

Future Directions in Personalised Medicine: A Horizon Scan for Artificial Intelligence, Genomics- Based HealthTech

Authors: Imogen Forsythe, Kate Lanyi, Elizabeth Green, Katie Twentyman,
Jabez Barnabas, Andrew Mkwashi

Date: November 2025



Professor Dawn Craig
Director

T: +44(0) 191 208 2259

E: info@io.nihr.ac.uk

www.io.nihr.ac.uk

Copyright © National Institute for Health and Care
Research Innovation Observatory (NIHR IO),
Newcastle University

How to Cite This Document

Forsythe, I., Lanyi, K., Green, E., Twentyman, K., Barnabas, J., & Mkwashi, A. Future Directions in Personalised Medicine: A Horizon Scan for Artificial Intelligence, Genomics-Based HealthTech. NIHR Innovation Observatory; Newcastle upon Tyne, 2025. DOI: 10.6084/m9.figshare.31112542

Acknowledgements and Disclaimers

This study/project is funded by the National Institute for Health and Care Research (NIHR) [NIHR IO/project reference HSRIC-2016-10009]. The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

We also thank our internal contributor Lena Schmidt who developed the SCANNAR News Search tool that was essential in capturing ambient scribe technologies not being evaluated in a clinical trial setting during our search.

Conflicts of Interest

No conflicts of interest to declare.

Contents

How to Cite This Document.....	2
Acknowledgements and Disclaimers.....	2
Conflicts of Interest.....	2
Abstract.....	4
Background	5
Aim.....	7
Objectives	7
Methods	7
Scope.....	7
Eligibility criteria:	8
Inclusion criteria	8
Exclusion criteria	8
Search Strategy	9
Sources	9
Data Extraction	9
Results	11
Prisma chart.....	11
NICE Disease Category	12
Technology Readiness Level (TRL)	12
Country of Development.....	14
Technology Purpose	14
Developer Type	15
Regulatory Status	15
Type of data analysed	16
Discussion.....	20
Appendix A: Search Strings	23
References	25

Abstract

Background:

Personalised, or precision medicine, is an emerging medical approach where diagnosis, prognostics, personalised treatment protocols and disease surveillance strategies are designed based on a patient's unique characteristics such as genetics, physiology, clinical history and ecological data. Artificial intelligence (AI) is rapidly accelerating the development and availability of these personalised technologies, as AI can analyse large datasets and integrate different data types rapidly. However, the extent and nature of AI's application in personalised medicine remain underexplored. Our horizon scan aimed to identify emerging AI technologies in this field to inform policymakers and aid rapid adoption of new technologies into the NHS and global healthcare systems.

Methods:

Using a diverse range of sources including clinical trials registries (ClinicalTrials.gov, ICTRP, EudraCT), bibliographic sources (Embase) and funding portals (UKRI, NIHR) we conducted a horizon scan identifying emerging AI technologies which could be used in personalised medicine. We focused our study particularly on technologies which analyse genomic or genetic data to inform decisions, as a key cornerstone of personalised medicine principles. Furthermore, we only included technologies intended to diagnose, plan or design therapeutic interventions, or technologies providing prognostic data.

Results:

We identified 104 unique technologies primarily focused on personalised treatment planning (68%) and precision diagnostics (26%). Data analysed included genetic, clinical, physiological, and socioecological data. Most technologies were in clinical evaluation stages (TRL 5-7), with only 5% reporting regulatory approval (UK CA, EU CE, or US FDA). Data types analysed by these technologies included genetic and genomic data, clinical history, physiological and socioecological data.

Conclusions:

AI technologies are essential for implementing personalised medicine but face regulatory and ethical challenges. Low regulatory approval rates and complex GDPR requirements for genomic data may hinder adoption. Addressing these barriers through streamlined regulatory frameworks and equity-focused design principles is critical to ensuring these technologies fulfil unmet needs and reduce health inequalities.

Background

Personalised, also referred to as precision medicine, is an emerging medical approach where treatment protocols are designed based on a patient's unique characteristics such as genetics, physiology, clinical history and ecological data.^{1,2} The adoption of personalised treatment approaches is rapidly expanding in clinical practise with the growing availability of AI-based technologies in healthcare.³ AI technologies use large datasets including electronic health records (EHRs), genomic profiles and biomedical imaging records to identify patterns and correlations between datasets, which can increase prognostic accuracy and inform how patients' may respond to different treatments.⁴ The use of AI in pharmacogenomics has the potential to increase medication efficacy, reduce adverse treatment reactions and improve patient outcomes.²

Increasing availability of AI analytics and decreasing genome sequencing costs are accelerating the transition towards personalised treatment pathways in the NHS and healthcare systems globally.⁵ Within the NHS, delivery of personalised medicine is focused on the "four Ps" or P4 medicine: prediction and prevention of disease, more precise diagnosis, personalised and targeted interventions and a more participatory role for patients.⁵ The predictive pillar uses big data and advanced analytics to anticipate disease onset and progression. The prevention pillar aims to use digital solutions and data to identify risk factors and provide early intervention to reduce disease risk. Personalised and targeted interventions refers to the use of genetic, environmental, socioecological and lifestyle factors to provide personalised treatment recommendations and enhance patient care.⁶ The final pillar, participation, refers to a more active role for patients in their own care including self-monitoring and self-assessments.⁷

Precision diagnoses can be achieved through integration of multiple data sources such as genomic, imaging data and clinical history (multi-omics).⁸ Use of multi-omics (integration of multiple data sources such as genomics, transcriptomics and epigenomics) analysis using AI could detect diseases earlier through recognition of patterns within datasets which may be missed using manual analytical methods.⁸⁻¹⁰ Earlier diagnosis and treatment may mitigate the need for more invasive and costly interventions, compared to later detection through conventional diagnostics following symptomatic deterioration.⁸ Multi-omic analysis using generative AI may result in more accurate prediction of disease progression by simulating various scenarios, contributing to a more proactive model of healthcare where early interventions can prevent symptomatic decline.⁹ AI analysis of genomic data is particularly beneficial when considering rare diseases. Patients impacted by rare conditions often experience a "diagnostic odyssey", with many individuals experiencing misdiagnosis and inappropriate treatment.¹¹ Genomic analysis using AI, may provide earlier access to precision medicines and appropriate care pathways for these patients.¹²

AI is also accelerating the transition towards personalised treatment plans and optimised care pathways for patients. Analysis of individuals' genomic data could enable clinicians to determine the most appropriate treatment pathway, by predicting physiological responses based on mutations identified using AI.¹³ For example, autoencoders and multimodal neural networks have been used in cancer care pathways to classify tumour subtypes, predict survival and model treatment response based on multi-omic analysis.¹⁴ This could potentially reduce the side effects experienced by patients and improve treatment efficacy through identification of the most compatible treatment strategies for individual patients.¹³ The use of genomic analysis to inform treatment decisions may also reduce NHS spending on adverse drug reactions or inefficient care.⁵

The increasing development and availability of AI used within personalised medicine is contributing to the transition towards a preventative model of healthcare.⁵ Prediction and prevention of diseases using AI can be achieved in numerous ways. AI tools can analyse large datasets (for example, UK Biobank) and sequencing data to enable accessible genomic-based screening; genomic data can be combined with other information such as clinical history and lifestyle information to determine individuals most at risk of chronic/preventable diseases.¹⁵ Genomic-based screening may be used for whole population screening, cascade screening or at an individual level.¹⁶ Genomic-based screening may allow for early detection of individuals at risk of certain diseases, and allow for personalised treatment pathways based on specific variants and mutations.¹⁶ Furthermore, wearable technologies integrating AI can also be used to monitor patients and prompt preventative measures when risk scores increase.¹⁵ Wearable monitors used in conjunction with genomic data and clinical history may be used to improve patient outcomes by personalising therapeutic pathways and predicting disease progression (for example, deep learning approaches which optimise drug prescriptions using multi-omic analysis and wearable technology data).¹⁷

Despite growing evidence of the advantages of using AI based technologies for personalised medicine, there remain significant barriers to implementation in healthcare systems. Within the NHS, data sharing is disconnected between different trusts meaning that not all patient data is available to AI systems. AI tools which integrate multiple data sources to generate precise diagnosis and personalised treatment plans may struggle to operate due to the fragmented data infrastructure.¹⁸ There is also the danger that AI tools may exacerbate health inequalities due to potential bias and discrimination within datasets. Algorithmic bias may occur when societal biases (race, gender, sexual orientation, socioeconomic diversity etc.) are amplified in training data. This can occur when marginalised communities are unrepresented in training data, or there is socio-historical bias present in datasets.¹⁹ Previous research has highlighted that for AI to improve patient outcomes in marginalised communities, data will need to be collected with sufficient detail to accurately capture clinically significant associations between ethnicity, demographic, clinical and social features.^{19,20} Policy and decision makers must also ensure equitable access to these technologies to both reduce and prevent worsening of health inequalities, particularly in areas of socioeconomic deprivation facing considerable funding and resource challenges.²¹

Additionally, there are significant concerns regarding data governance, particularly when considering ethical and legal handling of genetic/genomic data.²¹ AI analysis of genomic data to inform personalised diagnosis, treatment and prevention strategies can only be achieved with appropriate consent and robust governance strategies.²⁰ Currently, the MHRA considers any AI software used for diagnosis, monitoring or treatment to be a medical device. In these instances, developers must seek regulatory approval for their technology prior to launching their product, in addition meeting post-market surveillance requirements and adhering to transparency guidelines for machine learning medical devices.²²

There are further challenges for both developers and regulators relating to data protection and privacy. Under current GDPR legislation, genomic data is classified as “special category data” and use of such data requires informed consent from patients and enhanced cybersecurity protocols. This has posed some challenges to innovation as consent to the use of genomic data can only be given for specific and specified purposes. However, regulators are currently exploring the possibility of broadening the definition of consent to enable greater cross-border collaboration and streamlining the use of genetic information within healthcare systems.²³ To

address these challenges, the UK government has committed to engagement with the public and patients to increase trust and ensure an active role in decision making.²⁴

The transition towards personalised medicine using AI-based technologies represents an opportunity to transform the NHS and improve patient outcomes. However, there is currently a limited understanding of the development landscape for AI-technologies being used in personalised medicine. Horizon scanning is a systematic process for identifying and evaluating emerging health technologies based on their potential impact on healthcare systems.²⁵ Horizon scanning enables advanced signalling to regulators, researchers, clinicians and policymakers of new technologies in development with the potential to transform healthcare systems and improve patient outcomes through systematic searching of diverse sources.²⁵ Early identification of emerging technologies and development trends can support policymakers and regulators to ensure system readiness and support legislative development which contributes to the timely adoption of new technologies into clinical practise. As the use of AI in personalised medicine has been highlighted as a priority area within the NHS long-term plan, identification of emerging technologies and clinical development trends through horizon scanning will be essential in aiding the rapid adoption of novel AI technologies into clinical practice.

Aim

The aim of this horizon scan was to identify and analyse emerging AI and genomics-based technologies that have the potential to advance personalised medicine. This will provide policy makers with early intelligence about these emerging innovations and their potential impact, enabling faster implementation into healthcare systems.

Objectives

- Conduct a systematic horizon scan to identify weak signals of AI and genomics-based technologies relevant to personalised medicine.
- Evaluate technology maturity through capturing technology readiness levels (TRLs) and producing technology radars.
- Provide a landscape analysis of the identified technologies including information relating to developer, purpose, disease area and type of data collected.
- Identify opportunities, challenges and uncertainties that technologies pose to UK clinical practice.

Methods

We used horizon scanning methods as follows:

Scope

The scope of this horizon scan was to identify signals from clinical trials, and funding sources relating to genomics-based AI technologies being developed for use in personalised MedTech. Technologies being developed to support healthcare systems or healthcare professionals rather than directly for patient care were not included in the scope of this scan. Likewise, technologies being developed to screen healthy populations were not included within the scope of this scan to ensure the scan had a focus on patient centred innovations. Technologies across all TRLs from initial technology concept through to technologies ready to be implemented in a clinical setting were included in the scope of this scan.

Eligibility criteria:

Inclusion criteria

Medical device, digital health technology or diagnostic

To be eligible, technologies identified in the clinical trial must meet the criteria for being a regulated medical device, digital technology, or diagnostic as defined by EU Regulation 2017/755/ on medical devices (MDR) and EU Regulation 2017/746 on in vitro diagnostic medical devices (IVDR).

AI technology

The AI technology must also satisfy at least one of the following requirements to be considered AI:

- Clinical trial record uses keyword phrases specific to AI (e.g. “deep learning”, “machine learning”).
- One or more of the collaborators specialise in AI AND a relevant technology.
- A technology is described as “intelligent” AND a secondary source confirms the technology is AI-based.
- Significant computation (e.g., processing large datasets) is involved AND a secondary source confirms the technology is AI-based.
- Machine learning methodology is described (e.g. an algorithm is “trained” using (big) data).
- Data is collected with the stated intention to apply machine learning.
- Existing AI-based technology (e.g. smart watch) being evaluated for clinical use.
- A novel AI-based technology is in development for: Risk assessment or risk mitigation at the individual patient level; direct patient health impact; or diagnostic application.

Genetic and/or Genomic Component

- Technologies which use an individual's genetic/genomic information to inform diagnosis decisions and treatment recommendations
- Technologies may integrate genetic/genomic information with environmental factors (e.g. place of residence, pollutant exposure, etc.), clinical history and physiology to help inform diagnosis and treatment decisions
- Genetics components refer to technologies that measure, analyse, or manipulate individual genes or small groups of genes
- Genomic components refer to technologies and interventions that investigate, assess, or utilise the entire genome (all genes within an organism), including interactions among multiple genes and environmental factors

Exclusion criteria

- Technologies that do not integrate AI
- Technologies with no clinical application (i.e. research and development)

- Technologies used for prediction/prevention of disease, these technologies were excluded due to the rapid nature of the scan
- Technologies which do not use information from genomic information to help inform diagnosis/treatment decisions

Search Strategy

Searches for this horizon scan were conducted in September 2025 across all sources outlined below. A comprehensive list of keywords and concepts were compiled using MeSH/key terms with Boolean operators, crafted by the IO's Information Specialist Team, based on key indicator reports. Boolean terms were tested across all data sources used in the scan. For example, Boolean operators were used to combine terms such as 'personalised medicine' AND 'clinical trial' OR 'AI-based genomic technologies' to refine search results. The Boolean search terms were tested for sensitivity and specificity before finalising the search terms. This list of terms was refined using scoping searches, testing, and analysis of the relevance of each concept. A detailed search strategy is provided in Appendix A.

In order to ensure that technologies across all stages of TRL were included, funding portals and bibliographic databases were searched to identify technologies that were still in the early stages of development. Clinical trial registries were searched to identify technologies that were currently being evaluated in early or late-stage clinical trials.

Sources

Clinical trial registries

- ClinicalTrials.gov
- EudraCT
- International Clinical Trials Registry Platform (ICTRP)

Funding Portals

- UK Research and Innovation (UKRI)
- National Innovation for Health and Care Research (NIHR)

Literature Search

- Embase

Data Extraction

The following information shown in table 1 on each of the identified relevant technologies will be reported.

Data field	Description	Sources
Trial data	NCT number, study title, sponsor, collaborators, trial phase, trial description, trial start date, primary completion date	Trial registry
Indication	The indication as reported in the trial record or funding award	Trial registry Funding award News sources
NICE disease category	The indication will be classified as one of the 19 disease categories listed on the NICE website	Trial registry Funding award News sources NICE website
Technology description	Overview of the technology being reported	Trial registry Funding award News sources Developer website
Regulatory status	Whether the device is already approved for use	Trial registry Funding award News sources Company website
Intended purpose	Description of what the technology was being developed for. For example, treatment recommendations, integration of clinical notes into EHRs or automatic coding to the ICD-10.	Trial registry Funding award News sources Company website
Type of data analysed	Type of data analysed by technology to produce results e.g. genomic, genetic, clinical records, socioeconomic status etc.	Trial registry Funding award News sources Company website
Technology readiness level	TRLs help stakeholders understand the maturity of a technology (from level 1 to 9), which can inform decisions about funding, development, and commercialization	Trial registry Funding award News sources Company website
Sponsor type	Sponsor(s) of the trial: industry, non-industry or both.	Trial registry Funding award News sources Company website
Study type	Interventional, observational, or expanded access trial design.	Trial registry Funding award News sources
Locations	Location(s) where the technology is being evaluated. Standardised to countries rather than individual centres.	Trial registry Funding award News sources
Geographic region	Simplified version of the location – categorised to the broad country level.	Trial registry Funding award News sources

Table 1: Description of the data extraction fields

Results

Prisma chart

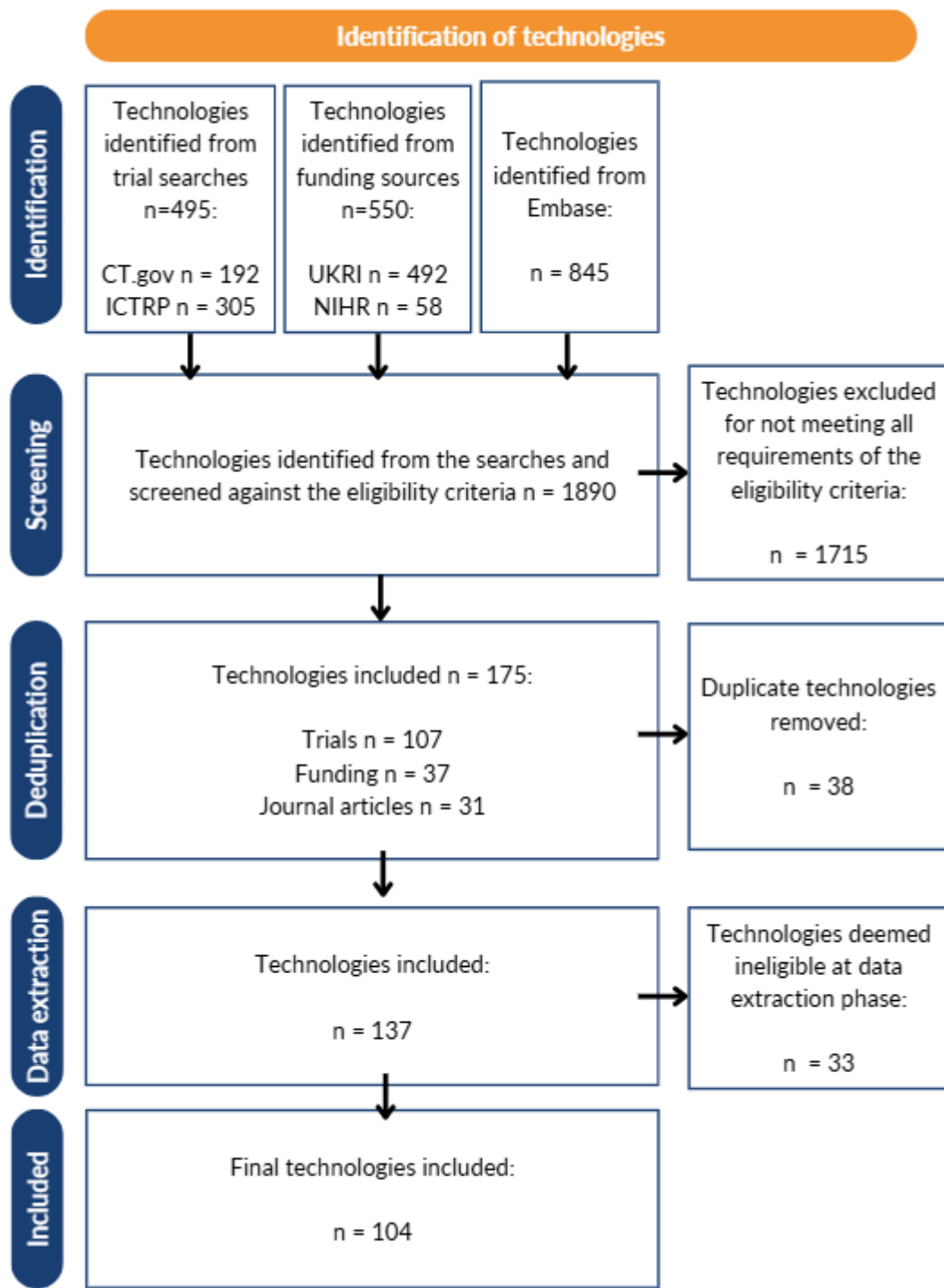


Figure 1. Prisma flowchart showing the number of technologies at each stage of the horizon scan

A PRISMA flow diagram (figure 1) was used to summarise the identification, screening, and inclusion of technologies in this review. Across three sources, 1,890 records were identified: 495 from trial registries (ClinicalTrials.gov: 192, ICTRP: 305), 550 from funding sources (UKRI:

492, NIHR: 58), and 845 from Embase (44.7%). After screening against eligibility criteria, 1,715 records were excluded. Deduplication of the remaining 175 technologies resulted in 137 entering the data extraction phase, with 33 deemed ineligible. Ultimately, 104 technologies met the predefined criteria and were included in the scan.

NICE Disease Category

The majority of technologies were for cancer indications (n=57), followed by cardiovascular (n=20) and mental health, behavioural, and neurodevelopmental conditions (n=5) (figure 2). Neurological conditions accounted for 4% of the indications. Other NICE disease categories, as shown in Figure 2, had three or fewer technologies.

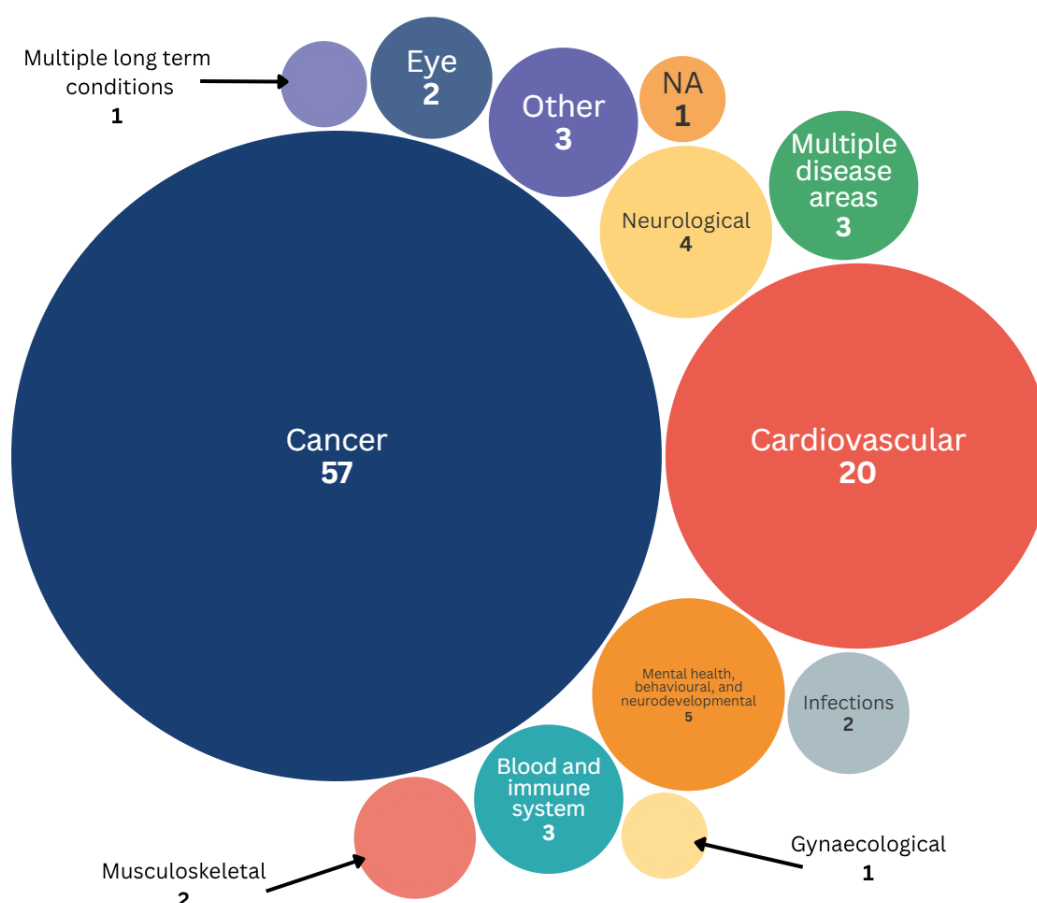


Figure 2: Count of NICE disease categories technologies were in development for.

Technology Readiness Level (TRL)

Most technologies were for cancer indications (n=67), in which the majority were identified as TRL 5 (n=21) and only four being at TRL 9 which were ClonoSEQ, CureMatch,

DOvEEgene/WISE Genomics and TEMPUS (figure 3). Cardiovascular technologies (n=20) also represented another major focus area, with most being at TRL 5 (n=9), followed by TRL 8 (n=7) and TRL 3 and TRL 2 each with 2 technologies. Technologies addressing blood and immune system disorders were generally at early development stages, ranging from TRL 3 to TRL 5 (n=1 at each level).

Neurological condition technologies were mainly in the early-development range, including TRL 2 (n=2) and TRL 3 (n=1) and only one technology at TRL 6. Musculoskeletal and multiple long-term condition technologies were each represented by small numbers of technologies, all within later TRLs (TRL 6–7). Mental health, behavioural, and neurodevelopmental technologies were spread across levels in small numbers (TRL 3–6), apart from the single TRL 9 technology, Neuropharmogen. Similarly, multiple disease areas were also sparsely spread from TRL 2–7.

There were two technologies related to infections both at TRL 7, one of which was I-GAME, while gynaecological and eye condition technologies were both represented by only one TRL, TRL 2 (SENSOPAD) and TRL 5 (n=2), respectively. Overall, the distribution shows that most technologies across domains were still in development, with relatively few reaching late-stage (TRL 8–9) maturity.

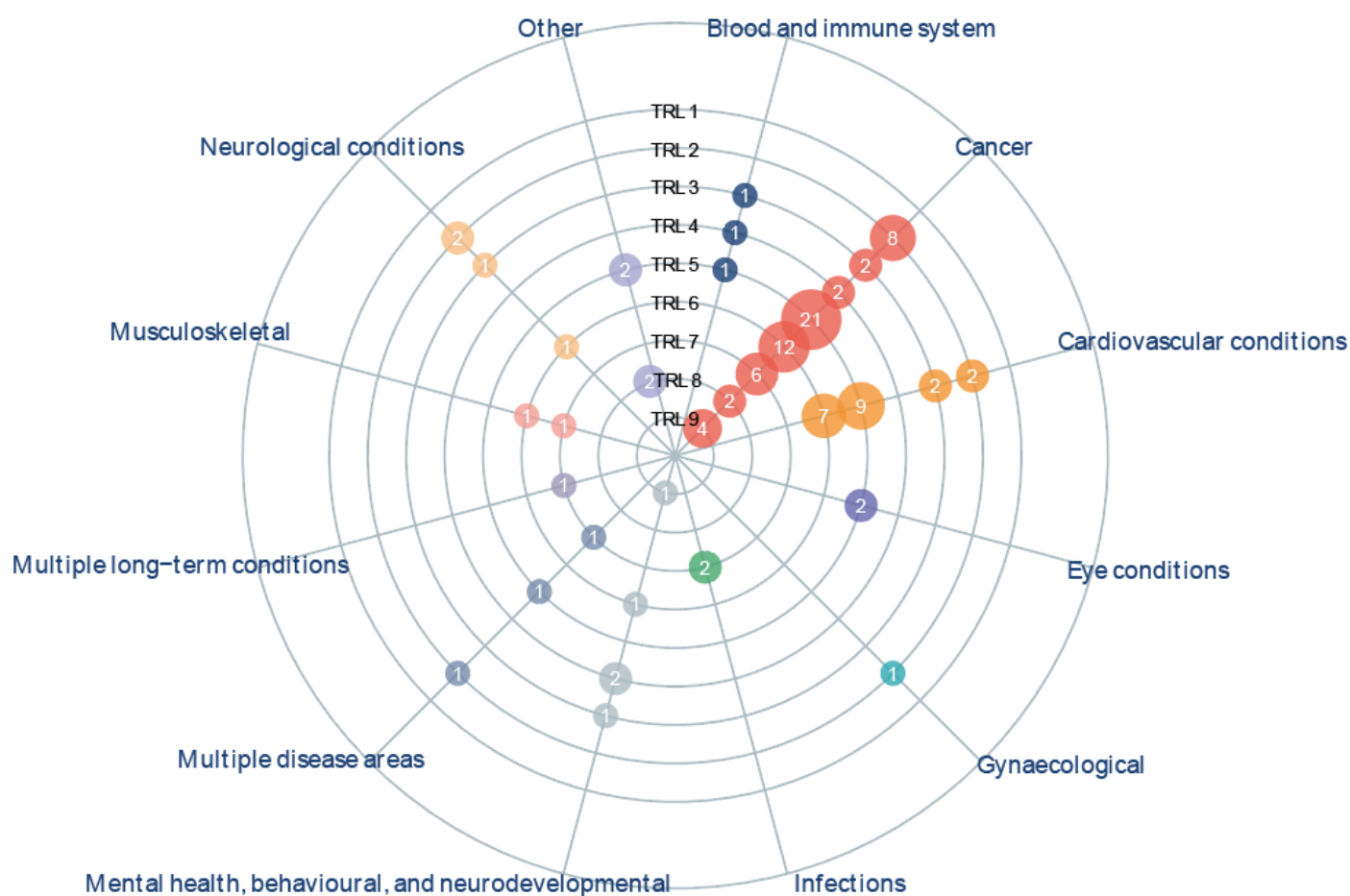


Figure 3. TRL radar of all technologies by their indication NICE category and TRL.

Country of Development

Forty percent of technologies were developed in the UK, 26% in China, and 22% in the USA (figure 4). In the UK, notable contributors included the University of Oxford (n=4), King's College London (n=3), and Imperial College London (n=3). Other countries with developers included Italy (n=5), Japan (n=4), France (n=3), and Canada (n=3).

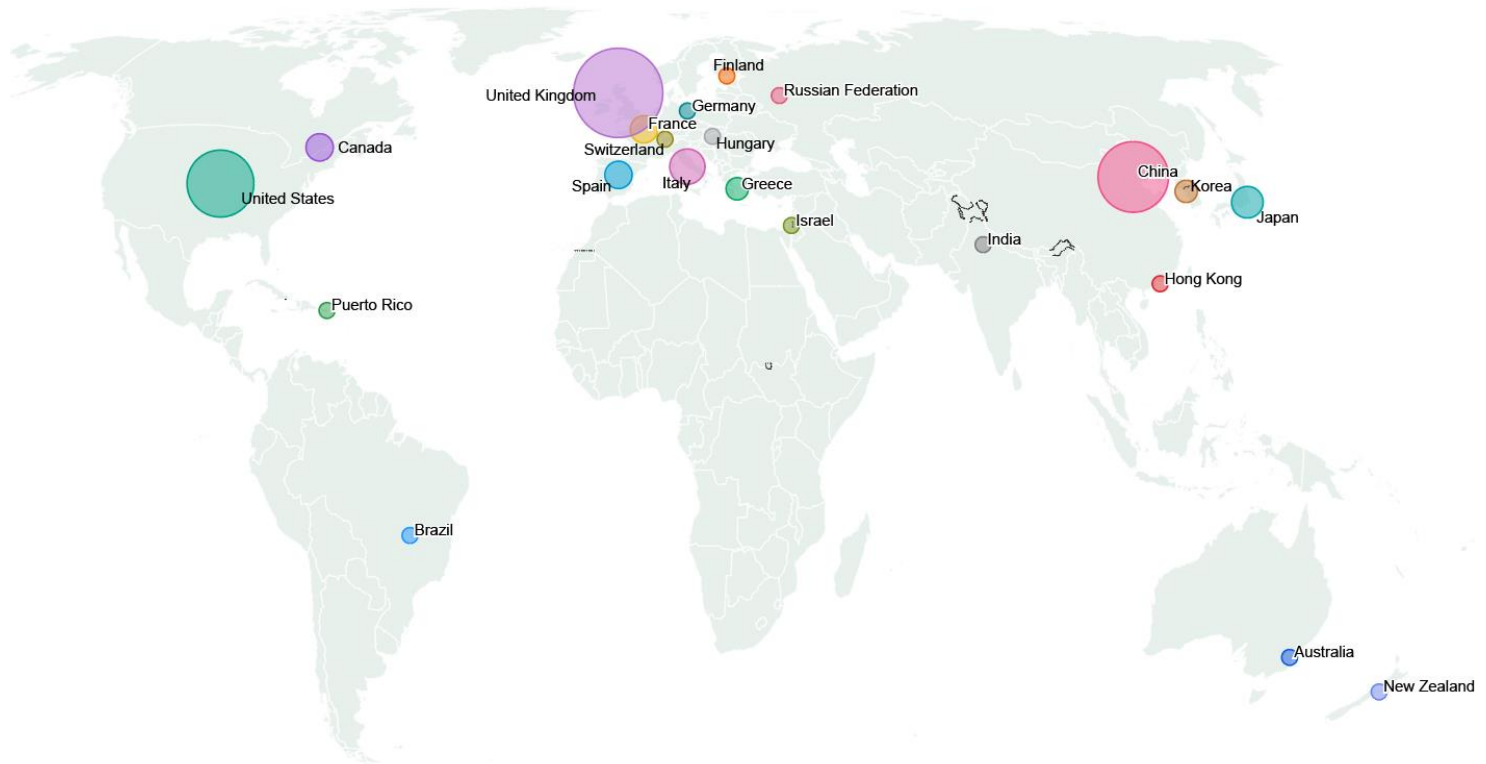


Figure 4. Map illustrating number of technologies by developer location.

Technology Purpose

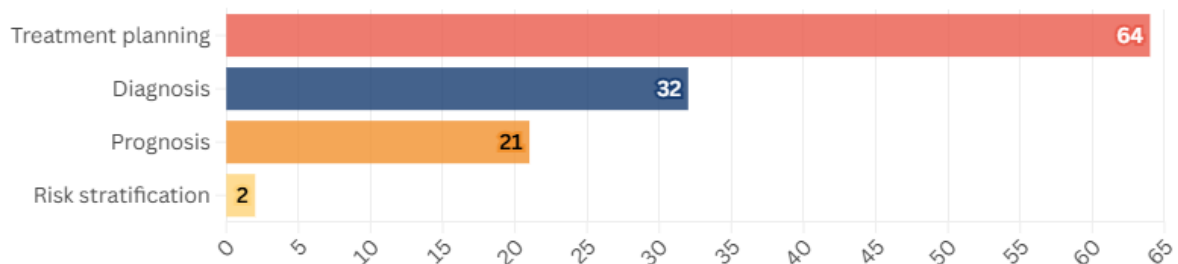


Figure 5. Number of technologies identified, according to technology purpose.

Of the 104 technologies identified, the majority (62%) were developed for treatment planning (figure 5). Diagnosis accounted for 31% of technologies, while 20% focused on prognosis and only 2% on risk stratification (figure 5). Some technologies served multiple purposes, for example treatment planning and risk stratification, resulting in a total of more than 104 purposes.

Developer Type

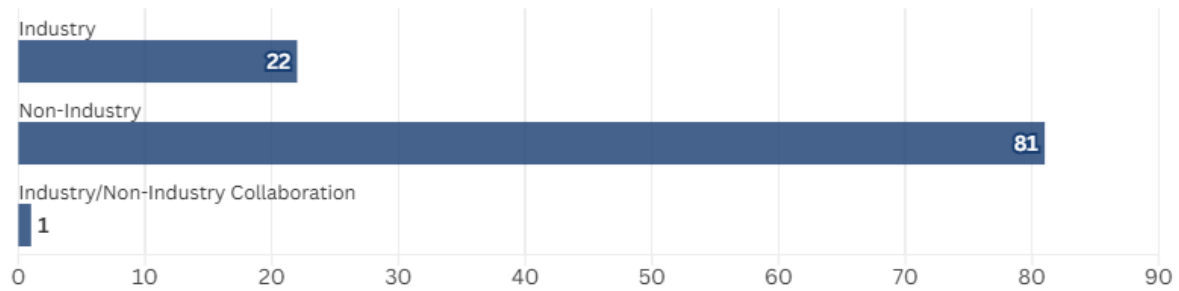


Figure 6. Technology developer type

Most of development sponsorship for AI technologies in personalised medicine were developed from non-industry sources (~79%) such as academia and healthcare providers (figure 6). Industry-sponsored development accounted for ~21%, with less than 1% resulting from industry and non-industry collaborations.

Regulatory Status

Only 5 out of 104 technologies reported regulatory status: three with a CE mark (3%), one with U.S. FDA authorisation (1%), and one with both (1%). The remaining 99 technologies (95%) did not report any regulatory approval.

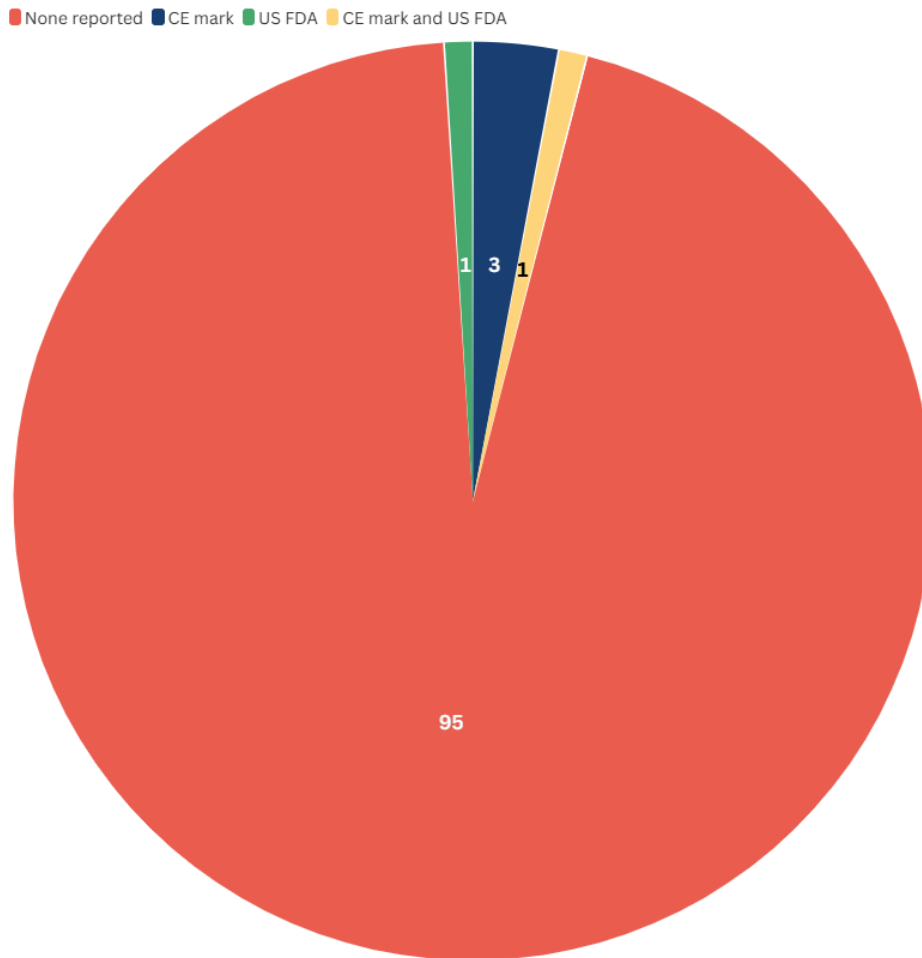


Figure 6. Percentage of technologies that had received regulatory approval

Type of data analysed

Personalised interventions rely on individual data to inform diagnosis and treatment planning. AI can integrate multiple data sources (e.g. genomic information and clinical history) to provide tailored diagnostic and treatment approaches. Our horizon scan identified technologies using a breadth of patient information to inform these decisions. Our analysis identified that ~48.5% of technologies used 2 or more different data types to provide diagnostic information or recommend therapeutic interventions (figure 8). ~24% used 2 data types, ~19% used 3 types of data and ~5% used 4 data sources. The majority of these technologies used genetic and/or genomic data complimented by analysis of imaging data, followed by clinical history and transcriptomic data (table 1). The most frequently used data types were genetic data (n=77), followed by genomic (n=20), imaging (n=20) and clinical history (n=15), (figure 9). The least used types of data included metabolic data (n=1), genetic biomarkers and EEG measurements (n=1 respectively), (figure 9).

The GLIOMATCH platform integrates single-cell multi-omics with MRI images to inform personalised therapy matching for glioblastoma and paediatric high-grade glioblastoma patients. Increased understanding of immunotherapies for glioblastomas may lead to improved patient outcomes, which are typically associated with extremely low survival rates.²⁶ Other types of data integrated with either genetic, genomic or transcriptomic data included histological, socioecological, immunomics, physiological and proteomics (table 2). For example, the iToBoS (NCT05955443) uses total body photography combined with genetic samples and

socioecological data to provide clinician support in screening for melanoma, which may lead to earlier diagnosis and intervention.

51.5% of technologies using only 1 data source, used patient genetic, genomic, transcriptomic or biomarker information for diagnoses or planning personalised treatment strategies.

Number of data types used per technology

■ One Data Type ■ Two Data Types ■ Three Data Types ■ Four Data Types

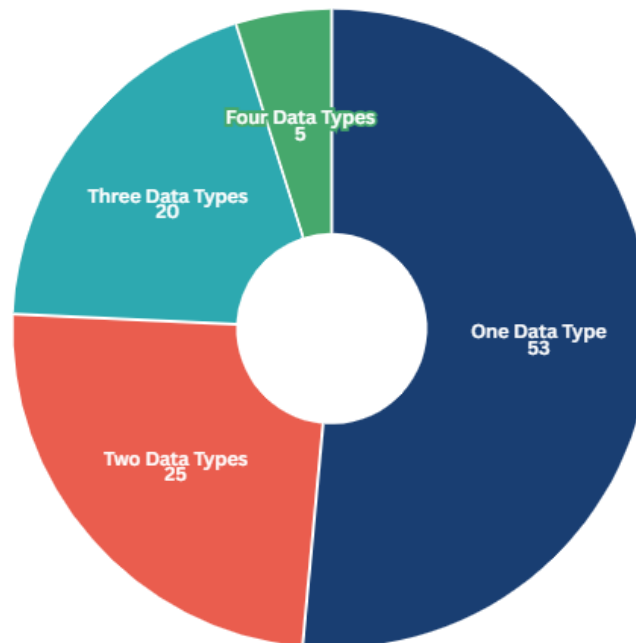


Figure 8. Number of data types analysed by technologies to inform diagnosis, treatment or disease management

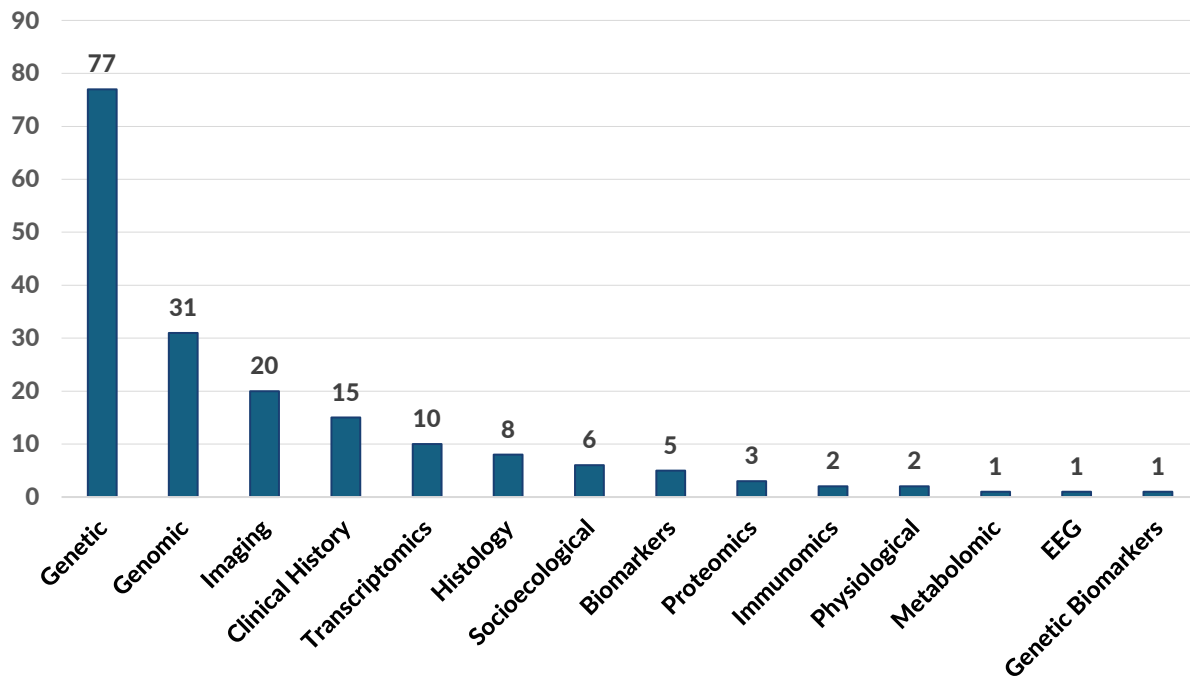


Figure 9. Number of technologies using each type of data.

Trial/Grant reference number	Intervention Name	Type of data analysed
NCT06320717	Not Reported	Biomarkers
ChiCTR2300068861	Assistant forecast system	Clinical History, Genetic, Socioecological
Not Applicable	AI-PROGNOSIS	Clinical History, Genetic, Genomic
DRKS00024705	Not Reported	Genetic, Genomic, Histology
NCT07101237	Not Reported	Imaging, Genetic, Proteomics, Transcriptomics
NCT04551287	Artificial Intelligence Cervical Cancer Screening (AICS) system	Genetic
NCT07030842	Not Reported	Imaging, Histology, Clinical History
NCT07009769	Not Reported	Genetic
ISRCTN25916392	Not Reported	Genetic
NCT06902688	Not Reported	Genetic
ChiCTR2500098347	Not Reported	Imaging, Genetic
ChiCTR2500096621	Not Reported	Genetic
ChiCTR2500096615	Not Reported	Imaging, Genetic
ChiCTR2400095044	Not Reported	Genetic
NCT06463444	Not Reported	Genomic, Imaging, Histology, Immunomics
NCT06410677	Not Reported	Imaging, Genetic
NCT06589154	BEAM model	Genetic, Imaging
NCT04889729	Not Reported	Genomic

JPRN-UMIN000043899	Not Reported	Genetic, Immunomics
NCT04746001	Not Reported	Genomic, Histology
ChiCTR2000036897	Not Reported	Genomic, Histology
NCT04220424	Not Reported	Imaging, Histology, Genetic
NCT04099914	Not Reported	Genetic
NCT04022018	Not Reported	Clinical History, Imaging
JPRN-UMIN000030903	Not Reported	Clinical History, Genetic, Biomarkers, EEG
NCT03150680	GEnetic Syntax Score-GESS	Genetic, Clinical History, Histology
NCT04996836	BR(E)2ASTOME	Genetic
JPRN-UMIN000052685	CALO mama Plus	Genomic
NCT02345356	Not Reported	Genetic, Clinical History, Socioecological
JPRN-UMIN000011639	Not Reported	NR
ChiCTR-TRC-11001852	Not Reported	Genetic
NCT01178034	Not Reported	Genetic, Physiology
Not Applicable	CUPiD	Clinical History, Genetic, Genomic
NCT00511173	Not Reported	Genetic
NCT00334464	Not Reported	Genomic
NCT04189029	Not Reported	Genetic, Imaging, Physiology, Biomarkers
Not Applicable	DCM NEXT	Genomic, Genetic, Clinical History
Not Applicable	Decipher	Transcriptomics
NCT05472844	Not Reported	Genetic
NCT06856616	Not Reported	Imaging, Genetic
NCT06342414	ELUCIDATE	Transcriptomics
NCT06192030	Not Reported	Genetic
NCT05596435	Not Reported	Genetic, Genomic
NCT06083779	Not Reported	Genetic, Genomic
NCT06841653	MultiOMics IMMune-IConographic Pattern (MOMIMIC Score)	Genetic, Genomic, Proteomics, Transcriptomics
NCT06515522	Not Reported	Genetic, Imaging, Socioecological
Not Applicable	Not Reported	Genetic, Genomic, Imaging
Not Applicable	Not Reported	Genomic
Not Applicable	GenePy	Genomic
Not Applicable	Not Reported	Genetics, Transcriptomics
ChiCTR2500101060	genetic imaging machine learning model	Genetic, Imaging, Biomarkers
Not Applicable	Not Reported	Imaging, Genetics, Clinical History

NCT06455384	Genetics Navigator	Genetic, Clinical History
NCT00839657	Not Reported	Genetic
Not Applicable	Not Reported	Transcriptomics, Imaging
Not Applicable	Not Reported	Genetic
Not Applicable	GLIOMATCH	Imaging, Genetic
Not Applicable	Not Reported	Genetic
Not Applicable	Not Reported	Genetic
Not Applicable	Not Reported	Genetic
Not Applicable	Not Reported	Genetic
10098097	Not Reported	Genomic
Not Applicable	Not Reported	Genetic, Imaging, Socioecological
Not Applicable	HER2 Dx	Genomic
Not Applicable	HT-ADVANCE	Genetic, Genomic, Metabolomic
Not Applicable	Genome-to-Treatment	Genomic
NCT05955443	iToBoS	Imaging, Genetic, Socioecological
Not Applicable	MRD-edge	Genetic, Genomic
Not Applicable	OncoNPC	Genetic, Genomic
NCT03015025	Pharmacogenetic Dosage Algorithm	Genetic, Clinical History, Socioecological
Not Applicable	RadExIORSBoost	Transcriptomics, Histology
Not Applicable	REFLECT	Transcriptomic, Genetic, Proteomic
Not Applicable	ScTherapy	Transcriptomics
NCT06789588	WARFALGORIT	Genetic
NCT01106144	Not Reported	Genetic
1399	Not Reported	Genetic
10117590	PharosAI	Genomic
2886852	Not Reported	Genetic
2903953	Not Reported	Imaging, Biomarkers
MR/U506746/1	I-GAME	Genomic
2929147	Not Reported	Genetic

Table 2 Data types analysed by AI-based technologies for use in personalised medicine.

Discussion

Our horizon scan identified 104 unique AI-based technologies in development which analyse genomic or genetic data, some in combination with other health data (e.g. imaging, socioecological), to enable personalised medicine approaches. Technologies were identified through searches of global clinical trials registries, grant and funding applications and bibliographic sources. The main NICE disease areas focused on by developers included cancer (n=55), cardiovascular conditions (n=19) and neurological conditions (n=6). Previous studies found that personalised treatment strategies for cardiovascular diseases (such as pharmacogenomic testing) were associated with higher economic benefits and reduced incremental cost-effectiveness ratios per quality adjusted life year.²⁷ Although the same study did indicate personalised cancer immunotherapies were less cost-effective compared to those

for cardiovascular disease, when considering long-term savings for healthcare systems personalised therapeutics reduced overall costs associated with cancer and rare disease treatment.²⁷ In 2022, the age-standardised (ASR) incidence rate of cancer was 196.9 per 100,000, and a mortality rate of 91.7 per 100,000; cardiovascular disease accounts for 32.9% of non-communicable disease-related deaths globally and ~18 million deaths annually.^{28,29} The high incidence and mortality rates associated with these disease categories may explain higher rates of development for personalised therapeutics and precision diagnostics.

Other notable specialities identified in our scan included mental health, haematology and immunology, which are also associated with significant challenges and burdens for patients and health systems.³⁰⁻³² Current statistics indicate the demand for mental health services is greater than resources available.³⁰ AI-based technologies could enable personalised treatment plans, therefore improving patient outcomes and alleviating pressure on NHS services.³³ For example, neuropharmogen uses a patient's genetic profile to predict response and tolerability to drugs for treatment of depression, bipolar disorder and schizophrenia. Multiple clinical trials have shown improved patient responses to treatment when guided by neuropharmogen, indicating the potential to improve treatment efficacy, improve safety and dose-optimisation.³⁴⁻³⁶

Most included technologies were designed for personalised treatment planning, followed by precision diagnostics, treatment response prediction and prognostic prediction. ~60% of technologies in development were rated between TRL 5-6, indicating most development is still in pre-clinical testing or clinical trials. Coinciding with low numbers of technologies reporting regulatory approval, this suggests that while there is significant interest in AI analytics for personalised medicine, that these technologies are still in the early stage of the product life cycle. In the UK, any AI-enabled device intended for diagnosis, treatment or prevention of disease must conform to the UK MDR 2002, thereby holding either a UKCA or CE mark. Our search identified only 4 devices with a CE mark, meaning only ~4% of included technologies met legal requirements for use in the NHS. Only 2 devices reported FDA approval, as 22% of included technologies reported a US based developer this could further evidence that AI-supported personalised medicine is still an emerging area which requires further development and regulatory support.

Furthermore, our study focused on a subset of personalised medicine devices using individuals' genetic or genomic information for precision diagnoses, personalised treatment planning and/or prognostic prediction. Genetic data is classified as a special category of personal data under GDPR legislation, meaning there are stricter requirements for data processing and individual's must provide explicit consent regarding how their genetic data is used. The complex ethical and legal requirements surrounding the use of genetic data could explain the general trend towards lower TRLs and limited reporting of regulatory approval.

In addition to genetic data, ~49% of technologies reported integrating 2 or more different data types to provide increased precision by considering multiple contributing factors for diagnosis and/or treatment planning. Combinations are often specific to the intended purpose of the technology, and if it has been developed to treat, diagnose and/or manage a specific condition. One example of this is GenAIS, which integrates genetic data, metabolic profiles, clinical history and patient biomarkers to provide more precise recommendations on dietary supplementation and interventions.³⁷ GenAIS continuously updates based on integrated patient information to provide treatment plans which evolve to suit the patients' needs over time. However, GenAIS developer Traingel Scientific, have not reported if the technology has regulatory approval or is compliant with GDPR/HIPPA legislation, therefore preventing its adoption into clinical

practice at this stage. Most technologies which did report regulatory approval were largely for analysis of only genetic data to support diagnostic or treatment decisions. However, the Tempus Tumour Origin assay which has FDA approval, uses both tumour genetic information and patient clinical history identify precise cancer subtypes.³⁸

Analysis of developer location revealed the 3 nations with the most reported development to be the UK, US and China. ~40% of included technologies were developed in the UK, followed by 26% in China and 22% in the US. Since the primary aim of this horizon scan was to identify innovations most applicable to the UK healthcare system, our funding searches were focused on UK-based registries and databases. This enabled us to undertake a pragmatic funding scan and identify technologies which are most likely to align with NHS priorities and UK regulatory pathways compared to global funding sources. Additionally, we did not include a grey literature search within the scope of this study, which may have revealed a higher number of developers in other nations. To fully understand the global development landscape for AI-based analytics in personalised medicine a more inclusive search strategy of additional sources should be conducted.

Patient consent and clinician support is vital to the adoption of AI-based technologies and the transition towards a personalised healthcare model. Whilst previous studies have indicated there is largely public and patient support for the use of these technologies, there is still a significant percentage of patients and clinicians who have legitimate concerns regarding how these technologies will be used and the challenges associated with implementing them.³⁹ A study conducted by the Health Foundation revealed that 1 in 6 patients and members of the public believed AI could worsen healthcare quality, citing reasons such as AI decision making accuracy and AI technologies distancing patients from NHS staff. Clinicians in NHS genomic services revealed similar concerns regarding AI analytical accuracy but also cited other barriers to adoption including lack of workforce education, inadequate IT infrastructure and resourcing constraints.⁴⁰ These studies show further engagement with both the public and clinicians is crucial to adoption of AI-based technologies in the NHS, particularly when considering AI for use in personalised medicine. Future studies should explore public, patient and clinician perspectives to fully understand perceived and actual barriers to adoption which are essential for policymakers to address.

Conclusion

In summary, AI-based technologies are rapidly accelerating healthcare systems towards a more personalised and preventative model of healthcare. Personalised treatment plans and diagnostics have the potential to reduce disease burden on healthcare systems and provide more timely, effective interventions, therefore improving patient outcomes. However, implementation of AI-based technologies to enable personalised medicine approaches are associated with numerous challenges such as lack of technical infrastructure, technology validation and regulatory restrictions. The most significant regulatory barriers include the need for compliance with stringent regulations such as the UK MDR 2002 and FDA requirements, as well as the complex ethical and legal considerations surrounding the use of genetic data under GDPR legislation. To overcome some of these challenges, early collaboration between developers, healthcare decision makers and regulatory agencies is essential to rapid adoption of innovative technologies into clinical practice. Regulatory agencies can facilitate adoption by providing clear guidelines and pathways for AI-based technologies, streamlining the approval

process, and offering support for compliance with legal and ethical standards. Engagement with public, patient and clinician stakeholders will be pivotal to increasing confidence in technology safety, accuracy and effectiveness. Our scan has highlighted the breadth of technologies in development to enable personalised medicine approaches across the time horizon. Whilst many identified technologies are still in pre-clinical development, the rapid pace of development necessitates close monitoring by regulatory and commissioning agencies as well as policymakers to facilitate swift adoption into clinical practice.

Appendix A: Search Strings

CT.gov

#	Searches
1	"personalised medicine" or "predictive, preventive, personalized and participatory" or "P4 medicine" or "precision medicine" or "stratified medicine" or "individualized medicine" or "customized medicine" or "tailored medicine" or "companion diagnostic*" or "targeted therapy" or "genomic medicine" or "molecular medicine" or "translational medicine" or "private medicine" or "bespoke medicine" or "opsonic therapy" or "systems medicine" or "targeted therapeutic" or "theranostics" or "AI-based genomics technologies" or AI-based genomic technology or "Machine Learning in Genomics" or "Deep Learning in Genomics" or "computational genomics" or "AI-powered genomic analysis" or "AI-driven precision medicine" or "Generative Genomics" or "Convolutional Neural Networks" or "Recurrent Neural Networks" or "Explainable AI"

ICTRP

#	Searches
1	"personalised medicine" or "predictive, preventive, personalized and participatory" or "P4 medicine" or "precision medicine" or "stratified medicine" or "individualized medicine" or "customized medicine" or "tailored medicine" or "companion diagnostic*" or "targeted therapy" or "genomic medicine" or "molecular medicine" or "translational medicine" or "private medicine" or "bespoke medicine" or "opsonic therapy" or "systems medicine" or "targeted therapeutic" or "theranostics" or "AI-based genomics technologies" or AI-based genomic technology or "Machine Learning in Genomics" or "Deep Learning in Genomics" or "computational genomics" or "AI-powered genomic analysis" or "AI-driven precision medicine" or "Generative Genomics" or "Convolutional Neural Networks" or "Recurrent Neural Networks" or "Explainable AI"

UKRI

#	Searches
1	"personalised medicine" or "predictive, preventive, personalized and participatory" or "P4 medicine" or "precision medicine" or "stratified medicine" or "individualized medicine" or "customized medicine" or "tailored medicine" or "companion diagnostic*" or "targeted therapy" or "genomic medicine" or "molecular medicine" or "translational medicine" or "private medicine" or "bespoke medicine" or "opsonic therapy" or "systems medicine" or "targeted therapeutic" or "theranostics" or "AI-based genomics technologies" or AI-based genomic technology or "Machine Learning in Genomics" or "Deep Learning in Genomics" or "computational genomics" or "AI-powered genomic analysis" or "AI-driven precision medicine" or "Generative Genomics" or "Convolutional Neural Networks" or "Recurrent Neural Networks" or "Explainable AI"

NIHR

#	Searches
1	"personalised medicine" or "predictive, preventive, personalized and participatory" or "P4 medicine" or "precision medicine" or "stratified medicine" or "individualized medicine" or "customized medicine" or "tailored medicine" or "companion diagnostic*" or "targeted therapy" or "genomic medicine" or "molecular medicine" or "translational medicine" or "private medicine" or "bespoke medicine" or "opsonic therapy" or "systems medicine" or "targeted therapeutic" or "theranostics" or "AI-based genomics technologies" or AI-based genomic technology or "Machine Learning in Genomics" or "Deep Learning in Genomics" or "computational genomics" or "AI-powered genomic analysis" or "AI-driven precision medicine" or "Generative Genomics" or "Convolutional Neural Networks" or "Recurrent Neural Networks" or "Explainable AI"

Embase

#	Searches
1	("personalised medicine" or "predictive, preventive, personalized and participatory" or "P4 medicine" or "precision medicine" or "stratified medicine" or "individualized medicine" or "customized medicine" or "tailored medicine" or "companion diagnostic*" or "targeted therap*" or "genomic medicine" or "molecular medicine" or "translational medicine" or "private medicine" or "bespoke medicine" or "opsonic therapy" or "systems medicine" or "targeted therapeutic*" or "theranostics").tw.
2	personalized medicine/
3	1 or 2

4	("artificial intelligence" or "natural language processing" or "neural networks" or "machine intelligence" or "computer?aided testing" or "machine learning" or "neural network").tw.
5	artificial intelligence/
6	4 or 5
7	3 and 6
8	limit 7 to yr="2022 - 2025"
9	limit 8 to english language

References

- Ghebrehiwet I, Zaki N, Damseh R, Mohamad MS. Revolutionizing personalized medicine with generative AI: a systematic review. *Artificial Intelligence Review*. 2024;57(5):128. Available from: <https://doi.org/10.1007/s10462-024-10768-5>.
- Taherdoost H, Ghofrani A. AI's role in revolutionizing personalized medicine by reshaping pharmacogenomics and drug therapy. *Intelligent Pharmacy*. 2024;2(5):643-50. Available from: <https://doi.org/10.1016/j.ipha.2024.08.005>.
- Schork NJ. Artificial Intelligence and Personalized Medicine. *Cancer Treat Res*. 2019;178:265-83. Available from: https://doi.org/10.1007/978-3-030-16391-4_11.
- Udegbe FC, Ebulue OR, Ebulue CC, Ekesiobi CS. AI'S IMPACT ON PERSONALIZED MEDICINE: TAILORING TREATMENTS FOR IMPROVED HEALTH OUTCOMES. *Engineering Science & Technology Journal*. 2024;5(4):1386-94. Available from: <https://doi.org/10.51594/estj.v5i4.1040>.
- UK Government, NHS. Fit for the Future: 10 Year Health Plan fo England. 2025. Available from: <https://assets.publishing.service.gov.uk/media/6888a0b1a11f859994409147/fit-for-the-future-10-year-health-plan-for-england.pdf> [Accessed 06 August 2025].
- Wolters Kluwer. *P4 Medicine: A modern approach to care*. 2025. Available from: <https://www.wolterskluwer.com/en/know/healthcare-topics/p4-medicine>.
- Flores M, Glusman G, Brogaard K, Price ND, Hood L. P4 medicine: how systems medicine will transform the healthcare sector and society. *Per Med*. 2013;10(6):565-76. Available from: <https://doi.org/10.2217/pme.13.57>.
- Md Sakil A, Azizur R. Integrative approaches of AI in personalised disease management: From diagnosis to drug delivery. *Paradise*. 2025;1(1). Available from: <https://doi.org/10.25163/paradise.1110339>.
- Jadhav A, Jadhav PT. The Role of Artificial Intelligence in Precision Healthcare Delivery: Integrating Real-Time Data and Personalised Medicine. *EC Paediatrics* 2025;14(6). <https://ecronicon.net/ecpe/the-role-of-artificial-intelligence-in-precision-healthcare-delivery-integrating-real-time-data-and-personalised-medicine>.
- HajYasien A. Introduction to Multiomics Technology. In: Alkhateeb A, Rueda L, eds. *Machine Learning Methods for Multi-Omics Data Integration*. Cham: Springer International Publishing; 2024: 1-11.

- 11 N J. *Diagnostic odyssey in rare disease*. 2024. Available from: <https://www.genomicseducation.hee.nhs.uk/genotes/knowledge-hub/the-diagnostic-odyssey-in-rare-disease/>.
- 12 National Health Service. *Accelerating genomic medicine in the NHS*. 2022. Available from: <https://www.england.nhs.uk/long-read/accelerating-genomic-medicine-in-the-nhs/>.
- 13 Sheliemina N. The Use of Artificial Intelligence in Medical Diagnostics: Opportunities, Prospects and Risks. . *Health Economics and Management Review*. 2024;5(2). Available from: <https://doi.org/10.61093/hem.2024.2-07>.
- 14 Srivastava R. Advancing precision oncology with AI-powered genomic analysis. *Frontiers in Pharmacology*. 2025;Volume 16 - 2025. Available from: <https://doi.org/10.3389/fphar.2025.1591696>.
- 15 Tale Y, Verma P, Pake T. Next-Gen AI in Healthcare: Shaping the Future of Precision and Preventive Medicine. In: 2025 International Conference on Machine Learning and Autonomous Systems (ICMLAS); 2025 10-12 March 2025; 2025. pp. 1220-7.
- 16 UK National Screening Committee. *Generation genome and the opportunities for screening programmes*. 2019. Available from: https://assets.publishing.service.gov.uk/media/5dc14e9d40f0b6379bf0f796/Generation_genome_and_the_opportunities_for_screening_programmes.pdf.
- 17 Xi L, Li C, Anari MS, Rezaee K. Integrating wearable health devices with AI and edge computing for personalized rehabilitation. *Journal of Cloud Computing*. 2025;14(1):64. Available from: <https://doi.org/10.1186/s13677-025-00795-0>.
- 18 Strain WD, Cronin-Lampe J, Evans M, Mitchell C, Padgett T, McEwan P. NHS 10 year plan: Can using AI offer a solution to the NHS' problems? *BMJ*. 2025;390:r1407. Available from: <https://doi.org/10.1136/bmj.r1407>.
- 19 O'Brien N, Van Dael J, Clarke J, Gardner C, O'Shaughnessy J, Darzi A, et al. *Addressing Racial and Ethnic Inequity in Data-driven Health Technologies*. 2022. Available from: <https://ora.ox.ac.uk/objects/uuid:76cf09cf-ddf7-43ae-a724-9b447136356a/files/ssn009z94p>.
- 20 UK Government. *Genome UK: the future of healthcare*. 2020. Available from: <https://www.gov.uk/government/publications/genome-uk-the-future-of-healthcare/genome-uk-the-future-of-healthcare#chapter-1-introduction>.
- 21 Pham T. Ethical and legal considerations in healthcare AI: innovation and policy for safe and fair use. *R Soc Open Sci*. 2025;12(5):241873. Available from: <https://doi.org/10.1098/rsos.241873>.
- 22 Agency MHPR. *Software and artificial intelligence (AI) as a medical device*. 2025. Available from: <https://www.gov.uk/government/publications/software-and-artificial-intelligence-ai-as-a-medical-device/software-and-artificial-intelligence-ai-as-a-medical-device#qualification-and-classification>.
- 23 Becker R, Chokoshvili D, Dove ES. Legal bases for effective secondary use of health and genetic data in the EU: time for new legislative solutions to better harmonize data for cross-border sharing? *International Data Privacy Law*. 2024;14(3):223-46. Available from: <https://doi.org/10.1093/idpl/ipae014>.
- 24 UK Government. *Genome UK: 2022 to 2025 implementation plan for England*. 2022. Available from: <https://www.gov.uk/government/publications/genome-uk-2022-to-2025-implementation-plan-for-england/genome-uk-2022-to-2025-implementation-plan-for-england#implementation-actions-2022-to-2025>.
- 25 Garcia Gonzalez-Moral S, Beyer FR, Oyewole AO, Richmond C, Wainwright L, Craig D. Looking at the fringes of MedTech innovation: a mapping review of horizon scanning and foresight methods. *BMJ Open*. 2023;13(9):e073730. Available from: <https://doi.org/10.1136/bmjopen-2023-073730>.
- 26 Gliomatch. *GLIOMATCH: Project*. 2025. Available from: <https://gliomatch.eu/project/>.

- 27 Syed Sibghatullah S. Cost-Effectiveness and Policy Implications of Personalised Medicine. *Premier Journal of Science*. 2024;2. Available from: <https://doi.org/10.70389/PJS.100018>.
- 28 Sung H, Ferlay J, Siegel RL, Laversanne M, Soerjomataram I, Jemal A, et al. Global Cancer Statistics 2020: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries. *CA Cancer J Clin*. 2021;71(3):209-49. Available from: <https://doi.org/10.3322/caac.21660>.
- 29 Zhu X-Y, Shi M-Q, Jiang Z-M, Xiao L, Tian J-W, Su F-F. Global, regional, and national burden of cardiovascular diseases attributable to metabolic risks across all age groups from 1990 to 2021: an analysis of the 2021 global burden of disease study data. *BMC Public Health*. 2025;25(1):1704. Available from: <https://doi.org/10.1186/s12889-025-22702-7>.
- 30 British Medical Association. *Mental health pressures in England*. 2025. Available from: <https://www.bma.org.uk/advice-and-support/nhs-delivery-and-workforce/pressures/mental-health-pressures-data-analysis>.
- 31 Office for National Statistics. *Hospital Admitted Patient Care Activity, 2024-25*. 2025. Available from: <https://digital.nhs.uk/data-and-information/publications/statistical/hospital-admitted-patient-care-activity/2024-25> [Accessed 09 October 2025].
- 32 The Royal College of Pathologists. *Clinical immunology workforce*. 2025. Available from: <https://www.immunodeficiencyuk.org/wp-content/uploads/2025/09/Briefing-RCPath-Clinical-immunology-workforce-2025.pdf>.
- 33 Gardiner H, Mutebi N. *AI and mental healthcare: opportunities and delivery considerations*. 2025. Available from: <https://researchbriefings.files.parliament.uk/documents/POST-PN-0737/POST-PN-0737.pdf>.
- 34 Pérez V, Salavert A, Espadaler J, Tuson M, Saiz-Ruiz J, Sáez-Navarro C, et al. Efficacy of prospective pharmacogenetic testing in the treatment of major depressive disorder: results of a randomized, double-blind clinical trial. *BMC Psychiatry*. 2017;17(1):250. Available from: <https://doi.org/10.1186/s12888-017-1412-1>.
- 35 Precision Genetics. *What is Neuropharmagen® and how can it help?* 2025. Available from: <https://neuropharmagen.com/for-patients/>.
- 36 Espadaler J, Tuson M, Lopez-Ibor JM, Lopez-Ibor F, Lopez-Ibor MI. Pharmacogenetic testing for the guidance of psychiatric treatment: a multicenter retrospective analysis. *CNS Spectr*. 2017;22(4):315-24. Available from: <https://doi.org/10.1017/s1092852915000711>.
- 37 Triangel Scientific. *Triangel Scientific: Revolutionizing Personalized Health with GenAIS*. 2025. Available from: <https://triangelcompany.com/healthwithai> [Accessed 14 November 2025].
- 38 George D. J, Moore E. C, Blobe G. C, DeVito N. C, Hanks B. A, Harrison M. R, et al. *Molecular Classification of Cancers of Unknown Primary Expands and Refines Treatment Options*. 2022. Available from: <https://www.tempus.com/publications/molecular-classification-of-cancers-of-unknown-primary-expands-and-refines-treatment-options/> [Accessed 19 November 2025].
- 39 Thornton N, Binesmael A, Horton T, Hardie T. *AI in health care: what do the public and NHS staff think?* 2024. Available from: <https://www.health.org.uk/reports-and-analysis/analysis/ai-in-health-care-what-do-the-public-and-nhs-staff-think> [Accessed 19 November 2025].
- 40 NHS Genomic AI Network. *Artificial Intelligence in NHS Genomic Medicine Services* 2024. Available from: <https://genomicainetwork.nhs.uk/wp-content/uploads/2025/01/AI-in-genomics-report-final-251124.pdf>.



NIHR Innovation Observatory
at Newcastle University

The Catalyst
Room 3.12, 3 Science Square,
Newcastle Helix,
Newcastle upon Tyne NE4 5TG

Copyright © National Institute for Health and Care
Research Innovation Observatory (NIHRIO),
Newcastle University

Copyright © National Institute for Health and Care
Research Innovation Observatory (NIHRO),
Newcastle University