinical practice?
    For each option specify impact (significant, moderate, no, not applicable) and transferability of practice (highly transferable, moderately transferable, limited transferability, I do not know or not applicable)
    - Conduct routine compliance audits to ensure adherence to regulatory requirements (e.g., HIPAA, GDPR)
    - Adopt a secure storage system to safeguard patient data and anonymization /encryption/de-identification techniques to block any unauthorized access and traceability.
    - Ensure secure data transfer protocols upon sharing data between systems to prevent interception, unauthorized access
    - Restrict access to authorized users
    - Utilize bias detection algorithms as well as bias mitigation techniques
    - Other (please specify)

20. To what extent do the following good practices addressing organisational and business challenges contribute to the effective and efficient deployment of artificial intelligence in healthcare and clinical practice?
    For each option specify impact (significant, moderate, no, not applicable) and transferability of practice (highly transferable, moderately transferable, limited transferability, I do not know or not applicable)

- Regular multidisciplinary clinician advisory boards to obtain user feedback, ensure the usability of the AI tools and their efficient integration into clinical practice, and look into areas for improvement
- Involvement of end-users in the development and deployment of the AI tool
- Conduct training programs for the healthcare professionals on the AI tools to be deployed.
- Conduct analyses on the healthcare facility's existing workflow to understand their process and accordingly redesign our AI tool to integrate seamlessly.
- Ensure stakeholder engagement including healthcare professionals, administrators, and support staff.
- Other (please specify)

21. Are you aware of the EU AI Act? *(Single answer)*
    - Yes
    - No

22. Are you prepared for the implementation of the AI Act and the associated obligations within it on developers of high-risk AI systems? *(Single answer)*
    - Yes (please specify
    - No (please specify)
    - Not applicable
    - I don't know

10.2.5 Regulatory Expert Survey

1. How familiar are you with the EU Regulatory landscape governing the use of AI? *(Single answer)*
    - Very familiar
    - Familiar
    - Not at all familiar
2. Are you aware of the EU AI Act? *(Single answer)*
    - Yes
    - No
3. To what extent do you believe the following challenges affecting the deployment of AI in healthcare addressed by the provisions of the AI Act? *(Options: High extent, moderate extent, small extent, I do not know, not applicable)*
    - Variations in performance across healthcare settings and populations
    - Quality concerns amongst end-users
    - Lack of transparency and explainability of AI tools
    - Lack of validation protocols for existing AI solutions
    - Lack of accountability and liability structure for errors by AI
    - Cybersecurity issues and vulnerability of data-to-data breaches
    - Complexity of regulatory approval process for AI product commercialisation

- Lack of technological skills and knowledge amongst healthcare professionals to use AI tools effectively
- Lack of human oversight over decisions made by AI-based tools.
- Low level of digital health literacy among healthcare providers and the general public
- Concerns about AI's impact on the personal relationship between doctor and patient
- Concerns about patient autonomy and consent in the use of AI tools for their care
- Lack of trust in AI tools
- Concern about skills required of notified bodies to apply the AI Act.

4. Are there any other challenges affecting the deployment of AI in clinical practice, beyond the ones listed above? *(Single answer)*
   - Yes (Please specify)
   - No
   - I do not know

5. To what extent are these other challenges addressed by the provisions of the AI Act? *(Single answer)*
   - High extent
   - Moderate extent
   - Small extent
   - I do not know
   - Not applicable

6. Do you believe the current provisions of the EU AI Act adequately cover generative AI models used in healthcare? *(Single answer)*
   - Yes
   - No
   - I do not know

7. Are you aware of the Product Liability Directive (September 2022) *(Single answer)*
   - Yes
   - No

8. Considering that AI in healthcare might be used as stand-alone software that would be essentially providing information to the healthcare professional, how should the requirement of "causation" in a liability action under the proposed product liability directive (PLD) be interpreted in such cases? *(Free text)*

9. Are you aware of the Health Technology Assessment Regulation? *(Single answer)*
   - Yes
   - No

10. At which stage in the life cycle of a health technology would AI have the greatest potential to support joint work through evidence generation such as for horizon scanning of emerging health technologies, joint scientific consultations, joint clinical assessments, and post-marketing? *(Free text)*

11. Are you aware of the General Data Protection Regulation that came into force in the EU in 2018?

12. To what extent are concerns surrounding data privacy and data protection (e.g., Growing concerns about the privacy and security of healthcare data collected, processed, and shared by AI systems) addressed by the provisions of the GDPR?
    - High extent
    - Moderate extent
    - Small extent
    - I do not know
    - Not applicable
13. To what extent are concerns about patient autonomy and consent in the use of AI tools for their care (e. g., concerns arise regarding patients' ability to understand, control, and consent to the use of AI-driven technologies in their diagnosis, treatment, and decision-making processes) addressed by the provisions of the GDPR? *(Single answer)*
    - High extent
    - Moderate extent
    - Small extent
    - I do not know
    - Not applicable
14. To what extent do concerns about patients' rights (in terms of GDPR) in the use of AI tools for their care align with the provisions of the AI Act (for example, in terms of impact assessment, right to an explanation of individual decisions, exceptional authorization for processing sensitive data for detecting and correcting negative biases with specific conditions)? *(Single answer)*
    - High extent
    - Moderate extent
    - Small extent
    - I do not know
    - Not applicable
15. Are you aware of the MDR/IVDR? *(Single answer)*
    - Yes
    - No
16. To what extent does the MDR/IVDR address the barriers in deploying AI in clinical practice (consider how the requirements under these Regulations could be applicable for AI-based solutions in terms of health, safety, and innovation in practice)? *(Single answer)*
    - High extent
    - Moderate extent
    - Small extent
    - I do not know
    - Not applicable
17. Are there any gaps in the MDR/IVDR when it comes to AI-based tools used in clinical settings? *(Single answer)*

- Yes (Please specify)
- No

18. Are there any additional complementary actions (regulatory or non-regulatory) needed to ensure the safe and effective deployment of AI in clinical practice? *(Free text)*

19. Are there any additional complementary actions (regulatory or non-regulatory) needed to enhance trust, acceptability, transparency and explainability of AI in clinical practice with respect to deployment? *(Free text)*

20. Are there any additional complementary actions (regulatory or non-regulatory) needed to ensure equal access for patients to the use of AI in clinical practice? *(Free text)*

21. Are you aware of any actions (regulatory/non-regulatory) implemented at national level within the EU that could be considered as best practices for the effective deployment of AI in clinical practice? *(Single answer)*
    - Yes (Please specify)
    - No

22. Are you aware of any actions (regulatory/non-regulatory) implemented outside the EU that could be considered as best practices for the effective deployment of AI in clinical practice? *(Single answer)*
    - Yes (Please specify)
    - No

10.3 Annex 3 – Interview guides

10.3.1 Targeted interview questions for AI developers

1. What are the current needs in clinical practice that AI can address? Consider:
    a. Healthcare workforce shortage
    b. Ageing population and rise in chronic and complex conditions
    c. Increased demand on healthcare services
    d. Rising costs of healthcare
    e. Inefficiencies within healthcare systems
    f. Increase in administrative burden faced by healthcare professionals
2. How can AI tools you have developed or are developing help in addressing some of the needs described previously? Consider:
    a. How do you decide what AI tools you will develop? Do you work closely with healthcare professionals to make sure the tool you are developing is addressing an unmet need?
3. In which medical specialties and what types of applications will be used in the short-term (in the next 2 years)? Consider:
    a. Radiology and digital pathology
    b. Tools used for administrative purposes and diagnostic purposes
4. In which medical specialties and what types of AI applications will be used in the longer term? Consider:
    a. The potential of generative AI
    b. The applications of generative AI
    c. The challenges faced for generative AI solutions versus traditional machine-learning models
    d. What are the challenges related to the development of generative AI solutions to be used in healthcare settings? How do these challenges impact deployment?
5. Can you describe any AI tools deployed in clinical practice that excite you and you believe are having a significant impact on healthcare systems today? These can be AI solutions you have developed.
6. How do you see the AI landscape in healthcare evolving in the coming years?
7. From your experience, how easy is it to deploy AI solutions in clinical practice?
8. What is the impact or expected impact of the AI tools you have developed and deployed (or not yet developed or deployed)? Consider:
    a. Impact on healthcare workforce working time
    b. Reduction of administrative burden and lower rates of burnout and fatigue
    c. Number of missed diagnoses avoided
    d. Length of stay of patients
    e. Time to treatment
    f. Collaboration amongst healthcare professionals and multidisciplinary teams
    g. Patient satisfaction and overall relationship between doctors and patients
    h. Operational efficiency and waiting times
    i. Costs on healthcare systems

9. How do you demonstrate the added value of AI solutions you developed versus existing clinical solutions? What metrics are used to assess added value? How do these metrics vary across different specialties and types of AI solutions? Consider the metrics described in Q4. Have you established a model to build a business-case for potential customers?

10. To what extent do technological and data challenges affect the deployment of AI solutions in clinical practice? Consider:

    a. Outdated IT infrastructure and lack of digitalisation (e.g., lack of EHRs, lack of cloud computing services)
    b. Lack of interoperability amongst existing IT solutions
    c. Lack of standardisation of data structures and data reporting requirements
    d. Poor quality of data
    e. Variations in performance across healthcare settings

11. What good practices have you employed to address technological and data challenges? Consider:

    a. Post-deployment monitoring mechanisms to assess performance in the given healthcare setting. What metrics are used to assess performance?
    b. Ensure generalisability within the specific healthcare setting
    c. Additional evaluations within specific healthcare settings to ensure the AI solution meets specific performance metrics and standards

12. To what extent do legal and regulatory challenges affect the deployment of AI solutions in clinical practice? Consider:

    a. The complexity of the regulatory approval process and lack of guidance on compliance of AI tools with existing legislation
    b. Concerns surrounding data privacy and data protection
    c. Cybersecurity issues and vulnerability of data to breaches
    d. Concerns regarding clinicians' liability/standard of care issues when suing the AI tool
    e. Concerns regarding transparency and explainability of decisions made by AI solutions
    f. Concerns surrounding equity and digital divide caused by AI

13. What good practices have you employed to address legal and regulatory challenges?

14. To what extent do organisational and business challenges affect the deployment of AI solutions in clinical practice? Consider:

    a. Lack of strategic direction from the decision makers of healthcare facilities to promote innovation and the deployment of AI solutions
    b. Lack of technological skills and digital health literacy amongst healthcare professionals
    c. Lack of assessment of added value of AI solutions versus existing clinical solutions
    d. Lack of funding, investment and financial incentives

15. What good practices have you employed to address organisational and business challenges? Consider:

    a. Training and upskilling of healthcare workforce. Was this carried out by you? How was this carried out?

16. To what extent do social and cultural challenges affect the deployment of AI solutions in clinical practice? Consider:
    a. Lack of trust in AI solutions from healthcare professionals and patients
    b. Concerns about the impact of AI solutions on the doctor-patient relationship
    c. Concerns about job security
17. What good practices have you employed to address social and cultural challenges? Consider:
    a. Education and training on how the AI systems are used
    b. Information material and/or explanations to be shared with patients
    c. Informing end-users (healthcare professionals) that the AI solution has undergone the relevant regulatory assessment and is CE marked/FDA approved
    d. Providing healthcare professionals with performance metrics within their healthcare setting and medical specialty
    e. Collaborations amongst the developers of the AI tools and those deploying and using it (e.g., healthcare professionals, hospital representatives, administrative staff). Have such collaborations been beneficial and why? Do such collaborations increase trust in AI solutions?
18. Are you aware of the EU AI Act and the various provisions published on the 12th July in the Official Journal of the European Union? Does the EU AI Act introduce new challenges and obstacles to developers such as yourself?
19. To what extent do the provisions address some of the challenges described above? Consider:
    a. Transparency and provision of information to deployers (Article 13)
    b. Data protection impact assessment (Article 26)
    c. Human oversight (Article 14)
    d. Monitoring of performance (Article 26)
    e. AI literacy (Article 4)
20. Why are the challenges described above not addressed by existing legal frameworks? Consider:
    a. GDPR in addressing data privacy concerns
21. Based on your knowledge, do the challenges described above differ across healthcare settings and regions? Consider:
    a. The deployment challenges in hospitals found in urban areas versus those in rural areas.
    b. Deployment in EU, USA, Israel, Japan
22. Based on your knowledge, to what extent are the good practices you employed transferable across healthcare settings and regions? Consider:
    a. Urban and rural areas
    b. Across the EU, USA, Israel etc.
23. How can the deployment of AI in clinical practice be scaled?
24. What complementary actions (regulatory/non-regulatory) are needed within the next 2-3 years to ensure the widespread deployment of AI tools in clinical practice? Consider:

a. Consolidated funding to support specific strategic priorities.
b. Ensure consistent access to public data and promoting open-data initiatives
c. Organisation and centralised collection of post-deployment data to monitor on the ongoing effectiveness of AI tools. How would this work in your opinion? Would this be centralised at an EU level?
d. Encourage the establishment of centres of excellence for AI in healthcare to concentrate talent and resources. How do you envisage such centres? How should they be established and structured to provide concrete benefits?
e. Establish an EU AI in healthcare centre to coordinate and facilitate AI deployment. How do you envisage such centres? How should they be established and structured to provide concrete benefits?
f. Redesigning workforce planning and clinical education to address future healthcare and AI professional needs, investing in upskilling frontline staff. How would this work in practice?
g. Development of platforms to facilitate dialogues and exchange of good practices to facilitate deployment of AI tools

10.3.2 Targeted interview guide for HCPs and hospital representatives

1. What are the current needs in clinical practice that AI can address? Consider needs relevant to your work such as:
    a. Healthcare workforce shortage
    b. Ageing population and rise in chronic and complex conditions
    c. Increased demand on healthcare services
    d. Rising costs of healthcare
    e. Inefficiencies within healthcare systems
    f. Increase in administrative burden faced by healthcare professionals
    g. Need for improved screening, diagnosis and treatment
2. How could AI help in addressing some of the needs described previously?
3. In which medical specialties and what types of AI applications (within your specialty) will be used in the short-term (in the next 2 years)? Consider:
    a. Radiology and digital pathology
    b. Tools used for administrative purposes and diagnostic purposes
4. In which medical specialties and what types of AI applications will be used in the longer term? Consider:
    a. Precision medicine and clinical decision support systems
    b. The potential of generative AI
    c. The applications of generative AI
    d. The challenges faced for generative AI solutions versus traditional machine-learning models
5. Can you describe a few AI tools deployed in clinical practice (and within your specialty if applicable) that excite you and you believe are having a significant impact on efficiency and effectiveness of healthcare? Why are these tools effective?
6. What is the impact of these AI tools? Consider:
    a. Impact on healthcare workforce working time
    b. Reduction of administrative burden and lower rates of burnout and fatigue
    c. Number of missed diagnoses avoided
    d. Length of stay of patients
    e. Time to treatment
    f. Collaboration amongst healthcare professionals and multidisciplinary teams
    g. Patient satisfaction and overall relationship between doctors and patients
    h. Operational efficiency and waiting times

    i. Costs on healthcare systems
7. Does the impact of the AI tool vary based on the healthcare setting? Why? Consider:
    a. Urban university hospital versus a hospital in a remote setting
    b. Existing clinical workflows and clinical guidelines
8. Given that there are many AI-based tools on the market today, how do you choose between solutions? Consider:
    a. Assessment of added value of AI-based solution versus existing clinical solutions. What metrics are used to assess added value? How do these metrics vary across different specialties and types of AI solutions? Consider the metrics described in Q4.
    b. The cost of the AI solution and potential reimbursement mechanisms.
    c. Assessment of whether the AI solution address a clear need highlighted by HCPs.
9. To what extent do technological and data challenges affect the deployment of AI solutions in clinical practice? Consider:
    a. Outdated IT infrastructure and lack of digitalisation (e.g., lack of EHRs)
    b. Lack of interoperability amongst existing IT solutions
    c. Lack of standardisation of data structures and data reporting requirements
    d. Poor quality of data
    e. Variations in performance across healthcare settings
10. What good practices have you employed to address technological and data challenges? Consider:
    a. Updating IT infrastructure and ensuring interoperability between systems and integration of AI-based solutions with EHR for seamless integration (e.g., minimise the amount of software and applications to be used amongst the healthcare workforce)
    b. Post-deployment monitoring mechanisms to assess performance in the given healthcare setting. What metrics are used to assess performance? Does performance change over time?
    c. Establishment of clear data governance to address data related issues (use standardised formats for data reporting, data quality requirements)
11. To what extent do legal and regulatory challenges affect the deployment of AI solutions in clinical practice? Consider:
    a. The complexity of the regulatory approval process and lack of guidance on compliance of AI tools with existing legislation
    b. Concerns surrounding data privacy and data protection
    c. Cybersecurity issues and vulnerability of data to breaches
    d. Concerns regarding clinicians' liability/standard of care issues when using the AI tool
    e. Concerns regarding transparency and explainability of decisions made by AI solutions
12. What good practices have you employed to address legal and regulatory challenges?
13. To what extent do organisational and business challenges affect the deployment of AI solutions in clinical practice? Consider:
    a. Lack of strategic direction from the decision makers of healthcare facilities to promote innovation and the deployment of AI solutions
    b. Lack of technological skills and digital health literacy amongst healthcare professionals
    c. Lack of assessment of added value of AI solutions versus existing clinical solutions

    d. Lack of funding, investment and financial incentives
14. What good practices have you employed to address organisational and business challenges? Consider:
    a. Training and upskilling of healthcare workforce. How was this carried out?
    b. Establishment of multidisciplinary teams which includes IT experts, data scientists, and/or data engineers to interpret and explain the decisions made by AI solutions
    c. Creating "AI champions" across different medical specialties to promote and encourage the healthcare professionals to use AI solutions.
    d. Establishment of an AI deployment strategy to increase adoption.
    e. Established models to assess added value and return-on-investment
15. To what extent do social and cultural challenges affect the deployment of AI solutions in clinical practice? Consider:
    a. Lack of trust in AI solutions from healthcare professionals and patients
    b. Concerns about the impact of AI solutions on the doctor-patient relationship
    c. Concerns about job security
16. What good practices have you employed to address social and cultural challenges? Consider:
    a. Education and training on how AI systems are used
    b. Information material and/or explanations to be shared with patients
    c. Informing end-users (healthcare professionals) that the AI solution has undergone the relevant regulatory assessment and is CE marked/FDA approved
    d. Providing healthcare professionals with performance metrics within their healthcare setting and medical specialty
    e. How do you enhance trust and acceptability of AI to your patients?
    f. How do you enhance trust and acceptability of AI to HCP?
    g. Collaborations amongst the developers of the AI tools and those deploying and using it (e.g., healthcare professionals, hospital representatives, administrative staff). Have such collaborations been beneficial and why? Do such collaborations increase trust in AI solutions?
17. Do you have any concerns surrounding equity and digital divide caused by AI? How can these be addressed?
18. Are you aware of the EU AI Act and the various provisions published on the 12th July in the Official Journal of the European Union? Does the EU AI Act introduce new challenges and obstacles to deployers/hospitals/HCPs? Do you have any concerns? Consider:
    a. Article 26 – Obligations for deployers of high-risk AI systems:
        i. Deployers of high-risk AI systems shall take appropriate technical and organisational measures to ensure they use such systems in accordance with the instructions for use accompanying the systems
        ii. Deployers shall assign human oversight to natural persons who have the necessary competence, training and authority, as well as the necessary support.
        iii. Deployers shall monitor the operation of the high-risk AI system on the basis of the instructions for use and, where relevant, inform providers
        iv. Deployers of high-risk AI systems shall keep the logs automatically generated by that high-risk AI system

   v. Before putting into service or using a high-risk AI system at the workplace, deployers who are employers shall inform workers' representatives and the affected workers that they will be subject to the use of the high-risk AI system.
   vi. Deployers of high-risk AI systems shall carry out a data protection impact assessment

19. To what extent do the provisions address some of the challenges described above? Consider:
    a. Transparency and provision of information to deployers (Article 13)
    b. Data protection impact assessment (Article 26)
    c. Human oversight (Article 14)
    d. Monitoring of performance (Article 26)
    e. AI literacy (Article 4)
20. Why are the challenges described above not addressed by existing legal frameworks? Consider:
    a. GDPR in addressing data privacy concerns
21. Based on your knowledge, do the challenges described above differ across healthcare settings? Consider:
    a. The deployment challenges in hospitals found in urban areas versus those in rural areas.
22. Based on your knowledge, to what extent are the good practices you employed transferable across healthcare settings and regions? Consider:
    a. Urban and rural areas
    b. Across the EU, USA, Israel etc.
23. How can the deployment of AI in clinical practice be scaled?
24. What complementary actions (regulatory/non-regulatory) are needed within the next 2-3 years to ensure the widespread deployment of AI tools in clinical practice? Consider:
    a. Consolidated funding to support specific strategic priorities.
    b. Ensure consistent access to public data and promoting open-data initiatives
    c. Organisation and centralised collection of post-deployment data to monitor on the ongoing effectiveness of AI tools. How would this work in your opinion? Would this be centralised at an EU level?
    d. Encourage the establishment of centres of excellence for AI in healthcare to concentrate talent and resources. How do you envisage such centres? How should they be established and structured to provide concrete benefits?
    e. Establish an EU AI in healthcare centre to coordinate and facilitate AI deployment. How do you envisage such centres? How should they be established and structured to provide concrete benefits?
    f. Redesigning workforce planning and clinical education to address future healthcare and AI professional needs, investing in upskilling frontline staff. How would this work in practice?
    g. Development of platforms to facilitate dialogues and exchange of good practices to facilitate deployment of AI tools

10.3.3 Interview Guide - Case studies

The case study interview guides can be found in the table below. The case studies will be submitted as a separate file.

Table 10: Case study interview questions

Question	AI developer	Hospital reps.	HCPs
1. **What needs in healthcare does the AI tool address?**	X	X	X
2. **Did you face any of the following challenges when deploying the AI tool in clinical practice (if so please specify):** **- Technological and data challenges** **- Legal and regulatory challenges** **- Organisational and business challenges** **- Social and cultural challenges**	X	X	
3. **Did these barriers and challenges differ across healthcare settings (e.g., urban versus rural) and/or regions (e.g., USA versus EU)?**	X	X	
4. **How did you address these barriers to ensure the AI tools is deployed in clinical practice in a way that is acceptable for and trusted by patients (e.g., for hospital representatives - how has the hospital addressed any staff concerns or resistance to adoption of the AI tool) ?**	X	X	
5. **Can you describe any good practices to ensure the efficient and effective deployment of the AI tool in clinical practice? Why were these successful?**	X	X	
6. **How transferable/adaptable is this good practice across healthcare settings (e.g., urban versus rural) and regions (e.g., USA versus EU)?**	X	X	
7. **What are the specific challenges you face when interacting with the AI tool in clinical practice?**			X
8. **How was the training process for using the AI tool conducted, and what were the challenges faced by healthcare professionals? What ongoing support mechanisms are in place?**		X	X
9. **To your knowledge, are there any challenges concerning clinicians' liability/standard of care issues when using the AI tool in clinical practice?**	X	X	X
10. **How does using the AI tool impact clinical workflows?**		X	X
11. **How does using the AI tool impact the application of clinical guidelines?**		X	X
12. **How does using the AI tool impact the healthcare system overall?**		X	X
13. **How does using the AI tool impact the collaboration amongst clinicians and healthcare**		X	X

professionals? How has adoption of the AI tool changed over time?			
14. **How does using the AI tool impact the healthcare workforce working time?**		X	X
15. **How does using the AI tool impact the relationship between healthcare professionals and patients?**		X	X
16. **How is deployment and the impact of the AI tool monitored? Do you use existing indicators, or have you developed new reporting or data collection requirements?**		X	X
17. **To your knowledge, what are the specific challenges surrounding patient specific concerns/hesitancy on using the AI tool in clinical practice?**		X	X
18. **To your knowledge, what are the specific challenges surrounding transparency issues with the specific AI tool?**	X	X	X
19. **To your knowledge, are there any ethical issues of using the AI tool in clinical practice?**		X	X
20. **What complementary actions (regulatory/non-regulatory) are needed within the next 2-3 years to ensure the safe and effective deployment of the AI tool in clinical practice providing concrete benefits to patients, healthcare professionals and healthcare systems?**	X	X	
21. **What complementary actions are required to enhance trust, acceptability and explainability of AI in clinical practice? How will the introduction of the Artificial Intelligence Act impact the deployment of AI in clinical practice?**	X	X	X
22. **What complementary actions are required to ensure equal access for patients to the use of AI in clinical practice?**		X	X
23. **Are there existing collaborations between the developers of AI tools and those deploying the AI tool (e.g., healthcare professionals, hospitals) for the effective and efficient deployment of the AI tool in clinical practice (e.g., to understand their needs and challenges)? If not, would such collaborations be beneficial?**	X	X	X
24. **What are the main lessons learned from the deployment of the AI tool in clinical practice?**	X	X	X

10.4 Annex 4 – Synopsis report

In the following sections, a summary of the findings from each of the consultation activities for each of the key themes of the study is presented, clearly indicating who said what, and end each section with a summary where the insights from the interviews, surveys and workshops are brought together. The findings contained herein should be reflected upon in careful consideration of the limitations of this study (section 2.5).

10.4.1 Current and future needs in clinical practice that AI can/will address

According to the **survey responses** from HCPs, hospital representatives, and AI developers, the existing needs in healthcare affecting productivity and patient care include **administrative burden**, **healthcare workforce shortages, long waiting times,** and **issues with digitalisation and interoperability.** For HCPs, the biggest concern is the growing administrative burden, with 53% of respondents indicating that non-medical tasks (e.g., report writing, clinical documentation etc.) impacts their productivity. On average, **HCPs reported spending 20-60% of their time on administrative tasks, such as clinical documentation**, a figure that is consistent between EU and international respondents, with averages of 41% and 47%, respectively. According to 51 HCPs, existing AI solutions ("low-hanging fruit") have the potential to address some of these needs by **optimising resource allocation and workflow efficiency** (73% of responses), **streamlining administrative tasks** (61% of responses), and **improving diagnostic accuracy** (57% of responses).

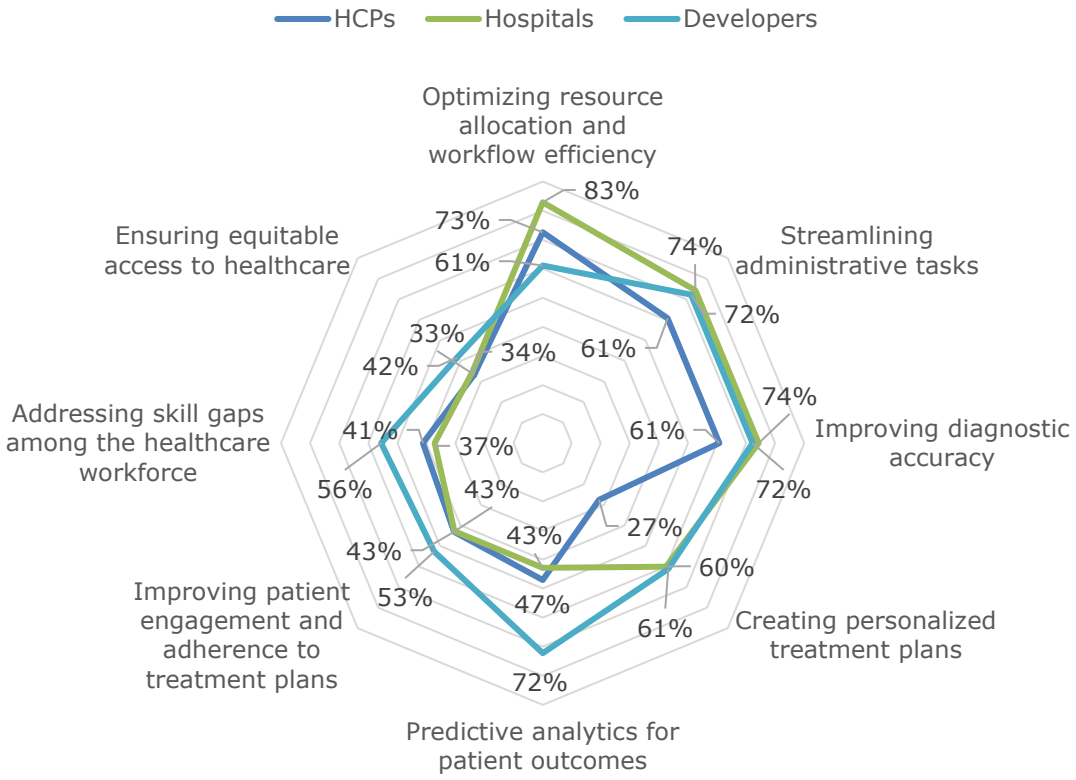
Hospital representatives similarly highlighted the current needs in healthcare posed by **workforce shortages** and **growing administrative burden**. Out of 35 respondents, 43% pointed to workforce shortages as the most important need, while 29% emphasised the burden of administrative tasks and bureaucratic procedures. According 60% of the hospital representatives, **HCPs within their healthcare facility spend between 20-60% of their time on administrative tasks related to healthcare provision**, which are not strictly medical. Unlike HCPs, however, hospital representatives placed more focus on the inadequacy of technology and IT infrastructure within healthcare settings (26% of responses). Some of the healthcare needs described above can already be addressed by existing AI solutions ("low-hanging fruit") according to the 35 hospital representatives. AI solutions can be used to **optimise resource allocation and improve workflow efficiency** (83% of responses), **improve diagnostic accuracy** (74% of responses), and **streamline administrative tasks** (74% of responses).

> *"The least risk and most acceptable AI-based solutions will likely be in medical billing, improving workflow efficiency in documentation, and in overall resource allocation optimization. These are unlikely to cause patient harm and more positioned to improve clinic operations and clinic finances, which are a significant motivator."* – **AI developer from the USA.**

AI developers, while acknowledging similar healthcare needs to HCPs and hospital representatives, provided more emphasis on technical and data-related needs. For AI developers, the most important need is **data access and quality**, with 47% of respondents pointing to issues with **unstructured data, fragmented healthcare systems, and poor data governance**. Administrative burden and workforce shortages were also mentioned by AI developers (28% and 17% of responses respectively), but with less emphasis than seen among HCPs and hospital representatives. Some of the healthcare needs described above can already be addressed by existing AI solutions ("low-hanging fruit") according to the 36 AI developers/AI developer associations that responded. AI solutions can be used for predictive analytics for patient outcomes (26

responses), improving diagnostic accuracy (72% of responses), and streamlining administrative tasks (72% of responses).

Figure 19: Healthcare needs that can already be addressed by existing AI solutions according to HCPs, Hospital representatives, and AI developers



When asked about future needs in healthcare that cannot be addressed by existing AI technologies but could be addressed within the next 5 years ("high-hanging fruit"), there was consensus among all stakeholder groups that AI advancements could **drive personalised medicine, real-time decision-making, and predictive healthcare**. All stakeholders believe AI has the potential to improve personalised patient care by tailoring treatment plans based on individual patient data, including genetic profiles.

From the **interviews** the most common challenges highlighted by 7 HCPs[336], 2 hospital representatives[337] and an EU-level association centred around the need to **alleviate the administrative burden** faced by HCPs and the excessive time spent on documentation, scheduling, and organisational/operational tasks. One HCP from Italy along with the AI developers from the Netherlands also pointed to challenges with **operational efficiency** that AI could help address by, for example, speeding up and increasing the efficiency of diagnosing and triaging of patients.

All stakeholder groups interviewed agreed that there is a need and potential for AI to improve **screening, diagnosis and treatment** as HCPs from the Netherlands, Spain the UK emphasised that they are facing an increased demand for diagnostics, particularly in the medical specialties of radiology and pathology. Four HCPs[338], two hospital representatives[339], four AI developers[340] and the EU-level association also

336 HCPs from Spain, Denmark, one from the UK, four from the USA
337 Hospital representatives from Japan and Belgium
338 Three HCPs from the UK, one from Denmark
339 Hospital representative from Japan and the USA
340 AI developers from the Netherlands, Germany, Japan, and the USA

mentioned **workforce shortages** as an issue that AI tools can help mitigate. For example, three hospital representatives from the UK explained that in radiology, AI has the potential to ease workload by identifying normal cases with a higher accuracy, especially in centres handling high volumes of scans where the majority are normal, requiring only radiologist to review the findings of the AI solution. AI developers from the US and the HCP from the Netherlands believe that AI has the potential to **aid in precision diagnostics** by identifying medical patterns that are too complex or subtle for the human brain to fully comprehend.

In the hospital workshop, hospital representatives provided further insights into the needs AI could address. A hospital representative from the USA described their approach of running **internal innovation competitions**, where clinicians apply highlighting a clinical need within their medical specialty that can potentially be addressed by AI solutions. In the latest round, **over 300 applications were submitted** across different medical specialties, with needs ranging from **staffing shortages** to **early disease detection**. A hospital representative from Italy highlighted the need for **AI systems that optimise entire hospital processes for sustainability and efficiency**, focusing on resource management rather than isolated, single-point solutions within diagnostics or therapy. These needs closely mirror the survey and interview findings, focusing on alleviating **administrative burden, workforce shortages, and improving technological infrastructure**

10.4.2 Impact of AI in clinical practice

The survey responses from patients, patient associations, HCPs, and HCP associations with advanced or solid knowledge of AI in healthcare provide a comparative perspective on the anticipated impact of AI in healthcare settings over the coming years. Both stakeholder groups—patients and HCPs—believe that **AI will have a positive impact**, particularly in improving diagnosis speed and accuracy as well as in managing chronic conditions through remote monitoring and proactive interventions.

From the patient perspective, 70% of the patients indicated that AI would have a **positive impact** across all areas. Among these areas, respondents highlighted the potential for AI to significantly improve **the speed and accuracy of medical diagnoses** (70% responses) and enhance **chronic condition management** (55% of responses), particularly through remote patient monitoring. Patients also highlighted several broader impacts, including improved doctor-patient interactions, reduced administrative burdens on HCPs, and enhanced education and training for HCPs. These factors suggest that patients expect AI to not only improve direct healthcare outcomes but also to **improve the experience and quality of care by improving efficiency and communication between HCPs and patients.**

The responses from HCPs (32 responses) align closely with the patient group in terms of their positive outlook on AI's future impact. Over 65% of HCPs indicated that AI would have a positive effect across most areas, with the greatest improvements expected in **diagnostic accuracy and chronic condition management**, where 91% of respondents believe that AI will have an important impact. However, HCPs were sceptical that adoption of AI tools would lead to cost savings in healthcare (28% of respondents indicating that AI adoption will have no impact on cost saving on healthcare expenses).

From the interviews, HCPs had a positive outlook towards the use of AI to improve **healthcare workforce well-being, working time and workload**. In the field of **radiology**, HCPs from the UK and Austria noted that AI automation allows for one radiologist to verify results rather than two, saving time and improving the overall

efficiency of the clinical workflow. Similarly, HCPs from the USA and Denmark highlighted that AI could improve work-life balance and efficiency, with tools like **AI-generated discharge letters and EHR-integrated systems easing administrative tasks.** The hospital representative from Japan described two AI solutions currently deployed in their hospital to assist with administrative documentation. Similarly, a hospital representative from the USA highlighted the benefits of using EHR vendors that incorporate AI solutions within their platform to streamline administrative tasks, such as virtual scribes and organising messages for easier management. On the other hand, one HCP from the UK believed that **some AI technologies do not provide added value in clinical settings**, with many tools, particularly in radiology often being "solutions looking for a problem".

HCPs, hospital representatives and AI developers all agreed on the benefits that AI has in **improving operational efficiency and care delivery**. A hospital representative from South Korea and two HCPs from the UK reflected on its ability to improve **detection efficiency, thereby shortening waiting time**. One HCP from the UK stated that tools that focus on narrow, well-defined tasks have the greatest positive effect because their use minimises disruptions elsewhere in the healthcare system. AI tools that **speed up diagnosis** were mentioned by the AI developer from the Netherlands and an HCP from Spain.

HCPs[341], hospital representatives[342] and AI developers[343] generally agreed on the transformative potential of AI tools in **enhancing diagnostic accuracy** across a number of medical fields, such as **lung cancer screening, breast cancer pathology, and rare disease identification**. One HCP from the UK highlighted AI's ability to improve efficiency in cancer detection when used alongside human reviewers. However, the hospital representative from Japan **raised concerns that AI could also potentially increase workload** due to the need for radiologists to review false positives. The hospital representative from Japan, HCPs[344], the EU-level organisation and one AI developer from the USA agreed on the positive impact of AI tools in **enhancing doctor-patient relationships[345]**. They noted that AI solutions, for example chatbots, provide layman-friendly explanations of diagnoses and medical decisions, which improves patient understanding and satisfaction. One HCP from the UK and one HCP from the USA also attributed **financial benefits to AI**, especially in settings where it is used for early detection, thereby reducing the cost of treatment. Two HCPs from the USA, one HCP from Austria, one HCP from the Netherlands, and an HCP from the UK believed that AI tools have the **potential to democratise healthcare as well as provide high-quality diagnostics in rural settings**. This would allow for the maintenance of consistent care quality across regions.

In the workshop, hospital representatives from Israel highlighted the positive impact generative AI tools could have on **hospital administration, back-office functions, and operational efficiency**. However, they stressed the importance of deploying, controlling, and monitoring these tools centrally within hospitals to ensure their effectiveness.

341 Healthcare professionals from the Netherlands, one from UK, one from Italy, one from the USA
342 Hospital representative from USA and Japan
343 AI developer from Germany, Japan, one from US
344 One healthcare professional from Italy, one healthcare professional from the UK
345 A reflection also provided by patients and patient associations in the survey (described above)

10.4.3 Areas where the use of AI has the greatest transformative potential

In this section, stakeholders' views on the areas where the use of AI is expected to have the greatest transformative potential in healthcare are presented. The analysis focuses on two key questions:

- Which medical specialties have the biggest potential for AI-driven transformation, as identified by hospital representatives.
- The specific AI applications that are expected to provide significant added value to healthcare delivery, as assessed by all stakeholder groups.

The survey responses from patients, HCPs, hospital representatives, and AI developers offer distinct yet overlapping perspectives on the use of AI in healthcare, particularly around comfort levels, transformative potential, and areas of concern. From the patient's perspective, 63% of the patients reported feeling generally comfortable with AI in healthcare, mostly in areas that indirectly affect their care, such as **support with administrative tasks** (83% of responses) and **optimisation with clinical workflows** (70% of responses)**.** However, patients expressed discomfort with the use of AI in conversational platforms, such as **chatbots for direct patient assistance**, with only 43% of respondents feeling comfortable. However, patients raised concerns about potential negative impacts. Key issues included **bias in AI algorithms leading to disparities** (63% of responses), **fear of loss of the human touch in healthcare** (60% of responses), **concerns about patient privacy and data security** (57% of responses), and **a perceived lack of regulation and oversight** (53% of responses).

The responses from HCPs, based on 51 respondents, align closely with the patient group in terms of their positive outlook on AI's potential role in supporting **administrative tasks** and **clinical workflow optimisation**. Over 70% of respondents believe AI tools for **managing tasks like electronic health records** and **clinical documentation** will have the greatest impact on healthcare delivery. However, only 20% of respondents believe **AI-assisted surgery** or **medical robotics** will add much value, reflecting a cautious view on these more complex AI applications. The **HCPs** highlighted, however, for AI to have an impact, better access to quality data, which includes diverse patient populations, and system interoperability is required.

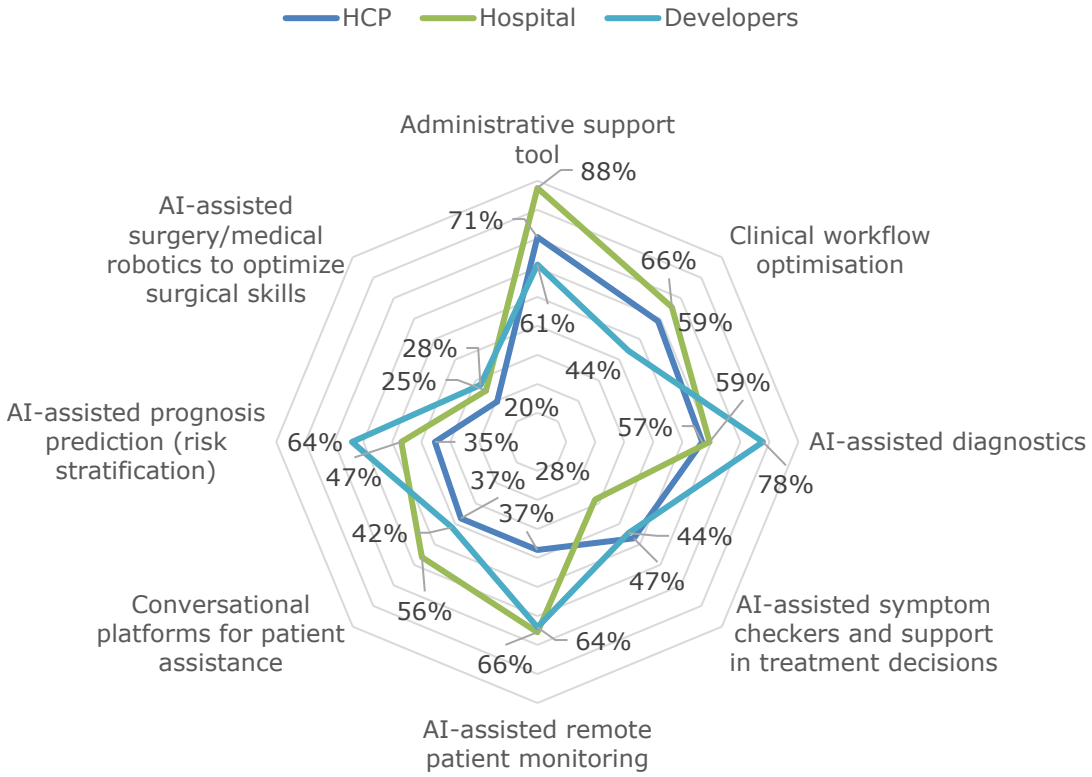
Hospital representatives (32 respondents) aligned with HCPs in their views on AI's potential in healthcare. Over 87% of respondents believe **administrative support tools**, such as AI systems for EHR management, will have the most transformative impact on healthcare delivery, with 65% of respondents highlighting **AI-driven clinical workflow optimisation** as another area of value. Interestingly, **hospital representatives** were also sceptical about the potential of **AI-assisted surgery**, with less than 30% of respondents seeing much value in its implementation. One key area where hospital representatives see the most transformative potential is in **radiology,** indicated by 94% of respondents.

AI developers and researchers (36 respondents) offered a different perspective. Over 70% of respondents believe **AI-assisted diagnostics** will have the most transformative potential, followed by **AI-assisted prognosis prediction** (64% of respondents). Like HCPs and hospital representatives, AI developers are less enthusiastic about the potential of AI-assisted surgery, with only 30% of respondents viewing it as adding value.

"AI has the potential to significantly enhance the delivery of healthcare in our medical specialty. By leveraging AI-assisted diagnostics, we can achieve more accurate and timely diagnoses, which is critical for effective patient treatment. AI-assisted surgery and medical robotics can optimise surgical outcomes, reducing recovery times and improving patient prognosis. Remote patient monitoring via AI can ensure continuous care, especially for chronic conditions, while AI-powered predictive maintenance ensures all medical equipment operates optimally. Additionally, AI-driven personalised patient education and mental health support tools can provide tailored and accessible care, further improving patient engagement and adherence to treatment plans. These applications collectively contribute to a more efficient, effective, and patient-centred healthcare delivery system."

- **Hospital representative from Portugal.**

Figure 20: Areas where the use of AI is expected to have the most transformative potential according to HCPs, hospital representatives, and AI developers.



In the **short-term**, the stakeholders participating in the **interviews** identified **radiology and pathology** as the medical specialties with the greatest potential for transformation, while **clinical decision support** along with **general administrative support** were highlighted as other key areas. Due to their potential to enhance diagnostic efficiency, the transformative potential of **AI tools in radiology, medical imaging and digital pathology** was highlighted by HCPs[346], AI developers[347], a hospital representative from Belgium and the EU-level organisation. One HCP from Italy noted that department-specific AI tools are likely to see the most widespread adoption due to a mature market, with capabilities to reduce diagnosis times and prioritise urgent cases in the Emergency Room. While the HCP from Denmark acknowledged the benefits of AI-assisted diagnostics, they also **cautioned that such tools may struggle to perform outside of their trained niches**. Similarly, one HCP from Italy believed that

346 Healthcare professional from the Netherlands, one from the UK, one from the USA
347 The AI developer from Germany, one from the US

the value of AI tools that focus on diagnostic or therapeutic improvements is often **difficult to quantify** because they bring limited improvement in the overall quality of care.

The HCP from the Netherlands believed that the **greatest transformative potential** is expected in patients with metastatic or advanced-stage tumours, **where AI-based clinical decision support tools can predict treatment responses for costly therapies**. One HCP from the USA, on the other hand, highlighted AI's **transformative potential in early detection and intervention** for cancers (e.g., pancreatic, prostate, breast), improving risk assessment and reducing the need for invasive procedures. The AI developer from Germany and the EU-level organisation agreed on the significance of decision-support tools, with the EU organisation also pointing out AI's potential to generate systematic reviews, thereby strengthening the evidence base for medical associations.

The hospital representative from South Korea explained that there is a lot of focus on the use of **AI tools that improve operational efficiency** such as those suggesting interventions for critically ill patients and continuously monitoring vital signs to predict patient outcomes. The HCP from Denmark reflected on the potential for AI tools in improving surgical operations, for example by **predicting capacity**, while one healthcare professional from the UK noted that AI currently excels in binary diagnostic tasks, like fracture detection, but faces **challenges with more complex diagnoses, such as identifying cancer in lung scans.**

Three HCPs[348], two AI developers[349] and two hospital representatives[350] reflected on the application of AI tools to **improve administrative efficiency** and streamline non-clinical tasks, for example summarisation tasks with the use of generative AI. One HCP from the USA explained that generative AI also has the potential to provide operational support for rural areas in streamlining patient workflows.

In the **long-term**, one HCP from the UK and one HCP from Denmark stated that they expect **digital pathology** to be the next medical specialty to experience transformative AI potential, after radiology.

In terms of application, one AI developer from the USA and two HCPs[351] expressed optimism about the future of **general-purpose AI tools** such as Large Language Models (LLMs). These tools could be used for example, to analyse population health data, streamline workflows in areas like surgical planning and medication logistics as well as measure the psychological well-being of healthcare professionals to prevent burnout. The hospital representative from the USA noted that current AI tools are primarily focused on point solutions for specific needs but also envision the application of general-purpose AI tools to provide comprehensive system-wide support in the future. The AI developer from Japan, one HCP from the UK and one HCP from the USA reflected that **generative AI models may hold significant potential**. Nevertheless, the HCP from the UK reflected that they currently require clinicians to verify the AI's outputs, limiting immediate time savings. The hospital representative from Japan and the HCP from Denmark, however, believed that AI-driven **chatbots can help mitigate the scarcity of HCPs as well as avoid patients paying high-costs for visits.** Hospital representatives from Japan, South Korea and Belgium also referenced the potential for **AI in genomics.**

348 HCPs from the US, Germany and one from the UK, one from Denmark
349 AI developer from Japan, one from USA
350 Hospital representative from the Netherlands and the USA
351 One healthcare professional from Italy and one from the UK, one from the USA

In the hospital workshop, the **hospital representatives** provided more specific insights into the types of AI applications. A **hospital representative** from the **USA** highlighted that **AI tools for organisational and administrative tasks** are the "low-hanging fruit" for achieving quick, measurable benefits in hospital settings. Similarly, a **hospital representative** from **Israel** noted that generative AI assisting HCPs in non-clinical settings, such as **hospital administration, back-office functions, patient communication bots, and scheduling,** can add value.

In terms of medical specialties, the **hospital representative** from the **USA** identified **radiology** as an **early adopter** due to the availability of vast amounts of data that have been aggregated over decades, along with the nature of the work that is closely tied to imaging technology. According to the representative, **cardiology** is the second medical specialty to follow in early adoption, and **behavioural health, psychology, and psychiatry** were viewed as slower adopters of AI tools.

10.4.4 State of deployment of AI in healthcare

The **survey** results from hospital representatives, and AI developers highlight varied experiences and challenges with AI deployment in healthcare settings, focusing on the practical deployment of AI tools, including generative AI, across these stakeholder groups.

Of the hospital respondents (35 respondents), 20 are currently piloting an AI solution, 19 have already purchased and deployed a commercially available solution, and 11 have developed and deployed an in-house AI solution. Only two hospitals have not yet adopted AI. However, challenges in deployment persist, particularly with **interoperability issues between AI tools and existing infrastructure** like EHRs and medical devices, which 17 respondents highlighted as an important barrier. Other challenges include the **ongoing testing and performance testing of AI tools for accuracy and safety** (16 responses) and a **lack of funding to support deployment** (15 responses). While 43% of respondents believe commercially available AI tools facilitate more seamless integration into clinical workflows, 20% see no difference between in-house and commercially available solutions. Among those hospitals that have deployed AI tools, only a minority track specific performance or efficiency metrics, highlighting a need for more structured evaluation of AI's impact on healthcare delivery.

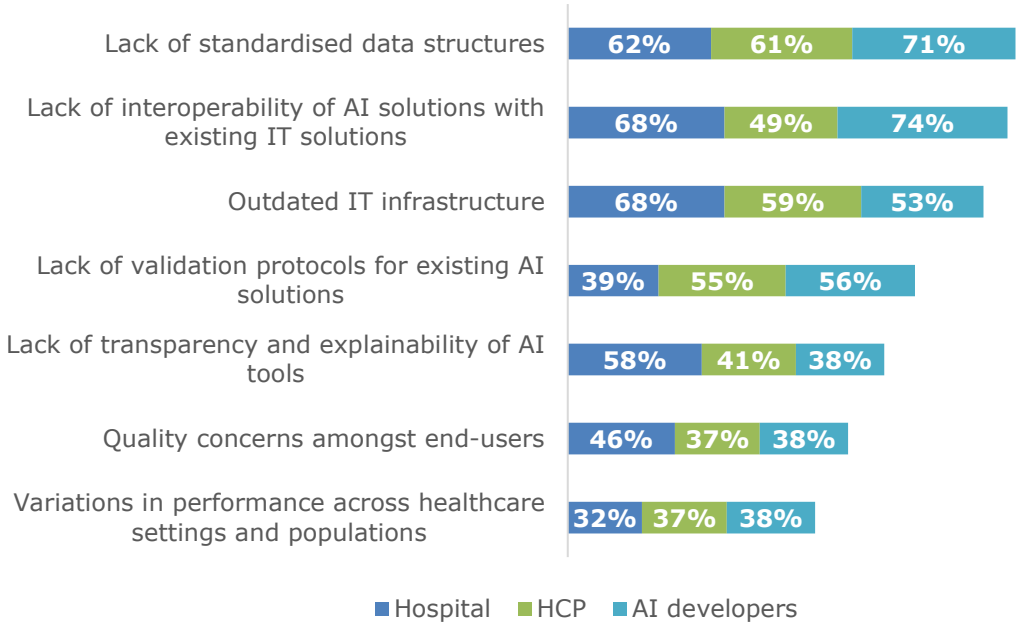
AI developers and researchers (36 respondents) present a more technical perspective, as 25 of them have developed or are developing AI tools for healthcare use, with all international respondents but only 16 EU respondents actively involved in AI tool development. A reason some AI tools have not yet been deployed is regulatory approval and the need for thorough **testing and performance testing to ensure the tools' safety and reliability**, echoing the concerns raised by hospital representatives. Another key issue, highlighted by an AI developer from the USA, is the **fragmented data landscape** in Europe, which complicates scalable solutions and necessitates extensive contracting. Post-deployment, AI developers provide significant support, including routine **communication, training, implementation support, system monitoring, and ensuring legal compliance**. This support is important to ensuring the tools' continued effectiveness and integration into healthcare systems. When it comes to generative AI, 18 out of the 36 developers are involved in the development of such tools, with 8 having deployed generative AI tools in clinical practice.

10.4.5 Challenges and accelerators to AI deployment in healthcare

10.4.5.1 Technological and data challenges and good practices

The **survey** results highlighted several technological and data challenges impacting the deployment of AI in healthcare (Figure 21). Although all groups recognize similar challenges, their emphasis and proposed solutions differ based on their specific roles within the AI ecosystem. The technological and data challenge believed to have the most significant impact on deployment of AI solutions according to all stakeholder groups is the **lack of standardised data structures**. Among HCPs, 61% respondents identified **data fragmentation** as an important challenge, as healthcare systems often use isolated or proprietary platforms with inconsistent data formats. This **lack of standardization** hinders AI's ability to analyse and aggregate data effectively across various systems. Hospital representatives concurred, with 62% of respondents pointing to the absence of uniform data models as a barrier to AI integration, particularly when working with external institutions that do not follow the same standards. AI developers also highlighted the importance of standardised data structures, with 71% of respondents indicating that the lack of uniform standards across regions, especially in Europe, complicates AI deployment.

Figure 21: Technological and data challenges believed to have a significant impact on the deployment of AI tools according to 26 hospital representatives, 49 HCPs, and 34 AI developers



Interoperability of AI solutions with existing IT systems is another key challenge shared by all three stakeholder groups. Among HCPs, 49% of respondents highlighted the difficulty AI tools face in integrating with existing healthcare systems such as EHR platforms, forcing manual data input and creating workflow inefficiencies. Hospital representatives agreed, with 68% of respondents emphasising that without seamless integration, AI systems disrupt clinical workflows, **increasing operational complexity and reducing user adoption**. AI developers also highlighted this issue, with 74% of respondents reporting that the fragmented nature of hospital IT systems, even within the same institution, is a major barrier to scaling AI tools across different healthcare settings.

> *"The lack of interoperability of AI solutions with existing IT solutions is the single most common challenge cited by customers. Transferring data from system to system is highly tedious, laborious, and can bring mistakes too easily."* – **AI developer from the USA.**

Another area of convergence between stakeholder groups is **outdated IT infrastructure**. Among HCPs and their associations, 59% of respondents indicated that outdated IT systems are a major barrier to effective AI deployment. Many healthcare facilities still operate with technology that cannot handle the large datasets and complex computations required for AI, leading to inefficiencies, higher costs, and limited scalability of AI applications. Hospital representatives echoed this concern, with 68% of respondents indicating that outdated infrastructure is a significant issue, especially in Europe where **hospitals in rural or underfunded regions face even greater challenges in updating their systems**. Similarly, 53% of AI developers reported that outdated IT infrastructure, including legacy systems like EHRs, complicates AI deployment due to poor interoperability with modern tools.

> *"The deployment of AI tools requires a base level of digital and physical infrastructure to be effective. However, many hospitals in Europe still have limited digitalisation requiring more investment in basic digital and physical infrastructure prior to deploying AI tools. Indeed, physical infrastructure is also essential for supporting AI, making sure that digital services are dependable, safe, and accessible to healthcare professionals in each hospital."* – **Hospital representative association based in Belgium.**

While these challenges are universally recognised, there are also key differences in how the stakeholder groups perceive and prioritise certain issues. HCPs expressed considerable concern about the **lack of clear performance testing procedures** for AI tools to assess variations in performance across healthcare settings, with 55% of respondents raising this issue. Many HCPs are sceptical about the **reliability of AI**, particularly due to the "black box" nature of many systems, which makes it difficult to understand how decisions are made. Without transparent and standardised performance testing processes, HCPs **lack trust** in AI-driven clinical decisions. Hospital representatives also raised concerns about performance testing, though their focus was more on **pilot studies and testing AI systems** within their specific infrastructure to ensure safety and efficacy before full deployment. In addition, 56% of AI developers reported that the lack of standardised performance testing protocols impacts AI adoption, particularly for teams with less experience. The absence of **consistent frameworks** leads to uncertainty about AI reliability, especially when integrating these tools into clinical workflows.

Explainability and trust in AI present another point of divergence. HCPs emphasised the need for transparency in AI decision-making, as the inability to understand how AI models arrive at their conclusions can undermine trust, especially in high-stakes clinical environments. Some international respondents further stressed that clear, concise guidelines on how AI models work are essential for improving transparency and building confidence among users. However, hospital representatives did not prioritise explainability to the same degree, focusing instead on ensuring the AI system's performance within their workflows. For AI developers, explainability was recognised as important but secondary to data quality and performance . Many developers believe that while transparency is essential in some contexts, AI performance and ease of use are more important for gaining clinician trust.

In terms of addressing these challenges, there is convergence on several good practices. One such practice is **post-deployment monitoring and performance assessment**.

Among HCPs, 84% of respondents highlighted the importance of real-time monitoring to ensure that AI systems perform effectively in diverse clinical settings. This includes continuous assessments and adjustments based on AI performance data and user feedback. Hospital representatives similarly highlighted the importance of monitoring AI systems post-deployment, often by **collaborating with AI developers** to implement performance tracking mechanisms. AI developers also agreed, with 49% of respondents highlighting that monitoring AI performance after deployment is crucial, particularly for ensuring that AI models remain fair and effective across different patient populations.

Another area of agreement is the need for **training AI models on diverse datasets**. Among HCPs, 80% of respondents emphasised the importance of training on diverse datasets to ensure that AI systems account for **variations in patient demographics and clinical environments**. Hospital representatives also recognised this need, indicating that AI models must be tested in different real-world settings to avoid performance biases. AI developers concurred, with 79% of respondents indicating that ensuring training data diversity is critical for developing AI models that can generalise effectively across different populations and healthcare systems.

The main challenges highlighted by the **interviewees** were related to **data accessibility, quality and standardisation**, **insufficient IT infrastructure** and the **lack of interoperability**. A **lack of standardisation in data structures** (for example between EHR systems), including the absence of a common language was highlighted by three HCPs[352] along with hospital representatives[353] and AI developers[354]. Additionally, four HCPs[355], the hospital representative from Japan and four AI developers[356] highlighted significant challenges **related to data quality and access**, which can be inaccurate or incomplete. One AI developer from the USA noted the overall limited availability of digitised data in the EU, which another AI developer from the USA believes is also due to the absence of secure cloud solutions. Two AI developers from the USA and one HCP from the UK highlighted concerns from hospitals when it comes to the applicability of AI models to their diverse patient populations.

Insufficient or outdated IT infrastructures pose major challenges to the deployment of AI in healthcare according to six HCPs[357], the hospital representative from South Korea and one AI developer from the USA. For example, five HCPs[358] and two the hospital representatives[359] explained that **interoperability issues can arise due to varying digital maturity** within healthcare centres that lack foundational systems such as EHR. Additionally, one HCP from Italy pointed out that some hospitals are not aware of the infrastructure requirements they should have in place, resulting in improper deployment of AI solutions. Additionally, issues with **seamless integration** were mentioned by one HCP form Denmark and one AI developer from the USA, highlighting the necessity to integrate solutions into a single platform. Furthermore, barriers due to **preferences in Europe for on-premises AI systems over cloud solution** was mentioned by one AI developer from the USA. One HCP from Denmark and the hospital representative from the USA agreed, highlighting a reluctance to transition to cloud-based solutions among hospitals due to concerns surrounding data privacy. Similarly, three AI developers from the USA as well as the hospital

352 HCPs from Austria, three from the USA, one from the UK
353 One hospital representative from Italy and one from the USA
354 AI developer from Japan, one from the USA
355 HCPs from the Netherlands, one from Italy, two from USA
356 AI developer from Germany, three from the USA
357 HCPs from the Netherlands, the US, one from Denmark, one from Italy
358 One HCP from the USA, three form the UK, one from Italy
359 The hospital representative from Japan and Belgium

representative from South Korea explained that many hospitals are still using on-premises systems which poses challenges for integration.

In terms of best practices to mitigate the abovementioned challenges, one AI developer from the USA explained that they conduct site assessments for data quality **prior to deployment**. Additionally, **post-deployment monitoring** is carried out by one HCP from the UK and two AI developers from the USA, to be able to flag when the algorithm does not work as well in a given population. Additionally, one HCP from the UK explained they continually test AI systems against historical data. To **collect accurate and representative data**, one AI developer from the USA, one HCP from Denmark, one HCP from the UK and the EU-level HCP organisation stressed the importance of facilitating collaborative data infrastructures for effective AI application in healthcare. For example, one AI developer from the USA establishes partnerships with clinical healthcare centres and research institutes, while one HCP from Denmark highlighted ongoing discussions to establish a **central entity for data collection and storage.** The EU-level HCP organisation highlighted a single platform where data science teams in urology will be able to analyse high-quality and anonymised data.

To ease the challenges stemming from interoperability, **investing in IT systems prior to adoption** was stressed by the hospital representatives from Italy, one HCP from the USA and one HCP from the UK with pilot testing AI systems. Additionally, the hospital representative from South Korea and one HCP from the UK **monitor and upgrade their AI algorithms alongside their hospital technologies** to better facilitate AI adoption and maintain accuracy post-deployment. One AI developer from the Netherlands along with one HCP from the USA also conduct rigorous **post-deployment assessment** to monitor for performance and effectiveness. **Adopting cloud-based solutions** for scaling and securely deploying AI solutions was emphasised by one AI developer form the USA, one HCP from the UK and the hospital representative from South Korea. One AI developer from the USA explained that cloud systems facilitate data sharing and enable post-deployment monitoring as well as help overcome any limitations with on-premises data storage.

In terms of the hospital workshop, the hospital representatives described several technological and data challenges specific to different regions. One hospital representative from Israel raised concerns over **variation in AI performance** due to differences in healthcare professionals' preferences, workflows, and the types of cases handled (inpatients versus outpatients). The other hospital representative from Israel echoed this challenge adding that each model behaves differently in different realities which, in absence of standardised methods to extract hospital specific value from performance profiles and the literature, means piloting is the only option.

A common challenge reported by hospital representatives from Israel and Italy was the **fragmentation of AI tools and vendors**, which makes piloting every available solution and determining which one would work best in specific hospital settings difficult. A hospital representative from the USA added that vendors provided **varying levels of post-deployment monitoring**, with some offering none. Moreover, this representative raised **concerns surrounding validation and accuracy**, highlighting that the main challenge with conducting quality assurance for the tools is the need to review thousands of radiology notes for diagnostic support tools.

Hospital representatives in the workshop also highlighted several good practices to address these challenges. To address **the fragmentation of AI tools and vendors**, a hospital representative from Italy reported that their healthcare facility developed a **feasibility checklist** to assess whether AI solutions could be adapted and/or integrated

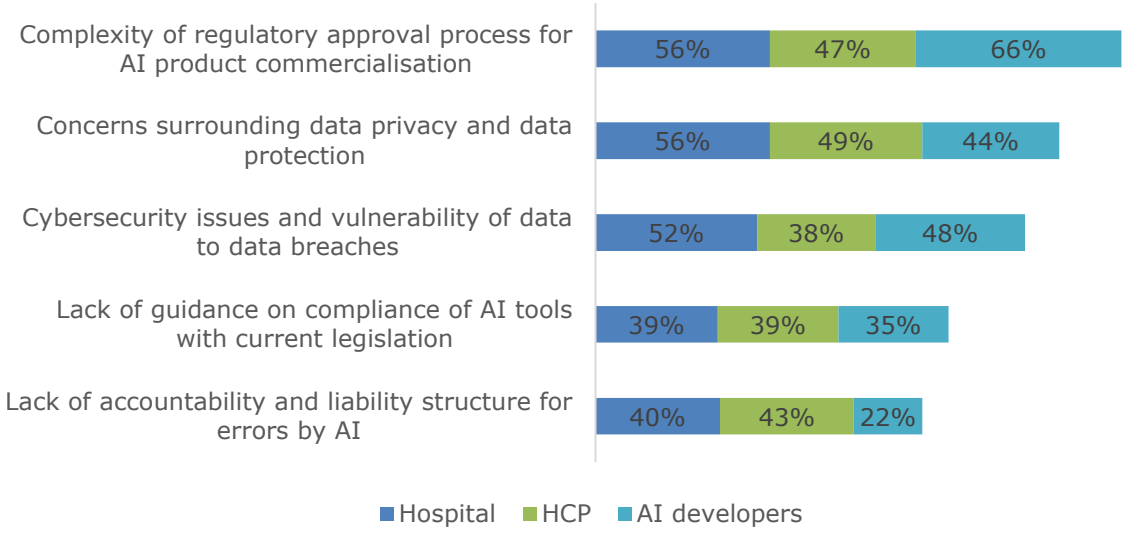
into their internal hospital framework. The representative also suggested a **catalogue of AI vendors** with **specific key performance indicators**. A hospital representative from Israel added that the catalogue could include **an "AI sandbox**" where hospitals could test AI products using anonymised data to evaluate the tool's performance in a standardised way. The hospital representative from Israel also described **single platforms provided by local vendors**, within which various AI solutions can be piloted and purchased, all integrated into the same platform for ease of integration.

To address the **variation in performance**, the hospital representative from Israel reflected upon the importance of **conducting pre-evaluation or pilot projects** within their hospital to ensure AI tools work correctly for their specific patient population, use cases, and clinical workflows. Lastly, to address the **lack of post-deployment mechanisms** a hospital representative from the USA explained that they developed an **AI hub to track every AI transaction,** including inputs and outputs. This information supports **quality assurance plans**, which then become the **vendor's responsibility.** Additionally, the hospital has **developed in-house solutions** to ensure internal monitoring and performance, with **set thresholds to ensure sustainable impact.**

10.4.5.2 Legal and regulatory challenges and good practices

In the survey, legal and regulatory challenges affecting the deployment of AI in healthcare revealed several points of convergence and divergence across stakeholder groups (Figure 22).

Figure 22: Legal and regulatory challenges believed to have a significant impact on the deployment of AI tools according to 25 hospital representatives, 47 HCPs, and 32 AI developers



One of the areas of convergence across all stakeholder groups is the concern surrounding the **complexity of the regulatory approval process** for AI products. HCPs (47% of respondents), hospital representatives (56% of respondents), and AI developers (66% of respondents) all view the EU regulatory frameworks, such as the Medical Device Regulation (MDR) and the AI Act, as barriers to market entry and adoption. HCPs and hospital representatives described the regulatory process as **slow and cumbersome**, and AI developers indicated that these lengthy approval processes, compared to those in the USA, hinder innovation by prolonging the time it takes for AI tools to reach the market.

Another common challenge is **data privacy and protection**, highlighted by HCPs (49% of respondents), hospital representatives (56% of respondents), and AI

developers (444% of respondents). All stakeholder groups indicated that AI requires the use of sensitive health data, raising **concerns about data breaches and misuse**. While the General Data Protection Regulation (GDPR) provides a framework for data protection, HCPs and hospital representatives highlighted the **lack of clear guidance** on how AI tools can comply with these regulations. AI developers added that the collection, storage, and sharing of data pose challenges that affect patient trust, as concerns over privacy increasingly impact how patients engage with AI technologies. The shared focus on data protection indicates a broad concern about how the current legislative landscape addresses AI's handling of sensitive information, with all groups calling for clearer compliance guidelines to improve trust in AI solutions.

Cybersecurity issues was a third area of convergence. HCPs (38% of respondents) indicated that **cybersecurity vulnerabilities, such as data breaches and unauthorised access,** undermine trust in AI systems and require costly protective measures, which can delay deployment. Hospital representatives (52% of respondents) acknowledged that while cybersecurity challenges existed before AI, the increased digitalization of healthcare, including AI tools, increases the importance of maintaining **data integrity and confidentiality**. AI developers (48% of respondents) highlighted the potential damage to patient trust from cybersecurity threats, emphasising the **risks of unauthorised access to sensitive medical data**, which could lead to identity theft and misuse.

The **lack of accountability and liability structures** for AI errors raised concerns for HCPs and hospital representatives. Both groups highlighted the uncertainty created by the absence of clear guidelines on who is responsible for AI mistakes. HCPs (43% of respondents) worried about the **legal repercussions** if they were held accountable for errors made by AI tools over which they have no control, and hospital representatives (40% of respondents) felt this uncertainty could **discourage reliance on AI in clinical settings due to fears of being blamed for AI-related errors**. In contrast, AI developers placed less emphasis on accountability concerns, focusing more on regulatory approval and getting their products to market, suggesting that while end-users are concerned about legal risks, they prioritise getting their products through regulatory approval and to market.

There were also divergences on how those stakeholder groups view the necessary practices to address the legal and regulatory challenges. Hospital representatives have implemented **compliance teams** to ensure adherence to privacy and data protection rules, while AI developers emphasised the **importance of routine audits** (e.g., for GDPR compliance) but cautioned that excessive audits could slow down the development of AI tools unless clearer guidance is provided. Additionally, both HCPs and hospital representatives, highlighted the need for **clearer legal frameworks** that define the responsibilities and liabilities of AI users, especially under regulations like the AI Act and GDPR, while AI developers focused more on addressing barriers to market entry.

In the interviews, key topics for challenges centred around the **complexity of the regulatory landscape, the difficulty of keeping regulations up to date with innovation** and **issues related to data security**. Challenges stemming from the **complexity of the regulatory landscape** was highlighted by one AI developer from the USA, both HCPs from Denmark, all four HCPs from the UK and the EU-level organisation. Specifically, both stakeholders from the USA, noted that the regulatory landscape in the EU is more fragmented than in the USA, with regulations existing at the EU-level as well as at individual country level that are often stricter, thereby hindering dataflow between countries. The stakeholders from Europe underpinned this,

highlighting that this challenge may be further compounded by fragmentation between regulations such as the EU AI Act, General Data Protection Regulation (GDPR)[360] and the Medical Device Regulation (MDR)[361].

Additionally, the AI developer form the Netherlands, one HCP from Denmark and one HCP from the USA noted **concerns regarding clinician liability** when using AI -driven tools due to their often opaque and potentially controversial decision-making processes. Two HCPs from the UK highlighted challenges with AI deployment under GDPR. In terms of monitoring, they noted that **patient anonymisation becomes difficult** for real-time algorithm evaluation, adding that there is unclear guidance on when and how to **inform patients about the use of AI** in their treatment.

Difficulties with keeping regulations up to date with rapid technological innovation was highlighted by four HCPs[362], the hospital representative from the USA and two AI developers from the USA. Specifically, the hospital representative form the USA as well as one HCP from Denmark expressed concerns that a lag in regulation can result in the unregulated use of certain tools, particularly in high-impact scenarios.

Challenges due to strict regulations on data sharing and the lack of clear guidelines on how data can be used was highlighted by three HCPs[363] and four AI developers[364]. The EU-level organisation added that different regulations between EU Member States on data governance also create inconsistencies with how data can be used, complicating the deployment of AI solutions across borders. On an international scale, one AI developer from the USA and the EU-level organisation agreed that diverging regulatory standards can create challenges for international companies when it comes to accessing and sharing data. The AI developer explained that the varying levels of strictness to privacy laws, for example, between the EU and the USA can sometimes result in tools being trained on lower-quality data.

Challenges with data security, particularly when it comes to cloud systems were expressed by the hospital representative from South Korea, the hospital representative from Belgium as well as the HCP from the USA and one HCP from Italy. For instance, the hospital representative from South Korea pointed out challenges with maintaining data security and quality when shifting from on-premises to cloud systems. In relation, the hospital representative from Belgium highlighted uncertainty about where cloud-stored data is sent, such as whether it stays in Europe or is transferred abroad.

Legal and regulatory best practices were described by three HCPs from the UK who explained they navigate the complex regulatory landscape through **dedicated platforms** that help AI developers, adopters and the public to navigate the regulations, guidelines and incident reporting around AI for health and care. They are also using **readiness checklists** to guide technical and governance requirements. The AI developer from Japan also mentioned country-wide systems in place that **eases regulatory complexity for developers** by allowing them to eliminate the need to

360 Official Journal of the European Union (2016). Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data. Available at: Link
361 Official Journal of the European Union (2017). Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices. Available at: Link
362 One HCP from the USA and three HCPs from the UK
363 HCP from the Netherlands, Austria, one from Denmark
364 The AI developer from the Netherlands, three from the USA

obtain approval for each new version of medical device software tools. Additionally, they also highlighted processes in place to speed up the approval process for certain tools.

In terms of best practices for data sharing, the AI developer from the Netherlands stated the importance of **forming long-term partnerships** with external companies to manage data privacy effectively. From the hospital point of view, one HCP from the UK described their practice of sending developers anonymised data to assess the algorithm's performance. This maintains the confidentiality of patient information while supporting the continuous improvement of the AI system. To ease the regulatory confusion around data privacy, one AI developer from the USA recommended having **standard regulations that go across all nations** with some-specific extra regulations for states such as California.

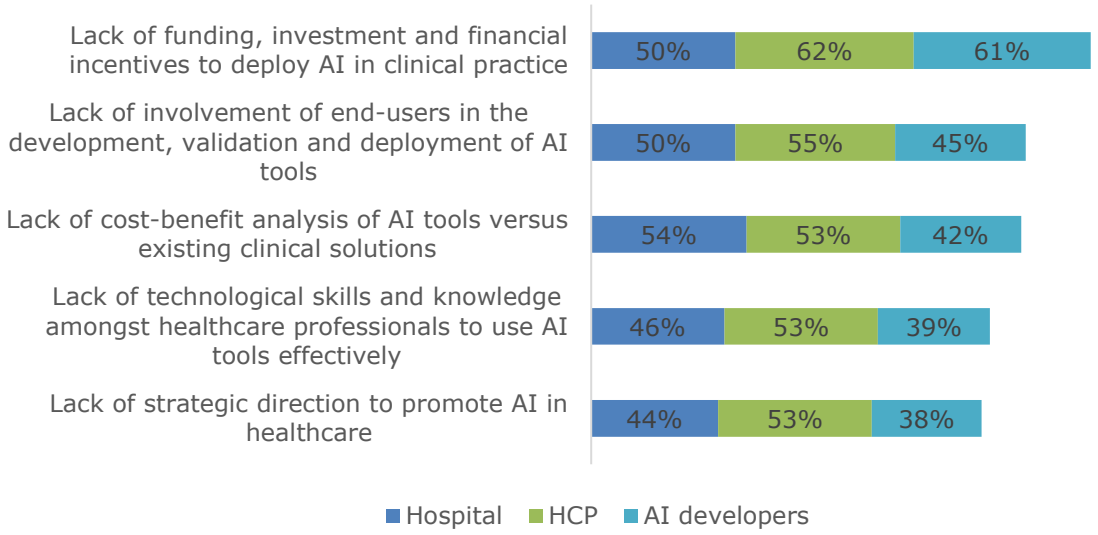
In the hospital workshop, hospital representatives highlighted the **complexity of the regulatory framework** as a barrier to effective deployment of AI. A hospital representative from Italy noted that the biggest challenge with complex frameworks, especially emerging ones like the AI Act, is **retrofitting regulatory compliance** for already-developed in-house solutions. The hospital representative from the USA added that such complex frameworks can sometimes burden and hinder advancements, like cloud migration, by **increasing costs and certification requirements.**

The hospital representatives described the practices they have adopted at their healthcare facilities to mitigate the legal and regulatory challenges. One hospital representative from Israel reported that, prior to implementation, an **internal review board (IRB) assesses the ethics and regulatory considerations** of AI tools. The representative highlighted that vendors of commercialised products that are considered medical devices must present the **necessary certifications, equivalent to the CE marking**, as a minimum requirement for deployment. Another hospital representative from Israel indicated that their healthcare facility similarly manages regulation in-house, including a **committee for cloud solutions and an IRB that reviews each new product**. A hospital representative from Italy added that before any AI project is considered, a **hospital readiness assessment and feasibility study** is conducted, along with extensive regulatory evaluation. The hospital representative from the USA reflected on the importance of **holding vendors accountable for efficacy and utility**, while also emphasising the need for a **fallback plan** to ensure safe hospital operations during outages.

10.4.5.3 Organisational and business challenges and good practices

The **survey** analysis revealed convergences and divergences in perspectives across stakeholder groups regarding the organisational and business challenges associated with AI deployment (Figure 23). Each stakeholder group highlights specific barriers and good practices, with some overlap in the key challenges they identify, while other concerns are more specific to certain stakeholder groups.

Figure 23: Organisational and business challenges believed to have a significant impact on the deployment of AI tools according to 25 hospital representatives, 47 HCPs, and 32 AI developers



The **lack of funding, investment, and financial incentives** for deploying AI tools in clinical practice is a common challenge across all stakeholder groups. This concern was raised by 62% of HCPs, 50% of hospital representatives, and 61% of AI developers. All groups agree that insufficient financial resources slow AI deployment, with AI developers highlighting the stark differences in funding availability between the USA and the EU. HCPs from countries like Portugal and Italy, along with EU-wide HCP associations based in Belgium, pointed out that the **lack of public funding** is a barrier for wider AI uptake. The shared concern among these stakeholders' points to a need for better financial models and clearer economic evaluations to demonstrate the value of AI, which is important for securing investment and achieving widespread adoption.

The **lack of involvement of end-users**—both HCPs and patients—in the development of AI tools is another point of convergence across stakeholders. HCPs and hospital representatives highlighted that the **absence of co-design and local performance testing processes** often results in AI solutions that are not aligned with clinical needs or workflows, making them difficult to integrate into daily practice. HCPs pointed out that older or less technologically competent staff members are particularly slow to adopt new technologies when they are not actively involved in their development or training. Hospital representatives agreed that **multidisciplinary collaboration and performance testing by end-users** are essential to ensure AI tools meet clinical needs. Similarly, AI developers acknowledged that a lack of user engagement leads to tools that are less usable or not trusted by HCPs. They pointed out that conservative attitudes among some HCPs further hinder adoption. This shared concern suggests a strong need for more **inclusive design and performance testing processes** that involve end-users early in development, fostering greater acceptance and integration of AI tools.

Another point of convergence is the **lack of cost-benefit analyses** of AI tools compared to existing clinical solutions. According to the survey responses, 54% of hospital representatives, 53% of HCPs and HCP associations, and 42% of AI developers reported that **failing to evaluate the economic value** of AI tools will make it harder for leaders to prioritise AI investments in financially constrained/low-resource environments and justify the high upfront costs of AI tools. AI developers also

emphasised the challenge, stating that they need to generate sufficient revenue to justify their tools, but the absence of robust cost-benefit studies complicates this effort.

Divergence emerged in views on **strategic leadership** and **AI training**. HCPs and hospital representatives emphasised **fragmented leadership in AI deployment as a barrier**, citing delays due to a lack of central coordination, redundant projects, and poorly allocated resources. Regarding **AI training**, HCPs highlighted insufficient AI training as an important barrier to effective AI use. They indicated that while some HCPs are willing to engage with AI if given the time to acquire the necessary skills, the **lack of structured training programs** hinders widespread adoption. On the other hand, AI developers placed more emphasis on the role of training programs for HCPs but were less concerned with resistance to technology. They believe that comprehensive training programs can overcome resistance and enable HCPs to use AI tools effectively. Hospital representatives also recognised training as an important component of AI adoption, with many already implementing staff training programs as part of their AI deployment strategies. This divergence suggests that while all groups see training as important, HCPs are more focused on the practical and psychological barriers to learning new technologies, while AI developers and hospital representatives view training as a more straightforward solution to the adoption challenge.

In terms of good practices, there is a general convergence across stakeholder groups. HCPs, hospital representatives, and AI developers all highlighted the importance of **testing/piloting AI tools before deployment** and ensuring they fit **seamlessly into existing clinical workflows**. **Multidisciplinary collaboration and stakeholder engagement**, including involving HCPs, administrators, and support staff, were seen as important for successful AI integration. AI developers also highlighted the importance of conducting **workflow analyses** within healthcare facilities to understand processes and redesign AI tools to fit into those workflows. These practices were described as transferrable across different regions and healthcare settings, highlighting broad agreement on the steps required to overcome organisational challenges and ensure the effective use of AI.

> *"Assessment helps justify the cost of AI technologies by demonstrating their potential benefits over traditional practices, thereby facilitating stakeholder buy-in. Aligning reimbursement models with value-based care ensures that the financial incentives for using AI tools reflect their actual contributions to patient outcomes. Having healthcare professionals validate AI systems before deployment not only ensures that the tools meet clinical needs, but at the same time helps reduce resistance. The recruitment of data scientists and AI specialists has so far enabled hospitals to tailor AI solutions to their specific clinical needs and integrate them into existing workflows. Alternative funding models, particularly for publicly financed facilities allow for continuous investment in upgrades and training."* – EU-wide **HCP association based in Belgium.**

Interviewees also reflected on several organisational and business challenges, with key themes emerging around **a lack of strategic direction by hospitals/healthcare systems, financial challenges, bureaucratic hurdles** in adopting AI tools as well as challenges related to **the lack of training and user literacy** when it comes to using AI tools.

From an AI developer point of view, **diverging strategic directions** causing challenges to AI deployment were pointed out by two developers from the USA, explaining the difficulties around meeting the often highly variable strategic directions of stakeholders. For example, healthcare systems with large budgets may be willing to experiment with innovative AI technologies, while others may prioritise tools that offer a clear return on

investment and cost-effectiveness. Additionally, one AI developer believes AI tools that provide a broad utility and ease workflows are more likely to see widespread adoption. However, one HCP from Denmark expressed concerns over having to tailor commercially available AI solutions to address specialised needs of subspecialties.

In terms of the hospital viewpoint, **differing approaches between hospital leaders and clinicians** can also cause strain when using AI tools according to the hospital representative from USA and one HCP from the UK. For example, while AI scribes can free up clinicians' time by handling note-taking, leadership might suggest using the time saved to increase patient load instead of allowing clinicians more time with their patients. Equally, one AI developer from the USA and one HCP from the USA explained that **a competitive mindset among hospital leadership** can result to a lack of collaboration and data sharing, both within and between healthcare organisations, thereby slowing down the adoption of AI solutions.

Challenges due to a **lack of strategic direction from leadership,** particularly in countries with fragmented healthcare systems was pointed out by one HCP from Denmark, one HCP from the UK and one AI developer from the USA. The HCP from Denmark and the HCP from Austria highlighted additional challenges posed by a **lack of collaboration between AI developers** and end-users as well, for example when communicating feedback and improvements to deployed solutions.

Challenges to AI adoption due to a lack of funding, investment and financial incentives were highlighted by the hospital representatives from Belgium and South Korea along with the AI developer from Japan. Five HCPs[365] along with one AI developers from the USA and one AI developer from Germany also pointed out that tight budgets and slim margins in healthcare systems make it hard to justify financial investments in AI tools. Specifically, the HCP from Austria and the HCP from Spain explained that financial constraints, particularly in public hospitals, make it challenging to translate the clinical value of AI into financial terms. Similarly, one HCP from the UK reflected that existing government funding is often used inefficiently by focusing only on implementing AI, without considering the broader needs like education, policy development, and the creation of necessary platforms to ensure effective AI integration in the healthcare system.

In terms of reimbursement, one AI developer from the USA, one HCP from Denmark and the hospital representative from Belgium also pointed out uncertainties around who should cover the costs of deploying AI, as well as **low reimbursement rates discouraging HCPs from using AI tools**, especially in radiology. The AI developer added that the financial burden and time required to conduct clinical trials further complicates AI tool adoption. One HCP from the UK agreed, stating that the long timelines needed to demonstrate the effectiveness of AI, such as in cancer treatment, make it hard for healthcare systems like the NHS to adopt AI innovations when immediate benefits are required. This leads to insufficient assessment of AI's added value compared to existing practices.

Inefficiencies in selecting and deploying AI solutions due to bureaucratic hurdles were mentioned by the HCP from Austria and the HCP from Spain from a hospital perspective. In terms of vendor selection, the HCP from Austria explained that different companies offer various financial models for AI tools, which makes it difficult for departments to standardise contracts. Following vendor selection, the HCP from Spain added that legal agreements for initial pilots as well as obtaining ethical

365 HCPs from Spain, one from Denmark, one from UK, one from US

committee approval, which can take approximately two years in Spain, are time-consuming for departments to negotiate and can cause delays for AI adoption. From the perspective of AI developers, one developer from the USA stated issues with the lack of support from professional societies and associations, which often avoid endorsing specific vendors to remain neutral. They stated that this neutrality can leave healthcare providers uncertain about which AI tools to deploy, thereby slowing down the deployment process. Another developer from the USA highlighted bureaucratic resistance from hospital administrators, who may refuse or delay the deployment of tools, even when it has been recommended by their healthcare professionals.

A lack of AI scientists and leadership in data literacy complicating the integration of AI was perceived by six HCPs[366] and one AI developer from Germany, concluding that without leaders who are well-versed in data-driven decision-making, it becomes difficult to coordinate AI efforts effectively. Another HCP from the UK noted that there is a lack of mandatory training and outcome checks for AI products, with minimal training required for the use of AI tools and sparse post-market surveillance.

In terms of good practices, hospital representatives, HCPs and AI developers shared several practices to mitigate organisational and business challenges related to AI deployment. These converged around highlighting the importance of collaboration, adopting a multidisciplinary approach, providing training for hospital staff as well as practices to mitigate financial challenges. The **importance of collaboration** for successful AI deployment in healthcare systems was emphasised by one HCP from Italy, one HCP from Denmark and one hospital representative from Japan. One AI developer from the USA added that it is important to collaborate with healthcare professionals who do not have a financial stake in the company, highlighting how they worked closely with urologists during the development of their AI tools. **On a networking level**, the HCP from Denmark participates in the **European University Hospital Alliance[367],** where specific forums are held to discuss key parameters related to AI implementation. One HCP from the USA also highlighted how major hospitals often work together in networks that facilitate collaboration and knowledge-sharing. They additionally noted the importance of public-private partnerships in fostering innovative patient care in a way that balances the interests of developers with societal benefits.

Adopting a **multidisciplinary approach** when deploying AI tools across healthcare systems was also recommended by two HCPs from the USA and one AI developer from the USA. Some centres integrate AI solutions through a comprehensive strategy involving multidisciplinary teams, including IT experts, data engineers, clinicians, and financial analysts.

Three HCPs from the UK and one HCP from the USA described **digital literacy efforts and various training programmes** for the use of AI tools. One HCP from the UK also explained that there is growing consideration for integrating AI training into medical curricula at both the undergraduate and postgraduate levels. These courses would include mandatory AI awareness training alongside existing modules like information governance and data protection. With reference to expert knowledge, the hospital representative from the USA sated that **investing in a team of technological leads** had been a key accelerator for AI deployment in their hospital.

To **mitigate financial challenges**, one HCP from the USA reflected on the benefits of segmenting AI projects into smaller, manageable use cases that can deliver faster

366 HCPs from the Netherlands, Austria, one from Denmark, two from the USA, one from UK
367 European University Hospital Alliance. Available at: Link

returns. Two AI developers from the USA also described measure and demonstrating the AI tool's impact across three key areas: clinical value (improved patient outcomes), operational efficiency (workflow improvements and time savings), and financial impact (cost-effectiveness). One HCP from the USA concluded that financial support from management contributes to the success of AI programmes, explaining that strong backing from top leadership is critical for building the necessary infrastructure for AI solutions.

The hospital representatives in the hospital **workshop** provided more specific challenges. Two hospital representatives from the USA described **challenges in recruiting and affording the right talent**. For instance, one representative indicated that the starting salary for a 23-year-old computer science graduate is considerably high, making it unaffordable for most hospitals. Additionally, one hospital representative from the USA highlighted the challenges in **defining and quantifying the return on investment (ROI).** The representative described that this metric is highly dependent on the healthcare system– public, private, not for profit etc which results in complexities in terms of how it can be evaluated. Furthermore, one hospital representative from Israel pointed out that **scaling AI solutions beyond niche applications, such as imaging and digital pathology, to a broader organisational level** is also a challenge. The representative explained that hospitals struggle to justify the ROI to the management and to manage the dozens of deployed models while integrating them into existing risk and quality assessment frameworks. This transition represents a new phase in AI deployment that healthcare facilities are still navigating.

Hospital representatives shared several best practices to mitigate organisational and business challenges related to AI deployment. A hospital representative from the USA emphasised the importance of having **multidisciplinary teams, operational readiness, and ensuring that data is prepared**. The representative described a **playbook** they created for late adopters to learn from early adopters' experiences. In addition, **department leaders** in the USA **are tasked with identifying AI use cases**, which are then centrally evaluated through a **business case process** to ensure **alignment with operational capabilities**. Another hospital representative from the USA highlighted that, rather than focusing on billing, they prioritised **efficiency gains from AI tools** and **warned against billing codes incentivising inappropriate AI tool use**. In terms of ROI, the representatives from the USA and Italy both stressed the importance of **learning from past implementations** and noted that **efficiency-focused AI tools are less impacted by regulations**, allowing faster deployment.

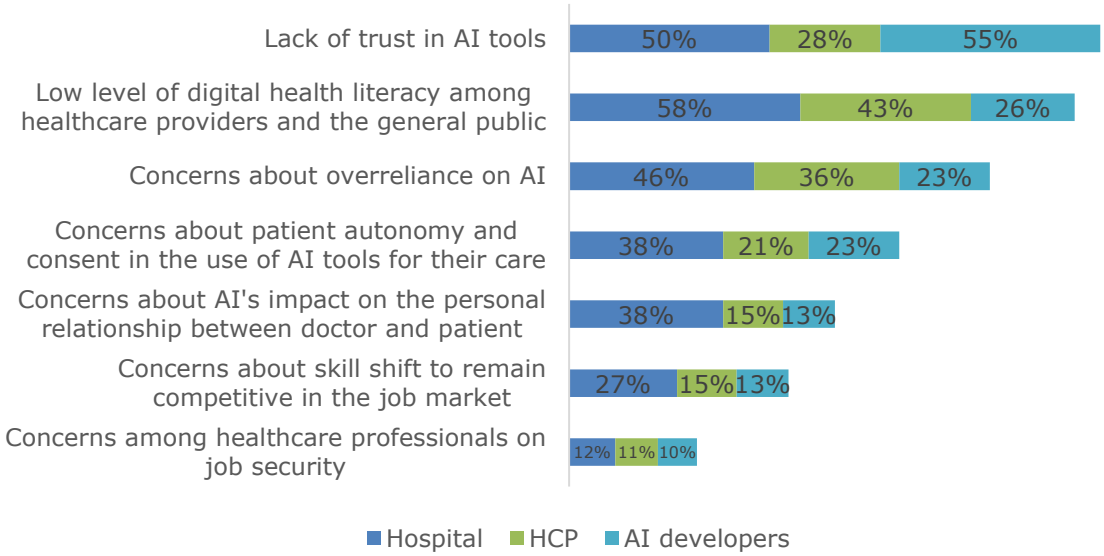
A hospital representative from Israel pointed to the **importance of having an AI champion within departments** to ensure effective deployment. The representative from the USA highlighted that their hospital took a holistic change management approach, involving business stakeholders, users, healthcare professionals, and nurses to foster **a person-centred understanding** of how AI will fit into workflows. The representative from the USA also promoted **internal innovation competitions**, where HCPs submit clinical needs for investigation. Finally, the hospital representative from Israel explained that **hospital advisory boards**, representing physicians, nurses, and researchers, can **gather input using a scoring system** to prioritise needs based on patient impact and urgency.

10.4.5.4 Social and cultural challenges and good practices

The **survey** provided converging and diverging perspectives across stakeholder groups on the social and cultural challenges affecting the deployment of AI in healthcare. Across HCPs, hospital representatives, and AI developers, several shared concerns emerged,

particularly regarding digital literacy, trust in AI, and concerns about overreliance on AI technologies (Figure 24).

Figure 24: Social and cultural challenges believed to have a significant impact on the deployment of AI tools according to 26 hospital representatives, 47 HCPs, and 30 AI developers



A shared concern is the **lack of trust in AI tools was** shared by hospital representatives (50%) and HCPs (28%) highlighting their concerns about the safety and transparency of AI in decision-making. Additionally, 59% of AI developers recognised that **trust issues slow AI adoption** describing that the lack of trust can lead to resistance to using these technologies. Patients may opt out of AI-assisted treatments or diagnostics, which could affect the overall effectiveness of their care and potentially limit the benefits that AI could offer.

Another area of convergence is the **low level of digital health literacy** among HCPs and the general public. In the survey, 43% of HCPs, 58% of hospital representatives, and 27% of AI developers agreed that limited digital literacy hinders effective AI deployment. **Upskilling staff and improving digital literacy** were seen as key to integrating AI in clinical practice, with continuous education and AI-related content in medical curricula identified as important steps. HCPs and hospital representatives also indicated that **older HCPs and patients may struggle with new technologies,** highlighting the need for targeted education efforts in these populations.

Divergence occurs in the perception of overreliance on AI and the implications this might have on healthcare delivery. While 46% of hospital representatives and 36% of HCPs identified it as a barrier, indicating that AI could undermine critical thinking and clinical judgment, only 23% of AI developers viewed it as a challenge. AI developers generally see AI as a tool to enhance decision-making, with less concerns on the risks of overreliance.

There is divergence in the perception of AI's effect on doctor-patient relationships. HCPs and hospital representatives are split on this issue, with some viewing AI as a threat to the personal connection between doctors and patients, while others see AI as a tool that can improve care by optimising time and resource allocation. There is also variation in how these challenges are perceived across regions. Some AI developers, particularly those from countries like Italy, Sweden, and Germany, noted that regional differences

in digital literacy, regulatory environments, and the level of trust in technology can influence the adoption of AI. For example, in regions that deal with vulnerable populations, such as migrants or the elderly, concerns about doctor-patient relationships and consent may be more pronounced, adding complexity to AI deployment.

In terms of good practices, there is a consensus on the **need for comprehensive education and training to tackle social and cultural challenges**. Both hospital representatives (57% of respondents) and HCPs (65% of respondents) emphasised the **importance of continuous learning and targeted training programs** to upskill HCPs and improve digital literacy.

> *"By incorporating AI and related technologies into medical education, you prepare future healthcare professionals not only to understand and effectively use AI tools in their practice, but most importantly to accept them. This approach helps overcome resistance due to unfamiliarity or fear of AI by embedding technological literacy from the start of their careers. Likewise, when all stakeholders understand how AI can improve patient outcomes, reduce workload, and enhance decision-making, it reduces fear and resistance. If we would like to prepare members of the health and care workforce for todays and tomorrow's challenges and opportunities – investing in skills is a must by updating university curricula, offering training programmes."* – EU-wide **HCP association based in Belgium.**

In the **interviews**, the key social and cultural challenges highlighted by stakeholders related to user's **resistance to change and lack of trust** as well as an **overreliance on AI's outputs**. On the part of healthcare professionals, the HCP from Italy along with one HCPs from the USA and the hospital representative Japan agreed that resistance to change can be compounded by the fear created due to uncertainties about how AI might affect healthcare roles, such as concerns about job loss. The hospital representative from Belgium added that fear over AI tools becoming decision-makers rather than being consultative tools can also cause reluctance in adoption by clinicians.

On the part of patients, the hospital representative from the Netherlands observed patient discomfort with a recently deployed digitalised therapy administration system, while the hospital representative from Japan and one AI developer from the USA noted **patient resistance, particularly when it comes to the uploading of AI data to the cloud**. Conversely, one HCP from the UK felt that there is a relatively high level of trust among patients for the use of AI within healthcare. Two HCPs[368], the hospital representatives from the USA and South Korea as well as one AI developer from the USA believed that **trust issues are more problematic among HCPs** than patients because they remain sceptical of the quality of AI tools. Similarly, the AI developer from Japan along with the hospital representative from the USA highlighted that there is a lack of willingness to change, especially among older HCPs. Nevertheless, the AI developer from Japan reflected that this resistance is slowly starting to shift as digital technology is becoming more widespread and accepted in healthcare.

Six HCPs[369] and two AI developers[370] also reflected that a lack of trust in AI is often compounded by **a lack of explainability** of AI's outputs, especially when it differs from human choices. Overall, the AI developer from the Netherlands pointed to the lack of requirements for explainability, stating that there are no obligations at present for vendors to provide detailed information about how an AI tool was tested, who conducted the testing, or other in-depth analyses. Nevertheless, they stated that in resource-

368 HCP from Austria, one HCP from Denmark, two from Italy
369 HCPs from the US, one from the UK, Austria, one from Denmark
370 AI developers from the Netherlands, one from the US

limited areas, traditional trust issues may be set aside in favour of adopting the most accessible AI solution, as it is better than having no solution at all.

One HCP from the UK, the HCP from Austria and the AI developer from Germany reflected that **overreliance on AI could lead to automation bias** and overshadow human expertise, particularly among younger clinicians, who may become too reliant or trusting of AI tools. One AI developer form the USA agreed with this sentiment, concluding that people tend to trust and adopt technologies that offer clear benefits more quickly.

To address challenges in AI transparency and trust, one AI developer from the USA, the hospital representative from Japan, one HCP from the UK and the EU-level organisation highlighted the importance of **clearly communicating with stakeholders**, including on the benefits of AI technologies to patients as well as how their data is managed. One HCP from the USA referred the best practices adopted by leading AI hospitals for communicating with their stakeholders about responsible AI adoption and implementation. These organisations clearly communicated their goals, benefits, and operational changes associated with AI integration to all stakeholder as well as shared their processes publicly, pointing out what they did, where they made mistakes, and where they could have improved for other centres to learn from those mistakes and best practices. To alleviate automation bias, one HCP from Austria explained that educating radiologists on the role of AI tools as supportive tools rather than definitive tools could be helpful.

The **low level of digital literacy** among HCPs and the public was a key challenge during the hospital workshop. A hospital representative from Israel emphasised that **limited AI literacy among HCPs** can lead to two issues: **reluctance to use AI out of fear** and **overreliance on AI technologies without proper education**. The representative explained that using AI without adequate training not only limits the value extracted from these technologies but also poses potential risks to patient safety.

Hospital representatives reported several social and cultural practices to address the challenges associated with AI deployment in healthcare. A hospital representative from Israel reported that the **proximity to an innovation ecosystem and local leading start-ups** might have been an accelerator for AI adoption in Israel. The representative added that for HCPs to use AI tools effectively, there must be a **degree of explainability tailored to their needs**. HCPs do not necessarily need to understand the complex computational processes behind algorithms but should be able to **understand what specific features resulted in the AI algorithms decision.** This approach fosters trust, promotes responsible usage, and establishes a common understanding between data scientists, engineers, and HCPs. A hospital representative from the USA echoed the importance of **user-tailored explainability** and highlighted **fellowship programs.** These programs aim to onboard a balanced cohort of 50% medical doctors engaged in research and 50% data scientists and computer scientists, fostering collaboration and improving AI integration into clinical practice. Lastly, this representative reported that this is a **cultural shift,** and the hospital has recently **recruited individuals to have a specific focus on data literacy, culture, and policy to champion the transformation**.

10.4.5.5 **Generative AI challenges and best practices**

The assessment of challenges affecting the deployment of generative AI tools in clinical practice reveals both convergence and divergence among HCPs, hospital representatives, and AI developers/associations according to the survey responses. All

stakeholder groups highlighted that generative AI tools pose distinct issues compared to traditional AI tools, particularly concerning **reliability, transparency, and ethical implications**. However, their perspectives differed on the specific nature of these challenges and the best ways to address them.

An area of convergence across the groups is the **concern about hallucinations**—AI-generated outputs that appear valid but are factually incorrect—and the low explainability of AI decisions. HCPs (43% of respondents) pointed out that **hallucinations and poor explainability are major challenges**, as the reliability of generative AI outputs is not yet guaranteed. This sentiment was echoed by hospital representatives (49% of respondents), with one from the **Netherlands** highlighting the importance of validating AI-generated information, as it fundamentally differs from traditional AI, which relies on existing patient data. Similarly, AI developers also **identified hallucinations as a key issue**, particularly with LLMs, as generative AI lacks the long-standing reliability mechanisms found in more traditional machine learning AI tools.

Another point of convergence across stakeholders is the **shared concern over data privacy and protection**. Both HCPs and hospital representatives recognised that generative AI, which **often requires large datasets for training**, must navigate the challenge of protecting **patient-identifying data (PID)**. HCPs highlighted that generative AI models might struggle with privacy concerns, particularly in cases where models are trained on limited or sensitive data. Hospital representatives highlighted the risk of personal data leakage and noted that generative AI might require local data processing to ensure security. AI developers also acknowledged that generative AI tools, many of which are designed for public datasets, face more challenges in healthcare environments due to the sector's strict data protection requirements.

A divergence appears, however, in how these groups perceive the **technological challenges**. HCPs and hospital representatives primarily focused on the practical implications of **AI-generated outputs in clinical contexts.** For example, HCPs expressed **concerns about generative AI's ability to accurately process medical information**, particularly given the variations in free-text writing, grammatical inconsistencies, and differing word meanings in medical documents. AI developers were more focused on the **broader technical limitations** of generative AI, such as its **lack of reliable error-prevention mechanisms** compared to traditional AI tools.

Legal and regulatory challenges were another area of divergence, where AI developers emphasised the **complexities of navigating intellectual property (IP)** rights, which were not a major concern for **HCPs** or **hospital representatives**. AI developers were particularly concerned with **the lack of clarity around IP protection for AI elements** such as training data, model outputs, and model improvements. On the other hand, HCPs and hospital representatives focused more on the **liability and accountability concerns associated with generative AI in clinical practice**.

In terms of good practices for deploying generative AI, only a small portion of HCPs (22% of 51 respondents) and hospital representatives (29% of respondents) reported knowledge of good practices. Among those who did, the focus was on **avoiding the inclusion of personal identifiable information in software outside the EHR system** and on **training and fine-tuning generative AI models with specific medical contexts** to improve their relevance in clinical settings.

10.4.6 Impact of the current regulatory landscape

On the impact of the current regulatory landscape within the EU, insights were gathered from hospital representatives, HCPs, AI developers/researchers, and EU regulatory experts through the surveys, the AI deployment journey workshop, the regulatory workshop, and the interviews.

From the survey, an area of convergence among the stakeholder groups is the **increased workload and resource demands** imposed by the **EU AI Act**. HCPs (87% of 30 respondents) believe the AI Act addresses key challenges in healthcare, such as **patient protection**, but 72% (25 respondents) indicated that it also adds new barriers, including **additional training requirements for accountability standards** and the **need for more risk management protocols**. Hospital representatives indicated that only 23% (6 out of 25 respondents) feel **prepared for the obligations introduced by the AI Act**, expressing concerns about the **financial and logistical burden of compliance, including difficulties in finding skilled personnel** and the **need for investments in infrastructure and training**. AI developers noted the **administrative burden of aligning with both the AI Act and the MDR,** with some finding the AI Act's impact marginal if they are already familiar with the MDR.

Training and compliance support emerged as another shared concern. HCPs suggested the **implementation of short, accessible training programs** that fit into their busy schedules and **proposed the establishment of peer-to-peer support networks** and **collaboration with legal experts**. Hospital representatives echoed the **need for government-accredited auditors** and **increased access to training resources**. **AI developers** who are prepared 47% of 34 respondents) for the AI Act have begun **creating frameworks for early identification of AI risks** and **conducting workshops to educate teams on compliance.**

The area of divergence was reported in how each stakeholder group perceived specific challenges introduced by the EU AI Act. HCPs expressed frustration over issues related to **accessing and assessing AI training data**, **uncertainties about HCP training requirements**, and the **extent of patient consent needed for AI use**. Hospital representatives focused on **financial and logistical compliance challenges**, with a hospital representative from Sweden noting **a lack of funding for legal advisory roles** and **difficulties adapting the AI Act to healthcare settings**, and hospital representatives from Finland and the Netherlands echoing this difficulty in adaptation and drawing parallels to earlier challenges with the GDPR. AI developers prioritised **legal and technical aspects**, highlighting challenges related to **intellectual property protection, transparency, and synthetic data usage.**

Another point of divergence relates to the **readiness for the AI Act's implementation**. Only 23% of hospital representatives (6 out of 25 respondents) reported feeling **prepared for the obligations introduced by the EU AI Act**, with only a small proportion taking concrete steps like **implementing oversight protocols** and **staff training**. However, the majority face **resource shortages** and **lack clarity on how to meet the Act's requirements**, particularly in risk assessment and data quality evaluation. In contrast, among **AI developers**, 47% (16 out of 34 respondents) are **prepared for the implementation of the AI Act and the associated obligations**, especially those experienced with MDR/IVDR compliance, viewing the AI Act as an extension of their current efforts. Some **AI developers** indicated they had already integrated transparency measures and ethical frameworks, though others remain in a transition phase, delaying new tool deployment until they fully understand the AI Act.

Regarding the **European Health Data Space (EHDS) regulation**, there is a lack of consensus on its effectiveness on the deployment of AI tools in healthcare. While 71% (18 out of 25 respondents) of hospital representatives are aware of the EHDS, only 48% (12 out of 25 respondents) believe it addresses challenges in deploying AI tools. On the contrary, AI developers have not expressed any concerns about the EHDS in relation to AI deployment, likely because their focus is more on regulatory frameworks like the AI Act and MDR, which have more direct implications for their operations.

In the **interviews**, four EU-level stakeholders (two HCPs[371] and two AI developers[372]) along with two AI developers from the USA and one hospital representative from the USA discussed the implications of the EU AI Act on the AI landscape in healthcare. One HCP from Italy and the AI developer from Germany first stated the benefits of the AI Act noting that it provides a clear regulatory framework for AI technologies. They emphasised that it helps address accountability by defining responsibilities when issues arise and brings a strong focus on data security and patient privacy.

Nevertheless, all four EU-level stakeholders also noted that the **initial regulatory transition to comply with the AI Act may present difficulties**, for example, when it comes to adapting existing processes to meet new regulatory requirements. As such, one HCP from Denmark surmised that the complex regulatory demand coupled with a lack of guidance risk driving AI developers towards regions like the USA, where regulations are more lenient. To help mitigate these challenges, one HCP Italy suggested that organisations and manufacturers already integrate compliance with the AI Act into their development processes from the outset.

The AI developers from the Netherlands and USA, along with a hospital representative from the USA expressed the need to **find the balance between regulations ensuring safety without hindering innovation**. To enable this, two AI developers from the USA called for a focus on simplicity and future proofing in regulations, for example, proposing deeper collaboration with regulators in order to ensure regulations are conducive to innovation while maintaining safety and effectiveness in AI deployment.

In terms of the hospital workshop, the participants provided insights into the regulatory landscape for AI in healthcare across different countries, highlighting varying levels of development and implementation of regulations. The hospital representative from Italy reported that the **compliance landscape** for the AI Act mirrors the initial challenges faced during the transition to GDPR compliance. The representative explained that, while there was confusion during the transition period, GDPR compliance eventually became integrated into existing processes.

As for the regulatory workshop with EU regulatory experts, several key challenges regarding the deployment of AI in healthcare were discussed. These included the complexity of the regulatory approval process for AI-based technologies, variation in AI performance across healthcare settings and populations, the lack of accountability and liability frameworks for AI errors, concerns about data privacy and cyberattacks, and the impact of AI on the doctor-patient relationship and the accuracy of AI decisions.

The challenge of the **complexity of the regulatory approval process for AI-based technologies** was discussed. According to the regulatory experts, the regulatory sandboxes for real-world testing under compliance introduced in the AI Act (**Article 57[373])**, along with the MDR, help address this challenge. Additionally, the experts added that the AI Act, sets market entry requirements and clarifies interactions with clinical

371 One HCP from Italy, one from Denmark
372 AI developers from Germany and the Netherlands
373 Article 57 of the AI Act introduces regulatory sandboxes to allow real-world testing of AI systems while ensuring compliance with regulations.

guidelines (**Article 8**[374]). However, despite those provisions, the regulatory experts identified persisting gaps, including the **discrepancies between the MDR and AI Act** regarding clinical investigations and certification of solutions before market entry, **concerns about the interpretation of some regulations** (e.g. confusion around the research exemptions for medical devices), the **complexity of MDR regulation for in-house solutions**, and **the high costs and resource demands associated with regulatory sandboxes**. Furthermore, the regulatory experts expressed **uncertainty about the EU's legal preparedness** and **whether sandboxes will facilitate AI acceptance** after CE[375] marking and deployment.

The **variation in AI performance across different healthcare settings and populations was** the second challenge discussed. According to the regulatory experts, provisions mandating a comprehensive risk management system (Article 9[376] of the AI Act), the stringent data governance for high-risk AI systems (Article 10[377]), the provisions on ensuring the accuracy, robustness, and cybersecurity of AI systems throughout their lifecycle (Article 15[378]), and the transparency and performance metrics requirements (Article 13[379]) partly address this challenge. Despite those efforts, the regulatory experts highlighted that there is **a lack of clear guidance** on how to manage AI performance variations across different populations and settings, raising concerns about **potential healthcare disparities.** They also discussed the **lack of alignment** between the GDPR and the AI Act in addressing bias, particularly **contextual bias**, and noted **insufficient data availability** for certain populations, which would further increase the disparities.

In discussing the **lack of accountability and liability** frameworks for AI errors, the regulatory experts acknowledged that the AI Act, which mandates a quality management system (QMS) for high-risk AI systems (Article 17[380]), as well as the Product Liability Directive, partly address this challenge. Nevertheless, gaps were identified, particularly inconsistencies across Member States regarding **liability laws**, which create confusion and hinder HCPs from using AI tools due to **fear of legal repercussions**. The regulatory experts also indicated a **lack of clarity** on the division of responsibilities at different stages of AI deployment and **inconsistencies** between the AI Act and GDPR regarding the role of the data controller.

Data privacy and cyberattacks were also discussed as pressing concerns. The provisions of the AI Act, addressing cybersecurity (Article 15), testing **in regulatory sandboxes (Article 57)**, informed consent (Article 61[381]), and the right to an explanation (Article 86[382]) partly address these concerns. However, the regulatory experts raised issues regarding the interaction between frameworks such as the GDPR, MDR, and EHDS. Specifically, they pointed to **discrepancies** between the AI Act, which

374 Article 8 sets out market entry requirements and clarifies interactions with clinical guidelines for high-risk AI systems.
375 CE marking (Conformité Européenne) certifies that a product meets EU safety, health, and environmental standards for sale within the European Economic Area.
376 Article 9 mandates that high-risk AI systems must implement a risk management system to identify and mitigate potential risks.
377 Article 10 outlines the need for proper data governance and the use of high-quality datasets for high-risk AI systems.
378 Article 15 ensures that AI systems maintain accuracy, robustness, and cybersecurity throughout their lifecycle.
379 Article 13 mandates that AI systems provide clear and transparent information on their capabilities, performance, and limitations.
380 Article 17 mandates that developers implement a quality management system (QMS) for high-risk AI systems.
381 Article 61 ensures that informed consent is obtained for real-world testing of AI systems on patients.
382 Article 86 grants patients the right to an explanation regarding the role of AI systems in decision-making processes.

supports comprehensive patient profiles, and GDPR, which emphasises **data minimization to protect patient privacy**. This misalignment creates **uncertainty** about the extent of data protection required**,** especially in cases involving EHRs.

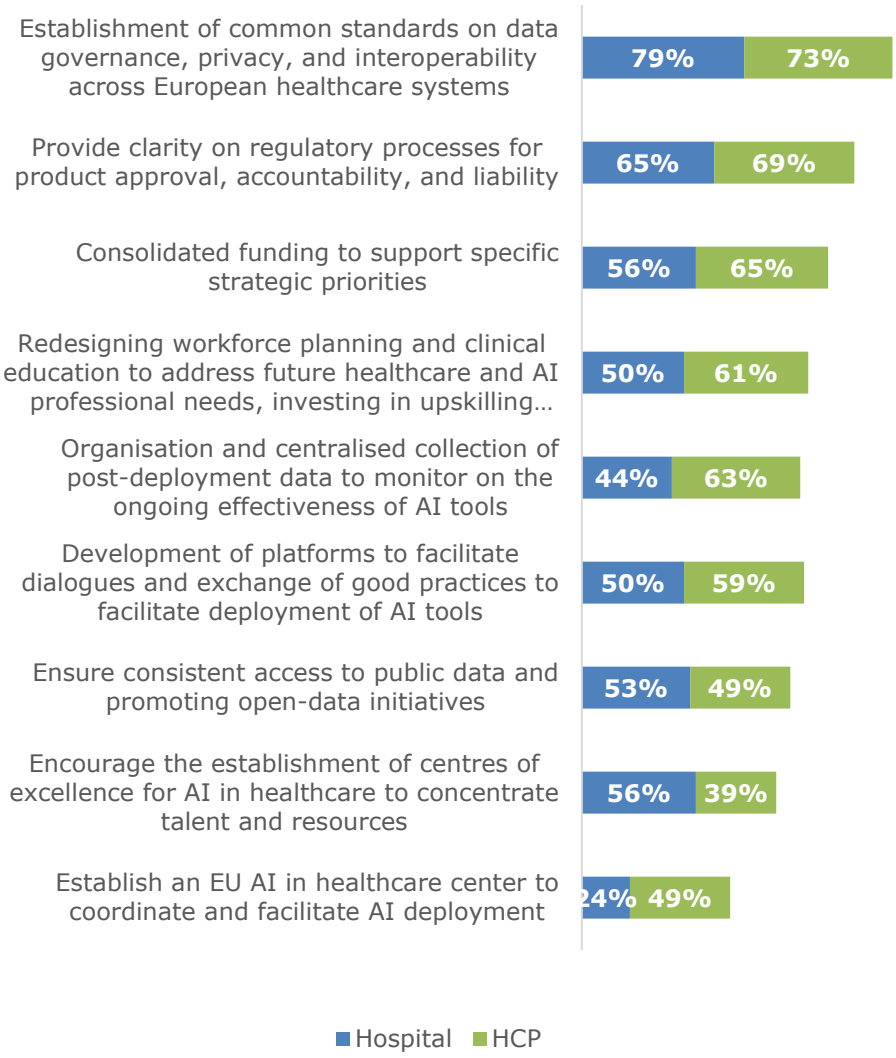
Concerns about **AI's impact on the doctor-patient relationship** were also raised. The provisions of the AI Act, which mandates transparency on AI system capabilities and limitations (Article 13), emphasises human oversight (Article 14[383]) and **requires qualified personnel** to oversee AI deployment (Article 26[384]), were designed to safeguard patient trust. While the regulatory experts acknowledge those provisions, they highlighted ongoing gaps, particularly regarding **informed consent**. There is still uncertainty about when and how patients should be informed about the use of AI tools, how much detail to provide, and the alternatives available. Regulatory experts explained that the misconception that the more impactful the AI tool, the more information needs to be disclosed can sometimes overwhelm patients and cause a **loss of trust**. Furthermore, differences in Member State requirements on **informed consent** make it challenging to provide consistent levels of explanation without overwhelming patients with technical details.

10.4.7 Considerations for future actions at EU level to support AI deployment

This section outlines considerations for future actions —both regulatory and non-regulatory that could be implemented at the EU level to support the deployment of AI tools in healthcare. Based on the **survey** responses, there was both convergence and divergence in the complementary actions with input from 35 hospital representatives and 52 HCPs (Figure 25).

383 Article 14 mandates human oversight for high-risk AI systems, allowing healthcare professionals to intervene when necessary.
384 Article 26 requires that qualified individuals oversee the deployment and monitoring of AI systems in clinical settings.

Figure 25: Considerations for future actions to facilitate the deployment of AI in healthcare according to hospital representatives and HCPs.



10.4.7.1 Common standards on data governance, privacy, and interoperability

- 73% of HCPs emphasised that **harmonised standards across European healthcare systems** are important for integrating AI tools without compromising data security or patient privacy.
- 79% of hospital representatives reported that **standardised data practices** would ease AI deployment across diverse platforms and healthcare systems.
- HCPs from Italy, Denmark and the UK, an AI developer from the USA, and the EU level association suggested creating a **centralised data platform** with standards in place to ensure **interoperability, data quality and performanc**e.
- Regulatory experts highlighted the importance of having clear interoperability standards to allow for the seamless integration of AI tools.
- A hospital representative from Belgium highlighted the importance of establishing cloud-based data-storage locations within Europe to facilitate data storage and sharing capabilities.

10.4.7.2 Clarity on regulatory processes

- 69% of HCPs and 65% of hospital representatives highlighted the importance of having **clear guidelines** for product approval, **accountability, and liability** to ensure that AI tools can be implemented without ambiguity regarding their legal and ethical implications.
- AI regulatory experts highlighted the importance of harmonising existing regulatory frameworks, such as the EU AI Act and the Medical Device Regulation (MDR), without introducing additional complexities by providing **clear and streamlined processes** to reduce uncertainty and foster more confidence in AI adoption.
- An AI developer and a hospital representative from Japan advocated for **better coordination** between regulatory frameworks.
- **Educational initiatives** to better navigate regulations was suggested by one HCP from Denmark, the hospital representative from Belgium and one AI developer from the USA.
- The EU-level association and regulatory experts suggested establishing **regulatory advisory bodies** to guide professionals through the regulatory framework.
- An HCP from Netherlands proposed having specialised **bodies** to provide stages and checkpoints to ensure a tools' usefulness and public acceptance.
- Regulatory experts proposed providing clear guidance and coordination at the EU level through **"regulatory sandboxes".**
- An AI developer and an HCP from the USA recommended developing a **checklist of regulations** along with **guidelines** for hospitals that want to develop AI tools.
- An AI developer and an HCP from the USA emphasised the importance of strong **public-private relationships**, for example with regulatory authorities to facilitate a bi-lateral flow of information between regulators and technology developers.

10.4.7.3 Consolidated funding and guidelines on reimbursement mechanisms

- 65% of HCPs and 56% of hospital representatives called for **targeted funding** to prioritise AI-related projects, particularly those that focus on healthcare-specific challenges.
- A hospital representative from Belgium, an AI developer from Japan and an HCP from Denmark proposed g**overnment reimbursement mechanisms**, for example, through higher payments or tax incentives for hospitals that deploy AI tools.

10.4.7.4 Common performance testing studies to assess variations in performance

- An HCP from Italy and the hospital representative from Belgium called for a **common performance testing framework** for AI solutions, particularly in areas like radiology and mammography, to enable the comparison of effectiveness, value, and efficiency gains across different AI products.

10.4.7.5 Centralised post-deployment monitoring of AI tools

- 63% of HCPs and 44% of hospital representatives highlighted the importance of post-deployment monitoring mechanisms through **centralized data collection to assess the ongoing effectiveness of AI tools.**
- Three HCPs[385] and one AI developer form the USA also recommended the strengthening of **testing and monitoring mechanisms** of AI tools post-deployment.
- A hospital representative from the USA highlighted the importance of having centralised **monitoring and quality assurance plans** to assess AI performance drifts post-deployment.

10.4.7.6 Redefining the healthcare workforce and promoting collaboration

- The HCP from Austria and one HCP from the USA emphasised the need to **re-design hospital workflows and introduce new roles**, such as data scientists and IT experts, within hospitals to enhance the understanding and transparency of AI tools and facilitate their integration into daily clinical practice.
- Four HCPs[386] advocated for **multidisciplinary collaboration** to better guide AI development. The EU-level organisation and one hospital representative from Italy emphasised the need for **multidisciplinary teams** that include data scientists and data engineers to facilitate the transfer of information from developers to end-users.
- HCPs from Austria and the UK, and a hospital representative from Italy highlighted the need for the **establishment of clinical champions** who can mediate between developers and healthcare professionals, speaking the language of both to ensure smooth communication and collaboration.

10.4.7.7 Centres of excellence for AI in healthcare

- 56% of hospital representatives indicated the importance of such centres to concentrate talent and resources, providing a dedicated space for research, training, and collaboration on AI-driven healthcare innovations.
- The EU-level organisation, one AI developer from the USA and the hospital representative from Belgium explained that **actively involving HCPS both in the development and deployment of AI**, listening to their concerns, and taking their feedback seriously helps foster trust between physicians and the AI development team.
- One HCP from Italy also suggested **involving patients alongside HCPs** in research projects to build awareness, acceptance and trust.
- An HCP from the UK suggested that national funding for AI centres, such as centres of excellence, should include requirements for training, post-deployment support, and performance testing protocols.
- Three HCPs[387], three hospital representatives[388] and the AI developer from Germany recommended EU-level guidelines to facilitate **the exchange of best**

385 The HCP from Austria, one from the UK, one from the USA
386 HCPs from the Netherlands, Austria, one from Italy, one from the USA
387 HCPs from Spain and one from the UK, one form US
388 Hospital representatives from South Korea, Belgium and Italy.

practices and experiences across different institutions to enhance the understanding and effectiveness of AI solutions.

- An HCP from the UK, one HCP from Italy, the hospital representative from the USA and one AI developer from the USA proposed creating **centres of excellence** to guide the deployment of AI, providing expert support to healthcare organisations for example with challenges related to regulation and capabilities.
- HCPs from Denmark and the USA, and an AI developer from the USA emphasised the importance of developing **roadmaps** to **guide organisations** through digital literacy and technology deployment via these centres of excellence.

10.4.7.8 Clear transparency and accountability mechanisms

- Regulatory experts stressed the importance of ensuring that the roles and responsibilities of AI usage in clinical practice are clearly defined.
- Regulatory experts highlighted the need for **transparency in the training data** used for AI models, especially in large language models (LLMs) via **clear documentation of the datasets and methodologies used**, to ensure regulatory compliance and build trust among healthcare providers and patients.
- One HCP from Denmark and one from Italy and two AI developers[389] suggested **providing clear transparency and explainability guidance** to help users understand how AI reaches clinical decisions.

10.4.7.9 Education and training programs to improve digital health literacy

- Regulatory experts highlighted the importance of training programs that are regularly updated to reflect the latest advancements of AI to ensure technological competence.
- An AI developer from Germany pointed out the importance of **training healthcare professionals** to use the AI solutions effectively, while one AI developer from the USA also noted the importance of in-person training during AI product demos at hospitals.
- Two HCPs from the UK, hospital representatives from Israel and the USA, and an AI developer from the USA proposed instating **continuous training programmes** for individuals, companies, and hospitals on AI solutions to ensure accountability, ongoing learning across the healthcare system and bolster confidence in adoption.
- Two HCPs[390], the hospital representative from the USA two AI developers[391] highlighted the need to **educate the population and HCPs** on AI's role as a supportive tool for augmentation, rather than replacement to improve trust in AI tools.

10.4.8 Conclusions

AI holds significant promise in addressing key healthcare challenges such as administrative burden, workforce shortages, and the need for improved technology infrastructure. Stakeholders agree that AI can streamline administrative tasks, reduce non-clinical workloads, and enhance overall workflow efficiency, allowing healthcare

389 AI developer from the Netherlands, one from the US
390 One HCP from UK, one from Denmark
391 AI developers from Netherlands and Germany

providers to focus more on patient care. AI's role in diagnostics, particularly in fields like radiology and pathology, is widely recognised for improving accuracy and speeding up results, which helps to alleviate the impact of workforce shortages and optimise hospital operations.

Looking ahead, AI's potential extends beyond current capabilities, with opportunities in personalised medicine, real-time decision-making, and hospital-wide optimisation. Stakeholders anticipate that AI will improve healthcare accessibility, particularly in underserved regions, and enhance doctor-patient relationships through clearer communication. While challenges remain, such as concerns over false positives and infrastructure limitations, AI is expected to play a transformative role in healthcare, improving patient outcomes and operational efficiency across diverse medical fields.

The integration of AI into healthcare is faced by a number of challenges, ranging from technical issues like data standardisation and interoperability to regulatory, ethical, and operational complexities. Key hurdles include fragmented healthcare data, outdated IT infrastructures, and a lack of clear regulatory and performance testing procedures for AI tools. Moreover, the complexity of the regulatory landscape, particularly in the EU with frameworks like the AI Act and GDPR, poses a steep learning curve for healthcare providers and AI developers alike. These challenges not only affect the deployment of AI but also raise concerns about data privacy, cybersecurity, and trust among healthcare professionals.

However, there are promising practices emerging globally that can help address these challenges. Collaborative data infrastructures and centralised data entities to overcome data fragmentation, and pilot projects have been useful in testing AI integration into existing workflows. Hospitals have shown success by adopting single platforms to consolidate AI solutions, while countries like the UK and Japan are pioneering regulatory innovations like fast-track approval processes and digital regulation platforms.

Investing in IT upgrades, fostering multidisciplinary collaboration, and promoting training programs for both HCPs and AI developers are important steps for the successful deployment of AI in healthcare. Hospitals are exploring various strategies, such as involving end-users in AI development, implementing cost-benefit analyses, and creating internal review boards to assess AI tools' regulatory compliance and liability. Addressing concerns about transparency and explainability of AI is also essential for building trust, with various initiatives emphasising the importance of clear communication and the continued human oversight of AI tools.

Moving forward, establishing a centralised body for AI assessment, local performance testing, and post-deployment monitoring would standardise evaluation processes and improve oversight. A structured local performance testing framework would enable performance benchmarking and address variations in performance across healthcare settings, while centralised monitoring mechanisms would track AI tool effectiveness over time, ensuring ongoing quality and compliance. In addition, centres of excellence for AI in healthcare could serve as dedicated hubs for research, training, and implementation support. These centres could provide expertise on regulatory compliance, digital adoption strategies, and best practices, ensuring AI solutions align with healthcare needs. Multidisciplinary collaboration would further support knowledge transfer and stakeholder engagement. Developing common standards for data governance, privacy, and interoperability, as well as consolidated funding and structured financing mechanisms would facilitate AI integration across healthcare systems. Targeted investment, reimbursement models, and financial incentives would encourage

deployment while ensuring long-term sustainability. Additionally, developing a comprehensive AI solutions catalogue would improve transparency and assist healthcare providers in selecting appropriate technologies. These initiatives collectively could support a structured and scalable approach to AI integration in healthcare.

10.5 Annex 5 – Details on data sources and methodology for market analysis

10.5.1 Research

An examination of the number of results on the academic library Scopus[392] for the search terms "Artificial Intelligence" and "healthcare" already provides an indication of the vast amount of literature and ongoing research on this topic. A search within article titles, abstracts, and keywords using the search string "("Artificial intelligence" AND healthcare)" yields 21,055 documents on the topic, with numbers skyrocketing after 2020, as 84% of the results pertain to publications from that date onward. However, significantly fewer papers are retrieved when one includes the words "Clinical practice" in the search string (1,188 results, i.e. only 5.6%).

The **Community Research and Development Information Service**[393] (**CORDIS**) database, serves as a proxy to indicate and evaluate research advancements in the field, as it highlights those areas where research projects are initiated. The search string using the key terms "Artificial Intelligence" and "healthcare" results in a list of **553 funded research projects** over the past 10 years (covering projects launched from 2014 to the present). The majority were initiated from 2019 onwards, beginning with 33 projects in 2015 and peaking at 85 projects in 2022 (Figure 7). Specifically, the number increased consistently from 2019 to 2022, **indicating a momentum for AI research in healthcare** during those years.

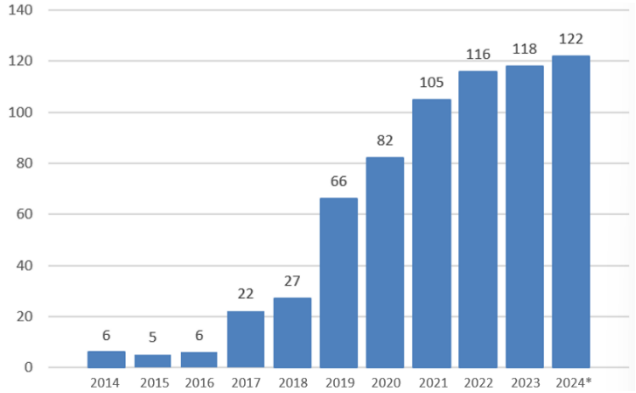
To provide estimates of patents in medical AI, we used data from the **European Patent Office** (**EPO**), which provides data on patents covering all EU27 Member States and the UK through **Espacenet**[394]. Espacenet is a structured public repository managed by EPO, and it provides free access to over 120 million patent documents from around the world, including technical information, patent classifications, bibliographic data, and legal statuses. General patenting trends throughout the years and the country of patents' applicants are described in the following paragraphs. We used the same search string, with the terms "Artificial Intelligence" and "healthcare" over the past 10 years. The search provided **675 results of patents**, with the majority of patents being filled from 2019 onward. As exhibited in Figure 26, there was a significant increase from 22 patents in 2017 to 118 in 2023 (representing a five-fold increase). It is also important to note that an all-time high has been already reached in year 2024 with 122 patents. This steady increase highlights a growing focus on AI/ML-enabled medical devices in recent years.

392 Scopus is a scientific abstract and citation database, launched by the academic publisher Elsevier. Available at: https://www.scopus.com/search/form.uri?display=basic&zone=header&origin=#basic

393 CORDIS is the European Commission's primary source of results from the projects funded by the EU's framework programmes for research and innovation. It has a structured public repository with all project information held by the European Commission such as project factsheets, participants, reports, deliverables and links to open-access publications. Available at: https://cordis.europa.eu/about

394 Espacenet is a structured public repository managed by EPO, and it provides free access to over 120 million patent documents from around the world, including technical information, patent classifications, bibliographic data, and legal statuses. Available at: https://worldwide.espacenet.com/

Figure 26: Number of patents on AI in healthcare published each year (2014-2024)*



* The number of patents published in 2024 is based on data last accessed on 13/11/2024 and may therefore be higher.

Source: Authors' elaboration based on Espacenet database.

As a final factor to estimate trends in term of research in AI in clinical practice, the study team also analysed available data on AI/ML-enabled medical devices in **clinical trials**. As part of clinical trials, medical devices are also tested to evaluate their effects on human health outcomes as a prior step to get regulatory approval and eventually be deployed. In this regard, various clinical trial registries exist to ensure that a comprehensive view of research is accessible to all stakeholders involved in healthcare decision-making. The **European Union Clinical Trials Register**[395] allows to search for protocols and results information on interventional clinical trials that were approved in the EU/EEA under the Clinical Trials Directive 2001/20/EC. Our search involved identifying clinical trials on AI/ML-based interventions using the terms '"Artificial Intelligence" OR "Machine Learning"' over the past 10 years (covering clinical trials conducted from 2014 to the present) and provided only 13 results. It should be noted that, starting of January 31st, 2023, and by January 30th, 2025, all initial clinical trial applications in the EU/EEA must be submitted through the Clinical Trials Information System. The latter date marks the end of a three-year transition period that began when the Clinical Trials Directive (EC) No. 2001/20/EC became applicable in the EU. The Clinical Trials Regulation (CTR) harmonised the processes for assessment and supervision of clinical trials throughout the EU. Under the CTR, clinical trial sponsors must submit all new clinical trial applications in the abovementioned **Clinical Trials Information System**[396] (CTRI). Our search involved identifying clinical trials on AI/ML-based interventions using the search terms '"Artificial Intelligence" OR "Machine Learning"' over the past 10 years (covering clinical trials conducted from 2014 to the present) and, not much differently from the search based on the EU Clinical Trials Register, provided only 12 results.

The **WHO International Clinical Trials Registry Platform**[397] (WHO ICTRP) aims to provide a single point of access to information about ongoing and completed trials. The WHO ICTRP compiles data from national and regional clinical trial registries worldwide, including ClinicalTrials.gov (USA), the EU CTRI, the Chinese Clinical Trial Registry, and the Japan Primary Registries Network. Thus, trial data from various countries is

395 https://www.clinicaltrialsregister.eu/ctr-search/search
396 https://www.ema.europa.eu/en/human-regulatory-overview/research-development/clinical-trials-human-medicines/clinical-trials-information-system
397 The WHO ICTRP provides a searchable database containing the trial registration data sets made available by data providers around the world meeting criteria for content and quality control. It compiles data from national and regional clinical trial registries worldwide, including ClinicalTrials.gov (USA), the EU Clinical Trials Register, the Chinese Clinical Trial Registry, and the Japan Primary Registries Network. Available at: https://www.who.int/clinical-trials-registry-platform

centralised, allowing for broader access and comparison. Our objective was to identify clinical trials involving AI/ML-based interventions. Given that clinical trials already pertain to the healthcare domain, the search string was changed accordingly, and we carried out two separate searches: one for 'Artificial Intelligence' and one for 'Machine Learning,' covering the past 10 years (from 2014 to the present). These two searches combined provided a total of 3,320 results between 2014 and 2024.

10.5.2 Development

Once a medical device has been developed, manufacturers in the EU and in the US must comply with respective laws and regulations before legally placing a medical device on the market. The situation on the regulatory approval of medical devices presents differences between the US and the EU. While the EU has a single competent authority handling the approval and monitoring of pharmaceuticals and biologics, the European Medicines Agency (EMA), **there is no centralised authority for medical devices**. The approval process relies instead on **Notified Bodies**, i.e., organisations designated by an EU Member State (or by other countries under specific agreements) to assess the conformity of certain products before being placed on the market. As of October 2024, there were **50 Notified Bodies** designated under the Medical Device Regulation (MDR)[398]. Given the relative novelty of AI in medical devices, **there is no current standard and specific categorisation of AI/ML-enabled medical devices**. Although it should be noted that some of the notified bodies are increasingly specialising in assessing whether manufacturers meet the state-of-the-art requirements for AI-driven medical devices, aiming to minimise regulatory compliance issues during certification, surveillance audits, and technical documentation reviews[399].

Moreover, in the EU, while AI-enabled medical technologies must generally comply with regulatory requirements applicable to all medical devices, there are at present no harmonised standards that specifically address the unique performance aspects of AI technologies[400]. Thus, efforts to study CE-marked medical devices in Europe may be impacted by the lack of a publicly accessible register of approved devices, the confidentiality of information submitted to Notified Bodies and regulators, and the decentralised process for CE-marking decisions[401,402]. According to the MDR, there are four different classes of medical devices depending on the risk level of the product (described in detail in section 5.1.4): class I low risk, class IIa low/medium risk, class IIb medium/high risk, and class III high risk[403]. Whereas a class I CE mark is obtained through self-certification, classes II and III necessitate an external evaluation by a notified body, which entails a more complex process that also includes the review of results[404].

As part of the updated **Medical Devices Regulation (MDR)**[405], the Commission set up the objective of establishing a centralised EU database on CE-marked medical devices

398 Fink and Akra, 2023. Comparison of the international regulations for medical devices–USA versus Europe.
399 See for example: https://www.tuvsud.com/en/industries/healthcare-and-medical-devices/artificial-intelligence-in-medical-devices
400 TÜV SÜD, 2021. Artificial Intelligence in Medical Devices. Verifying and validating AI-based medical devices. White Paper.
401 Hwang et al., 2016. Comparison of rates of safety issues and reporting of trial outcomes for medical devices approved in the European Union and United States: cohort study.
402 Kramer and Kesselheim, 2012. How does medical device regulation perform in the United States and the European union? A systematic review.
403 For more information, please refer to : https://webgate.ec.europa.eu/udi-helpdesk/en/other-relevant-information/medical-device-classification.html (Last accessed 10/10/2024).
404 Van Leeuwen et al., 2021. Artificial intelligence in radiology: 100 commercially available products and their scientific evidence.
405 https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745

in the EU – the **European Database on Medical Devices (EUDAMED)**. Notably, Article 34 established the gradual roll out of EUDAMED which was initially set to become fully operational in May 2022. The full functionality has not been achieved yet, with the Commission postponing the mandatory use of EUDAMED to early 2026. The information included in **the database is therefore updated on a voluntary basis by medical devices manufacturers and is therefore not comprehensive**.

Conversely, in the United States, the **FDA** oversees the regulation of medical devices, pharmaceuticals, and biologics. The FDA provides **publicly accessible information on approved medical devices** through summary documents that include details about the device description, indications for use, and performance data from the device's evaluation study[406]. Given the lack of data available on CE-marked devices, for our analysis on developed AI/ML-enabled medical devices we have analysed the data provided by the FDA.

Before medical hardware or software can be legally introduced to the US market, the parent company must submit it to the FDA for **evaluation**[407]. Depending on the devices' risks, the FDA centrally approves medical devices through three pathways: the **premarket approval pathway** (the most rigorous review for high-risk devices), the **de novo premarket review** (for low and moderate-risk devices), and the **510(k)** pathway, each of which needs specific criteria to be fulfilled in order to be granted to be granted (see Table 11)[408]. For simplicity, we use "approval" to denote the clearance of these devices.

Table 11: Description of the types of FDA approvals for AI/ML-based medical technologies

Level of FDA clearance	Description
510(k) clearance	A 510(k) clearance for an algorithm is granted when it has been shown to be at least as safe and effective as another similar, legally marketed algorithm. The submitter seeking this clearance must provide substantial proof of equivalence in their application. Without an approval of being substantially equivalent to the other algorithm, the one pending approval cannot be legally marketed. An example of AI/ML-based medical technology that has been approved through the 510(k) clearance is a deep-learning model used in radiology which accelerates MRI scans by up to 50% by enhancing low-quality initial outputs from accelerated scans.
Premarket approval	Premarket approval is issued to algorithms for Class III medical devices. The latter are those that can have a large impact on human health as such, their evaluation undergo more thorough scientific and regulatory processes to determine their safety and effectiveness. To approve an application, the FDA determines that the device's safety and effectiveness is supported by satisfactory scientific evidence. Upon approval, the applicant can proceed with marketing the product. An example of AI/ML-based medical technology that went through the FDA's premarket approval is a breast imaging system used in radiology which provides substantially improved confidence in breast cancer diagnostics thanks to a non-invasive, real-time ultrasound scan.
De novo pathway	Regarding the de novo classification, it is used to classify those novel medical devices for which there are no legally marketed counterparts, but which offer adequate safety and effectiveness with general controls. The FDA performs a risk-based assessment of the device in question before approval and allowing the device to

406 Wu et al., 2021. How medical AI devices are evaluated: limitations and recommendations from an analysis of FDA approvals.
407 Benjamens et al., 2020. The state of artificial intelligence-based FDA-approved medical devices and algorithms: an online database.
408 Muehlematter et al., 2021. Approval of artificial intelligence and machine learning-based medical devices in the USA and Europe (2015–20): a comparative analysis.

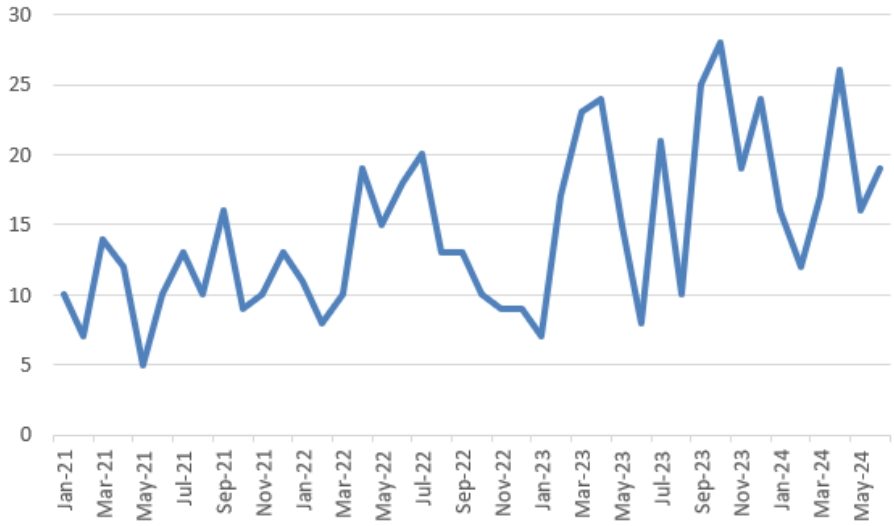
	be marketed. An example of AI/ML-based medical technology that has been approved through the de novo pathway is an end-to-end approach used in cardiology for detecting and directing hypertrophic cardiomyopathy patients.

Source: Authors' elaboration based on Benjamens et al. (2020)

For the development and marketing of medical algorithms, the FDA's stringent regulatory requirements currently pose important challenges to the companies developing them. In the past, every new product had to go through the regulatory process. However, as companies update their algorithms on a much shorter time scale, namely in days, the FDA has realised that this process might become impossible to maintain[409]. Therefore, the FDA started to consider "a total product lifecycle-based regulatory framework for these technologies that would allow for modifications to be made from real-world learning and adaptation, while still ensuring that the safety and effectiveness of the software as a medical device is maintained"[410].

In the figure below we provide the monthly approvals of FDA medical devices in the US between January 2021 and May 2024.

Figure 27: Number of FDA approvals of AI/ML-enabled medical devices between 2021 and 2024 (per month)



Source: Authors' elaboration based on FDA database

10.5.3 Deployment

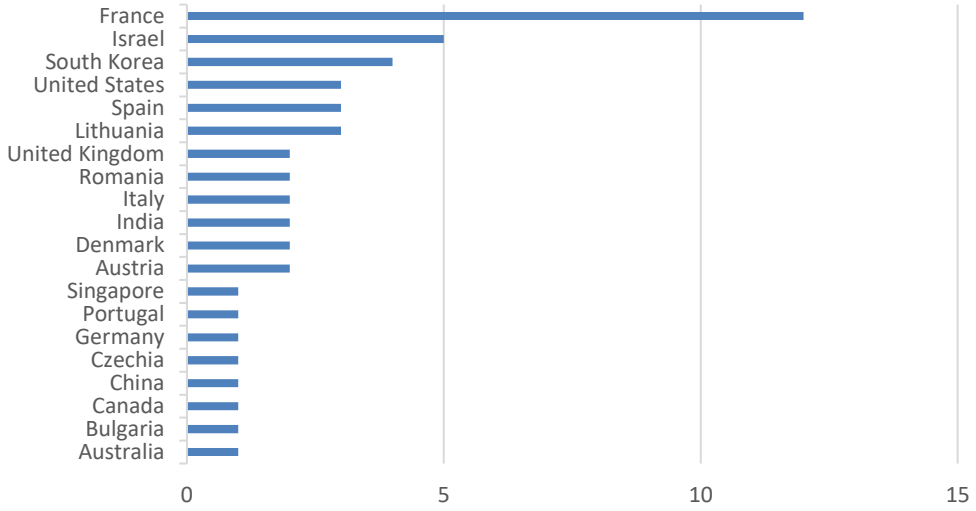
The **Radiology Health AI Register**[411] is an online overview of CE-marked AI products based on vendor-supplied product specifications created by a research team from the Department of Medical Imaging at the Radboud University Medical Center (The Netherlands). To build the register, first the team at Radboud University Medical Center mapped and reviewed AI software products from exhibitor lists from the Radiological Society of North America (RSNA) and European Congress of Radiology (ECR) as well as marketplace offerings. Additionally, news sources were monitored to identify the emergence of new vendors, products, or certifications[412]. In a second step, a

409 Benjamens et al., 2020. The state of artificial intelligence-based FDA-approved medical devices and algorithms: an online database.
410 Regulations.gov, 2019. Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) – Discussion Paper and Request for Feedback. https://www.regulations.gov/document/FDA-2019-N-1185-0001
411 The database can be accessed via the following link: www.radiology.healthairegister.com (Last accessed 10/10/2024).
412 Van Leeuwen et al., 2021. Artificial intelligence in radiology: 100 commercially available products and their scientific evidence.

comprehensive assessment was carried out on the existing scientific literature on the identified products, gathering details such as their modality, subspeciality, main task, regulatory information, deployment, and pricing model. In a final step, vendors for these products were contacted to verify the information collected. According to the authors, the Register is currently the most comprehensive overview of available AI-based software for clinical radiology practice. We believe that the data on AI medical devices in the field of radiology could work as a good proxy on the number of CE-marked AI medical devices given that the majority of medical devices are developed for this medical specialisation.

As can be seen in Figure 28, the majority of devices were developed by organisations based in France (12 out of 50, 24%), followed by Israel (5 devices, 10%), South Korea (4 devices, 8%), Lithuania, Spain and the United States (each of them with 3 devices, 6%). The remaining countries, as observed in the graph below, accounted for 20 devices (40% of the total).

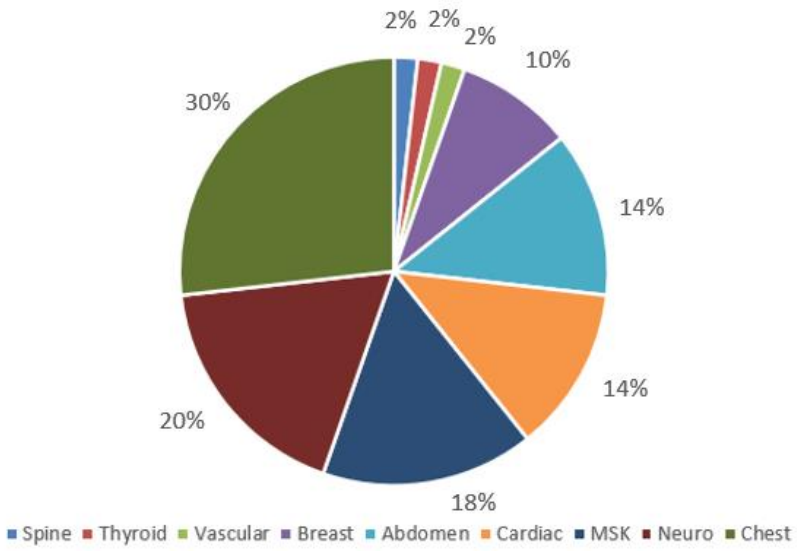
Figure 28: Number of medical devices for clinical radiology on the market per origin country of the manufacturer



Source: Authors' elaboration based on the Radiology Health AI Register

Results in Figure 29 show that available AI products mostly addressed chest radiology (15, i.e. 30% of 50 devices), followed by neuroradiology (10 devices, i.e. 20%), musculoskeletal (MSK) radiology (9 devices, i.e. 18%), abdomen radiology (7 devices, i.e. 14%), and cardio radiology (7 devices, i.e. 14%).

Figure 29: Number of medical devices for clinical radiology on the market per subspeciality



Source: Authors' elaboration based on the Radiology Health AI Register

Regarding the modalities, we observe that products are distributed over **CT** (34%, 17 out of 50 devices), MR and X-ray (each of them accounting for 13 devices, 26%), ultrasound (4 devices, 8%), and mammography (3 devices, 6%). These figures are in line with the results of a 2024 survey among members of the European Society of Radiology, whereby AI impact was predominantly expected on breast and oncologic imaging, primarily involving CT, mammography, and MRI[413]. The extensive use of AI tools for CT is justified by the high volume of imaging data it generates and its critical role in diagnosing complex conditions, making it ideal for leveraging AI to enhance accuracy and efficiency[414].

In terms of tasks performed, the main ones are **diagnostic tasks** (39 devices, 78%), AI-assisted prognosis prediction and risk stratification (18%, 9 out of 50 devices), and AI-assisted symptom checker and support in treatment decisions (4%,2 out of 50 devices). AI devices, in this regard, are particularly helpful for diagnostic tasks as they excel at analysing complex imaging data to detect abnormalities with high accuracy[415].

413 Zanardo et al., 2024. Impact of AI on radiology: a EuroAIM/EuSoMII 2024 survey among members of the European Society of Radiology.
414 Mello-Thoms and Mello, 2023. AI in imaging and therapy: innovations, ethics, and impact: review article.
415 Mello-Thoms and Mello, 2023. AI in imaging and therapy: innovations, ethics, and impact: review article.

Figure 30: Number of medical devices for clinical radiology on the market per modality

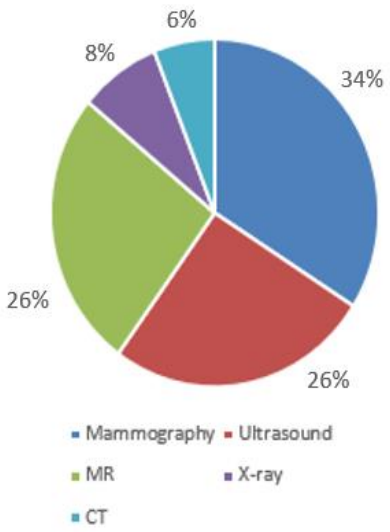
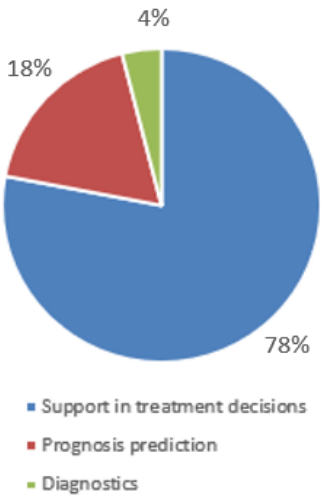


Figure 31: Number of medical devices for clinical radiology on the market per main functionality



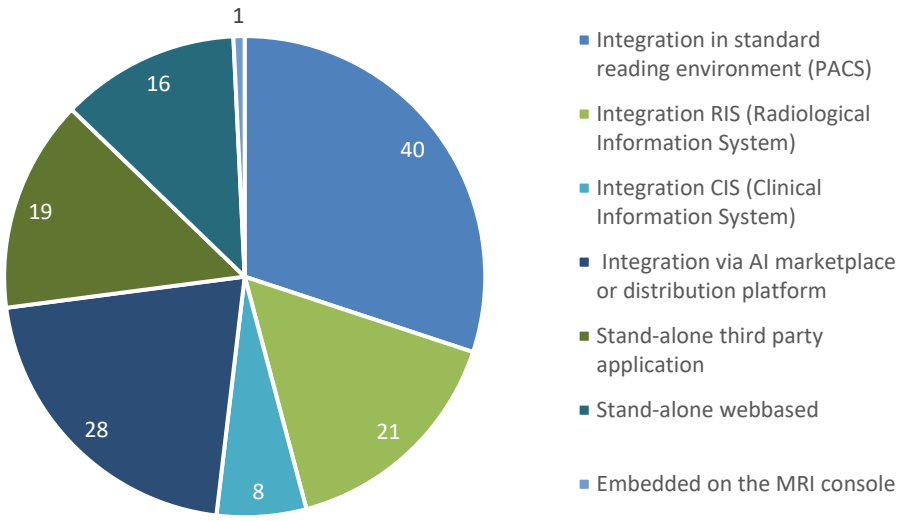
Source: Authors' elaboration based on the Radiology Health AI Register

Regarding the class of approval, 25 out of the 50 products (50%) are marked with IIa risk class, 13 of them (26%) with IIb risk class, and 12 devices (24%) with I risk class, showing that AI in radiology is mostly used for devices with low and medium risk levels. Additionally, 20 out of 50 analysed medical devices also obtained a class II approval via the 510(k) pathway from the FDA.

The Register also provides commercial information for 26 out of the 50 medical devices that had been CE-marked between January 2021 and June 2024. The 26 AI medical devices were in use in **11 different countries**. In these countries, there were 201 paying customers who were using the devices for clinical purposes while 19 were using them for research or for testing. This distinction was made since many companies tend to claim that they have deployed their technology in several centres when, in reality, it is just for performance testing studies or free installation for a specific doctor to test the tool.

Lastly, the Radiology AI Health Register also provided information on **the type of integration needed** for the deployment of each of the AI medical devices listed. In this case there were also some pre-defined categories of integration: integration in standard reading environment (PACS); integration in Radiological Information System (RIS); integration in Clinical Information System (CIS); integration via AI marketplace or distribution platform; stand-alone third-party application; stand-alone web based; and embedded on the MRI console. There was information available for 48 out of the 50 analysed AI medical devices. It was also the case that the AI tools could be integrated via various of the integration options, while the majority of analysed AI tools could be integrated via PACS (83%, 40 out of 48 devices). The second most available option for integration was via AI marketplace or distribution platform (58%) followed by integration in RIS (44%). In the figure below we provide an overview on the information provided for each integration model. This provides evidence that the adoption of AI in radiology may be facilitated by the fact that there are available several standard information systems to which AI tools can be easily adapted to.

Figure 32: Type of integration model for the analysed AI medical devices in radiology



Source: Authors' elaboration based on the Radiology Health AI Register

10.5.4 Overall data limitations and challenges

Some limitations need to be mentioned regarding the approach followed for the market analysis conducted in the context of this study. Firstly, detecting FDA-approved and CE-marked AI/ML-based medical devices is challenging, as the use of the **terms associated with AI/ML on manufacturers' websites and in news articles might be different**. This inconsistency may also contribute to a lower number of detected AI/ML-based devices. Moreover, as already mentioned throughout the text, **the EU lacks a comprehensive database for CE-marked medical devices**, significantly hindering the transparency of the CE-marking process in the EU.

Concerning the FDA database of AI/ML-based devices approved, it should be noted that the number of FDA-approved devices **does not provide insights into whether these devices are deployed in practice**. Conversely, there may be AI/ML-based medical devices developed and **used internally within hospitals** or research institutions **without obtaining approval**[416]. Hence, although FDA approval permits commercial distribution, we cannot assess the actual availability and clinical deployment of these devices in healthcare facilities, making it challenging to evaluate the real-world impact of AI/ML devices[417]. Secondly, the FDA **does not require companies to label their technology as AI/ML-based**, even if it is: while some companies disclose that their technology is AI/ML-based in their FDA approval announcements, including the specific ML methods used, others do not provide this information[418]. Moreover, because of the strong incentives for companies to market and sell their devices as widely as possible, some devices might contain **references to AI/ML to be more attractive on the market**, although they are not fully AI/ML-based[419].

Similarly, concerning the **Radiology Health AI Register**, defining AI and its role in clinical radiological practice is quite complex, making the **criteria for product**

416 Muehlematter et al., 2021. Approval of artificial intelligence and machine learning-based medical devices in the USA and Europe (2015–20): a comparative analysis.
417 Zhu et al., 2022. The 2021 landscape of FDA-approved artificial intelligence/machine learning-enabled medical devices: An analysis of the characteristics and intended use.
418 Benjamens et al., 2020. The state of artificial intelligence-based FDA-approved medical devices and algorithms: an online database.
419 Muehlematter et al., 2021. Approval of artificial intelligence and machine learning-based medical devices in the USA and Europe (2015–20): a comparative analysis.

inclusion debatable. For instance, products that analyse cardiac ultrasound were excluded from the database, as these are frequently associated with cardiology. Moreover, some vendors did not respond to the authors' requests for information or opted not to be included, choosing to retain some information. In addition, **vendors often do not specify on their websites whether their products carry a CE mark** and, even when they do, they do not specify which risk class applies. For some products, the missing information was completed with public data where possible. Therefore, while the website aims to offer a continually updated overview of AI radiology products and is maintained **voluntarily** by the study team, the database **cannot be regarded as comprehensive and complete** as an official governmental database (e.g. the FDA database).

In light of the above, it is important to note that our analysis primarily focused on FDA-approved devices and CE-marked AI tools used in radiology that are available on the EU market. This scope significantly **limits the generalisability of our conclusions**. Moreover, while these indicators demonstrate whether the tools are commercially distributed, **they do not provide insight into their actual availability or clinical deployment in healthcare facilities**, making it **challenging to assess the real-world impact of AI/ML devices**.

To fill such gaps, insights from the **survey results** were included in the analysis, although there were also some **limitations** concerning the data collection and analysis of such responses as well. In particular, the responses come from a **limited number of stakeholders** which cannot be considered as representative sample to assess the actual state of deployment of AI medical devices in the EU. Hence, the analysis provided works as an estimation on the deployment of healthcare, but the analysis needs to be interpreted carefully without leading to significant conclusions.

10.6 Annex 6 – List of specific actions for each consideration for future action

Recommendations	Specific actions
Establishing common standards for data governance, privacy, and interoperability	Rules to standardise data formats, protocols and metadata
	Standards on mechanisms to support real-time data exchanges
	Incentives to adopt interoperable technologies
Establishment of Centres of Excellence for AI healthcare	Actual establishment of Centres of Excellence of AI in healthcare
	Provision of advanced training programmes for healthcare workforce
	Run digital health literacy programmes for the general public
	Creation of a collaborative environment for knowledge and best practice sharing
	Drafting of guidelines on data governance and privacy
	Drafting of protocols to identify and mitigate biases in AI models
Consolidated funding and introduction of financing mechanisms	Introduction of financing mechanisms to support strategic priorities for AI in healthcare
	Introduction of standardised EU-level reimbursement framework for AI in healthcare
Establishment of a centralised body for added-value assessment, local performance testing and post-deployment monitoring of AI solutions	Establishment of a network of assurance labs to test the performance of AI tools for healthcare
	Provide standardised infrastructure for evaluating AI models at local/regional level
	Establishment of performance benchmarks designed for different AI tools to be used by local performance testing centres
	Provision of sandbox environment to test the performance of AI tools
	Promote collaboration across EU Member States with a central data repository
	Value proposition research activities using evidence-based frameworks to quantify and articulate the specific benefits of AI tools
	Collection and dissemination of real-world evidence and case studies demonstrating the practical effectiveness and impact of AI tools
	Establishment of a centralized governance body to oversee the implementation and refinement of the evaluation model
Development of a catalogue of AI solutions	Inclusion of detailed performance metrics for each listed AI tool, user reviews, and feedback mechanisms
	Inclusion of user guides, case studies, and tutorials, helping healthcare providers understand and implement AI solutions effectively
	Establishment of a governance framework to oversee the catalogue's operations

10.7 **Annex 7 – Triage Use Case – Case Study 1**

This case study report focuses on an AI solution used in cardiology for triage purposes that has been developed by a large enterprise and has been approved by the U.S. Food and Drug Administration (FDA), the Therapeutic Goods Administration (TGA) of Australia, and has a European Conformity marking (CE marked) and deployed in healthcare settings globally. To provide an overview of the AI solution, we conducted desk research and in-depth interviews with 5 selected stakeholders:

- the developer of the AI solution from Israel,
- 1 healthcare professional from the USA using the AI solution,
- 1 healthcare professional from Sweden using the AI solution,
- 1 representative of a hospital from Israel that has deployed the AI solution,
- 1 representative of a hospital from Belgium that has deployed the AI solution.

The insights gathered contribute to building an overall picture of the use case and its impact, in addition to gathering information on the challenges and good practices employed in its deployment in healthcare settings.

10.7.1 Overview of the need

Pulmonary Embolisms (PE), a form of Venous Thromboembolisms (VTEs), are potentially life-threatening conditions that require timely and accurate diagnosis for effective treatment. PE is the third most common cause of cardiovascular death in the United States, with an annual mortality rate of 100,000[420]. Diagnosing PE often requires a specific type of Computed Tomography (CT) scan called a CT Pulmonary Angiogram (CTPA). PE's can be prone to missed or delayed diagnosis due to their often-varied clinical presentations, making them challenging to detect. In some cases, PEs are detected in routine chest imaging procedures without the presence of symptoms which are referred to as incidental PEs[421]. Approximately 44.8% of incidental PEs are not detected by radiologists, with miss rates ranging from 32% to 79%[422].

The treatment of PE varies depending on the size, location of the embolus, and the patient's overall risk factors for thromboembolic events such as strokes and heart attacks. Treatment options vary from anticoagulants in less urgent cases to surgery in more urgent and serious cases. Having a multidisciplinary team, such as a Pulmonary Embolism Response Team (PERT)[423], is the most effective approach to developing personalized treatment plans for patients at risk of PE or with a suspected PE (see figure below). Despite such benefits, 75% of PE patients still receive standard bedside treatments such as anticoagulants irrespective of PE severity, rather than being referred to a PERT for personalised care.

420 Rothenberg SA, Savage CH, Abou Elkassem A, et al. 2023. Prospective Evaluation of AI Triage of Pulmonary Emboli on CT Pulmonary Angiograms.

421 Incidental PEs are found unexpectedly during imaging tests (like CT scans) performed for reasons unrelated to PE suspicion. For example, a patient might undergo a CT scan for cancer staging or abdominal pain, and a PE is noticed on the scan. Patients with incidental PE typically do not present with the classic symptoms associated with PE. Although these PEs are found by chance, they can still be clinically significant.

422 Topff L, Ranschaert ER, Bartels-Rutten A, et al. 2022 Artificial Intelligence Tool for Detection and Worklist Prioritization Reduces Time to Diagnosis of Incidental Pulmonary Embolism at CT

423 A PERT often includes emergency physicians, radiologists, pulmonologists, cardiologists and vascular surgeons.

	Personalised procedures	Intensive care unit days	Overall length of stay
With PERT	46.3%	4.4 days	6.3 days
Without PERT	1.8%	6.9 days	9.2 days

Figure 33: Impact of a PERT on the number of personalised procedures, intensive care unit days, and overall length of stay.

The workload of radiologists has increased over the past decades with reports showing a higher demand and complexity of imaging examinations. This has led to backlogs of unreported examinations, especially during unexpected surges in imaging requests. The detection of incidental PEs, where patients do not present with classic symptoms, can be particularly challenging under these conditions, due to the requirement for careful review of CT scans, often in a high-pressure environment. This can result in delays in identifying both non-urgent and urgent cases of PEs, and a subsequent delayed time to treatment[424]. This can compromise the prognosis of patients, as evidence suggests that the survival outcome is directly linked to the speed of intervention, with one study reporting that in the most severe cases up to 10% of PE patients can die within the first hour following the onset of symptoms.

Recent studies highlight the potential for Artificial Intelligence (AI)-enhanced PERT workflows to help prioritize the most urgent and serious cases for personalised treatments and increase efficiencies in healthcare delivery by enhancing patient outcomes, reducing hospital stays and optimizing the cost of PE triage and treatment.

10.7.2 Overview of the use case

The AI solution is a platform that assists in the rapid diagnosis, prioritisation, and treatment of PEs by reviewing CT scans and streamlining communication and coordination among multidisciplinary teams, facilitating timely decision-making and patient care. The AI solution is used both for patients that present with symptoms of PE, and in patients at risk of incidental PE, for example patients undergoing surgery, immobilized patients following surgery, long term hospitalizations and patients with specific conditions (i.e. heart disorders, chronic disorders, cancer, history of thrombolytic events) [425]. The AI solution assists radiologists in the detection of PE, risk stratification and post treatment patient management.

Studies indicate that the AI solution has improved time-sensitive outcomes, such as the time required for radiologists to interpret and report the findings of CT scans known as turn-around time, time to treatment, wait time, and length of stay of patients with PEs. It has also shown to affect the quality of radiological interpretations such as the diagnostic accuracy, the sensitivity and specificity, and the overall coordination and collaboration of healthcare professionals involved in patient care.

10.7.3 Challenges to Deployment

10.7.3.1 Technical and Data Challenges

The AI developer described several technological and data challenges, particularly in Europe. One of the main barriers is the **reluctance of healthcare providers to use cloud services**, with a preference for local servers. While there are often concerns

424 Topff L, Ranschaert ER, Bartels-Rutten A, et al. 2022 Artificial Intelligence Tool for Detection and Worklist Prioritization Reduces Time to Diagnosis of Incidental Pulmonary Embolism at CT
425 American Heart Association. 2023. Risk Factors for Venous Thromboembolism

surrounding the security of cloud services, the hospital representative from Israel reported that there is a **common belief that data in the cloud is less secure than on-premises data.**

While it was not specifically flagged as a concern during the deployment process, the AI developer noted that **interoperability is lacking between advanced AI solutions and existing hospital systems**. This problem is attributed to the **incomplete implementation of electronic health records (EHRs)** and the fragmented digital health infrastructure, which creates obstacles to seamless integration and data sharing. Additionally, according to the developer of the AI solution, **the high costs associated with integrating AI solutions**, partly due to the lack of standardized processes across healthcare systems, presented a significant challenge. This challenge of interoperability was also raised by the healthcare professional from a hospital in Sweden. According to them, **interoperability, and successful integration of AI solutions is a complex and time-consuming process**. The healthcare professional from Sweden reflected that increased interoperability of solutions may help overcome this obstacle.

The hospital representative from Israel reflected on the **fragmentated market of AI solutions**, with many companies developing niche algorithms for specific tasks. For hospitals who want to integrate AI solutions, they must contract with numerous companies and integrate diverse solutions using limited IT resources which is impractical.

The **challenges surrounding post-deployment monitoring mechanisms** were also raised by the hospital representative from Israel. According to the interviewee one of the key issues debated is **whether AI companies should be mandated to have an annual review of the performance of their products**. The Israeli hospital representative emphasized the **importance of ensuring that the training data reflects the patient population** that the AI solution will be used on. This is crucial because the performance promised by the vendor (i.e., the developer of the AI solution) may not be the same when deployed in a different healthcare setting.

10.7.3.2 Legal and Regulatory Challenges

The developer of the AI solution stated that the complex regulatory landscape in Europe is an obstacle to deployment. While the solution successfully obtained a CE marking, the **stringent regulatory requirements** posed some challenges. More specifically, the interviewee highlighted that it could take significant time to gather data, creating a barrier to market entry, especially for smaller startups.

In combination with the aforementioned challenges related to the reluctance towards use of cloud services, the healthcare professional from a hospital in Sweden highlighted the complexity surrounding cloud computing regulations. The interviewee stated that **varying rules regarding the use of cloud services for medical data** complicates the standardization of AI deployment across multiple sites.

Concerns surrounding liability due to AI errors were raised by the hospital representative from Belgium and the healthcare professional from the hospital in Sweden. The healthcare professional emphasized such concerns particularly in cases of discrepancies between AI-generated results and radiologists' diagnoses, especially if a mistake leads to adverse patient outcomes. He added that **hospitals may have varying tolerance levels for AI's confidence in diagnoses**.

10.7.3.3 Organisational and business challenges

The developer of the AI solution highlighted a general lack of dedicated budgets for AI solutions in hospitals, in addition to an **unclear division of responsibilities in**

hospitals regarding AI deployment (for example the radiology department, innovation department, CEO or the IT department). Furthermore, hospitals may **lack the necessary IT capacity** and **have difficulties in attracting the expertise required** for effective AI deployment, such as data scientists and engineers.

The hospital representative from Belgium echoed these concerns and emphasized the **difficulty in selecting the right AI solution due to the exponential increase of alternative options** available in recent years. The Belgian stakeholder also reflected that the widespread deployment of AI technology is limited by the **lack of reimbursement mechanisms**. In terms of funding, the stakeholder perceived that deployment of AI solutions may be more widely found in University Hospitals who are more willing to obtain research grants, innovate and investigate in comparison to public hospitals.

In contrast, the healthcare professional in the USA indicated that from their experience there were no significant organizational or business challenges in the deployment of the solution. The AI solution was integrated without burdening healthcare professionals with unnecessary technical details, facilitated by extensive support and training from the developer.

10.7.3.4 Social and Cultural Challenges

The representative from Israel shared the general **concern that healthcare professionals may become over-reliant on AI**. Particularly **junior clinicians and interns who may potentially lose the opportunity to fine-tune their image reading skills** without support from AI solutions. The representative from Israel also reflected that **the level of concern raised varies between healthcare professional groups** – for example, those in the emergency department may be more eager to use the AI solution for decision-making (e.g., discharging patients based on AI evaluations before a radiologist reviews the study), whereas other groups may be more cautious, potentially due to **concerns regarding job security**.

The hospital representative from Israel also added that there is a growing concern about **healthcare professionals experiencing cognitive overload due to the need to switch between different AI systems**. This challenge is closely related to the recognized **gap in digital health literacy** among healthcare professionals, particularly regarding the understanding and use of AI solutions, a need that is acknowledged by the Israeli stakeholder.

Conversely, the hospital representative from Belgium perceived that there were no significant concerns from healthcare professionals in the deployment of the AI solution in their specific context. The radiologists at the hospital were described as driven by innovation and open to cutting-edge tools, creating a supportive environment for AI deployment. The healthcare professional in the USA echoed these views, reporting no significant resistance during implementation. The healthcare professional from the hospital in Sweden also added that patients also have a positive attitude towards the use of the AI solution in their care, particularly since it speeds up the time to treatment.

10.7.4 Accelerators to Deployment

10.7.4.1 Technical and Data

According to the hospital representative from Israel, the most critical step of effective deployment is **seamless integration within the existing IT infrastructure**. In their deployment the AI solution integrated with existing systems and provided a familiar user interface that radiologists recognize and can easily interact without significant reskilling. This seamless integration is attributed to the developer's design of the

solution to be compatible with existing software. In addition, the hospital is also focused **upon integrating all AI solutions into a single user interface** to alleviate the cognitive burden experienced by healthcare professionals when interacting with multiple separate AI tools.

The hospital representative from Israel also referenced the use of cloud computing as an accelerator to AI deployment, noting the advanced nature of their own cloud adoption. They highlighted benefits in cloud computing including improved reliability, flexibility, and agility compared to on premises solutions which made the technological deployment of cloud-based AI solutions smoother and more streamlined. This process was also facilitated by the **creation of a committee within the hospital**, whose role is to approve and certify all cloud-related solutions before they are implemented, making the integration process easier.

The Belgian stakeholder reflected on strategies implemented to **monitor and take agile action on alarm fatigue**[426] experienced by healthcare professionals using some AI clinical decision support systems. Monitoring of alarm frequency enabled the hospital to fine-tune the stratification of urgent and non-urgent cases. Similar adjustments are being considered in other medical specialties to prevent overwhelming healthcare professionals with unnecessary alarms and reduce the perception of the AI tools as a burden.

10.7.4.2 Organisational and Business

The hospital representative from Belgium highlighted the **importance of a comprehensive approach (model) for assessing the added value of an AI solution in comparison to others**. To assess the value of the AI solution, the hospital is focusing on various metrics, including the time required for accurate diagnosis, improvements in hospital capacity, reductions in staff working hours, enhanced availability of services, and the speed of diagnosis. By using these indicators, the hospital aims to quantify how the AI solution contributes to patient outcomes and operational efficiency, thereby providing a comprehensive evaluation of its impact and justifying its integration into clinical practice. The hospital representative from Sweden highlighted the importance of selecting AI solutions based upon addressing a specific need, and in turn the conduct of pilot studies tailored to the unique environment of the hospital setting.

The Belgium hospital representative reflected upon **the importance of multidisciplinary teams combining data scientists and engineers and healthcare professionals** which can support the overall more comprehensive understanding of AI tools, facilitate explainability and interpretability and encourage inter-professional learning. The healthcare professional from a hospital in the USA reflected that they avoid, where possible, adding additional burden to their healthcare professionals with excessive technical detail on the AI solutions. The AI developer highlighted that the company **provides training sessions for the relevant individuals in hospitals**, tailored to their schedules to ensure they are comfortable with the technology without feeling overwhelmed.

The healthcare professional from Sweden highlighted the importance of **training a "super user"** and conducting **introductory sessions with radiologists** to present the AI solution and its features. The hospital also conducted **pilot studies** on the AI tools performance to compare its findings with the radiologists, complemented with a **rapid feedback loop allowing for open discussion** of uncertain findings and

426 The experience of an overwhelming number of alerts, many of which did not require immediate action, leading to the risk of important notifications being overlooked and potentially compromising patient safety.

continuous feedback resulting in iterative improvements and adjustments to the solution. With this in mind, the healthcare professional emphasised the importance to consider that the deployment of AI solutions is not as an isolated one-time event, but an ongoing process involving continuous evaluation and adaptation to ensure performance is as expected.

10.7.4.3 Social and cultural

The hospital representative from Belgium emphasized several important practices to support clinicians in the deployment of AI technologies. Starting with the **development of a clear strategic vision for innovation** and **robust security requirements to build trust**, and a safe, innovative environment. The stakeholder also reflected on the importance that AI tools are perceived as supportive tools, rather than healthcare professional replacements, and in this regard the **positioning of AI tools as enhancements to existing clinical workflows facilitates smoother deployment and acceptance**.

The hospital representative from Israel ensured that **relevant stakeholders (including healthcare professionals) were involved earlier in the decision-making process** for new technologies including AI, through revising their internal procedures. The stakeholder also referred to the **implementation of their own internal rules regarding AI technology, ensuring that any new AI solution is accompanied with proper training to all impacted stakeholders.** The hospital representative from Belgium also emphasised the importance of improving digital literacy amongst healthcare professionals, and noted the added benefit that this can improve the utilisation of tools, but also can encourage innovation.

The radiologist from a hospital in Sweden noted that **open communication on the use of the AI solution with patients** and provision of a **standardized note for radiologists to explain the purpose of the solution** helped build trust and fostered a positive attitude toward the technology.

10.7.5 Complementary Actions

On the technological side, the developer of the AI solution described the importance of developing a **European cloud service** to avoid concerns regarding data control and compliance with European data protection standards. The AI developer, the hospital representative from Israel and the healthcare professional from Sweden also discussed the importance of **setting interoperability standards to facilitate the seamless integration of AI solutions into different healthcare systems** with minimal disruption to existing clinical workflows, enabling better data sharing and operational efficiency. While it is challenging to force AI developers to consolidate or create a single platform, standardization could help address the issue and avoid adding further complexity to the daily tasks of healthcare professionals. Standardization could ensure that AI solutions have a **consistent user interface and reporting format**, including the transmission of results and confidence intervals.

The hospital representative from Belgium, the developer of the AI solution and the healthcare professional from Sweden suggest that regulatory frameworks should be adjusted to better accommodate for smaller AI startups, which often face high barriers to market entry. By tailoring requirements, regulators can encourage innovation and make the market more accessible. They suggest **providing appropriate guidance on how to comply with the Medical Device Regulation (MDR) and increasing the capacity of notified bodies to speed up the approval process,** facilitating the easier and faster deployment of AI tools in clinical settings by avoiding lengthy and complex approval processes.

The developer of the AI solution emphasized the importance of **national initiatives and funding mechanisms**. Additionally, the developer highlighted the importance of creating **robust models to assess the added value and return-on-investment of AI solutions** to clearly demonstrate the benefit of deploying AI solutions to hospital representatives. Such models should consider factors like improved diagnosis accuracy, increased hospital capacity, reduced working hours, and enhanced service availability.

Furthermore, the developer believes that **increasing IT capacity** in hospitals and **establishing multidisciplinary teams** that include data scientists and IT experts would facilitate the deployment of AI solutions. These teams can support the technical aspects of AI deployment and ensure smooth integration with existing systems without further burdening healthcare professionals.

The developer also recommends more **flexible testing environments and quick assessment processes to evaluate the effectiveness of AI tools** quickly. From the perspective of the healthcare professional from Sweden, deploying an AI solution requires continuous evaluation and adaptation to ensure it effectively improves hospital operations and patient outcomes. The interviewee added that radiologists and other stakeholders need to be involved throughout the entire process—from initial pilots to long-term use—to ensure that the AI solution meets the specific needs and standards of the hospital. The developer of the AI solution echoed this statement and pointed out that early collaboration with end-users, particularly healthcare professionals, is a key factor in developing relevant and practical, user-friendly AI tools that address specific clinical needs. Centres could be established to centralise these testing environments and assessment processes and promoting collaboration between healthcare professionals and AI developers.

10.8 Annex 8 – Administrative Use Case – Case Study 2

This case study report focuses on a generative AI solution for clinical documentation purposes that has been developed by a large enterprise. The specific generative AI solution does not require regulatory approval before use in the USA nor in Europe. To provide an overview of the AI use case, we conducted desk research and in-depth interviews with 6 selected stakeholders[427]:

- 1 healthcare professional from the United States using a clinical documentation AI solution,
- 3 representatives of different hospitals from the United States that have deployed a clinical documentation AI solution,
- 2 representatives of the same hospital in Canada that have deployed a clinical documentation AI solution.

The insights gathered contribute to building an overall picture of the use case and its impact, in addition to gathering information on the challenges and good practices employed in its deployment in healthcare settings.

10.8.1 Overview of the need

Staffing shortages, increased demand for services fuelled by the growing aging population, poor patient experiences and burned-out healthcare professionals are some of the many challenges facing healthcare systems today. Many of these challenges are interconnected and share a consistent factor: the burden of clinical documentation. According to the American Medical Association, healthcare professionals spend more time documenting care than delivering it, spending up to two hours on administrative

427 In this specific case study, the developer of a clinical documentation AI solution did not participate in an interview.

tasks for each hour of care provided[428]. A separate study in Italy reported that healthcare professionals spend on average 47% of their time on administrative tasks, with 63% of respondents reporting spending at least half of their time on such activities[429]. According to a recent survey by Medscape, more than half (54%) of healthcare professionals would sacrifice some of their salaries to have a better work-life balance[430].

The administrative burden faced by healthcare professionals has several knock-on effects. Firstly, the burden of clinical documentation puts increased pressure on healthcare professionals and has led to higher rates of burnout and turnover, resulting in a negative impact on patient safety and patient experience. The Health and Human Services in the USA predict there will be a shortage of nearly 90,000 clinicians by 2025 as a result of burnout, COVID-19, retirement and limits on medical school and residency programs[431]. In addition, the number of clinicians aged 60 years and older in 2020 was 31%[432]. Since 2020, 1 in 5 healthcare professionals have quit their jobs, with surveys suggesting that up to 47% of US healthcare professionals planning to leave their positions by 2025[433].

Secondly, patients are increasingly report experiencing reduced engagement with healthcare professionals that are often rushed or distracted during visits as a result of the documentation burden, resulting in poor patient experiences. In a survey conducted by Dynata, 71% of patients said they are frustrated with their healthcare experience, and 61% said they would visit their healthcare professional more often if the communication experience felt more personalized[434]. Reducing the growing clinical documentation burden faced by healthcare professionals today can improve the clinician experience by reducing cognitive load and burnout, improve clinician-patient relationships and patient care, and reduce administrative costs through more efficient and effective documentation methods[435].

10.8.2 Overview of the use case

AI solutions developed for clinical documentation leverage conversational AI and generative AI technology to transcribe and contextualise the patient-healthcare professional (HCP) conversation. The solutions enable clinicians to engage in natural conversation with patients and other family members, connecting with patients rather than screens. The output of the AI solution (once the HCP-patient conversation has ended, and recording stopped) can be uploaded into the patients Electronic Health Record (EHR) for final review, edit and signature by the healthcare professional.

10.8.3 Challenges to Deployment

10.8.3.1 Technical and Data Challenges

Several technological and data challenges were described by the stakeholders interviewed. One barrier highlighted by one of the hospital representatives in the United

428 Colligan L et al., 2016. Sources of physician satisfaction and dissatisfaction and review of administrative tasks in ambulatory practice: A qualitative analysis of physician and staff interviews.
429 Petruzzelli et al., 2024. Exploring the administrative burden faced by haematologists: a comprehensive study in Italy.
430 Jon McKenna, 2024. Medscape Physician Lifestyle & Happiness Report 2024: The Ongoing Struggle for Balance.
431 Shanafelt TD et al., 2016. Potential Impact of Burnout on the US Physician Workforce.
432 Young A et al., 2021. FSMB census of licensed physicians in the United States, 2020.
433 Elsevier Health, 2022. Clinician of the Future.
434 Redpoint global, 2020. 75% of U.S. Consumers Wish Their Healthcare Experiences Were More Personalized, Redpoint Global Survey Reveals.
435 Sloss et al., 2024. Toward Alleviating Clinician Documentation Burden: A Scoping Review of Burden Reduction Efforts.

States is **the variation in performance of the AI solution across different medical specialties.** The hospital representative from the United States reported that this poses a challenge for medical specialties with specific needs. Hospital representatives from Canada also raised concerns about performance variability. They noted that while the solution performs well in ambulatory settings, healthcare professionals in complex internal medicine settings with long consultations can experience difficulties

The other hospital representative from the United States highlighted a similar challenge. According to the interviewee, although time savings of up to two hours daily have been reported in healthcare settings where documentation is usually typed and that these **benefits appeared less significant in settings where documentation processes were simpler**. In inpatient environments, issues like noise and the fast-paced nature of emergency departments, where work is often done outside the patient's room, present obstacles. In critical care, the presence of simultaneous conversations among multiple healthcare professionals adds further complexity.

One hospital representative from the United States noted that a barrier to the deployment of the AI solution across EU Member States may be the **language** as its effectiveness in other EU languages may add complexity to cross-region transferability.

The healthcare professional from the United States reflected **concerns surrounding the accuracy of the AI solution's performance.** According to the interviewee, the AI solution occasionally misses some discussion points, requiring manual reconciliation by healthcare professionals.

Another challenge raised by the healthcare professional from the United States **are the concerns surrounding training and tuning the AI solution** to match the personalized preferences of the healthcare professionals. The interviewee reported that even within the same medical specialty, healthcare professionals' preferences and approaches may vary.

10.8.3.2 Legal and Regulatory Challenges

Two hospital representatives from the United States stated that **privacy concerns** were barriers to deployment. At enterprise level, there are concerns about where the data collected by the AI solution is stored, its potential uses, and the risks of data breaches. On an individual level, the hospital representative reported that there is a requirement to obtain verbal or written consent from patients before using ambient technology, ensuring transparency and compliance with privacy standards.

Additionally, another hospital representative from the United States reported that AI developers who access data in the cloud are required to demonstrate **certification and qualification according to specific cybersecurity regulations**. While such regulations may not be a problem for large developers, their **stringency could pose challenges for smaller startups.** The hospital representatives from Canada reflected the same concerns and added that the negotiations with the legal counsel prior to the deployment to ensure safety and security were months long and delayed the process. A hospital representative from the United States also raised concerns about **liability and accountability**.

10.8.3.3 Organisational and business challenges

Hospital representatives from the United States highlighted that the **high cost** limits the deployment of the AI solution to only a number of healthcare professionals, primarily the 'heavy users'. The hospital representatives from Canada echoed those concerns and added that the high cost, along with the general lack of funding, limits their goal to scale the AI solution further.

10.8.3.4 Social and Cultural Challenges

All the hospital representatives from the United States raised concerns about **healthcare professionals' resistance to change.** One hospital representative reported that the initial interest among healthcare professionals was around 60-70% but dropped to about 50% after the trial period. This resistance was attributed to the healthcare professionals' preference for their own familiar, personalized templates or, as some reported, the language used by the AI solution that included a lot of laymen terms instead of precise medical terminology. Another hospital representative from the United States echoed this resistance, attributing it to a preference for an alternative, familiar solution that not only transcribes notes but also sends orders and prepares charts ahead of visits. Additionally, the healthcare professional from the United States highlighted that the resistance was particularly strong among older practitioners who were accustomed to other tools, attributing this reluctance to a desire to maintain established routines than to distrust of the new technology.

The hospital representatives from Canada also reflected resistance to the solution at their hospital, adding that the non-familiarity with the language was evident in the early stage of deployment.

Regarding the patient's attitude towards the AI solution, one hospital representative from the United States reported some **patient resistance** mainly due to privacy concerns. Additionally, the hospital representative highlighted that some patients were **concerned about the lack of human oversight**, fearing that healthcare professionals might become overly reliant on the AI solution, potentially leading to missed information or gaps in their care.

10.8.4 Accelerators to Deployment

10.8.4.1 Technical and Data

All stakeholders interviewed reported that a key accelerator of the deployment process is **the seamless integration of the AI solution within the existing IT infrastructure**. The AI solution integrated seamlessly within existing EHR systems and provided a familiar user interface that healthcare professionals already use and can easily navigate, reducing the cognitive burden of interacting with multiple software. One hospital representative from the United States noted that the solution works well with most local systems, which could facilitate cross-region deployment, particularly in rural areas or locations still reliant on paper charts due to limited digital infrastructure such as EHRs.

One hospital representative from the United States highlighted **the leadership's early decision to invest in infrastructure and equip every room with computers** as a key accelerator. This proactive approach eased the downstream deployment and minimized logistical and financial challenges. Another hospital representative from a different hospital in the United States added that the hospital **intentionally slowed down the initial deployment process to observe the solution's impact on workflow and functionality**.

The hospital representatives from Canada reported that the project evaluation approach prioritized both timeliness and completeness by implementing a two-stream strategy. Recognizing the need for rapid results to address initial concerns from the leadership team, the evaluation team established a plan for early data collection and frequent reporting of key performance indicators (KPIs). Although timeliness was prioritized, the evaluation team also integrated academic rigor by involving a health economist and applying a health economics methodology.

For post-deployment monitoring, the hospital representatives from Canada highlighted that **the hospital's existing EHR software automatically collects data**, such as time spent on administrative tasks, enabling easy before-and-after comparisons.

One hospital representative from the United States reported conducting **post-deployment testing to ensure that the AI solution is a good fit,** with assessments being more qualitative rather than quantitative. Another hospital representative from a different hospital in the United States added that the hospital conducted **a usability analysis to compare charting time across different settings, four months before and after deployment**.

To **ensure the AI solution's adaptability to healthcare settings**, the hospital representatives from Canada and the AI developer agreed to **pilot it among physicians across several medical specialties**. This ensured the AI solution addressed the specific needs of each subspecialty. The healthcare representatives emphasized that the **expertise of the AI developer** was a key factor in accelerating the deployment.

10.8.4.2 Legal and Regulatory

The healthcare representatives from Canada identified several practices they implemented to address legal and regulatory challenges. They began by conducting **due diligence with the AI developer**. This helped **define liability and accountability measures in the event of unforeseen issues.** Following this, **open conversations were held with the AI developer**. These discussions helped the hospital to better understand the risks, implications, and mitigation measures involved in deploying the AI solution. Finally, the hospital consulted with its **legal counsel** to **ensure compliance with data protection and security standards** before proceeding with the deployment.

10.8.4.3 Organisational and Business

Stakeholders from the United States emphasized the crucial role of **clinical champions**—healthcare professionals who are knowledgeable about AI and actively advocate for its adoption within their specialties. One hospital representative highlighted the importance of these champions being deeply involved in their fields, enabling them to pinpoint specific needs that AI solutions should address. Once these needs are identified, multidisciplinary teams, including data scientists, IT specialists, and AI developers, work together to refine and adapt the AI solution to fit seamlessly into clinical workflows.

A hospital representative from the United States highlighted that in one hospital **a specific annual budget was allocated for AI licenses**, distributed through a selection process that considered factors like ambulatory visits per week, potential value of use, and current usage of other tools. This approach allowed the center to identify candidates who would benefit most from the solution and ensure equitable distribution across specialties.

Hospital representatives from Canada proposed a **gradual scale-up approach**, beginning with early investments in a small group of physicians and subspecialties. This controlled rollout made it easier to manage and adjust the implementation in later stages, with scalability in mind. The goal was to steadily build a solid foundation for wider hospital adoption, ensuring that the expansion remained manageable and sustainable. Representatives explained that the hospital planned to evaluate the return on investment (ROI) once the AI solution was deployed to a larger group of healthcare professionals.

Regarding workflow integration, a U.S. hospital representative emphasized their hospital's long-term investment in IT personnel. These specialists play a critical role in translating the solution's functionality into practical applications for healthcare professionals, providing on-site support to facilitate seamless integration into daily workflows. The representative also highlighted a growing trend of **appointing chief innovation officers (CIOs)** with clinical backgrounds, ensuring that AI tools align closely with clinical needs.

Canadian hospital representatives similarly stressed the importance of **adjusting workflows to integrate the AI solution** effectively, acknowledging an initial learning curve for users. They observed that as healthcare professionals became more familiar with the solution, productivity and efficiency improved, enhancing overall effectiveness in clinical settings.

10.8.4.4 Social and cultural

The healthcare professional from the United States identified a few practices to deploy the AI solution while addressing social and cultural challenges. To ensure transparency and patient comfort, the interviewee recommended including **a written consent form and an informational note in the template for all users**. This documentation should explain what the AI solution is and how it functions. This approach would help manage patient expectations and clarify the AI solution's role in their care. Additionally, instead of broadly informing all patients about the AI solution, the hospital representative reported that the hospital **only communicates such for patients coming in for visits in the chosen subspecialties where the AI solution is used**. This targeted communication minimizes unnecessary concerns among patients who are not affected by its use.

The hospital representatives in Canada implemented several best practices to ensure the AI solution's successful integration and use in their clinical settings. To facilitate continuous learning and adaptation, **a multifaceted education strategy was adopted**. This strategy includes **gate checks every two months**, where healthcare professionals participate in 30-minute calls, with 5 minutes dedicated to data presentation and the remaining 25 minutes for informal peer discussions. These sessions create a space for reflection and sharing experiences, fostering a supportive learning environment.

Additionally, **a dedicated communication channel** was established to ensure continuous interaction between healthcare professionals and the developers. This ongoing communication supports **regular feedback collection through discussion sessions, workshops, and surveys.**

The hospital representatives from Canada reported closely **tracking the usage of the AI solution** by healthcare professionals to identify those who may not be utilizing it adequately. Feedback is gathered to determine whether low use is due to dissatisfaction with the solution or a lack of necessary skills. Finally**, training healthcare professionals to navigate the complexity of clinical work with the AI solution** was also recognized. As clinical work itself is inherently complex, this training supports teams and introduces streamlined workflows, ultimately reducing barriers to the solution's effective use.

The hospital representative from the United States echoed the importance of ensuring healthcare professionals are comfortable and competent to use the solution. An additional accelerator reported by the stakeholder was the **involvement of early**

adopters in the pilot studies. Those early adopters provided positive feedback on the solution to their colleagues, encouraging its use.

10.8.5 Complementary Actions

On the technological side, the healthcare representative from the United States emphasized the importance of **selecting the appropriate solution for each specific task**, following clear discussions with developers about the solution's limitations. The healthcare professional added that for any AI solution to be effective, **simplicity and consistency in design** are essential. This approach enhances user-friendliness, allowing reliable, long-term use. Additionally, the healthcare professional recommended that **healthcare professionals should have the ability to directly train and adjust the solution in real-time clinical settings.** This hands-on involvement of the users would facilitate the customization of the solution to meet specific clinical needs and address functionality gaps more effectively.

Another hospital representative from a different hospital in the United States recommended **establishing assurance labs** to rigorously validate AI tools before deployment. Such labs would serve as controlled environments to test the tools' reliability, accuracy, and performance, ensuring they meet the necessary standards for clinical use. The interviewee also emphasized the **importance of creating standardized data structures** to ensure interoperability across systems, which would improve the usability of AI tools and help users understand and mitigate potential biases in the models. Furthermore, these standardized data structures should be diverse and representative of patient populations to ensure the AI models are equitable and applicable in varied clinical settings.

From an organizational and business perspective, the healthcare representatives from Canada pointed to the necessity of establishing **funding and reimbursement mechanisms** to support AI deployment and scalability. On the social and cultural side, the hospital representative from the United States recommended **educating healthcare systems on both the capabilities and constraints of the solution to avoid potential setbacks** and mitigate unrealistic expectations. The hospital representatives from Canada focused on the **importance of educating healthcare professionals on the cultural shift**. They noted that AI deployment is accelerating rapidly, and preparing healthcare professionals now will ease the transition when AI tools become more widely integrated into clinical practice.

10.9 Annex 9 – Cancer Treatment Use Case – Case Study 3

This case study report focuses on an AI solution used in the treatment of cancer that has been developed by a small-medium enterprise (SME) and has been approved by the U.S. Food and Drug Administration (FDA) and has a European Conformity marking (CE marked) and deployed in urban healthcare settings globally. To provide an overview of the AI solution, we conducted desk research and in-depth interviews with a range of stakeholders to understand the current need in healthcare addressed by the AI solution, its impact on clinical workflow and overall delivery of care, the challenges faced during deployment, and any good practices that facilitated its deployment. A total of 5 stakeholders were interviewed:

- the developer of the AI solution from France,
- 1 healthcare professional from Germany using the AI solution,
- 1 healthcare professional from France using the AI solution,
- 1 hospital representative from France that has deployed the AI solution,

- 1 hospital representative from Germany that has deployed the AI solution.

The insights gathered contribute to building an overall picture of the use case and its impact, in addition to gathering information on the challenges and good practices employed in its deployment in healthcare settings.

10.9.1 Overview of the need

Cancer is responsible for one in every four deaths in Europe, making it the second leading cause of death and disability after cardiovascular disease. The impact of cancer on European healthcare systems is expected to increase, with the number of people diagnosed with cancer across Europe having risen by approximately 50% over the past two decades[436]. Given an ageing and growing European population, this trend is set to continue with the cancer incidence and mortality in Europe expected to increase by 38% and 44% respectively by 2040[437].

Radiation therapy is an effective cancer treatment, with at least half of all cancer patients expected to undergo radiotherapy (RT) at some stage during their care. However, more than one out of four cancer patients in Europe do not receive the radiotherapy they need[438]. Limited availability of the necessary resources – in terms of both trained personnel and equipment – is one of the biggest barriers contributing to suboptimal access to radiotherapy. Moreover, effective RT planning may be challenging as each patient's tumour characteristics, such as size, location, and sensitivity to radiation are unique. Tumours can also move due to patient breathing or changes in body position, making real-time monitoring and accurate targeting complex. Additionally, RT can cause acute and long-term side effects, such as skin irritation, fatigue, and damage to healthy organs[439]. RT planning must account for these risks, particularly for tumours located near sensitive structures.

Tumour contouring, or target delineation, consists of the process of outlining the shape, size, and location of a tumour and surrounding critical structures on medical imaging scans. It is a critical step in RT planning, due to its impact on both treatment efficacy and patient safety, as it defines the area that will receive the radiation dose while sparing healthy tissues as much as possible[440]. Considering the above, to be as effective as possible, contouring must be precise, focused on the tumour, and be personalised for each patient to minimise any potential side effects.

Computed tomography (CT) is currently the gold standard for tumour contouring. Nevertheless, as a patient's anatomy changes during treatment, the initial CT-based treatment plan may no longer accurately reflect the dose being delivered to the tumour and surrounding organs at risk (OARs)[441]. Repeated imaging, such as cone-beam computed tomography (CBCT), which is often used for patient positioning, can assist in making plan adaptation decisions[442].

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436 Hofmarcher T, Bradvik G, Svedman C, et al. 2019. Comparator Report on Cancer in Europe 2019.
437 European Commission – Joint Research Centre. 2023. Cancer in 2040: Estimates for an ageing Europe.
438 Zeman EM, Schreiber EC, Tepper JE, et al. 2020. Basics of radiation therapy.
439 Zeman EM, Schreiber EC, Tepper JE, et al. 2020. Basics of radiation therapy.
440 Jameson MG, Holloway LC, Vial PJ, et al. 2010. A review of methods of analysis in contouring studies for radiation oncology.
441 Precise contouring of all OARs is needed to minimise damage to surrounding healthy tissues and organs. This process is often tedious, time-consuming, and costly, requiring significant resources and expertise
442 Yoo S, Yin FF. 2006. Dosimetric feasibility of cone-beam CT-based treatment planning compared to CT-based treatment planning.

Magnetic resonance imaging (MRI) is frequently used alongside CT imaging to improve the contouring of tumours and OARs due to its superior soft-tissue contrast[443]. MRI offers additional advantages over CT, such as the use of non-ionising radiation and the ability to gather more detailed information on tumour activity and response to therapy. However, despite these benefits, radiotherapy planning cannot rely solely on MR images, as they do not provide the tissue electron density[444] information required for dose calculations in a treatment planning system (TPS)[445].

Adaptive radiotherapy (ART) is a treatment strategy developed in recent years to address anatomical variations between treatment sessions. ART enables more precise and personalised radiation delivery, with the potential to enhance patient outcomes. The primary aim of ART is to enhance the accuracy of dose delivery to patients while minimising the risk of side effects on healthy tissues. ART can be applied to various cancer types, including prostate, lung, and head and neck cancers. A key factor enabling ART is the advent of image-guided radiotherapy, where patients undergo repeated imaging, such as CBCT[446]. Once several 3D images are obtained, they need to be registered, by aligning multiple 3D images of the same patient into a unified coordinate system for precise comparison, analysis, and merging of data from different imaging modalities or time points. However, CBCT images have several limitations, including poor image quality, soft-tissue differentiation, and a limited field of view. These issues restrict the effectiveness of CBCT images for dose calculations and objective clinical decision-making regarding the need for adaptation[447].

Moreover, these tasks are highly time-consuming. Within the current clinical workflow of adaptive MR-guided radiotherapy, the most time-consuming factor is a new daily accurate and consistent annotation of structures. As these tasks need to be carried out manually by radiotherapists, this workflow not only limits the number of patients being treated, but also introduces time delays which can result in intra-fractional motion (i.e. movement of a patient's tumour or internal organs during a RT session) of the relevant structures[448].

To address these challenges, an Artificial Intelligence (AI) based solution has been developed for ART.

10.9.2 Overview of the use case

The AI use case is a radiotherapy software that assists in automatic contouring delineation of anatomical regions on 3D images of cancer patients scheduled for radiotherapy, hence optimising the treatment process, from preparation to follow-up.

443 Nachbar M, Lo Russo M, Gani C, et al. 2023. Automatic AI-based contouring of prostate MRI for online adaptive radiotherapy.
444 Electron density refers to the average number of electrons per unit of volume of material. This information is used to assess how different tissues absorb or scatter radiation from X-ray cancer therapy and is crucial for guaranteeing an efficient treatment.
445 Khoo VS, Joon DL. 2006. New developments in MRI for target volume delineation in radiotherapy.
446 Alves A, Dias JM, Rocha H, et al. 2021. Assessing the need for adaptive radiotherapy in head and neck cancer patients using an automatic planning tool.
447 Gianoli C, De Bernardi E, Parodi K. 2024. "Under the hood": artificial intelligence in personalized radiotherapy.
448 Nachbar M, Lo Russo M, Gani C, et al. 2023. Automatic AI-based contouring of prostate MRI for online adaptive radiotherapy.

10.9.3 Challenges to Deployment

10.9.3.1 Technical and Data Challenges

The hospital representative from France noted that **requirements specific IT infrastructure** such as a server with a Graphics Processing Unit (GPU) resulted in additional deployment costs. The hospital representative from France also emphasised the risks of **high fragmentation of AI solutions market**, hence entailing **significant challenges in terms of interoperability of solutions**. The stakeholder emphasised that **merging distinct products into one single, unified AI solution** could streamline processes and lower costs, although reflected that the technology to achieve this "multi-modal" approach may not yet be available.

10.9.3.2 Legal and Regulatory Challenges

The AI developer reflected on the **complex regulatory processes in the EU**. Despite the AI solution being CE marked, the AI developer highlighted that the auditing and approval process was considerably longer and more burdensome than in the USA. In relation to deployment, the AI Developer highlighted that the cost of regulatory procedures increases the cost of deploying the AI solution in Europe.

Similarly, the hospital representative from France highlighted the importance of **targeted financial support for Small-Medium-Enterprises (SMEs)**, noting that whilst SMEs are frequently the main source of AI innovations, they encounter significant regulatory and financial barriers when trying to enter the market.

10.9.3.3 Organisational and business challenges

The stakeholders interviewed also highlight some organisational and business challenges affecting the deployment of the AI solution. The introduction of any type of technology always involves an **assessment of added value to select the best solution available**. As noted by a healthcare professional of a hospital in Germany, it was challenging to convince some members of the management team of the added value of the AI solution versus existing clinical solutions. Since such AI tools are often expensive to deploy, it is necessary to clearly outline to the decision makers within a healthcare facility that the investment was worthwhile (i.e. return on investment).

Another major issue highlighted by the AI Developer is that **AI innovations often fall outside the scope of European reimbursement frameworks**. The AI developer also highlighted a significant difference between the EU and the USA on how decisions are taken regarding the deployment of AI technologies within a healthcare facility, as the value attributed to **efficiency gains and time savings** are considered differently among healthcare facilities.

Moreover, the AI developer emphasised the need for **wider utilisation of innovative AI tools in public healthcare institutions**. The AI developer added that European public healthcare facilities, despite having a strong demand for these advancements, are frequently the last to adopt them, and this lag is primarily caused by **bureaucratic obstacles**. Consequently, the stakeholder emphasised that these facilities require a fast-track pathway for financing and adopting AI solutions, as the current process is excessively long and time-consuming.

10.9.3.4 Social and Cultural Challenges

One of the key challenges highlighted by all stakeholders interviewed is the **hesitation of some healthcare professionals to adopt the AI solution**. Stakeholders reflected

upon a **generational divide in attitudes towards AI**, with younger doctors generally more open to incorporating AI solutions into their practice. According to the AI developer, younger healthcare professionals are less inclined to spend time on tedious tasks that can be carried out by the AI solution, freeing up their time for direct patient care. A healthcare professional from a German hospital noted that the presence of many younger doctors in their institution played a crucial role in promoting the adoption of the AI solution.

Moreover, according to the AI developer, some doctors fear **that over-reliance on the solution could diminish younger doctors' ability to perform tasks independently**, and in turn result in over-reliance which degrades essential medical skills, or prevents them being fine-tuned (for example, doctors may not develop their own critical decision-making abilities when preparing contouring delineations).

The healthcare professional from a hospital in Germany highlighted that **some doctors were uneasy about using an AI solution for tasks traditionally performed by highly trained medical professionals,** and that this underscores the need for rigorous validation and transparent testing of the AI system to build confidence. The representative from the French hospital echoed similar sentiments, stressing the **importance of verifying the AI solution's results to make sure no eventual errors go unnoticed.** This professional emphasized that ultimate accountability lies with the doctors, who are responsible for patient outcomes.

10.9.4 Accelerators to Deployment

10.9.4.1 Technical and Data

The hospital representative from France emphasized the advantages of **upgrading their IT infrastructure** which significantly enhanced the hospital's operations, allowing healthcare professionals to move more efficiently between various tools and data sets. With this system in place, staff no longer need to manually enter all the information, which **streamlines the process of uploading and downloading data**. This not only saves time but also bolsters data integrity, as reducing manual input helps **minimize the risk of errors**.

Alongside these infrastructure improvements, the hospital has benefited from **enhanced interoperability between tools**. This seamless integration allowed healthcare professionals to experience the advantages of the AI solution from the early stages of deployment. Importantly, this interoperability ensures that the AI solution complements, rather than disrupts, existing workflows. By integrating smoothly with the hospital's current systems, the AI solution increases efficiency without the need for extensive retraining or major adjustments from the staff, making the transition easier and more effective.

According to the healthcare professional from a hospital in Germany, the AI solution was **seamlessly integrated into the existing IT infrastructure and was compatible with other tools in use**. They highlighted key features like the AI's **user-friendly design**, **easy installation process**, and **strong interoperability with current systems** as critical factors in its success. The integration also facilitated reliable data exchange between systems, supporting more accurate and comprehensive analysis. These practices reflect a focus on user-centred design, smooth data integration, and maintaining high standards of data quality, all of which contributed to the solution's effective deployment.

10.9.4.2 Organisational and Business

One key approach highlighted by the AI developer was the importance of **conducting pilot studies with as many future users as possible before rolling out the AI solution widely**. This strategy helped **mitigate resistance to change by allowing healthcare professionals to validate the AI's performance in their specific settings.** The healthcare professional from a hospital in Germany emphasized that such **pilot studies were important in addressing concerns among colleagues**. Some healthcare professionals initially doubted the AI solution's ability to save time, while others believed that although the solution might speed up tasks, they would still need to verify the results, potentially offsetting any time saved. The healthcare professional of a hospital in Germany explained that **demonstrating measurable improvements in clinical outcomes and workflow efficiency was key to securing management's support**, as without clear evidence of these advantages decision-makers might have hesitated to commit to such a financial investment.

Another good practice involved the **provision of highly effective training during the deployment phase by the AI developer.** According to the hospital representative from Germany, the training was concise and focused on the practical use of the AI solution, which helped build confidence among healthcare professionals. The involvement of project managers, who were also lead physicists, further ensured a smooth deployment process. These **"AI champions" were important in managing workflows and optimizing the integration of the AI solution within the institution.**

Additionally, the healthcare professional of a French hospital emphasised the **value of strong collaboration** between the deployers and AI developers. **Healthcare professionals played an active role in validating the AI's results and providing detailed feedback on any discrepancies**. Since the data used for testing the solution came from within the hospital, it was easier for professionals to verify the AI's accuracy. This ongoing **feedback loop between the hospital staff and developers** was essential in building trust and confidence in the technology and is a practice that should extend beyond the deployment phase.

10.9.4.3 Social and cultural

When discussing social and cultural practices that accelerated the deployment of the AI solution, the healthcare professional of a hospital in France emphasised that having a **deep understanding of the AI solution's capabilities**, **the data it was trained on**, and the **quality control processes** behind it, helped **build trust in the technology**. Since healthcare professionals remain fully responsible for their actions, **complete confidence in the AI solution** is essential to ensure its widespread adoption.

The AI developer emphasised the importance of ensuring **confidence and trust in the AI solution** from a healthcare professional's perspective. Demonstrating the development process in terms of the AI solution's internal validation procedures and highlighting the number of institutions that have already deployed the AI solution helps build trust and confidence, allowing for more widespread deployment. As more centres deploy the solution and share its benefits and added value, new facilities are more easily persuaded to try and eventually deploy the AI solution. As a result, due to the **demonstrated added value of such AI solutions**, there is overall acceptance among healthcare professionals for its widespread use.

10.9.5 Complementary Actions

The AI developer highlighted that the **regulatory process should be streamlined.** Notably, to reduce the time-for-approval, the interviewee mentioned that **more AI experts should be involved in the process to support the assessment and audit of AI-based medical devices**. In this regard, the developer suggested offering clear regulatory guidance and **expanding the resources of notified bodies** to accelerate the process. This would help alleviate delays, enabling quicker and smoother integration of AI tools in healthcare and, thus, streamline the approval procedures while reducing potential bottlenecks.

The healthcare professional and the management representative of a hospital in France as well as the healthcare professional from a hospital in Germany agreed that defining and optimising the **quality assurance and monitoring processes** is a necessary step to further streamline the regulatory process. Since single hospitals might not have defined processes in place to monitor the quality of the AI tools they use, **EU-level guidelines on how AI should be used and monitored in European hospitals should be developed**.

The healthcare professional of a hospital in Germany emphasised that **clear patient-friendly assurance about how their health data is protected should be provided at EU-level** through regulation so as to make sure that any AI healthcare solution is in line with GDPR requirements. The interviewee noted that patients are increasingly worried about the safety of their data and need reassurance to accept the use of AI technologies as part of their healthcare services. Additionally, the interviewee stressed that anonymisation might not always be sufficient, as some AI tools require access to patients' personal data.

Concerning the issues at the business and organisational level an action highlighted by the AI developer was the provision **of funding to public healthcare facilities support a faster adoption of AI tools**. In this respect, the **AI developer reflected upon the different reimbursement models** by which hospitals deploying the solution could choose. The representative of a hospital in Germany recognised that this was an advantage that facilitated the introduction of the AI solution in their circumstance.

The hospital representative from France stressed that specific **support should be given to SMEs developing AI healthcare technology**. The hospital representative from France also emphasised that, although many tools are being introduced to the market, **certain disease areas receive limited funding for R&D**. This raises the risk that patients in these areas may fall behind in accessing new AI solutions.

10.10 Annex 10 – Cancer Detection Use Case – Case Study 4

This case study report focuses on an AI use case used in radiology for the early detection of metastasis that has been developed by a large enterprise and deployed in healthcare settings in Japan. To provide an overview of the AI solution, we conducted desk research and in-depth interviews with 5 selected stakeholders[449]:

449 In this specific case study, the developer of the AI solution did not participate in an interview.

- two healthcare professionals from Japan using the AI solution who were also involved in the development of the AI solution,
- two healthcare professionals from Japan of different hospitals using the AI solution in their clinical practice,
- one representative of a hospital from Japan that has deployed the AI solution.

The insights gathered contribute to building an overall picture of the use case and its impact, in addition to gathering information on the challenges and good practices employed in its deployment in healthcare settings.

10.10.1 Overview of the need

Metastasis is the process by which cancer cells spread from the primary tumour site to other parts of the body. Bone metastasis, in particular, occurs when cancer cells migrate to the bones, with bone being the third most common site for metastasis, after the lungs and liver[450]. This spread can lead to bone pain, fractures, and other complications as the cancer cells disrupt normal bone tissue. Thus, if identified or treated late, bone metastases can impair motor function and severely impact a patient's quality of life. Vertebral metastases, in particular, may lead to compression fractures and neurological issues, such as quadriplegia. Although advancements in anticancer treatments have reduced complications, early detection remains essential, underscoring the importance of clinical follow-up to prevent these issues through prompt diagnosis and intervention[451].

Computed tomography (CT) serves as the primary tool for early and precise detection of bone metastases in cancer follow-ups. Since cancer patients undergo frequent CT scans to monitor local recurrence and distant metastasis, early detection is possible. Recent advances in CT technology allow for the identification of small, subtle lesions. However, such lesions are often obscured by the vast amount of anatomical detail, which can delay radiologists in locating them. Although CT capabilities have improved with higher resolution and better signal-to-noise ratios, the increased volume of anatomical data has heightened the challenge for radiologists, making timely detection more difficult[452]. Furthermore, the high CT density of bone compared to other organs makes it challenging to clearly visualise density changes caused by bone metastases on standard CT images[453].

Additionally, comparing past and current CT images is subject to several complexities. Even for the same area on the same person, variations in body condition can alter how tissue appears on imaging (e.g. cancer patients may experience changes like weight loss). This requires highly precise image alignment technologies. Without this precision, numerous other differences - such as subtle variations due to breathing depth during scans- would appear on subtracted images, complicating the detection of bone

450 Onoue K, Yakami M, Nishio M, et al. 2021. Temporal subtraction CT with nonrigid image registration improves detection of bone metastases by radiologists: results of a large-scale observer study.
451 Onoue K, Nishio M, Yakami M, et al. 2019. CT temporal subtraction improves early detection of bone metastases compared to SPECT.
452 Sakamoto R, Yakami M, Fujimoto K, et al. 2017. Temporal subtraction of serial CT images with large deformation diffeomorphic metric mapping in the identification of bone metastases.
453 Onoue K, Yakami M, Nishio M, et al. 2021. Temporal subtraction CT with nonrigid image registration improves detection of bone metastases by radiologists: results of a large-scale observer study

metastases[454]. Other methods to identify bone metastasis, such as bone scintigraphy[455], have also proven to be time-consuming, placing significant burden on both patient and doctor[456].

Detecting bone metastases with CT remains challenging, with a risk of missing potentially dangerous lesions[457]. As highlighted by a healthcare professional interviewed for this case study, the process of examining bone metastases can be cumbersome, repetitive and is often completed at the end of the CT review sequence. Typically, the examination begins with the chest, followed by the abdomen, with the bones examined last. Consequently, when the patient volume is high, this step may sometimes be overlooked. This is particularly concerning given the current shortage of radiologists, and the significant increase in their workloads in recent years given the greater demand and complexity of CT interpretations. These factors combined have led to backlogs of unread CT scans, potentially delaying the identification of bone metastases in cancer patients[458].

In response to the above, the AI developer has partnered with university hospitals to create an AI solution for early detection of bone metastasis.

10.10.2 Overview of the use case

Temporal subtraction (TS) is a technique used to extract an earlier image from the latest scan, utilising medical images captured at two distinct times in a sequence[459]. In other words, this technique allows to compare the same body part between two points in time. The use of TS with CT images enhances the ability of radiologists to identify new bone lesions, including bone metastasis. Traditionally, identification of differences between two scans is a manual process performed by radiologists. Since its introduction, the TS method has evolved, allowing for better visualisation of bone metastasis[460]. AI solutions can streamline this process by automatically retrieving previous images, identifying bone regions, reduce noise perform and the analysis – transmitting the outputs into medical image repository.

10.10.3 Challenges to Deployment

10.10.3.1 Technical and Data Challenges

The representative of a Japanese hospital highlighted **interoperability issues** with pre-existing systems, along with **limited accessibility to the hospital's patient medical records**. This restricted access posed significant challenges for the deployment of the AI solution, as this relies on patient data to function effectively, raising concerns related to **data transparency and privacy**.

454 Onoue K, Yakami M, Nishio M, et al. 2021. Temporal subtraction CT with nonrigid image registration improves detection of bone metastases by radiologists: results of a large-scale observer study

455 This method involves using a specialised camera to capture images of radioactive substances injected into the patient's bloodstream.

456 Yang HL, Liu T, Wang XM, et al. 2011. Diagnosis of bone metastases: a meta-analysis comparing 18 FDG PET, CT, MRI and bone scintigraphy.

457 Onoue K, Nishio M, Yakami M, et al. 2019. Temporal subtraction of computed tomography images improves detectability of bone metastases by radiology residents.

458 Yamada K. 2023. What has caused the shortage of radiologists? Features exclusive to Japan.

459 Iima M, Sakamoto R, Kakigi T, et al. 2023. The efficacy of CT temporal subtraction images for fibrodysplasia ossificans progressiva.

460 Onoue K, Nishio M, Yakami M, et al. 2019. Temporal subtraction of computed tomography images improves detectability of bone metastases by radiology residents.

Moreover, a healthcare professional involved in the development of the solution observed that **integrating the AI solution within the department's existing medical image repository** required **careful planning** to maintain efficient data flow, as the additional data processing demands of the AI solution risked slowing down the system and potentially delaying access to critical imaging information. As highlighted by the healthcare professional, in fact, ensuring seamless integration was essential to avoid workflow disruptions and maintain the timely delivery of patient care.

Given that the AI solution operates without requiring specialised IT infrastructure, its integration was streamlined. Nonetheless, the **limited storage capacity** at the hospital prompted radiologists to explore options with the developers for reproducing the AI outputs should they be inadvertently deleted.

Additionally, significant efforts were made to **keep all data on-premises within the hospital**, as this is a strict requirement from the IT department. However, this approach may vary depending on the hospital's capacity.

10.10.3.2 Legal and Regulatory Challenges

The healthcare professionals interviewed emphasised that no significant legal or regulatory challenges were encountered during the specific adoption of the AI solution in their clinical settings: the regulatory process for the AI solution proceeded smoothly, allowing for its adoption in the hospital without legal obstacles.

A healthcare professional emphasised that the radiology department staff faced some considerations specific to data privacy concerns. For instance, medical personnel engaged in detailed discussions with the AI developers to determine the **source of images accessed by the solution**, **the recipients of the solution's output**, and the **duration for which this output should remain accessible**.

The Japanese government has a **reimbursement system encouraging the uptake of AI solutions in healthcare facilities**, approximately 50 hospitals in Japan are entitled to receive additional diagnostic allowance from the government for adopting AI solutions. The current reimbursement system requires healthcare facilities to comply with certain requirements. In particular, healthcare facilities need to have in place appropriate safety management of diagnostic imaging assistance software utilizing artificial intelligence-related technologies based on the guidelines established by related academic societies (i.e. Japanese Society of Radiological Medicine)[461]. Other requirements involve having a certain amount of full-time equivalent radiologists working in the facility for image diagnosis[462]. Smaller **hospitals usually in rural settings may not fulfil the requirements to be reimbursed for the introduction of AI solutions in diagnostics**.

10.10.3.3 Organisational and business challenges

According to one healthcare professional interviewed, the introduction of any new technology necessitates a thorough **assessment of its added value to ensure the selection of the most suitable solution**.. According to the hospital representative, extensive internal discussions took place among radiologists, the hospital

461 Reference only available in Japanese: Japanese Society of Radiological Medicine. 2024. List of AI Software Certifications. Available at: https://www.radiology.jp/member_info/ai_softwear_ninsyou.html
462 Reference only available in Japanese, template on requirements to receive reimbursement for the use of AI tools in for diagnostic in radiology: https://kouseikyoku.mhlw.go.jp/kinki/r6-t32.pdf

administration, the management board, and other departments to assess the implications of adopting the AI solution. This included **determining whether modifications were required to the hospital's internal IT and information storage systems**. Subsequently, **multiple rounds of testing** were conducted to evaluate the solution's performance and outcomes, ultimately leading to its adoption once its effectiveness was demonstrated.

Lastly, a significant obstacle highlighted by an interviewed healthcare professional pertains to the **limited time available for training doctors** to effectively use the AI solution. Physicians are often occupied with demanding schedules, and this time constraint frequently poses a substantial challenge to the introduction of any new technology. Additionally, some doctors may perceive the **training process as an inefficient use of time** that could otherwise be allocated to their primary responsibilities. Moreover, AI solutions may occasionally require additional **time to generate precise results**, which can be challenging for doctors who operate within strict time constraints. Often, if results are not available within one to two seconds, many physicians may opt to proceed without them, potentially bypassing the solution's insights due to the demands of their workflow.

10.10.3.4 Social and Cultural Challenges

As noted by a healthcare professional, the cultural context in Japan influences patients' expectations regarding diagnoses. Patients prefer that their findings from CT scans be interpreted and communicated by radiologists rather than by a machine or an AI solution. A significant proportion of Japanese patients express **distrust toward AI-generated results**, as they seek diagnoses from human physicians. Additionally, concerns regarding the potential misuse of their data for training other AI solutions contribute to this scepticism.

Moreover, regarding the **reluctance of some colleagues** within the department to adopt the AI solution, a healthcare professional observed that more experienced clinicians often find it challenging to embrace AI deployment. These individuals tend to view the solution as less of a supportive resource for error prevention, preferring to rely on traditional manual methods. In contrast, **younger generations recognise the solution's potential** and are generally more receptive to its use. Consequently, this reluctance appears to correlate with individual careers and attitudes toward technology. Ultimately, not all radiologists utilise the solution.

Lastly, the hospital representative acknowledged that, after observing the AI solution in operation, many healthcare professionals who were initially sceptical understood that the solution serves to assist rather than replace them. Consequently, their **concerns regarding job security** and **over-reliance on technology** significantly diminished.

10.10.4 Accelerators to Deployment

10.10.4.1 Technical and Data

As noted by a healthcare professional, prior to deploying the solution, it was essential to engage in **discussions with the IT department and continuous communication with the AI developer**. The healthcare professional reflected that during the adoption phase, regular meetings were held with the developers to discuss and promptly resolve any technical issues that arose. Additionally, since the solution's implementation had to align with the specific infrastructure of each hospital, significant **customisation** was often required. This customisation process has proven to be a valuable practice, as it

ensures that the existing infrastructure is adequately assessed, and that the solution is tailored to meet the department's specific needs effectively.

10.10.4.2 Legal and Regulatory

All of the interviewees highlighted the **reimbursement system and financial incentives** established by the Japanese government as an accelerator to the deployment of AI solutions in healthcare. The reimbursement system in fact aims at **encouraging the integration of AI in clinical settings**. In Japan, a unique reimbursement structure exists, wherein hospitals are not directly reimbursed for the AI solutions themselves but rather for their management. Initially, reimbursement was directed toward tools for image digitalisation, later expanding to cover the management of AI systems. A list specifies reimbursement eligibility for these tools[463]. Within this framework, reimbursement served as a significant driver for the solution's adoption. In this regard, as highlighted by a hospital representative interviewed, this increased the incentives for hospital management to accept requests from healthcare professionals on the possibility to introduce AI solutions in clinical settings.

10.10.4.3 Organisational and Business

A healthcare professional stated that, given the novelty of the solution and the potential challenges associated with troubleshooting, the developers have shown a **high level of responsiveness and support**. Lectures on the solution's usage were conducted, accompanied by detailed information on its features and functionalities. Additionally, at the start of the solution's introduction, an initial **training** session was conducted, including both a lecture and **hands-on activities** that allowed clinicians to familiarise themselves with the solution. According to the interviewee, providing hands-on experience and concrete examples of its diagnostic support also serve to encourage adoption, particularly among younger clinicians.

Another effective practice highlighted by the hospital representative involved **simulating the deployment of the AI solution** to assess its impact on workload and efficiency. This process included measuring reductions in working hours and associated costs over time, once staff became familiar with the solution. Based on these simulations, estimates were made regarding the decrease in labour hours and financial expenditure. Effectiveness was evaluated in terms of potential revenue changes, with specific consideration for diagnostic AI solutions, as the government has adjusted reimbursement rates for hospitals adopting AI technologies. By **calculating the financial impact** of AI adoption versus non-adoption, hospitals are able to make informed decisions about investment in such tools.

Lastly, it was observed that appointing a **mediator**, such as the Chief Information Officer (CIO), who is fluent in both the technical language of developers and the clinical language of healthcare providers, proved to be an effective strategy for facilitating the adoption process and ensuring that solution was aligned with the practical needs of the hospital and clinicians.

10.10.4.4 Social and cultural

To overcome the reluctance of some healthcare professionals to use the AI solution, a healthcare professional mentioned that within their healthcare institution, repeated **demonstrations of the AI solutions were conducted**. Specifically, cases were

463 https://www.radiology.jp/member_info/ai_softwear_ninsyou.html

shared in which the AI solution successfully identified findings that had been overlooked by radiologists, thereby highlighting its value as a diagnostic aid. These instances were presented within the department to illustrate the solution's effectiveness in supporting diagnostic accuracy. In the case of another hospital, the healthcare professionals involved in the development of the solution were willing to provide explanations to those who were hesitant to use it and conducted several trials to demonstrate its functionality.

Additionally, to address some concerns related to data privacy concerns with the use of cloud services to start images and reports generated by the AI solution, a hospital representative interviewed mentioned that further explanation on what is cloud computing would help to gain acceptance. This refers to the healthcare professionals constantly explaining to patients what cloud services mean, and how data protection is guaranteed; but also further efforts could be made on to include more information on cloud services and AI technologies in the media.

10.10.5 Complementary Actions

In light of the technological and data challenges outlined above, the hospital representative emphasised the need for **enhanced collaboration between developers and healthcare institutions**. Such collaboration would enable developers to gain a clearer understanding of current **market demands** and to address potential barriers, particularly those concerning **data accessibility** and **interoperability**.

With regard to the legal and regulatory framework, the **reimbursement system** introduced by the Japanese government proved to be successful in encouraging the uptake of AI solutions in healthcare. In this respect, the hospital representative emphasised the importance of establishing **clear reimbursement mechanisms** to facilitate developers' entry into the market. In rural areas, where the availability of radiologists is especially limited, deploying AI solutions is crucial to help mitigate the **shortage of medical personnel**.

In considering the organisational and business actions required, a healthcare professional highlighted that diagnostic imaging practices vary among individual radiologists, underscoring the need for **standardised guidelines** to promote greater consistency across hospitals and among radiologists. Specifically, guidelines on utilising the solution's findings, as well as on reviewing images based on those findings, would support uniformity..

Another healthcare professional suggested that for the software to be more effective within the hospital, efforts should prioritise **educating colleagues and physicians across departments**. This initial educational focus would allow for a broader adoption of the solution. Specifically, healthcare staff should first gain an understanding of the solution's features, including its strengths and potential limitations, to foster informed use. Furthermore, AI solutions that alleviate rather than add to the workload of healthcare professionals should be prioritised.

Finally, when considering social and cultural aspects, a healthcare professional believed that it is essential to first establish a **professional consensus** on the implementation and usage of AI solutions before **introducing these concepts to patients**. Ideally, patients should have a clear understanding of both the benefits and limitations of AI solutions; therefore, prior to sharing AI-generated results, efforts should be made to inform patients and, ideally, reach a shared understanding on how these tools should be utilised in the clinical context. To address their resistance stemming from data

privacy concerns related to the use of cloud services to store data generated by AI solutions, continuous **information** might also be provided **through newspapers, websites, and social media**. Such efforts would help clarify data management practices and foster a better understanding of cloud computing among patients.

10.11 Annex 11 – Monitoring framework

The Commission will oversee the design and operationalisation of the data collection and reporting of the developed monitoring framework. In this regard, as part of this study, we have set a list of recommendations on how the data collection and reporting could be done in an efficient manner.

Based on the monitoring tool developed, the study team proposes a reporting template which will take the form of a table to be filled out to facilitate the reporting of data as well as the cross-country comparison. The reporting template lists each recommended action and the corresponding indicators that will inform on the level of implementation and effectiveness of each action.

For each indicator, the data collectors will fill up the information and include the source from which the information was retrieved from. When they indicate the source of the data, a link to the source needs to be included in the column "Link to source of information". Additionally, depending on the unit of measurement of each indicator, the information to be provided in this column will differ. In some cases, specific figures are requested such as the number of assurance labs established in each Member State. In other cases, a binary (yes or no) response is requested on, for instance, whether a central data repository has been created or not. For qualitative information, data collectors will include free text always with a mandatory link where to find the information included in the value cell. In the table below we have included an illustrative example of the reporting template for the considerations for future actions.

Table 12: Monitoring framework template

Consideration	Evaluation question	Target	Type of Indicator	Indicator	Data source	Limitations	Reporting method
Establishing common standards for data governance, privacy, and interoperability							
Rules to standardise data formats, protocols and metadata	Are data formats, protocols and metadata standardised across the EU?	All data formats, protocols and metadata follow common standards across the EU	Output	Establishment of common EU standards on data formats, protocols and metadata	Desk research: EU official communications	No information with regard to the establishment of other national standards	Single reporting
							Annual
			Outcome	Estimated percentage of data that follows the common EU standard format	Desk research: hospitals using standard data format	Data on number of standardised data may not be up to date or comprehensive	Upon request
			Impact	Higher number of AI integrated into various healthcare systems	Surveys with AI developers, healthcare professionals, and hospital representatives	Responses collected from a sample of stakeholders may not be representative	Upon request
			Impact	Improved data exchanges / improved interoperability between healthcare organisations	Surveys with healthcare professionals/hospital representatives		

Standards on mechanisms to support real-time data exchanges, for both primary and secondary use	Are mechanisms to support real-time data exchanges standardised across the EU?	Mechanisms to support real-time data exchanges follow common standards across the EU	Output	Establishment of common EU standards on data formats, protocols and metadata	Desk research: EU official communications	No information with regard to the establishment of other national standards	Single reporting
			Outcome	Increase in the flow of real-time data exchanges across the EU	Surveys with healthcare professionals/hospital representatives	Responses collected from a sample of stakeholders may not be representative	Upon request
Establish incentives to adopt interoperable technologies	Are there incentives to adopt interoperable technologies in place?	The adoption of interoperable technologies is incentivised by EU institutions	Input	Funding allocated to incentivise the adoption of interoperable technologies in healthcare institutions	Annual reporting on EU budgetary plans	Funding plans do not translate in actual funding spent	Annual
			Output	Number and type of supporting actions to incentivise the adoption of interoperable technologies in healthcare institutions	Desk research: EU official communications	Data on number of supporting actions might not be up to date	Continuous
			Outcome	Number of interoperable technologies adopted by healthcare institutions	Desk research: information provided by AI developers and healthcare institutions	Data on number of interoperable technologies might not be up to date or comprehensive	Continuous
					Surveys with AI developers, healthcare professionals, and hospital representatives	Responses collected from a sample of stakeholders may not be representative	Upon request
			Impact	Higher level of interoperability of the technologies adopted by healthcare institutions	Information on metrics and feedback provided by healthcare institutions	It might be challenging to evaluate the increased level	Upon request

						of interoperability	
Establishment of Centres of Excellence for AI healthcare							
Actual establishment of Centres of Excellence of AI in healthcare	Are there Centres of Excellence of AI in healthcare established in all EU Member States?	Every EU Member State has established a Centre of Excellence	Output	Number of Centres of Excellence established	Desk research: official EU communication, MS national authorities' communications	Information may not be comprehensive or up to date	Continuous
Provision of advanced training programmes for the healthcare workforce	Do the Centres of Excellence of AI provide advanced training programmes for the healthcare workforce?	All Centres of Excellence of AI provide advanced training programmes for the healthcare workforce with high participation and satisfaction levels	Output	Number of advanced training programmes offered by Centres of Excellence of AI	Desk research: information on websites of Centres of Excellence of AI	Information may not be comprehensive or up to date	Continuous
			Outcome	Number of healthcare professionals who participated in the training programmes	Desk research: information on websites of Centres of Excellence of AI	Information may not be comprehensive or up to date	Continuous
			Outcome	Level of satisfaction of participants to the training programmes	Surveys with participants to training programmes	Responses collected from a sample of stakeholders may not be representative	Upon request
			Impact	Increased number of healthcare professionals who are willing to deploy AI medical devices in their clinical practice	Surveys with healthcare professionals	Responses collected from a sample of stakeholders may not be representative	Upon request
Provision of digital health literacy programmes for the general public	Do the Centres of Excellence of AI provide digital health literacy programmes for the general public?	All Centres of Excellence of AI provide advanced digital health literacy programmes for the general public with high participation and satisfaction levels	Output	Number of digital health literacy programmes offered by Centres of Excellence of AI	Desk research: information on websites of Centres of Excellence of AI	Information may not be comprehensive or up to date	Continuous
			Outcome	Number of individuals who have participated in the digital health literacy programmes	Desk research: information on websites of Centres of Excellence of AI	Information may not be comprehensive or up to date	Continuous
			Outcome	Level of satisfaction of participants to the digital health literacy programme	Surveys with participants to training programmes	Responses collected from a sample of stakeholders may not be representative	Upon request

			Impact	Increased number of citizens who are willing to be treated with AI medical devices	Surveys with general public	Responses collected from a sample of stakeholders may not be representative	Upon request
Creation of a collaborative environment for knowledge and best practice sharing	Is there a central collaborative environment for knowledge and best practice sharing among Centres of Excellence of AI?	All Centres of Excellence of AI are collaborating and sharing best practices through the collaborative environment for knowledge	Output	Establishment of a collaborative environment for knowledge and best practice sharing	Desk research: information on websites of Centres of Excellence of AI	Information may not be comprehensive or up to date	Continuous
			Outcome	Number of articles, papers, conference proceedings, and other forms of knowledge available in the collaborative environment	Desk research: information on collaborative environment of Centres of Excellence of AI	Information may not be comprehensive or up to date	Continuous
			Outcome	Number of best practices shared among Centres of Excellence of AI	Desk research: information on collaborative environment of Centres of Excellence of AI	Information may not be comprehensive or up to date	Continuous
			Outcome	Number of downloads of different type of documents available in the collaborative environment	Information provided by company running the data repository on traffic to the website	A high number of readers/downloads does not imply that they found them useful	Upon request
			Outcome	Percentage of stakeholders who found the resources in the collaborative environment relevant and useful	Surveys with AI developers, healthcare professionals and hospital representatives	Responses collected from a sample of stakeholders may not be representative	Upon request
Drafting of guidelines on data governance and privacy	Did the Centres of Excellence of AI draft common guidelines on data governance and privacy?	Issuance of common guidelines for data governance and privacy by the Centres of Excellence of AI	Output	Issued guidelines for data governance and privacy	Desk research: information on websites of Centres of Excellence of AI	No information with regard to the establishment of other national standards	Single reporting
			Outcome	Number of readers/downloads of the	Information provided by company running the	A high number of readers/downlo	Upon request

				data governance and privacy guidelines	data repository on traffic to the website	ads does not imply that they found them useful	
Drafting of protocols to mitigate biases in AI models	Did the Centres of Excellence of AI draft protocols to mitigate biases in AI models?	Issuance of common protocols to mitigate biases in AI models by Centres of Excellence of AI	Output	Issued protocols to mitigate biases in AI models	Desk research: information on websites of Centres of Excellence of AI	No information with regard to the establishment of other national standards	Single reporting
			Outcome	Number of readers/downloads of the protocols	Information provided by company running the data repository on traffic to the website	A high number of readers/downloads does not imply that they found them useful or that they apply them	Upon request
			Impact	Increased trust in AI medical devices which have applied the protocols	Surveys with AI developers, healthcare professionals and hospital representatives	Responses collected from a sample of stakeholders may not be representative	Upon request
Development of AI playbooks with regulatory roadmap	Did the Centres of Excellence of AI release an AI playbook including regulatory roadmap?	The Centres of Excellence for AI released an AI playbook including regulatory roadmap that relevant stakeholders find useful	Output	Release of AI playbook with regulatory roadmap			
			Outcome	Number of readers/downloads of the AI playbook	Information provided by company running the data repository on traffic to the website	A high number of readers/downloads does not imply that they found them useful	Upon request
			Outcome	Percentage of stakeholders who find the AI playbook useful and clear	Surveys with AI developers, healthcare professionals and hospital representatives	Responses collected from a sample of stakeholders may not be representative	Upon request
			Impact	Improved understanding of the requirements of the AI Act leading to increase	Surveys with AI developers, healthcare	Responses collected from a sample of	Upon request

				implementation of AI solutions in healthcare	professionals and hospital representatives	stakeholders may not be representative	
Consolidated funding and introduction of financing mechanisms							
Introduction of financing mechanisms to support strategic priorities for AI in healthcare	Are strategic priorities for AI in healthcare supported through adequate financing mechanisms?	Strategic priorities for AI in healthcare are supported through adequate financing mechanisms	Input	Amount of funding provided at EU level to support strategic priorities for AI in healthcare	Annual reporting on EU budgetary plans	Not all budgetary plans may be translated into actual funding	Annual
			Output	Number of financing mechanisms introduced to support strategic priorities for AI in healthcare	Desk research: Official EU communication	Financing mechanisms may have been established but the numbers of applicants/awarded entities may be low	Continuous
			Outcome	Number of projects/initiatives funded through the established financing mechanisms	Desk research: Official EU communication	Data may not be up to date or comprehensive	Upon request
					CORDIS database	Data may not be up to date or comprehensive	Continuous
			Impact	Strategic priorities for AI in healthcare are enhanced via projects funded through the established financing establishments	Desk research: evaluation reports by the Commission services; publications by relevant stakeholders	Difficulty in assessing the level of achievement of strategic priorities with unbiased indicators	Continuous/ Upon request
Introduction of a standardised EU-level reimbursement framework for AI in healthcare	Is there a standardised EU-level reimbursement framework for AI in healthcare in place?	Establishment of a standardised EU-level reimbursement framework for AI in healthcare	Output	Actual establishment of standardised EU-level reimbursement frameworks for AI in healthcare	Desk research: Official EU communication	No information with regard to the establishment of other national programmes	Single reporting
			Outcome	Number of reimbursements provided	Information provided by competent EU institution	Data on reimbursement	Upon request

				to healthcare institutions for the adoption of AI tools in healthcare		provided may not be publicly available	
			Impact	Increased percentage of healthcare institutions adopting AI medical devices	Survey with AI developers, healthcare professionals, and hospital representatives	Responses collected from a sample of stakeholders may not be representative	Upon request
Establishment of a centralised body for added-value assessment, local performance testing and post-deployment monitoring of AI solutions							
Establishment of a network of assurance labs to test the performance of AI tools for healthcare	Is there at least one assurance lab available in each EU Member State?	Every EU Member States has an assurance lab	Input	Amount of funding provided at EU and Member State level to establish assurance labs	Annual reporting on EU/MS budgetary plans	The fact that funding was allocated does not mean that validation labs were efficiently established	Annual
				EU projects funded with the objective of establishing assurance labs	CORDIS database	Missing national funding initiatives	Continuous
			Output	Number of assurance labs established	Desk research: Official MS' national gazette reporting, desk research	An assurance lab may have been established but might not be efficiently operating	Continuous
			Outcome	Number of AI tools tested for performance via assurance labs Number of AI tools validated via assurance labs	Desk research: Information provided by assurance labs	Data on tested AI tools may not be up to date	Continuous/ Upon request
			Impact	Higher adoption rates of AI tools which have been validated by assurance labs	Desk research: commercial information available in AI developers' websites, hospitals adopting the technology; Annual surveys to collect information	Data on adoption rates of AI tools may not be available, nor those not validated for	Continuous/ Upon request

					Eurostat data on enterprises using AI in the EU (isoc_eb_ai)	comparison purposes	Continuous
				Positive evaluation of post-market monitoring of deployed AI tools which have been validated by assurance labs	Reporting on post-market monitoring system to be established for high-risk systems according to Article 72 EU AI Act	Only AI tools under the high-risk categorisation are obliged to comply with this provision.	Continuous
Establishment of performance benchmarks designed for different AI tools to be used by performance testing centres	Do all established assurance labs use the same set of performance benchmarks which are adequately testing the performance of AI tools?	All established assurance labs use the same set of performance benchmarks adequately testing the performance of AI tools	Input	EU institutions support in establishing EU-level harmonised standards for evaluation according to Article 40 EU AI Act	Annual reporting on EU budgetary plans	The fact that funding was allocated does not mean that support in establishing EU-level harmonised standards for evaluation was efficiently provided	Upon request
			Output	Assurance labs' infrastructure for evaluating AI models with the same performance benchmarks	Information provided by assurance labs	It might be challenging to evaluate the quality of assurance labs' infrastructure	Upon request
			Outcome	Increased level of accuracy, reliability and safety as measured in the evaluations of AI models carried out by assurance labs	Information provided by assurance labs	Data on evaluated AI models may not be up to date	Upon request
					Reporting on post-market monitoring system to be established for high-risk systems according to Article 72 EU AI Act	Only AI tools under the high-risk categorisation are obliged to comply with this provision.	Continuous
			Impact	Higher performance standards of AI tools	Desk research: commercial information available in AI developers' websites,	Data on quality of AI models may not be available	Continuous

					hospitals adopting the technology		
Provision of sandbox environment to test the performance of AI tools	Do all assurance labs provide sandbox environments to test the performance of AI tools?	Every assurance lab provides a sandbox environment to test the performance of AI tools	Output	Number of sandbox environments established in assurance labs	Information provided by assurance labs in their website	Data on sandbox environments may not be up to date or comprehensive	Continuous/ Upon request
					Reporting on compliance with Article 57 of the EU AI Act	Information on activities successfully carried out by in the sandbox only collected upon request (Article 57(7))	Upon request
			Outcome	Number of issued "Model Report Card" or "Model Fact Label" Number of successfully issued "Model Report Card" or "Model Fact Label"	Information provided by assurance labs in their website	Data on sandbox environments may not be up to date or comprehensive	Continuous/ Upon request
				Number of exit proofs issued	Information provided by national competent authorities as established by Article 57(7) of EU AI Act	Potential lack of standardisation on information provided in these proofs	Continuous
			Impact	Enhanced trust and reliability on tested AI tools	Desk research: commercial information available in AI developers' websites, hospitals adopting the technology, Annual surveys to collect information from HCPs using AI tools as well as patients	It might be challenging to evaluate the increase in trust and reliability following testing	Continuous/ Upon request
Promote collaboration across EU Member States with a central data repository	Did the EU Member States create a central data repository to enhance collaboration?	Member States have a central data repository	Output	Creation of a central data repository	Desk research: EU official communications	-	Continuous
			Outcome	Number of collaboration partnerships across EU Member States on healthcare data	Desk research: data repository website	Not all collaboration partnerships	Continuous

						might be published	
			Outcome	Level of use of the repository	Information provided by company running the data repository on traffic to the website	A high number of visitors does not imply a high level of engagement	Continuous
			Impact	Enhanced collaboration across EU Member States	Information provided by Member States	No information available for the quality of the collaborations	Upon request
Collection and dissemination of good practice case studies	Did the centralised body collect and disseminate good practice case studies?	Collection and dissemination of good practice case studies	Output	The central data repository includes good practice case studies	Desk research: EU official communications	-	Continuous
			Outcome	Number of good practice case studies in the repository	Desk research: data repository website	Databases might not be up to date or comprehensive	Continuous
Development of a catalogue of AI solutions							
Include detailed performance metrics for each listed AI tool, user reviews, and feedback mechanisms	Does the catalogue of AI solutions include detailed performance metrics for each listed AI, user reviews, and feedback mechanisms?	The catalogue of AI solutions includes detailed performance metrics for each listed AI, user reviews, and feedback mechanisms	Output	Release of a catalogue of AI solutions including detailed performance metrics for each listed AI, user reviews, and feedback mechanisms	Desk research: EU official communications	-	Single reporting
			Outcome	Number of AI tools listed with detailed performance metrics, user reviews, and feedback mechanisms	Desk research: website of the catalogue	Database might not be up to date or comprehensive	Continuous
			Outcome	Number of visitors to the catalogue of AI solutions	Information provided by company running the data repository on traffic to the website	A high number of visitors does not imply a high level of engagement	Continuous
Include user guides, case studies, and tutorials, helping healthcare providers understand and implement AI solutions efficiently	Does the catalogue of AI solutions include user guides, case studies, and tutorials, helping healthcare providers understand and	The catalogue of AI solutions includes user guides, case studies, and tutorials, helping healthcare providers understand and implement AI solutions efficiently	Output	Inclusion of user guides, case studies, and tutorials in the catalogue of AI solutions	Desk research: website of the catalogue	Database might not be up to date or comprehensive	Continuous
			Outcome	Number of user guides, case studies, and tutorials	Desk research: website of the catalogue	Database might not be up to	Continuous

	implement AI solutions efficiently?			available in the catalogue of AI solutions		date or comprehensive	
Establishment of a governance framework to oversee catalogue's operations	Does the catalogue of AI solutions include a governance framework to oversee catalogue's operations?	The catalogue of AI established a governance framework to oversee catalogue's operations which is up to date	Output	Establishment of a governance framework to oversee the catalogue's operations within the AI catalogue	Desk research: website of the catalogue	Database might not be up to date or comprehensive	Single reporting
			Outcome	Number of catalogue's operations overseen by the governance framework	Desk research: Information provided by the governance framework	Data on operations may not be up to date or comprehensive	Upon request
			Impact	Higher governance standards in catalogue's operations	Desk research: commercial information available in AI developers' websites, hospitals adopting the technology	It may be challenging to assess the increase in governance standards	Upon request

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