BRITISH JOURNAL OF HOSPITAL MEDICINE

REVIEW

Artificial Intelligence in UK Hospital Medicine: From Innovation to Implementation

Dervla Carroll[1], Vijna Boodhoo[1], David J Lowe[1,2], Christopher Carlin[3,*]

[1]Digital Health Validation Lab, College of Medicine, Veterinary and Life Sciences, University of Glasgow, Glasgow, UK
[2]Emergency Department, Queen Elizabeth University Hospital, National Health Service Greater Glasgow and Clyde, Glasgow, UK
[3]Department of Respiratory Medicine, Queen Elizabeth University Hospital, National Health Service Greater Glasgow and Clyde, Glasgow, UK
*Correspondence: chris.carlin3@nhs.scot (Christopher Carlin)

Abstract

Artificial Intelligence (AI) has the potential to enhance patient care in the UK's increasingly pressured healthcare system. As AI's applications in healthcare are expanding, healthcare professionals should understand the processes underpinning how AI tools translate from research to clinical application. There are several stages: (1) training and validation on healthcare data, (2) generation of evidence demonstrating performance and safety, (3) regulatory compliance, (4) AI product procurement, (5) implementation in clinical settings, and (6) ongoing monitoring and oversight of deployed AI. Each step presents unique challenges and opportunities that can influence successful integration. Clinicians should understand AI's capabilities and limitations to ensure its appropriate and effective use in practice. This review aims to provide a structured overview of the AI adoption pathway in healthcare, with a view to supporting clinicians in critically appraising its potential and limitations, optimising its integration into clinical practice, and engaging with AI in an informed manner.

Key words: artificial intelligence; delivery of healthcare; routinely collected health data; medical device legislation

Submitted: 22 May 2025 Revised: 28 July 2025 Accepted: 12 August 2025

Introduction

Artificial Intelligence (AI) refers to the ability of a machine to perform tasks which were previously felt to require human thought (Turing, 1950). This includes generating predictions based on many variables within large datasets (machine learning), processing visual data (computer vision) and analysing linguistic data (natural language processing) (Alowais et al, 2023). These capabilities have resulted in the increasing prevalence of AI within multiple industries, from entertainment to finance. Healthcare has proven to be a promising domain for the application of AI technologies. A well-known example of AI within healthcare is computerised electrocardiogram (ECG) analysis. Available since the 1970s, research was conducted shortly after to understand the accuracy of machine-derived ECG interpretation in comparison to clinicians (Jakobsson et al, 1985) and between computerised

How to cite this article:
Carroll D, Boodhoo V, Lowe DJ, Carlin C. Artificial Intelligence in UK Hospital Medicine: From Innovation to Implementation. Br J Hosp Med. 2025. https://doi.org/10.12968/hmed.2025.0468

methods of ECG analysis (Jakobsson et al, 1989). Although AI's underlying computing techniques have since become increasingly sophisticated, the fundamental questions of accuracy and reliability persist today.

In parallel to the rapid advancement of computing capabilities, the demand for healthcare has exponentially risen, outpacing resource allocation. UK healthcare expenditure continues to rise annually (Stoye et al, 2024), responding to the needs of an older, increasingly comorbid UK population (Darzi, 2024). Despite this, only 34% of healthcare workers feel there are enough staff in their organisation for them to do their job properly (NHS Staff Survey, 2024). The number of patients waiting in excess of the four-hour target after presenting to the emergency department (ED) has risen by 531% over the past decade, while referral to treatment times for consultant-led elective care have increased by 74% in the last 13 years (Danechi et al, 2025). These are indicators of mounting pressures and systemic strain within acute care services. It is evident that the current traditional healthcare system cannot cope with the growing demand.

AI offers the potential to reshape and relieve an overstretched healthcare system by providing time and cost efficiencies through the creation of novel patient care pathways. Automating time-intensive, repetitive tasks could allow National Health Service (NHS) staff time to be redirected towards patient care. Using AI to process large volumes of data could enhance capacity for population screening, which may be impractical to conduct manually (Germain et al, 2025). AI can be used as a tool to support early detection and treatment of disease, which may deflect unscheduled care presentations through enhanced outpatient care (Elvas et al, 2025). Disruptive technologies such as large language models could transform healthcare provision by facilitating patient education, summarising patient notes or supporting clinical decision-making (Lin and Kuo, 2025).

While the potential benefits of AI have generated significant interest from healthcare organisations, this has not universally translated into widespread implementation in routine UK clinical practice. AI-derived software is currently recommended by the National Institute for Health and Care Excellence (NICE) for a number of specific use cases. This includes rapid stroke detection from computed tomography (CT) brain imaging, triaging of potentially malignant skin lesions, fracture detection from X-ray imaging, remote ECG monitoring for arrhythmia detection and radiotherapy treatment planning NICE (n.d.-a). However, not all health technology assessments have recommended the implementation of AI products, even for well-known applications of AI in healthcare. Early Value Assessments (EVAs) have highlighted a lack of UK evidence to support the use of AI products outside of research for chest X-rays (NICE, 2023b) and CT lung nodule detection (NICE, 2023a).

The transition of AI from research into UK clinical practice is defined by a number of stages (Fig. 1):

(1) Data: AI algorithms are trained and tested using healthcare data.

(2) Evidence Generation: AI algorithms are evaluated in research to determine their performance and safety for clinical use.

(3) Regulation: Regulatory requirements must be met to allow access to the UK market.

(4) Procurement: Commissioners must select the most appropriate products for use in their local healthcare system.

(5) Implementation: AI algorithms must be integrated and used within healthcare organisations.

(6) Monitoring: Appropriate oversight must be put in place to ensure ongoing safety and performance across the total AI product lifecycle.

Together, these stages aim to safeguard patient safety and clinical care (Fig. 1). This article outlines key considerations at each stage which may affect clinicians using AI in research or in patient care. However, it is important to recognise that patient perspectives and engagement with AI in clinical practice are equally important for a successful transition to routine use in patient management.

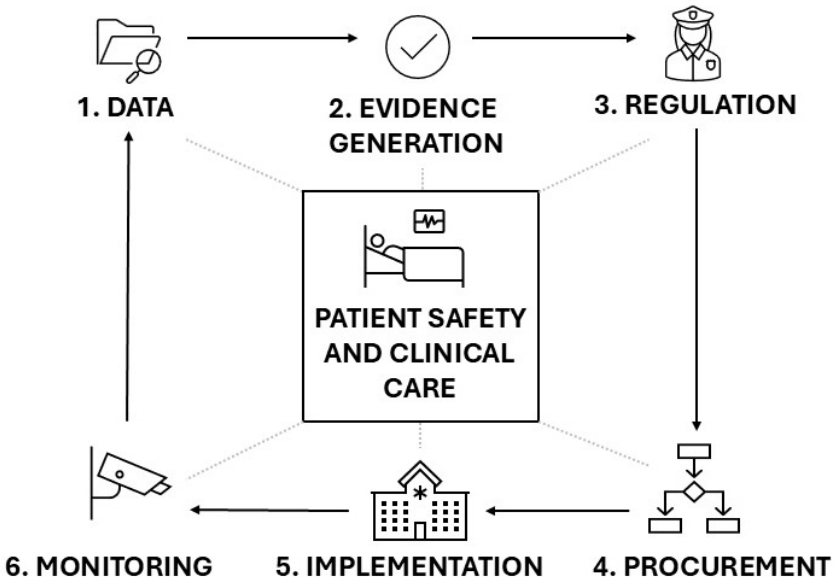

Fig. 1. Schematic depicting the transition of Artificial Intelligence (AI) from research into clinical practice. Engagement with all stages is necessary for patient safety and the delivery of patient care. Created in Microsoft PowerPoint Version 2506 (Microsoft Corporation, Redmond, WA, USA).

Stage 1: Obtaining and Using UK Health Data

Training AI algorithms requires large volumes of labelled patient data. Labelling ascribes the presence or absence of specific features within a dataset. It is used by AI algorithms to 'learn' patterns (training dataset) and subsequently to fine-tune the parameters of the model to improve performance (test dataset). The final model should then be validated on an external source of data to ensure the results are generalisable (validation dataset). AI models tend towards reduced accuracy when an outcome is statistically less likely. Due to variations in the prevalence of disease and demographics, models developed with training data from one demo-

graphic group or geographical area may not have equivalent performance in another (Mittermaier et al, 2023). This is described as model bias. Safely deploying AI models in the UK requires access to UK data, either as part of model development or to demonstrate model performance.

The NHS has access to significant volumes of patient data. Centrally collected and securely held healthcare data could be a significant resource for the UK (Sudlow, 2024). However, UK data is fragmented within different NHS organisations, such as regional Trusts or Boards (Zhang et al, 2023). As a result, obtaining data for AI research can be challenging. Given the volume of data required, individual patient consent is impractical. Access to data is therefore facilitated through publicly available, disease-specific datasets or through Trusted Research Environments (TREs) (UK Health Data Research Alliance and NHSX, 2021). TREs provide researchers with the opportunity to access pseudonymised electronic health record (EHR) data collected during routine care. This does not require patient consent under Article 9 of the General Data Protection Regulation (GDPR) legislation, although ethical approval is needed. TREs ensure that patient data is handled ethically and securely, and that the data accessed is appropriate and proportionate to the intended use case. This is in keeping with the values of the UK public (Transformation Directorate, 2025).

Both publicly available datasets and TREs present individual challenges for researchers and developers. Publicly available datasets are often labelled with regard to the purpose for which they were originally curated. Using imaging data as an example, this may mean that only certain imaging abnormalities are described. If unlabelled abnormalities are relevant to the conditions the AI model is being trained to detect, this will have implications for the subsequent performance of the algorithm (Paullada et al, 2021). It is unlikely that publicly available data is sufficient to validate an AI model.

Conversely, TREs present an opportunity for direct curation of datasets and bespoke labelling of EHR data. However, labelling is time-intensive and requires clinical expertise. Structured EHR data, which can be easily extracted through TREs, may be inaccurate. For example, an analysis of NHS digital data to identify hospitalisation due to heart failure found that International Classification of Diseases 10 (ICD-10) code sets alone provided a positive predictive value of 36.4% at best in comparison to expert validation (Soltani et al, 2024).

Beyond inaccuracies, there is considerable regional variation in the quality and volume of accessible data. As NHS Boards and Trusts hold patient data separately, each of the four devolved nations has independent TREs (Fig. 2). In England and Scotland, datasets are additionally split by region. Furthermore, not all data categories (such as primary care, social care, mortality or imaging data) are homogenously available between regions (NHS England, 2025c). Variation in how data is stored within systems can create additional barriers. For example, clinical letters may be stored as text in some systems, but as images or fixed files (such as PDF) in others, which are less accessible for research. This can create missing data: for example, within NHS Greater Glasgow and Clyde (NHS GGC), pulmonary function test results and smoking status are presently unable to be extracted through NHS

GGC Safe Haven (Taylor et al, 2023). Both inaccurate and missing training data can compromise model performance.

Pragmatically, ensuring validation of an AI model on data which is representative of the entire UK population requires repeated scoping for the same research purpose across the different regional data silos. This poses challenges for both the NHS and companies seeking to use UK data to train or validate AI models. For the NHS, duplication of work across the TREs could represent an inefficient use of NHS resources. For AI-based companies, there are significant financial and time implications. This makes it more difficult for patients and clinicians to access new solutions which could improve clinical care. The impact of UK health data management is underlined by the Sudlow report, which recommends a single, UK-wide system for managing access to health data (Sudlow, 2024). While an overarching NHS England Secure Data Environment has since been introduced, a large-scale project using NHS England unstructured primary care data has been paused following data protection concerns (Armstrong, 2025).

More novel approaches include federated learning. Rather than centrally compiling data for training purposes, models are trained locally at multiple sites. The parameters of the model can be aggregated to develop a single, global model (Soltan et al, 2024). This may limit data protection concerns by reducing the need for patient data transfers outside of hospital systems.

Understanding the scale and quality of data-driven AI research in the UK is difficult. Studies using retrospective EHR data do not require registration on ClinicalTrials.gov or similar databases. Assessing publication bias within the field is challenging (Han et al, 2024). This has ramifications for understanding the true efficacy of AI-based products. The Health Data Research Innovation Gateway (Health Data Research UK, n.d.) aims to improve the visibility of data-driven research by registering health databases, documenting the organisations applying to use health data, and recording subsequent research publications. Trial registration is mandatory for clinical trials of investigational medicinal products (i.e., novel drugs). Without similar standards for AI, it will be difficult to judge the extent of AI-related research this platform captures.

Stage 2: Evidence Generation

Evidence generation for AI has multiple phases, reflecting the technological maturity of the solution (Fig. 3). As with all healthcare research, Public and Patient Involvement and Engagement (PPIE) is foundational to ensuring that research is in keeping with the values of the local public, and that study procedures and patient-facing documentation are acceptable to patients (Bird et al, 2020). Mapping usual care workflows and patient journeys can help to understand whether AI is a pragmatic solution to a clinical problem. Stakeholder focus groups can help to exemplify the need for an AI solution and which AI outputs may be most relevant to end-users (Burns et al, 2024). In parallel to data-driven development, research should be undertaken to demonstrate acceptability and enhance usability. This in-

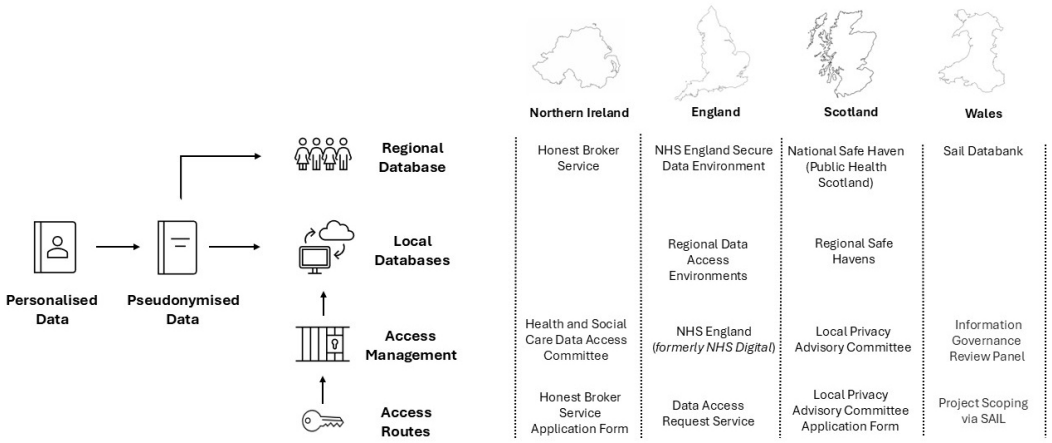

Fig. 2. Regional structuring of Trusted Research Environments (TREs) in the UK. Created in Microsoft PowerPoint Version 2506 (Microsoft Corporation, Redmond, WA, USA). Country outlines obtained under Adobe Standard License: Northern Ireland (luisrftc/stock.adobe.com), England (agrus/stock.adobe.com), Wales (Alex/stock.adobe.com) and Scotland (RN3540/stock.adobe.com). SAIL, Secure Anonymised Information Linkage.

cludes designing an end-user interface which can communicate outputs effectively (Deniz-Garcia et al, 2023).

Developed algorithms should undergo retrospective internal and external validation. Internal validation evaluates the performance of an AI algorithm on data from the same source, but which is separate from the training dataset. During external validation, the model is tested on data from a different source (such as a different hospital site).

The majority of published AI research focuses on retrospective, data-driven projects (Nagendran et al, 2020). A systematic review of AI in intensive care found that, while the number of studies describing model development and prototyping has increased over time, there is limited progression within the field towards prospective clinical evaluations of AI solutions (van de Sande et al, 2021).

Multiple factors influence this. Although the number of potential AI solutions continues to increase, evaluating AI in UK practice also requires dedicated resources from NHS partners (including technical expertise). As part of an implementation of AI-supported stress echocardiography (EchoGo Pro) in 20 NHS Trusts, qualitative research described that capacity within NHS Information Technology (IT) teams limited the number of technical updates which could be made to systems (Fazakarley et al, 2023). Most prospective studies evaluating AI in clinical practice focus on single-site deployments (Han et al, 2024), potentially reflecting operational difficulties in achieving simultaneous deployment across multiple sites. Additionally, clinical research is often costly and time-consuming, utilising both internal company resources and public grant funding. For example, median full economic costs for a 5.5-year, multi-site non-pharmacological Randomised Controlled Trial (RCT) from a sample of 10 UK Clinical Trial Units were approximately $1,013,925 (£750,000) (Hind et al, 2017).

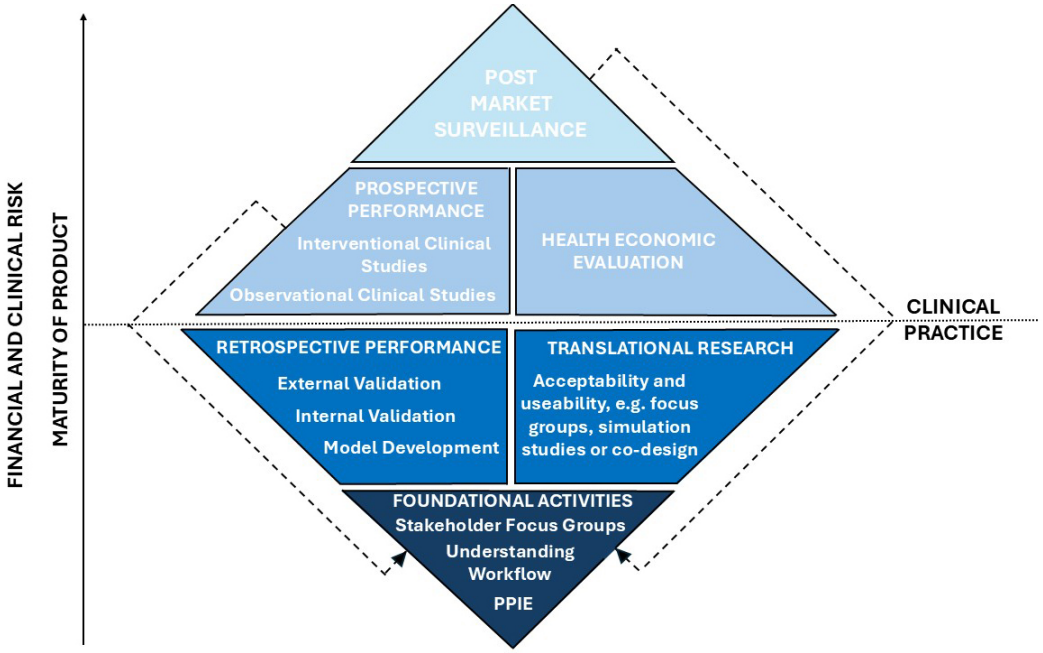

Fig. 3. Schematic depicting the evidence generation process for new AI innovations. Foundational activities such as Public and Patient Involvement and Engagement (PPIE), understanding workflows, and stakeholder focus groups are crucial to progression to further stages. Retrospective performance evaluations are aimed at developing and evaluating the underlying algorithm. Translational research aims to optimise the end-user interface and gather early indications of clinical support. Insights provided from prospective performance and post-market surveillance may underscore a need for further product development or alternative solutions, resulting in the need for foundational activities to support redesign and re-development of AI solutions. Created in Microsoft PowerPoint Version 2506 (Microsoft Corporation, Redmond, WA, USA).

Even after surmounting these challenges, results from prospective studies may be mixed. In a recent report, only 3 of 9 completed Phase 4 AI projects included within the NHS Artificial Intelligence Lab programme clearly demonstrated benefits to the NHS (Cresswell et al, 2025). For some projects, limitations in the chosen outcome measures were contributing factors. Retrospectively, key clinical benefits or cost-savings were not captured in the evaluation. For others, the study duration was not sufficient to capture the longer-term benefits of AI implementation. Some evaluations were unable to obtain the necessary baseline data to demonstrate quantitative evidence of effect. This may indicate that researchers and clinicians are still developing their expertise in designing evaluations of AI products.

AI products are novel, complex interventions which may not be easily evaluated using traditional trial designs. Blinding of clinicians to AI outputs is often not possible or ethical in interventional studies, particularly when novel AI tools require clinical oversight. Randomisation is challenging. Deploying AI often involves significant change to hospital workflows: if randomisation occurs at an individual patient level, there is the potential for contamination between the control and intervention arms. Addressing these problems requires a pragmatic trial design. Stepped-wedge, cluster randomised trials may be attractive for AI evaluations (Jin et al, 2024): as the AI intervention is introduced sequentially at each site, compar-

isons can be made between sites and between pre- and post-implementation outcomes (Vimalesvaran et al, 2024). Mixed-methods approaches allow quantitative data to be enriched with qualitative themes (Duncan et al, 2024). This can explore reasons for underwhelming real-world performance and inform the design of more appropriate evaluations.

Generating comparable, high-quality research can be challenging in novel research fields. Well-known reporting guidelines include Consolidated Standards of Reporting Trials (CONSORT)-AI for randomised trials (Liu et al, 2020), Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT)-AI for randomised trial protocols (Cruz Rivera et al, 2020) and the newly updated Transparent Reporting of a multivariable prediction model for Individual Prognosis Or Diagnosis (TRIPOD)+AI for evaluations of multivariable prediction models (Collins et al, 2024). However, a recent systematic review identified a total of 26 reporting guidelines spanning pre-clinical, translational and clinical stages of evidence (Kolbinger et al, 2024). Many have been developed by a single stakeholder group. With heterogeneity in relevant data items for guidelines aimed at similar stages, the desire to standardise reporting also risks creating uncertainty in which guideline should be adhered to.

Stage 3: Regulatory Approval

Evidence generation and regulatory approval are intrinsically linked. Demonstration of safety and efficacy is a prerequisite for market authorisation within regulatory pathways. However, clinicians should recognise that existing regulatory pathways may not demand in-depth, comprehensive evidence for all AI solutions.

AI, which aims to diagnose, monitor or treat medical conditions, is classed as Artificial Intelligence as a Medical Device (AIaMD) under UK (Medical Device Regulations 2002) and European Union (EU) law (Regulation (EU) 2017/745, 2017). The Medicines and Healthcare products Regulatory Agency (MHRA) allows vendors to place products on the UK market provided they show evidence of safety and performance (Medical Device Regulations 2002). Regulatory compliance is demonstrated through UK Conformity Assessment (UKCA) marking. *Conformité Européene* (CE) marks, the European Union equivalent, are also accepted in the UK until 2030 (MHRA, 2025a). Northern Ireland continues to operate separately, using CE or United Kingdom Northern Ireland (UKNI) marks.

Standards for clinical evidence escalate depending on the level of risk associated with the product. High-risk AI devices (Class III) will undergo rigorous assessment, whilst low-risk (Class I) products can self-certify their compliance with MHRA or EU regulations, providing they show evidence of a clinical evaluation demonstrating safety and efficacy (Table 1) MHRA (n.d.-a). For example, AI algorithms which generate individualised physiotherapy programmes may not be expected to show results from randomised controlled trials (RCTs) to facilitate market access. This allows for significant variation between vendors in the quality of clinical evaluation and evidence generated. Once market access has been granted, there

may be less commercial incentive to demonstrate performance within a research setting.

Table 1. MHRA device classifications with example intended use and products.

Device class	Examples of indications	Example	Conformity assessment?
Not a medical device	Monitoring of fitness, health or well-being; patient medical education; some symptom checkers.	Avey—symptom checker (Hammoud et al, 2024).	Nil.
Class I	Lowest risk devices, including app-based devices, which do not fall into other classes.	Wysa—app-based, AI-delivered CBT and chatbot (Inkster et al, 2018). Flok Health—app-based, AI-delivered physiotherapy (NICE, 2023c).	Self-declaration of conformity*.
Class IIa	Medium risk, including devices which allow direct diagnosis.	Limbic Access—predicts psychiatric diagnoses based on app-based patient/chatbot interactions (Habicht et al, 2024).	UK Approved body assesses compliance.
Class IIb	Medium risk, including devices used for contraception or the prevention of sexually transmitted diseases.	Natural Cycles—a contraceptive app which uses body temperature to determine fertile periods) (Pearson et al, 2021).	UK Approved Body assesses compliance.
Class III	Highest risk devices, including active implantable devices.	DERM—an AI algorithm to triage potentially malignant dermatoscopic skin lesions, which can autonomously discharge patients from the cancer pathway (Marsden et al, 2023).	UK Approved Body assesses compliance.

* Sterile Class I devices, Class I devices with a measuring function or Class I devices which are re-usable surgical instruments must be assessed by a UK-approved body. *In vitro* diagnostic tools (not listed) have independent classes. CBT, Cognitive Behavioural Therapy; DERM, Deep Ensemble for the Recognition of Malignancy; MHRA, Medicines and Healthcare products Regulatory Agency.

Regulation of medical devices in the UK is complex, with many specific rules. The intended use and claims of the device are critical in defining classification. The following products would have different classifications MHRA (n.d.-d):

- Not a medical device: an AI symptom checker which alphabetically lists all matching conditions that fit the given symptoms.
- Class I medical device: an AI symptom checker which lists differential diagnoses with corresponding probability scores.
- Class IIa medical device: an AI symptom checker which claims to provide a direct medical diagnosis.

For many small companies, achieving a direct route to market is economically beneficial. An unintended consequence of current medical device regulations is that vendors may intentionally limit the functionality of new innovations to avoid products being classed as a medical device, or to receive a lower classification (Baines et al, 2023). For clinicians, practising safely using AIaMD requires an awareness of the classification of these products and their intended use. Transparency is key to this. The MHRA Public Access Registration Database (PARD) allows the public to search registered medical devices by product name or device type, including AIaMD MHRA (n.d.-b). While PARD displays the classifications of medical devices, it does not display a list of AI products approved for use in the UK. Records do not include whether individual medical devices use AI or provide details of intended use statements. The lack of granularity makes it difficult for clinicians to contextualise approved AIaMD products in the UK.

Significant funding and expertise are required for regulation to keep pace with AI innovation. The Darzi (2024) report has emphasised the need to build regulatory capacity and expertise with sustained funding for the MHRA and training for regulators. The report advocates for clear regulatory pathways across a model's entire lifecycle, with guidance for developers and dynamic frameworks to keep pace with this rapidly evolving field. The MHRA has similarly described plans for regulatory change, including new pre-market regulations (MHRA, 2025a). Collaboration among stakeholders (including industry, academia, healthcare providers, and patients) is recommended to ensure diverse perspectives in the development and regulation of AI in healthcare.

Stage 4: Procurement

AIaMD selected for procurement must be safe, fair and effective, in addition to meeting technical specifications. Once EU CE- or UKCA-marked, there are two broad routes to adoption depending on the intended use of AI. Patients may independently use commercially available AI-based products in their own self-management. Alternatively, Trusts or hospitals can purchase AI-based algorithms to facilitate patient care. For a small number of AI devices, the government has directly influenced the procurement of AIaMD.

Unlike approvals for new medicines used in the NHS (The King's Fund, 2025), there is no requirement for medical devices (including AIaMD) to be evaluated by NICE or equivalent organisations prior to procurement by regional or local NHS service providers. Presently, NICE Medical Technologies Guidance is cited as taking approximately 38 weeks to produce NICE (n.d.-b). Given that the volume of approved AI products continues to increase, guideline development is unlikely to shape procurement decisions for the majority of AI products in the immediate future. By the time guidelines are generated, they may become rapidly outdated. Some AI products which are not recommended may already be in routine use at the time of publication.

Procurement decisions regarding AIaMD are often made at regional—or even hospital–level (Cresswell et al, 2025). Procurement may occur through various

routes, including direct purchase by NHS Trusts or primary care organisations, regional procurement hubs, NHS supply chain frameworks, national collaborative frameworks, or competitive government tenders (Health Innovation Network, n.d.). A decentralised approach to procurement has potential disadvantages. For regional NHS purchasers, procurement decisions have been described as overwhelming, requiring the development of bespoke local scoring systems (Shelmerdine et al, 2024). For vendors of AI products, heterogeneous procurement processes may also be difficult to navigate. However, there are two key domains where local procurement is particularly advantageous: choosing products with good local performance and technical compatibility.

Local Performance and Technical Compatibility

AI performance is inherently variable. For example, a comparative analysis of 21 AI algorithms to identify diabetic retinopathy requiring ophthalmology input showed variable performance (Kubin et al, 2024). Specificity ranged from 20 to 100%. Sensitivity ranged from 13.3 to 96.7%. Individual results for vendors were masked; however, 8 CE-marked devices were included in the analysis. If poor local performance was discovered after procurement, significant financial resources may already have been committed to a suboptimal product. This underscores the importance of local evaluations in choosing AI products to procure. The Regulatory Horizons Council (2022) identified retrospective local evaluations and 'silent' deployments (whereby AI does not influence patient care) as key strategies to increase NHS confidence in AI's performance prior to commissioning.

Basic hardware, software and connectivity issues within the NHS limit usual clinical care (British Medical Association (BMA), 2024b). The British Medical Association (BMA) (2022) reported that only 4% of doctors agree that the software they use is 'completely' adequate and fit for purpose. Some hospitals still lack digitalisation of day-to-day clinical processes, such as referrals and hospital documentation (Sudlow, 2024). A recent implementation of a lung nodule detection algorithm within the NHS was hampered by basic Wifi connectivity issues (Farič et al, 2024).

With this in mind, the technical requirements for implementation influence algorithm selection. Electronic systems used in patient care can differ within and between regions. Lack of communication between systems in the same hospital can present a barrier to obtaining data for AI implementation (Fazakarley et al, 2023). For the South West London AI Working Group, ease of integration with existing IT and Picture Archiving and Communication System (PACS) framework was described as the final deciding factor in selecting an AI chest X-ray (AI CXR) tool to support prioritisation of CXRs for reporting (Shelmerdine et al, 2024). A substantial initial investment is often required to ensure new AI models are compatible with existing local systems. This can influence the cost-effectiveness of any potential AI solution. For example, an NHS cost-effectiveness evaluation of an AI breast cancer screening tool (Mia, Kheiron Medical Technologies, London, UK) included a set-up cost of approximately $47,330 (£35,000), in addition to a running fee per scan performed and a maintenance cost of $22,989 (£17,000) per

year (Vargas-Palacios et al, 2023). Although this scenario was shown to be cost-effective (under uncertainty) when Mia was used to replace a human second reader, this represents a significant initial outlay for Trusts seeking to implement this technology.

Procurement Processes

Procurement has traditionally been navigated using Framework Agreements (FAs). FAs are a type of contract commonly used throughout the NHS to provide pre-defined terms and conditions for purchase from an approved list of suppliers (Evans et al, 2025). In the UK, FAs have been used successfully to support the procurement of stroke detection algorithms for CT brain imaging (Roberts, 2022). While FAs can help to standardise processes across NHS Trusts, criticisms of FAs include that they may not respond dynamically to market change: included vendors, pricing and duration may be fixed at the outset, and contracts can be awarded directly to a single supplier. A potential solution is Competitive Flexible Procedures (CFPs), as advocated by the AI Opportunities Action Plan (Department for Science and Innovation and Technology, 2025). CFPs demand multiple stages of evaluation as part of the procurement process. Proposed benefits include a unified digital portal, flexible terms and more rapid access to small amounts of funding. This may ensure NHS Boards and Trusts robustly consider the local suitability of procured solutions and support phased deployment.

Centrally Directed Procurement

There are mechanisms by which the central UK government can influence regional procurement. Funding for new innovations must either be obtained from existing budgets or from ring-fenced government funds. Products which are expected to generate a cost-saving for the NHS within 3 years may be included within the Medical Technologies Funding Mandate (MTFM), whereby NHS commissioners are directed to fund new technologies as part of their existing budget (NHS England, n.d.-b). Heartflow is an example of an AI product which has been supported by the MTFM (NHS England, n.d.-b). It provides AI-assisted 3D visualisation of CT coronary angiograms, reducing the need for further investigations in patients with previously unknown conditions. Prior to the inclusion of Heartflow, the high costs of the technology delayed adoption (Ray and Clarke, 2023). The MTFM has directly influenced rapid adoption into 60 NHS hospitals (NHS England, 2025a).

However, there is no doubt that utilising existing budgets for expensive technologies represents an opportunity cost. The provision of additional funding for government-directed procurement may seem more palatable to regional services. The Brainomix e-Stroke platform, which detects large vessel occlusions in stroke from CT head scans, is one example of this. It was funded for deployment in an additional 5 UK stroke networks through part of the $166,283,700 (£123 million) AI in Health Care Award. Interestingly, a post-implementation analysis at a UK district general hospital described significantly reduced positive predictive value (0.5) in comparison to prior work (0.96), and calls for local evaluations prior to deployment (Merchant et al, 2025).

Stage 5: Implementation

Following procurement, translating potential benefits into practice requires changes to existing hospital processes and engagement from clinical staff.

Workflow Adaptation

When effectively integrated into hospital systems, AI holds significant potential to improve healthcare delivery. Successful implementation requires a redesign of the clinical workflow to incorporate the AI tool, with early and active engagement of all key stakeholders, including patients, and operational strategies for managing AI outputs (Sendak et al, 2020). Ideally, model development would be undertaken in parallel with workflow adaptation to ensure technical compatibility and operational coherence (Burns et al, 2024). Given there is significant variation in workflows between NHS sites and many Trusts seek to implement AI products developed elsewhere, specific implementation teams can coordinate efforts to redesign clinical pathways. Successful implementation often includes representation from managerial, technical, clinical, and governance domains (Burns et al, 2024; Shelmerdine et al, 2024).

AI can influence UK workflows in a variety of ways. The simplest and least disruptive workflow adaptation is to provide clinical decision support by acting as an AI-mediated second reader, where AI is accessed at the clinician's discretion. With more integrated use, AI can augment existing pathways by streamlining patient flow and optimising clinician time: during the Coronavirus Disease 2019 (COVID-19) pandemic, an AI-driven ED triage system prospectively identified patients with COVID-19 from routine blood tests and clinical observations in Oxford University Hospitals, showing enhanced negative predictive value and time-to-result over lateral flow tests (Soltan et al, 2022).

By contrast, some implementations can fundamentally reshape the workflow by eliminating or adding additional steps. For instance, Heartflow (described above) has transformed the UK chest pain diagnostic pathway by reducing additional non-invasive cardiac testing and invasive cardiac procedures by 14% and 5% respectively (Fairbairn et al, 2025). An example of AI supporting additional workflow steps to promote access to healthcare includes the use of a generative AI telemedicine assistant to autonomously conduct additional post-cataract surgery follow-up calls in the UK (Meinert et al, 2024).

Disruptive technologies may reform workflows around AI tools. The most obvious example is autonomous reporting, which may liberate resources to be used elsewhere. The UK National Screening Committee proposed a potential AI-assisted workflow by which AI retinal screening tools could remove 90% of AI-negative diabetic retinopathy screening photographs from requiring human grading, with 10% reviewed for ongoing performance monitoring (Macdonald et al, 2025).

Even within a single clinical workflow, AI can have radically different impacts, depending on its maturity, intended purpose, and the point and manner of its integration. For instance, AI algorithms for detecting abnormalities on CXR analysis can be integrated in different ways in the workflow (Table 2).

Table 2. Potential impacts of AI on an exemplar radiology workflow.

Workflow adaptation	Descriptor	Example—Radiology
Support	Supporting current pathways by providing AI insights.	AI analysis to provide clinical decision support in CXR interpretation to non-radiologists (UK, *in silico*) (Khan et al, 2024).
Augment	Extending clinical capabilities using AI. AI is applied to all investigations within a pathway, managed within existing resources.	Prioritising CXRs flagged for malignancy for radiological review (UK, protocol) (Duncan et al, 2024).
Transform	Redesign eliminates redundant steps in the pathway or provides additional supportive services.	CXRs flagged by AI for malignancy receive a same-day CT scan following radiographer review (UK, protocol) (Baldwin, 2023).
Disrupt	Revolutionary care models emerge. Redesign of pathways due to novel capabilities of AI tools.	ChestLink has been awarded a Class IIb CE mark for autonomous reporting of normal CXRs (Oxipit, 2022).

CXRs, chest X-rays; CT, computed tomography; CE, *Conformité Européene*.

Workforce Considerations

Engagement with AI tools by clinicians is fundamental to their use in clinical settings. When a new AI device is employed in clinical practice, the MHRA recommends that information is provided to the end user regarding the intended purpose, target population and medical condition (MHRA, 2024). However, human factors can influence the clinical performance of a new AI algorithm in practice. Automation bias is described as a failure to detect AI errors or to implement machine-generated decisions despite evidence to the contrary. For example, radiologists provided with incorrect AI CXR reports were found to be more likely to make incorrect recommendations (Bernstein et al, 2023). The effects of the incorrect reports were mitigated if the AI report included a box surrounding the region of interest. Interestingly, believing the AI report would not be retained on patient records also had a positive effect on performance.

This study highlights two important components of the interplay between AI and clinicians: explainability and liability. Explainability is one of the most frequently examined factors relating to healthcare experts' trust in AI (Tucci et al, 2022). AI is often described as a 'black box', meaning that the processes by which AI generates predictions may not be transparent to the end-user. If clinicians are unable to understand the basis of model outputs, they may be reluctant to act on AI-generated recommendations. Enhancing the interpretability of AI can improve clinician trust. Examples of this are textual explanations, feature maps, or feature-based explanations (Chaddad et al, 2023). Wang et al (2024) propose four key considerations for achieving explainability: identifying stakeholders and their needs, determining when explanations should be provided, anticipating user questions, and ensuring responses are tailored to stakeholder requirements.

With regards to liability, AI carries significant medico-legal implications. Determining responsibility for clinical errors involving AI can be challenging. Worries about mediating disagreements between clinicians and AI may prevent healthcare professionals from engaging with newly deployed algorithms. In a recent online survey, 73% of UK doctors reported concerns about their legal responsibility in using AI for diagnosis or treatment planning (Warrington and Holm, 2024). In 2023, a UK government policy paper stated that it was 'too soon to make decisions about liability' regarding AI (UK Government, 2023). However, it is important to recognise that delays in decision-making may not be protective for clinicians. Without active changes to current policy, it is likely that doctors may be held responsible for patient harm caused by following incorrect AI recommendations (British Medical Association (BMA), 2024a). A recent white paper from the shared Clinician and Artificial Intelligence Research (CAIRE) project team underlined that doctors had the potential to act as a 'liability sink', absorbing medicolegal responsibility where the AI system is a major contributing factor (Lawton et al, 2024; Lawton et al, 2025). Alternatively, NHS England guidance on the use of ambient scribes in healthcare settings described that liability remained 'complex and uncharted', but that liability may default to the Trust in cases of clinical negligence claims associated with AI products (NHS England, 2025b). In a systematic review addressing liability in AIaMD, manufacturers, clinicians and healthcare providers (such as NHS Trusts) have all been identified as possible individual or collective recipients of legal liability (Cestonaro et al, 2023). A shared responsibility model would acknowledge that clinical outcomes may be increasingly influenced by a combination of clinical expertise and AI outputs, dividing accountability between those who use, design, validate, deploy, and govern AI systems (Smith et al, 2024). The Fairness, Universality, Traceability, Usability, Robustness, and Explainability (FUTURE)-AI guidelines recommend that individual and collective liability for AI-related errors should be incorporated into accountability mechanisms (Lekadir et al, 2025). It is important that these guidelines are reflected in practice and in professional bodies' guidance on the use of AI in healthcare.

Clinician involvement requires doctors to be educated on the novel technologies. Implementation of AI requires a digitally literate workforce that understands the wider legal and regulatory implications of using AI in clinical practice. In contrast to the rapid expansion of AI capabilities and applications, traditional curricula remain relatively static. Evaluations of UK postgraduate programmes have revealed a lack of AI information and health informatics competencies in postgraduate medical education (Jidkov et al, 2019). Recognising the advantages of improved AI literacy, NHS England has recommended AI training for health and social care workers (NHS England, n.d.-a). As the use of AI in clinical practice increases, there is a need for updated medical school curricula and Continuous Professional Development (CPD) programmes, in addition to role-specific training for new posts that may arise from AI implementation. Opportunities for further upskilling and developing leadership capability may include targeted learning opportunities such as dedicated clinical AI fellowships.

Stage 6: Oversight and Monitoring

It remains important to monitor AI systems after implementation. Once deployed, inconsistent input data quality, changes to disease patterns and variations in populations can negatively affect algorithm outputs (data drift). For example, an evaluation of a breast cancer screening tool found that a sudden drop in performance was temporally correlated with a software upgrade to the mammography equipment (de Vries et al, 2023). Ongoing post-market surveillance (PMS) presents an opportunity to identify and address these issues.

Legislation Regarding PMS

Post-market surveillance is the legal responsibility of the developer (AI and Digital Regulations Service for Health and Social Care, 2023). Requirements for PMS have been recently clarified with a 2024 amendment to the UK Medical Devices Regulations (MDR) 2002 (MHRA, 2025b). The PMS period has been legally defined as starting when a medical device is first placed on the market or put into service. It continues until the end of the period whereby the manufacturer has validated the device to be used as intended. The amendment establishes new, legally-binding obligations for manufacturers of medical devices (including AIaMD) to develop and maintain a proactive, risk-based PMS system. Obligations include (MHRA, 2025b):

(1) Submitting regular safety and performance reports at pre-defined intervals.

(2) Documenting a PMS plan, with surveillance measures proportional to risk. This includes details on how performance data will be collected and risk management strategies.

(3) Outlining formal processes for model updates and for field safety corrective actions (FSCAs) (which address risks for faulty devices presently on the market).

(4) Reduced reporting timelines for serious incidents and mandatory reporting of errors, including ‘near misses’.

Methods of Monitoring AI in Practice

Although PMS is essential, the practicalities of delivering this at scale are still being uncovered. An example of good PMS within the NHS is a post-deployment performance evaluation of Deep Ensemble for the Recognition of Malignancy (DERM) (a triage tool for potentially malignant skin lesions). False negative AI results prompted a root cause analysis, whereby a panel of three dermatologists and an AI expert reviewed all case details (Marsden et al, 2023). Additionally, the cumulative UK performance of DERM (as indicated by their PMS reports) is publicly available on their company website (Skin Analytics, n.d.).

PMS often requires communication between healthcare providers and manufacturers. As the volume of UK-approved algorithms increases, undertaking continuous PMS may become more resource-intensive for NHS Trusts and Boards. AI itself may offer a promising solution. The Portfolio of AI Assurance Techniques raises the visibility of potential solutions for monitoring AI. For instance, Aival

Table 3. Summary recommendations for optimal AI development and application in healthcare.

Stage	Recommendation
Data	Ongoing central and local efforts to enhance and unify structured data storage within NHS systems. Standardisation of pathways for NHS data access across TREs, extending to Scotland, Northern Ireland and Wales. Requirements for registration of data-driven projects on trial registries or the Health Data Research Gateway, as part of obtaining local TRE approvals.
Evidence generation	Early stakeholder engagement prior to developing or deploying AI models. Enhanced accessibility of specialist expertise for scoping activities relating to AI (e.g., E-Health). Increased visibility of evidence requirements for each classification of medical device at the point of UKCA marking. Ongoing dedicated public funding opportunities to support prospective evidence generation for the use of AI in healthcare.
Regulation	Inclusion of intended use statements on PARD, in addition to a list of AI UKCA-approved products. Clinician-facing and manufacturer-facing MHRA guidance documents clearly outlining the regulatory process for AIaMD.
Procurement	Publicly available reports detailing decisions made in local procurement processes. Ring-fenced, flexible local budgets to deploy tools which display good local performance and clearly address a clinical need. Local evaluations of AI tools prior to procurement decisions.
Implementation	Increased investment in AI literacy for the healthcare workforce. Formal development of local AI implementation teams within NHS Trusts and Boards. Legal clarity regarding liability for AI-related errors.
Post marketing surveillance	AI monitoring boards with multidisciplinary stakeholder members (including patients, clinicians, and technical support teams). MHRA-enforcement of manufacturer adherence to PMS legislation and guidelines. Publication of PMS reports by vendors. Enhanced visibility of the Yellow Card Scheme in clinical and patient areas, and within apps.

NHS, National Health Service; TREs, Trusted Research Environments; UKCA, UK Conformity Assessment; MHRA, Medicines and Healthcare products Regulatory Agency; PARD, Public Access Registration Database; AIaMD, Artificial Intelligence as a Medical Device; PMS, post-market surveillance.

Monitor (Department for Science and Innovation and Technology, 2024a) and Newton's Tree's Federated AI Monitoring Service (FAMOS) platform (Department for Science and Innovation and Technology, 2024b) have the potential to assess AI radiology solutions using labelled imaging data. By enabling federated evaluation across imaging modalities, they have the potential to detect algorithmic drift, performance degradation, or unexpected inequities in performance. If appropriately validated, they align closely with the 2024 PMS regulatory framework, which mandates real-world performance data collection and continuous safety oversight.

The Role of Patients and Clinicians in Monitoring AI Solutions

Patients and clinicians play an important role in the oversight of AIaMD. While manufacturers can report adverse events through the Manufacturer's Online Reporting Environment (MORE) (MHRA, 2025c), few reports are received by the MHRA due to failures to recognise indirect harms caused by AI (MHRA, 2023). The MHRA Yellow Card scheme allows patients or clinicians in Northern Ireland, England or Wales to directly flag adverse incidents or near misses relating to AIaMD (MHRA, n.d.-c). In Scotland, healthcare professionals should report to the Incident Reporting and Investigation Centre, in addition to the local incident reporting system (e.g., Datex). Additional roles for patients in PMS have been strengthened: the amended regulations emphasise that manufacturer PMS plans should be informed by PPIE (MHRA, 2025b). Oversight of AI in healthcare should therefore be a shared endeavour between regulators, NHS organisations, AI developers, patients and clinicians.

PMS should be carried out across the entire lifecycle of the technology, with feedback informing further development. Ultimately, monitoring of AI in clinical practice generates a continuous stream of real-world performance data, which itself requires systematic analysis. The rapid pace of innovation for AIaMD means that PMS is particularly crucial in both identifying technologies for procurement and in decommissioning obsolete products. The implementation of AI is therefore not a linear process, but an iterative pathway. Deployment, monitoring, adaptation, evidence generation and revalidation are interconnected. In this respect, the process by which AI is translated from research to clinical practice is cyclical (Fig. 1).

Conclusion

It is essential for clinicians to understand the processes underpinning AI applications in healthcare. This is particularly important given the increasing prevalence of AIaMD and its potential to address the growing pressures faced by the UK healthcare system. Understanding the journey of an algorithm from ideation to implementation in healthcare allows AI to be contextualised and utilised optimally. This review has provided an overview of the AI journey into clinical practice. Key stages relevant to AI for healthcare use have been outlined, alongside challenges and opportunities inherent to each stage. These sequential stages include model training, evidence generation, regulatory compliance, NHS procurement, implementation, and post-deployment monitoring. These processes are still evolving,

reflecting the dynamic nature of both AI and the UK healthcare landscape. Summary recommendations for positive change are listed in Table 3. If understood and harnessed appropriately, AI has the potential to support the NHS in becoming a more intelligent and responsive healthcare system, ultimately enhancing outcomes for both patients and providers.

Key Points

- Standardised, ethical and secure processes to access data in the UK would facilitate data acquisition for AI training, validation and development.
- The evaluation of AI solutions should follow a multi-phase approach to assess safety and efficacy and include all relevant stakeholders, including patients and clinicians.
- The regulatory standards for AIaMD vary according to risk classification, allowing low-risk products to self-certify with minimal evidence while higher-risk devices undergo rigorous assessment.
- AI algorithms should be procured based on their suitability for the local healthcare context, considering national guidelines, local performance data, and institutional IT capabilities.
- Successful implementation necessitates engaging and supporting the workforce with AI literacy, role adaptation, and clarification of liability and accountability in AI-assisted decision-making.

Availability of Data and Materials

Not applicable.

Author Contributions

CC, DJL, DC and VB conceived of the work. DC and VB wrote the manuscript and contributed equally. The manuscript was edited by CC and DJL. CC is the guarantor. All authors contributed to the important editorial changes in the manuscript. All authors read and approved the final manuscript. All authors have participated sufficiently in the work and agreed to be accountable for all aspects of the work.

Ethics Approval and Consent to Participate

Not applicable.

Acknowledgement

Not applicable.

Funding

This research received no external funding.

Conflict of Interest

The authors declare no conflict of interest.

References

AI and Digital Regulations Service for Health and Social Care. Understanding post-market surveillance of medical devices. 2023. Available at: https://www.digitalregulations.innovation.nhs.uk/regulations-and-guidance-for-adopters/all-adopters-guidance/understanding-post-market-surveillance-of-medical-devices (Accessed: 24 July 2025).

Alowais SA, Alghamdi SS, Alsuhebany N, Alqahtani T, Alshaya AI, Almohareb SN, et al. Revolutionizing healthcare: the role of artificial intelligence in clinical practice. BMC Medical Education. 2023; 23: 689. https://doi.org/10.1186/s12909-023-04698-z

Armstrong S. NHS England faces investigation over granting Foresight access to GP patient data. BMJ. 2025; 389: r1192. https://doi.org/10.1136/bmj.r1192

Baines R, Hoogendoorn P, Stevens S, Chatterjee A, Ashall-Payne L, Andrews T, et al. Navigating Medical Device Certification: A Qualitative Exploration of Barriers and Enablers Amongst Innovators, Notified Bodies and Other Stakeholders. Therapeutic Innovation & Regulatory Science. 2023; 57: 238–250. https://doi.org/10.1007/s43441-022-00463-4

Baldwin D. Does triage of chest X-rays with artificial intelligence shorten the time to lung cancer diagnosis: a randomised controlled trial. 2023. Available at: https://www.isrctn.com/ISRCTN78987039 (Accessed: 24 July 2025).

Bernstein MH, Atalay MK, Dibble EH, Maxwell AWP, Karam AR, Agarwal S, et al. Can incorrect artificial intelligence (AI) results impact radiologists, and if so, what can we do about it? A multi-reader pilot study of lung cancer detection with chest radiography. European Radiology. 2023; 33: 8263–8269. https://doi.org/10.1007/s00330-023-09747-1

Bird M, Ouellette C, Whitmore C, Li L, Nair K, McGillion MH, et al. Preparing for patient partnership: A scoping review of patient partner engagement and evaluation in research. Health Expectations. 2020; 23: 523–539. https://doi.org/10.1111/hex.13040

British Medical Association (BMA). Getting IT right: The case for urgent investment in safe, modern technology and data sharing in the UK's health services. 2022. Available at: https://www.bma.org.uk/media/6578/bma-infrastructure-2-report-getting-it-right-dec-2022.pdf (Accessed: 24 July 2025).

British Medical Association (BMA). Principles for Artificial Intelligence (AI) and its application in healthcare. 2024a. Available at: https://www.bma.org.uk/advice-and-support/nhs-delivery-and-workforce/technology/principles-for-artificial-intelligence-ai-and-its-application-in-healthcare (Accessed: 24 July 2025).

British Medical Association (BMA). Technology, infrastructure and data supporting NHS staff. 2024b. Available at: https://www.bma.org.uk/media/2080/bma-vision-for-nhs-it-report-april-2019.pdf (Accessed: 24 July 2025).

Burns S, Cushing A, Taylor A, Lowe DJ, Carlin C. Supporting long-term condition management: a workflow framework for the co-development and operationalization of machine learning models using electronic health record data insights. Frontiers in Artificial Intelligence. 2024; 7: 1458508. https://doi.org/10.3389/frai.2024.1458508

Cestonaro C, Delicati A, Marcante B, Caenazzo L, Tozzo P. Defining medical liability when artificial intelligence is applied on diagnostic algorithms: a systematic review. Frontiers in Medicine. 2023; 10: 1305756. https://doi.org/10.3389/fmed.2023.1305756

Chaddad A, Peng J, Xu J, Bouridane A. Survey of Explainable AI Techniques in Healthcare. Sensors. 2023; 23: 634. https://doi.org/10.3390/s23020634

Collins GS, Moons KGM, Dhiman P, Riley RD, Beam AL, Van Calster B, et al. TRIPOD+AI statement: updated guidance for reporting clinical prediction models that use regression or machine learning methods. BMJ. 2024; 385: e078378. https://doi.org/10.1136/bmj-2023-078378

Cresswell K, William R, Dungey S, Anderson S, Bernabeu MO, Mozaffar H, et al. Putting the United Kingdom at the forefront of using artficial intelligence for the benefit of health and care: a mixed methods formative evaluation of the NHS Artificial Intelligence Lab. 2025. Available at: https://usher.ed.ac.uk/sites/default/files/2025-04/AI%20Lab%20Evaluation%20Final%20Report%20April%202025_0.pdf (Accessed: 24 July 2025).

Cruz Rivera S, Liu X, Chan AW, Denniston AK, Calvert MJ. Guidelines for clinical trial protocols for interventions involving artificial intelligence: the SPIRIT-AI extension. The Lancet. Digital Health. 2020; 2: e549–e560. https://doi.org/10.1016/S2589-7500(20)30219-3

Danechi S, Harker R, Stiebahl S. NHS Key Statistics: England. 2025. Available at: https://researchbriefings.files.parliament.uk/documents/CBP-7281/CBP-7281.pdf (Accessed: 24 July 2025).

Darzi A. Independent investigation of the national health service in England. 2024 Available at: https://assets.publishing.service.gov.uk/media/66f42ae630536cb92748271f/Lord-Darzi-Independent-Investigation-of-the-National-Health-Service-in-England-Updated-25-September.pdf (Accessed: 24 July 2025).

de Vries CF, Colosimo SJ, Staff RT, Dymiter JA, Yearsley J, Dinneen D, et al. Impact of Different Mammography Systems on Artificial Intelligence Performance in Breast Cancer Screening. Radiology. Artificial Intelligence. 2023; 5: e220146. https://doi.org/10.1148/ryai.220146

Deniz-Garcia A, Fabelo H, Rodriguez-Almeida AJ, Zamora-Zamorano G, Castro-Fernandez M, Alberiche Ruano MDP, et al. Quality, Usability, and Effectiveness of mHealth Apps and the Role of Artificial Intelligence: Current Scenario and Challenges. Journal of Medical Internet Research. 2023; 25: e44030. https://doi.org/10.2196/44030

Department for Science, Innovation and Technology. AI Opportunities Action Plan. 2025. Available at: https://www.gov.uk/government/publications/ai-opportunities-action-plan/ai-opportunities-action-plan (Accessed: 24 July 2025).

Department for Science, Innovation and Technology. Aival Monitor, Aival Analysis Lab: enabling organisations to understand how a deployed AI product is working over time. 2024a. Available at: https://www.gov.uk/ai-assurance-techniques/aival-monitor-aival-analysis-lab-enabling-organisations-to-understand-how-a-deployed-ai-product-is-working-over-time (Accessed: 24 July 2025).

Department for Science, Innovation and Technology. Newton's Tree's Federated AI Monitoring Service (FAMOS). 2024b. Available at: https://www.gov.uk/ai-assurance-techniques/newtons-trees-federated-ai-monitoring-service-famos (Accessed: 24 July 2025).

Duncan SF, McConnachie A, Blackwood J, Stobo DB, Maclay JD, Wu O, et al. Radiograph accelerated detection and identification of cancer in the lung (RADICAL): a mixed methods study to assess the clinical effectiveness and acceptability of Qure.ai artificial intelligence software to prioritise chest X-ray (CXR) interpretation. BMJ Open. 2024; 14: e081062. https://doi.org/10.1136/bmjopen-2023-081062

Elvas LB, Almeida A, Ferreira JC. The Role of AI in Cardiovascular Event Monitoring and Early Detection: Scoping Literature Review. JMIR Medical Informatics. 2025; 13: e64349. https://doi.org/10.2196/64349

Evans TD, Ahmad O, Alderman JE, Bailey G, Bannister P, Barlow N, et al. The role of procurement frameworks in responsible AI innovation in the National Health Service: a multi-stakeholder perspective. Frontiers in Health Services. 2025; 5: 1608087. https://doi.org/10.3389/frhs.2025.1608087

Fairbairn TA, Mullen L, Nicol E, Lip GYH, Schmitt M, Shaw M, et al. Implementation of a national AI technology program on cardiovascular outcomes and the health system. Nature Medicine. 2025; 31: 1903–1910. https://doi.org/10.1038/s41591-025-03620-y

Farič N, Hinder S, Williams R, Ramaesh R, Bernabeu MO, van Beek E, et al. Early experiences of integrating an artificial intelligence-based diagnostic decision support system into radiology settings: a qualitative study. Journal of the American Medical Informatics Association. 2024; 31: 24–34. https://doi.org/10.1093/jamia/ocad191

Fazakarley CA, Breen M, Leeson P, Thompson B, Williamson V. Experiences of using artificial intelligence in healthcare: a qualitative study of UK clinician and key stakeholder perspectives. BMJ Open. 2023; 13: e076950. https://doi.org/10.1136/bmjopen-2023-076950

Germain DP, Gruson D, Malcles M, Garcelon N. Applying artificial intelligence to rare diseases: a literature review highlighting lessons from Fabry disease. Orphanet Journal of Rare Diseases. 2025; 20: 186. https://doi.org/10.1186/s13023-025-03655-x

Habicht J, Viswanathan S, Carrington B, Hauser TU, Harper R, Rollwage M. Closing the accessibility gap to mental health treatment with a personalized self-referral chatbot. Nature Medicine. 2024; 30: 595–602. https://doi.org/10.1038/s41591-023-02766-x

Hammoud M, Douglas S, Darmach M, Alawneh S, Sanyal S, Kanbour Y. Evaluating the Diagnostic Performance of Symptom Checkers: Clinical Vignette Study. JMIR AI. 2024; 3: e46875. https://doi.org/10.2196/46875

Han R, Acosta JN, Shakeri Z, Ioannidis JPA, Topol EJ, Rajpurkar P. Randomised controlled trials evaluating artificial intelligence in clinical practice: a scoping review. The Lancet. Digital Health. 2024; 6: e367–e373. https://doi.org/10.1016/S2589-7500(24)00047-5

Health Data Research UK. Discover Data on the Gateway. n.d. Available at: https://www.hdruk.ac.uk/access-to-health-data/health-data-research-gateway/ (Accessed: 23 July 2025).

Health Innovation Network. NHS procurement explained. n.d. Available at: https://thehealthinnovationnetwork.co.uk/how-we-can-help-you/support-for-innovators/nhs-procurement-explained (Accessed: 24 July 2025).

Hind D, Reeves BC, Bathers S, Bray C, Corkhill A, Hayward C, et al. Comparative costs and activity from a sample of UK clinical trials units. Trials. 2017; 18: 203. https://doi.org/10.1186/s13063-017-1934-3

Inkster B, Sarda S, Subramanian V. An Empathy-Driven, Conversational Artificial Intelligence Agent (Wysa) for Digital Mental Well-Being: Real-World Data Evaluation Mixed-Methods Study. JMIR MHealth and UHealth. 2018; 6: e12106. https://doi.org/10.2196/12106

Jakobsson A, Ohlin P, Pahlm O. Does a computer-based ECG-recorder interpret electrocardiograms more efficiently than physicians? Clinical Physiology. 1985; 5: 417–423. https://doi.org/10.1111/j.1475-097x.1985.tb00772.x

Jakobsson A, Pahlm O, Reichert L, Edenbrandt L, Nilsson B. On the consistency of ECG reports from two different computer-based ECG recorders. Clinical Physiology. 1989; 9: 289–294. https://doi.org/10.1111/j.1475-097x.1989.tb00981.x

Jidkov L, Alexander M, Bark P, Williams JG, Kay J, Taylor P, et al. Health informatics competencies in postgraduate medical education and training in the UK: a mixed methods study. BMJ Open. 2019; 9: e025460. https://doi.org/10.1136/bmjopen-2018-025460

Jin MF, Noseworthy PA, Yao X. Assessing Artificial Intelligence Solution Effectiveness: The Role of Pragmatic Trials, Mayo Clinic Proceedings: Digital Health. 2024; 2: 499–510. https://doi.org/10.1016/j.mcpdig.2024.06.010

Khan F, Das I, Kotnik M, Wing L, Van Beek E, Murchison J, et al. AI-assisted detection for chest X-rays (AID-CXR): a multi-reader multi-case study protocol. BMJ Open. 2024; 14: e080554. https://doi.org/10.1136/bmjopen-2023-080554

Kolbinger FR, Veldhuizen GP, Zhu J, Truhn D, Kather JN. Reporting guidelines in medical artificial intelligence: a systematic review and meta-analysis. Communications Medicine. 2024; 4: 71. https://doi.org/10.1038/s43856-024-00492-0

Kubin AM, Huhtinen P, Ohtonen P, Keskitalo A, Wirkkala J, Hautala N. Comparison of 21 artificial intelligence algorithms in automated diabetic retinopathy screening using handheld fundus camera. Annals of Medicine. 2024; 56: 2352018. https://doi.org/10.1080/07853890.2024.2352018

Lawton T, Morgan P, Porter Z, Hickey S, Cunningham A, Hughes N, et al. Clinicians risk becoming 'liability sinks' for artificial intelligence. Future Healthcare Journal. 2024; 11: 100007. https://doi.org/10.1016/j.fhj.2024.100007

Lawton T, Porter Z, Habli I, Sharma V, Morgan PD, Iacovides J, et al. Avoiding the AI 'Off-Switch': Make AI Work for Clinicians, to Deliver for Patients. 2025.Available at: https://www.thempsfoundation.org//docs/foundationlibraries/foundation-default-library/white-papers/ai-white-paper_the-mps-foundation.pdf (Accessed: 24 July 2025).

Lekadir K, Frangi AF, Porras AR, Glocker B, Cintas C, Langlotz CP, et al. FUTURE-AI: international consensus guideline for trustworthy and deployable artificial intelligence in healthcare. BMJ. 2025; 388: e081554. https://doi.org/10.1136/bmj-2024-081554

Lin C, Kuo CF. Roles and Potential of Large Language Models in Healthcare: A Comprehensive Review. Biomedical Journal. 2025; 100868. https://doi.org/10.1016/j.bj.2025.100868

Liu X, Cruz Rivera S, Moher D, Calvert MJ, Denniston AK, SPIRIT-AI and CONSORT-AI Working Group. Reporting guidelines for clinical trial reports for interventions involving artificial intelligence: the CONSORT-AI extension. The Lancet. Digital Health. 2020; 2: e537–e548. https://doi.org/10.1016/S2589-7500(20)30218-1

Macdonald T, Zhelev Z, Liu X, Hyde C, Fajtl J, Egan C, et al. Generating evidence to support the role of AI in diabetic eye screening: considerations from the UK National Screening Committee. The Lancet. Digital Health. 2025; 7: 100840. https://doi.org/10.1016/j.landig.2024.12.004

Marsden H, Morgan C, Austin S, DeGiovanni C, Venzi M, Kemos P, et al. Effectiveness of an image analyzing AI-based Digital Health Technology to identify Non-Melanoma Skin Cancer and other skin lesions: results of the DERM-003 study. Frontiers in Medicine. 2023; 10: 1288521. https://doi.org/10.3389/fmed.2023.1288521

Meinert E, Milne-Ives M, Lim E, Higham A, Boege S, de Pennington N, et al. Accuracy and safety of an autonomous artificial intelligence clinical assistant conducting telemedicine follow-up assessment for cataract surgery. eClinicalMedicine. 2024; 73: 102692. https://doi.org/10.1016/j.eclinm.2024.102692

Merchant F, Choulerton J, James R, Pang CL. Real world clinical experience of using Brainomix e-CTA software in a medium size acute National Health Service Trust. The British Journal of Radiology. 2025; 98: 592–599. https://doi.org/10.1093/bjr/tqaf019

MHRA. Guidance | Medical device stand-alone software including apps (including IVDMDs). n.d.-a. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1168485/Medical_device_stand-alone_software_including_apps__including_IVDMDs_.pdf (Accessed: 24 July 2025).

MHRA. Guidance | Manufacturer's Online Reporting Environment (MORE). 2025c. Available at: https://www.gov.uk/guidance/manufacturers-online-reporting-environment-more (Accessed: 24 September 2025).

MHRA. Guidance | Software and AI as a Medical Device Change Programme roadmap. 2023. Available at: https://www.gov.uk/government/publications/software-and-ai-as-a-medical-device-change-programme/software-and-ai-as-a-medical-device-change-programme-roadmap#introduction (Accessed: 24 September 2025).

MHRA. Guidance | Transparency for machine learning-enabled medical devices: guiding principles. 2024. Available at: https://www.gov.uk/government/publications/machine-learning-medical-devices-transparency-principles/transparency-for-machine-learning-enabled-medical-devices-guiding-principles (Accessed: 18 November 2025).

MHRA. Implementation of the future regulations. 2025a. Available at: https://www.gov.uk/government/publications/implementation-of-the-future-regulation-of-medical-devices/implementation-of-the-future-regulations (Accessed: 24 July 2025).

MHRA. Public Access Registration Database. n.d.-b. Available at: https://pard.mhra.gov.uk/ (Accessed: 24 July 2025).

MHRA. The Medical Devices (Post-market Surveillance Requirements) (Amendment) (Great Britain) Regulations 2024 Summary of main changes introduced with the statutory instrument (SI) and associated guidance. 2025b. Available at: https://assets.publishing.service.gov.uk/media/684bfe2e19e3b84158cba2ba/20250515_Table_of_key_changes_updated_FINAL.pdf?utm_source=chatgpt.com (Accessed: 24 July 2025).

MHRA. Welcome to the Yellow Card reporting site. n.d.-c. Available at: https://yellowcard.mhra.gov.uk/ (Accessed: 24 July 2025).

MHRA. Appendix 1 – Symptom checkers. n.d.-d. Available at: https://assets.publishing.service.gov.uk/media/64a7d235c531eb000c650051/Appendix_1_-_symptom_checkers.pdf (Accessed: 24 July 2025).

Mittermaier M, Raza MM, Kvedar JC. Bias in AI-based models for medical applications: challenges and mitigation strategies. NPJ Digital Medicine. 2023; 6: 113. https://doi.org/10.1038/s41746-023-00858-z

Nagendran M, Chen Y, Lovejoy CA, Gordon AC, Komorowski M, Harvey H, et al. Artificial intelligence versus clinicians: systematic review of design, reporting standards, and claims of deep learning studies. BMJ. 2020; 368: m689. https://doi.org/10.1136/bmj.m689

NHS England. Developing healthcare workers' confidence in artificial intelligence (AI) (Part 2). n.d.-a. Available at: https://digital-transformation.hee.nhs.uk/building-a-digital-workforce/dart-ed/horizon-scanning/developing-healthcare-workers-confidence-in-ai (Accessed: 24 July 2025).

NHS England. Futuristic 3D heart scans on NHS speed up diagnosis and save millions. 2025a. Available at: https://www.england.nhs.uk/2025b/05/futuristic-3d-heart-scans-speed-up-diagnosis-and-save-millions (Accessed: 24 July 2025).

NHS England. Guidance on the use of AI-enabled ambient scribing products in health and care settings. 2025b. Available at: https://www.england.nhs.uk/long-read/guidance-on-the-use-of-ai-enabled-ambient-scribing-products-in-health-and-care-settings (Accessed: 24 July 2025).

NHS England. Medical technology (MedTech) funding mandate and support. n.d.-b. Available at: https://www.england.nhs.uk/aac/what-we-do/how-can-the-aac-help-me/the-medtech-funding-mandate (Accessed: 24 July 2025).

NHS England. The NHS Research Secure Data Environment Network. 2025c. Available at: https://digital.nhs.uk/data-and-information/research-powered-by-data/sde-network (Accessed: 23 July 2025).

NHS Staff Survey. NHS Staff Survey National Results. 2024. Available at: https://www.nhsstaffsurveys.com/results/national-results (Accessed: 12 July 2025).

NICE. AI-derived computer-aided detection (CAD) software for detecting and measuring lung nodules in CT scan images. 2023a. Available at: https://www.nice.org.uk/guidance/dg55 (Accessed: 23 July 2025).

NICE. Artificial intelligence-derived software to analyse chest X-rays for suspected lung cancer in primary care referrals: early value assessment. 2023b. Available at: https://www.nice.org.uk/guidance/hte12 (Accessed: 20 July 2025).

NICE. Artificial Intelligence. n.d.-a. Available at: https://www.nice.org.uk/guidance/health-and-social-care-delivery/artificial-intelligence/products?Status=Published&ProductType=Advice&ProductType=Guidance (Accessed: 23 July 2025).

NICE. Assessment report: Digital technologies for managing low back pain (addendum). 2023c. Available at: https://www.nice.org.uk/guidance/hte16/documents/supporting-documentation-3 (Accessed: 24 July 2025).

NICE. How we develop medical technologies guidance. n.d.-b. Available at: https://www.nice.org.uk/what-nice-does/our-guidance/about-medical-technologies-guidance/how-we-develop-medical-technologies-guidance (Accessed: 24 July 2025).

Oxipit. Oxipit Awarded CE Mark For First Autonomous AI Medical Imaging Application. 2022. Available at: https://oxipit.ai/news/first-autonomous-ai-medical-imaging-application (Accessed: 24 July 2025).

Paullada A, Raji ID, Bender EM, Denton E, Hanna A. Data and its (dis)contents: A survey of dataset development and use in machine learning research. Patterns. 2021; 2: 100336. https://doi.org/10.1016/j.patter.2021.100336

Pearson JT, Chelstowska M, Rowland SP, Mcilwaine E, Benhar E, Berglund Scherwitzl E, et al. Natural Cycles app: contraceptive outcomes and demographic analysis of UK users. The European Journal of Contraception & Reproductive Health Care. 2021; 26: 105–110. https://doi.org/10.1080/13625187.2020.1867844

Ray S, Clarke SC. Getting It Right First Time (GIRFT): transforming cardiology care. Heart. 2023; 109: 344–348. https://doi.org/10.1136/heartjnl-2021-320370

Regulatory Horizons Council. The Regulation of Artificial Intelligence as a Medical Device. 2022. Available at: https://assets.publishing.service.gov.uk/media/6384bf98e90e0778a46ce99f/RHC_regulation_of_AI_as_a_Medical_Device_report.pdf (Accessed: 23 September 2025).

Roberts M. Streamlining access to innovative stroke imagery analysis technology. NHE. 2022. Available at: https://btpubs.co.uk/article/Streamlining+access+to+innovative+stroke+imagery+analysis+technology/4236597/741633/article.html (Accessed: 24 July 2025).

Sendak MP, Ratliff W, Sarro D, Alderton E, Futoma J, Gao M, et al. Real-World Integration of a Sepsis Deep Learning Technology Into Routine Clinical Care: Implementation Study. JMIR Medical Informatics. 2020; 8: e15182. https://doi.org/10.2196/15182

Shelmerdine SC, Togher D, Rickaby S, Dean G. Artificial intelligence (AI) implementation within the National Health Service (NHS): the South West London AI Working Group experience. Clinical Radiology. 2024; 79: 665–672. https://doi.org/10.1016/j.crad.2024.05.018

Skin Analytics. DERM performance. n.d. Available at: https://skin-analytics.com/ai-pathways/derm-performance/ (Accessed: 24 July 2025).

Smith H, Birchley G, Ives J. Artificial intelligence in clinical decision-making: Rethinking personal moral responsibility. Bioethics. 2024; 38: 78–86. https://doi.org/10.1111/bioe.13222

Soltan AAS, Thakur A, Yang J, Chauhan A, D'Cruz LG, Dickson P, et al. A scalable federated learning solution for secondary care using low-cost microcomputing: privacy-preserving development and evaluation of a COVID-19 screening test in UK hospitals. The Lancet. Digital Health. 2024; 6: e93–e104. https://doi.org/10.1016/S2589-7500(23)00226-1

Soltan AAS, Yang J, Pattanshetty R, Novak A, Yang Y, Rohanian O, et al. Real-world evaluation of rapid and laboratory-free COVID-19 triage for emergency care: external validation and pilot deployment of artificial intelligence driven screening. The Lancet. Digital Health. 2022; 4: e266–e278. https://doi.org/10.1016/S2589-7500(21)00272-7

Soltani F, Bradley J, Bonandi A, Black N, Farrant JP, Pailing A, et al. Identification of heart failure hospitalization from NHS Digital data: comparison with expert adjudication. ESC Heart Failure. 2024; 11: 1022–1029. https://doi.org/10.1002/ehf2.14669

Stoye G, Warner M, Zaranko B. The Past and Future of UK Health Spending. IFS Report: London. 2024.

Sudlow C. Uniting the UK's Health Data: A Huge Opportunity for Society. 2024. Available at: https://dx.doi.org/10.5281/zenodo.13353747 (Accessed: 24 July 2025).

Taylor A, Cushing A, Dow M, Anderson J, McDowell G, Lua S, et al. Long-Term Usage and Improved Clinical Outcomes with Adoption of a COPD Digital Support Service: Key Findings from the RECEIVER Trial. International Journal of Chronic Obstructive Pulmonary Disease. 2023; 18: 1301–1318. https://doi.org/10.2147/COPD.S409116

The King's Fund. Access to new medicines in the English NHS. 2025. Available at: https://www.kingsfund.org.uk/insight-and-analysis/long-reads/access-new-medicines-english-nhs (Accessed: 24 July 2025).

Transformation Directorate. National engagement on data: Cohort 1 report. 2025. Available at: https://transform.england.nhs.uk/key-tools-and-info/data-saves-lives/national-public-engagement-on-the-use-of-health-data/national-engagement-on-data-cohort-1-report (Accessed: 23 July 2025).

Tucci V, Saary J, Doyle TE. Factors influencing trust in medical artificial intelligence for healthcare professionals: a narrative review. Journal of Medical Artificial Intelligence. 2022; 5. https://doi.org/10.21037/jmai-21-25

Turing AM. Computing Machinery and Intelligence. Mind. 1950; 59: 433–460. https://doi.org/10.1093/mind/LIX.236.433

UK Government. A pro-innovation approach to AI regulation. 2023. Available at: https://www.gov.uk/government/publications/ai-regulation-a-pro-innovation-approach/white-paper (Accessed: 24 July 2025).

UK Health Data Research Alliance and NHSX. Building Trusted Research Environments - Principles and Best Practices; Towards TRE ecosystems. 2021. Available at: https://zenodo.org/records/5767586 (Accessed: 24 July 2025).

van de Sande D, van Genderen ME, Huiskens J, Gommers D, van Bommel J. Moving from bytes to bedside: a systematic review on the use of artificial intelligence in the intensive care unit. Intensive Care Medicine. 2021; 47: 750–760. https://doi.org/10.1007/s00134-021-06446-7

Vargas-Palacios A, Sharma N, Sagoo GS. Cost-effectiveness requirements for implementing artificial intelligence technology in the Women's UK Breast Cancer Screening service. Nature Communications. 2023; 14: 6110. https://doi.org/10.1038/s41467-023-41754-0

Vimalesvaran K, Robert D, Kumar S, Kumar A, Narbone M, Dharmadhikari R, et al. Assessing the effectiveness of artificial intelligence (AI) in prioritising CT head interpretation: study protocol for a stepped-wedge cluster randomised trial (ACCEPT-AI). BMJ Open. 2024; 14: e078227. https://doi.org/10.1136/bmjopen-2023-078227

Wang Z, Huang C, Yao X. A roadmap of explainable artificial intelligence: Explain to whom, when, what and how? ACM Transactions on Autonomous and Adaptive Systems. 2024; 19: 1–40. https://doi.org/10.1145/3702004

Warrington DJ, Holm S. Healthcare ethics and artificial intelligence: a UK doctor survey. BMJ Open. 2024; 14: e089090. https://doi.org/10.1136/bmjopen-2024-089090

Zhang J, Morley J, Gallifant J, Oddy C, Teo JT, Ashrafian H, et al. Mapping and evaluating national data flows: transparency, privacy, and guiding infrastructural transformation. The Lancet. Digital Health. 2023; 5: e737–e748. https://doi.org/10.1016/S2589-7500(23)00157-7