Horizon Scanning Report: An Investigation into the Development of Artificial Intelligence (AI), Machine Learning (ML) and Deep Learning (DL) - Enabled Healthcare Technologies

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List of abbreviations

AI	Artificial Intelligence
AIaMD	AI as Medical Device
CTs	Clinical Trials
DL	Deep Learning
FDA	United States Food and Drug Administration
EU	European Union
IO	Innovation Observatory
IVDR	EU In-vitro Diagnostic Medical Devices Regulation (2017/746)
MDR	EU Medical Device Regulation (2017/745)
ML	Machine Learning
NICE	National Institute of Health and Care Excellence
NIHR	National Institute for Health Research
ROW	Rest of World
WHO	World Health Organisation

Glossary

Artificial Intelligence: can be defined as "The design and study of machines that can perform tasks that would previously have required human (or other biological) brainpower to accomplish. AI is a broad field that incorporates many different aspects of intelligence, such as reasoning, making decisions, learning from mistakes, communicating, solving problems, and moving around the physical world".[1]

Machine learning: is a subset of AI using computer algorithms capable of learning by finding patterns in data, which can then be applied to new data to make predictions and provide other useful information.[1]

Deep learning: is subset of machine learning "that uses computational structures known as 'neural networks' to automatically recognise patterns in data and provide a suitable output, such as a prediction or evidence for a decision".[1]

Neural networks: (a computational network which artificially mimics activity of neurons in human brains), which enable learning of complex tasks such as identifying features in images and speech.[1]

1.0 Introduction

The use of Artificial intelligence (AI) is rapidly expanding and evolving in the clinical practice and community care settings. Artificial Intelligence can be defined as "the design and study of machines that can perform tasks that would previously have required human (or other biological) brainpower to accomplish. AI is a broad field that incorporates many different aspects of intelligence, such as reasoning, making decisions, learning from mistakes, communicating, solving problems, and moving around the physical world".[1] Proponents of AI in healthcare claim that it has the potential to improve patient outcomes by aiding the advancement of personalised medicine, reduce the workload of healthcare professionals, and make medical care more accessible and affordable. [2,3]

AI-based healthcare technologies encompass a diverse range of technologies. In general, these technologies are designed to learn from their experiences, adapt to new inputs, and perform a variety of tasks, such as making predictions, recommendations, and decisions. For the purposes of our study, we focused on the development of artificial intelligence-enabled healthcare technologies along with their associated subtypes (machine learning and deep learning). In the healthcare sector, AI/ML/DL-based medical devices aim to improve patient care by uncovering new insights from big data generated by an individual patient and the collective experience of many patients.

AI-based technologies also have the potential to improve clinical efficiency, which not only would improve patient outcomes but also reduce costs within healthcare systems. For example, AI-based technologies can be used to analyse radiographic images and report on conditions such as fractures.[4] These technologies could be applied in different settings to improve clinical efficiency, such as in Accident and Emergency departments where AI-based technologies could function as a triage system.[4] These technologies have the potential to not only improve patient outcomes, but also reduce costs within healthcare systems. This may be achieved by minimising time spent on routine administrative tasks, which can occupy up to 70% of a healthcare practitioners time.[5] AI-based technologies may increase home monitoring capabilities, reducing costs by enabling patients to be monitored from home and potentially reducing hospital admissions.[5] In public health systems such as the NHS, AI-based technologies could make services more sustainable and more easily accessible.

Machine learning is a subset of AI using computer algorithms capable of learning by finding patterns in data, which can then be applied to new data to make predictions and provide other useful information.[1] AI-based devices such as biosensors, telemedicine and mobile diagnostics collect large quantities of patient information, which can be used with machine learning algorithms to provide more accurate diagnoses, monitoring and unique, personalised therapeutic options. AI-based technologies using machine learning may also be able to analyse complex big data sets to provide individualised treatments.[6] However, AI-based technologies can be prone to bias if the data used to train them is not properly collected or analysed.

A new subset of machine learning called deep learning has gained significant traction in recent years. Deep learning uses computational structures known as 'neural networks' to automatically recognise patterns in data and provide a suitable output, such as a prediction or evidence for a decision".[1] Deep learning has been used for a variety of tasks, including image recognition, natural language processing, and time series forecasting. It has also been used in medical applications such as diagnosis and drug discovery.

However, AI-based technologies present their own set of challenges. In light of the fact that these technologies are capable of learning and evolving following their initial approval by regulatory bodies, updated regulations for medical devices will be required to keep pace with these technologies. However, frameworks are still being developed due to the complex challenges posed by these technologies.[7] The key challenges of regulating these technologies are in cybersecurity and data protections, quality control and product safety, informed patient consent and liability.[7] Post-market surveillance of these technologies will be necessary to manage risks and continuous quality management of technologies will be required.[8] The approval of medical devices and their regulation are handled differently in the USA and Europe. There is currently no specific regulatory pathway for AI/ML/DL-based medical devices in the USA or Europe.

One potential drawback of deep learning is that it is computationally intensive. Deep learning models require large amounts of data, and they require a lot of computing power to train and process the data. This can make deep learning models more difficult and expensive to develop and maintain.

In 2021, AI in healthcare was worth 11 billion U.S. dollars globally, by 2030 it is predicted that it will be worth 188 billion U.S. dollars globally.[9] The exponential growth of the market could be driving development of new technologies. In the EU, a report claimed that the integration of AI into European healthcare systems has the potential to save up to 212.4 billion euros in annual healthcare expenses while also saving up to 403,000 lives.[10] Despite this market growth and potential financial benefits of these technologies, very few studies have been conducted to collect information from clinical trials and medical regulatory agencies to identify trends in the development of AI-based health care. That is what this study is aiming to achieve. A thorough understanding of products in pipeline development is fundamental to accurately forecasting when technologies will enter the market and be available for clinical use. The factors driving innovation of AI-based medical technologies include the increasing cost of medical care, the need for more accurate diagnosis and faster treatments, and the growing demand for personalized medical care.

The purpose of this project is to provide new insights into AI-based medical technology innovations, and to assist healthcare providers, regulators, and patients in staying abreast of emerging trends and developments in this area. Insights gained from various AI applications can serve as important evidence to inform guidelines and policies to ensure a safe and equitable health care system. The objectives and scope of our project are outlined below.

1.1 Objectives & Scope

This horizon scan was undertaken as part of the NIHR Innovation Observatory's proactive initiatives in order to:

- Identify artificial intelligence-based healthcare technologies that are presently being developed.
- Identify those that have recently gained approval for use in the healthcare industry.
- Provide a comprehensive overview of the current state of AI-based healthcare technologies in development, the trends, as well as the potential implications for healthcare providers and patients.
- Provide insights into the key factors driving the development of AI-based healthcare technologies.
- Present an overview of AI and discuss the associated challenges for its implementation.
- Gain insight and understanding of current and upcoming developments in healthcare using artificial intelligence.
- Conduct an analysis of the funding landscape, health conditions being addressed, and types of interventions.
- Discuss the future of EU and FDA regulations regarding AI.

As illustrated in Figure 1, AI is not a single technology, but rather a constellation of techniques and processes.

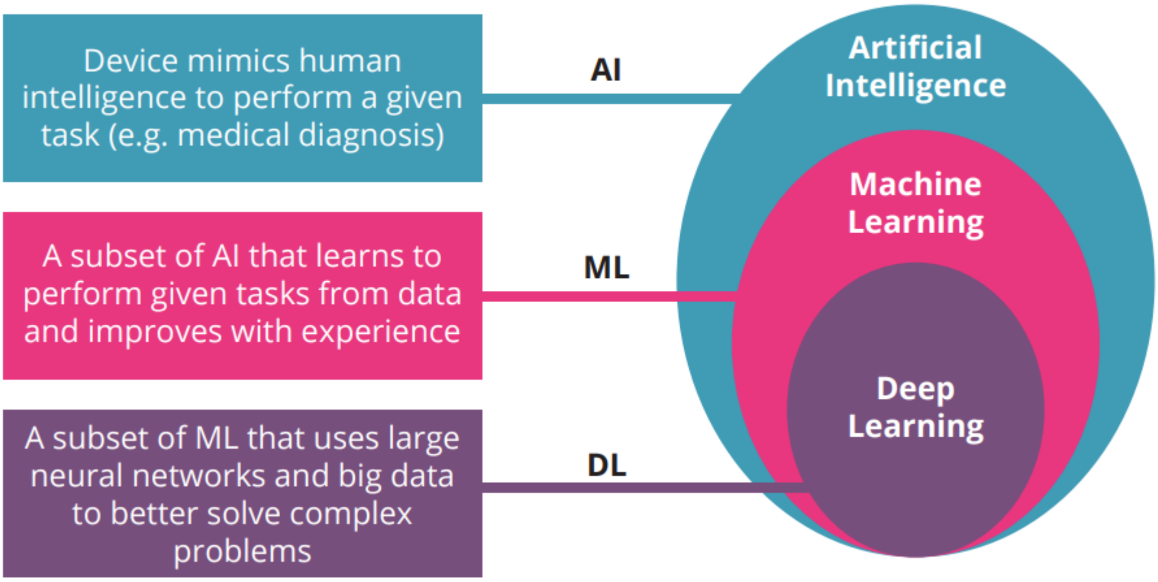


Figure 1: Overview of AI and associated subtypes, adapted from [11]

2.0 Methods

2.1 Horizon Scanning for Artificial Intelligence Technologies

Horizon scanning methodologies developed by the Innovation Observatory (IO) were used to identify the pipeline of AI-based technologies. Primary and secondary information sources in datasets specific to AI technologies or that included textual 'signals' for Artificial Intelligence technologies were identified, the latter were systematically scanned using traditional (manual) and some automated techniques.

2.2 Search Strategy and Sources

The FDA database that contains publicly available information on AI/ML-enabled devices was searched in order to identify recently approved AI-enabled devices.[12] Based on our search, 691 AI/ML devices were identified and downloaded for analysis in Excel format. According to FDA, this list of newly approved medical devices does not constitute a complete or exhaustive list of AI/ML-based medical devices. Rather, it is a list of medical devices that incorporate AI/ML across medical disciplines, primarily based on information provided in the summary descriptions of their marketing authorization document. No further screening of these was performed as no information on AI sub-types was included. This database was selected to provide an exhaustive snapshot of AI technologies recently approved by the USA's FDA. It is imperative to note that some types of medical devices are not required to undergo clinical trials. As an example, most class I medical devices are not subject to clinical trials as they are considered low risk; however, some may require a "safety and effectiveness study". Thus, relying solely on clinical trial databases may have resulted in the missed detection of a number of technologies in development. As a solution to this issue, we collected information about recently approved technologies from the FDA database. Through this method, we were able to identify potential new medical devices that had not been evaluated in clinical trials.

The Clinical Trials Registry clinicaltrials.gov was searched for relevant studies published in the last three years (August 2020 to August 2023). ClinicalTrials.gov is an international, English-language database with multiple searchable text fields. An extensive collection of clinical studies conducted throughout the world, both publicly funded and privately funded, is included in this database. A comprehensive list of search terms was compiled based on the IO's previous scan of AI technologies conducted in 2021.[13] Inclusive search strategy did not rely on keyword phrases such as "artificial intelligence" being sequentially paired in the source text. Any novel descriptors of AI (phrases not identified in the previous AI keyword analysis) were noted at the screening stage.

Search terms were: artificial intelligence; AI artificial intelligence; machine intelligence; neural network; deep learning; computational intelligence; natural language processing; learning algorithm; continuous learning algorithm; intelligent device.*

2.3 Inclusion and exclusion criteria (clinical trials)

Inclusion criteria:

Clinical trials identified by the search were screened against the following criteria.

- Meet the criteria for being a regulated medical device, digital health technology, or diagnostic as defined by the two new EU regulations (EU Regulation 2017/745 on medical devices (MDR) and EU Regulation 2017/746 on in vitro diagnostic medical devices (IVDR)) AND:
- Clinical trial record uses keyword phrases specific to AI e.g. “deep learning”, OR
- One or more collaborators specialise in AI, AND a relevant technology, OR
- A technology is described as ‘intelligent’ AND a secondary source confirms AI, OR
- Significant computation is involved (big-data) AND a secondary source confirms AI, OR
- Machine learning methodology is described, i.e. ‘training’ an algorithm with (big) data, OR
- Data is being gathered with the stated intention to apply machine learning, OR
- Existing AI (e.g. apple smart-watch) is being tested for clinical use, OR
- A novel AI is in development for
  - direct patient health impact, OR
  - diagnostic use or support, OR
  - risk assessment or risk mitigation at the individual level.

Where the trial record implied AI but was not specific, a secondary search for published information on the technology type was conducted using the Clinical trial reference, company name or technology brand-name as search terms.

Studies relating to neural networks of the human brain were common and were further screened for the use of AI based on the exact context of “neural network” or other AI terminology.

If the study did not specifically mention AI, ML, or DL, we assessed it in light of the characteristics or description of these technologies. Characteristics of AI include the ability to process large amounts of data, learn from it, and make decisions or predictions based on the data. ML and DL which are subsets of AI, are characterized by their ability to recognize patterns and relationships in data. The trials included were subjected to a comprehensive review and a data extraction process to identify all key information. The extracted data was then used to conduct a systematic analysis of the trials.

Exclusion criteria:

- Clinical trials using AI in the training and education of health professionals.
- Clinical trials using AI to improve health outcomes at hospital level or disaster management level, etc, not at the individual level.
- Primary research conducted in the clinical setting
- Patient information/education tools not purposed to improve health outcomes

- 'Intelligent' technologies that gather enriched information but do not perform independent analysis.

Screening:

Clinical trials meeting the inclusion criteria were further screened for indicators of ML and DL and classified as one of three AI types. The technologies were assigned to the category that best reflected the application evidence. The AI category may include trials that use machine learning but did not say so, and similarly the ML category is expected to include some deep learning technologies. Trials that used one or more separate AI applications, e.g. first to gather data and then to analyse it, were assigned to the category of the AI in development or if both were in development, the most specific available sub-type.

- Artificial intelligence: any computational system replicating intelligence, i.e. performing autonomous analysis. The simplest autonomous chat-bots to the most complicated diagnostic analysis of raw imaging data would be included in this category if not confidently placed in one of the subsets.
- Machine learning: either the clinical trial record or a published description of the technology states ML, or that a training data set was used, or states natural language processing (a ML subtype).
- Deep learning: either the CT record or a published description of the technology states DL, or neural network of any type. All neural network technologies were assumed to be 'deep' (multi-layered) as this is the current industry standard. [14,15]

Data on Clinical trial locations and the NICE condition categories were extracted from the trial records and cleaned by standardizing to clinical and geographical categories. Pragmatically, the 'multiple conditions' category includes technologies that relate to any of several conditions as well as those for individuals with comorbidities. Key data fields included list of interventions and the tests they were being used in CTs, the clinical condition being diagnosed in the trial, NICE categories were used to group the conditions to facilitate analysis, type of sponsor and the geographical categories of trial locations.

3.0 Results

In this section, the latest developments in the use of Artificial Intelligence in healthcare technologies are presented, in addition to the current global trends in development and funding. This section will also focus on the different types of artificial intelligence technology being developed and the conditions in which artificial intelligence is being used.

3.1 Product Pipeline

Figure 2 illustrates an overview of AI-based healthcare technologies identified in our Horizon scan dataset. A total of 4998 clinical trials were initially identified within the scope of the search. An analysis of these trials resulted in the inclusion of 2060 trials that were deemed relevant and included in the final analysis. The dataset was manually curated and validated to ensure accuracy and completeness.

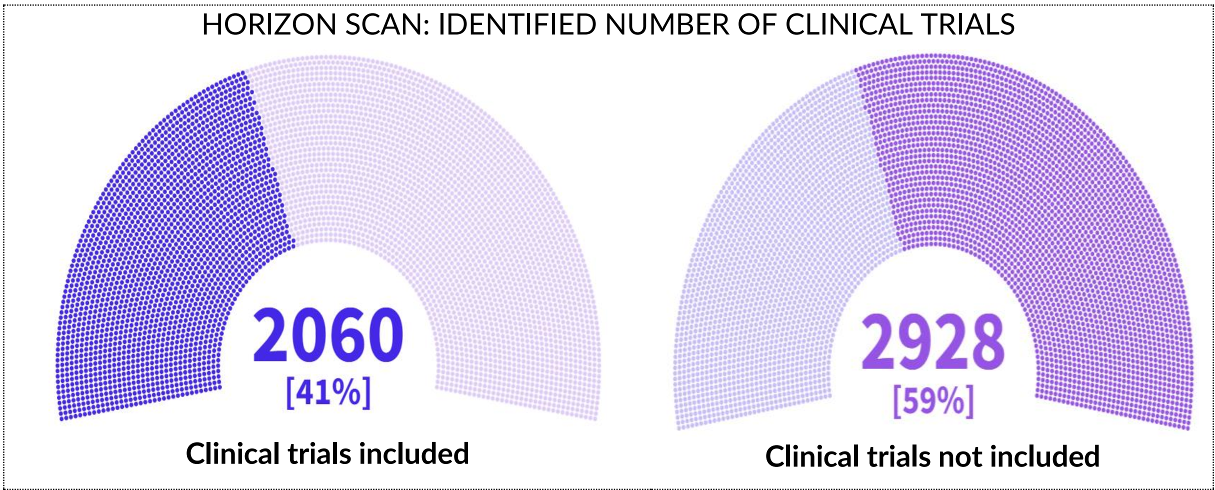


Figure 2: Overview of AI-based healthcare technologies identified in our Horizon scan

The Horizon scan dataset was then used to present an overview of the current state of AI-based healthcare technologies and analysed to identify trends and patterns in the trials. As shown in Figure 3, out of the 2060 clinical trials that were identified as relevant by the sifting process, more than half used artificial intelligence (1059), followed by machine learning (569) and deep learning (432), respectively.

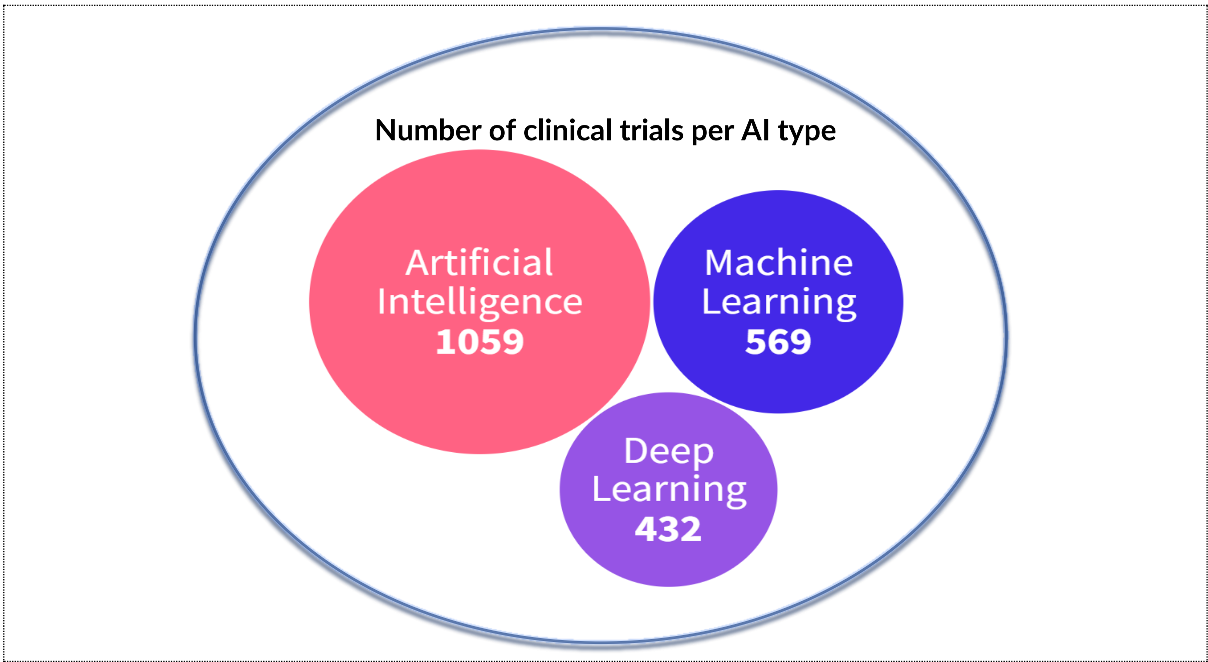


Figure 3: Number of clinical trials using artificial intelligence and associated subtypes

Additional keywords for AI identified in the sources were: computational learning; computational intelligence; neuronal networks; convolutional networks; intelligent [device], (e.g. intelligent stethoscope)]. It was not necessary to 'snowball' the search.

The difference in the number of trials per AI type could be explained by the fact that machine learning is a subset of AI and deep learning is a subset of machine learning. Therefore, we are observing that as the intervention becomes more specific, there are fewer trials using this technology. Deep learning is an evolution of machine learning, involving neural networks and complex algorithms. As deep learning is a more recently evolved subset of machine learning, it may explain why fewer trials were classified as deep learning. Deep learning is also a newer field of research, although it is rapidly advancing. Figure 4 illustrates the number and percentage of clinical trials conducted by type of study.

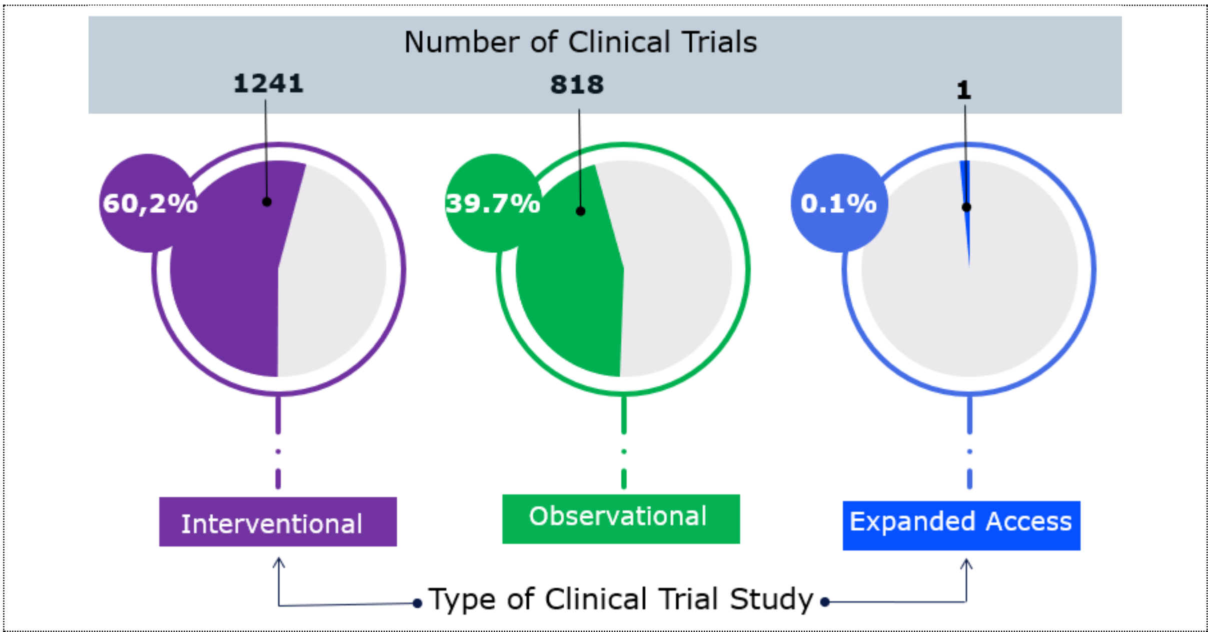


Figure 4: Number of clinical trials per study type

As shown in Figure 4 above, the main clinical study types used for the clinical trials included in this report were interventional study (1,241 trials) and observational study (818 trials). Interventional study also known as experimental research, are the only type of research that allow conclusions to be drawn about cause and effect relationships between an intervention or treatment and an outcome. [16]

3.2 Conditions and disease areas

As illustrated in Figure 5, the technologies identified are currently being developed for diagnosing and treating a wide range of conditions and diseases. Many of these technologies are in the early stages of development but have the potential to revolutionise healthcare delivery. As these technologies become more widely available, they could have a significant impact on the healthcare industry.

Number of Clinical Trials per condition

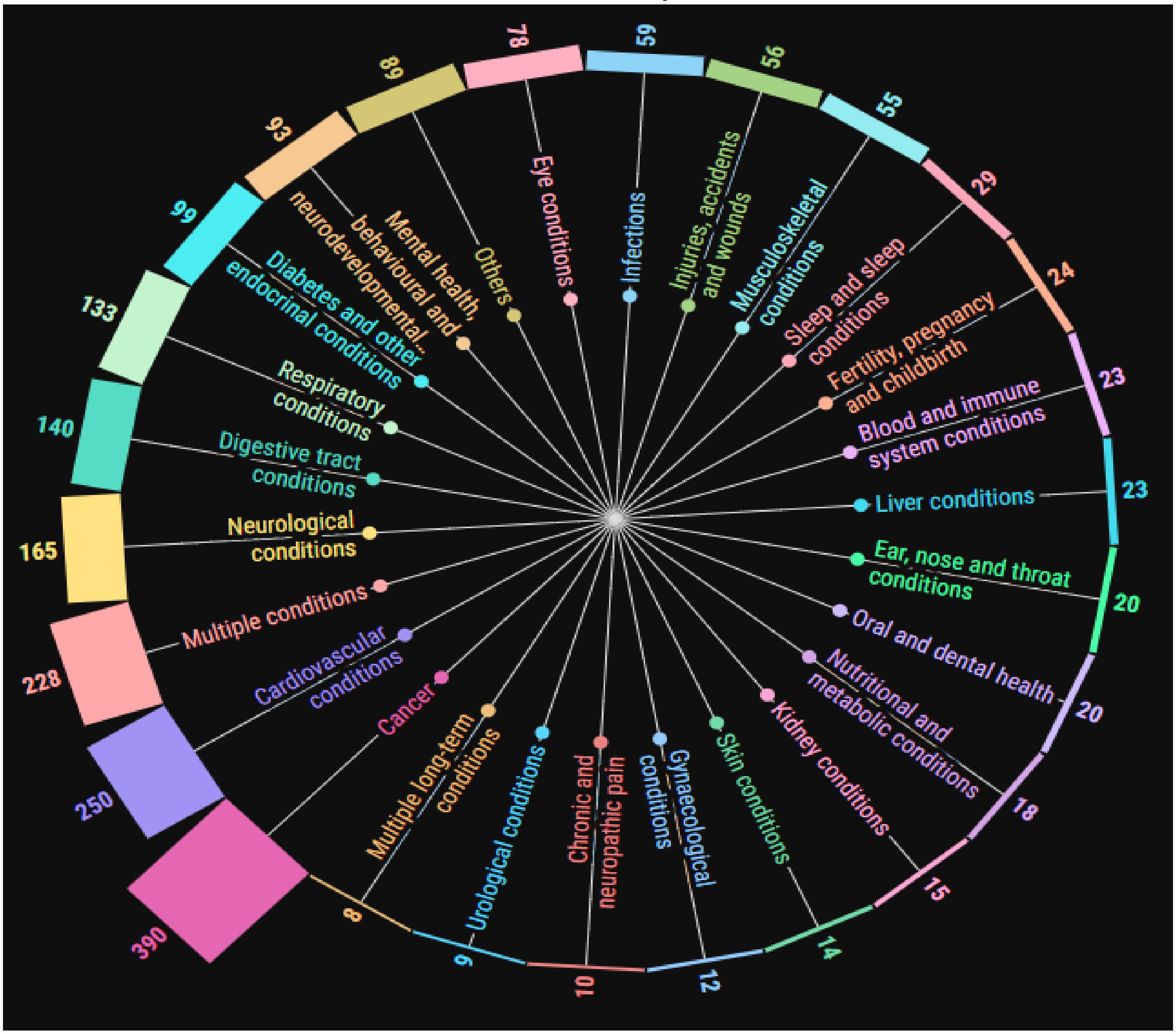


Figure 5: Number of clinical trials using AI categorised by clinical condition areas

The most common condition for the use of these technologies is cancer (390). This suggests that there is a great level of demand for development in technologies for cancer treatment and diagnosis. Considering that cancer is such a broad disease area and is extremely prevalent among the population, it is not surprising that so many developments have been made in this area. Cancer is one of the leading causes of death worldwide, accounting for one out of six deaths in 2020.[17] Because of this, cancer research receives substantial funding. Artificial intelligence is now used in a variety of ways in cancer diagnosis and treatment. One way in which artificial intelligence is being applied is through the use of personalised treatment plan for cancer patients based on factors like patient history and genetics. AI technologies can also be used to grade biopsies in some cancers faster and with more accuracy.[18]

After cancer, cardiovascular conditions are the second most common disease area in which AI technologies are being developed. Cardiovascular conditions, like cancer, are also common and a broad disease area. Therefore, the focus on cardiovascular conditions is to be expected. In 2019, it is estimated that 17.9 million people died from cardiovascular diseases which accounts for 32% of all deaths globally. Cardiovascular conditions are the leading cause of deaths globally which could explain the high numbers of clinical trials using AI for this condition.[19] In cardiovascular conditions, an example of AI technology being utilised is through the analysis of electrocardiograms to predict heart failure. It is also used in outcome prediction of cardiovascular disease.[20]

We also found a high number of clinical trials using the AI technology for use in multiple conditions (228). This suggests that AI technologies can be versatile and used in more than one clinical area, giving them potential to be cost effective as well as useful.

Many trials using artificial intelligence for neurological conditions (165) were also identified. Artificial intelligence can be used in neurological conditions to detect and diagnose conditions by analysing large amounts of data on brain patterns as well as for analysing imaging data.

Using AI technology for cancer, cardiovascular conditions and multiple conditions were the most common according to our analysis, but as previously mentioned we found AI used in a vast range of disease areas as indicated in Figure 5. Other conditions that frequently appeared in our search included digestive tract and respiratory conditions.

We conducted a further analysis to determine which type of AI category was used most frequently in each condition or disease area, as depicted in Figure 6 and 7. While Figure 6 depicts the numbers of each AI type by clinical condition or disease area, Figure 7 shows the percentage of AI type used in each condition or disease area. This allows for the comparison of number of trials per AI types across clinical conditions and disease area.

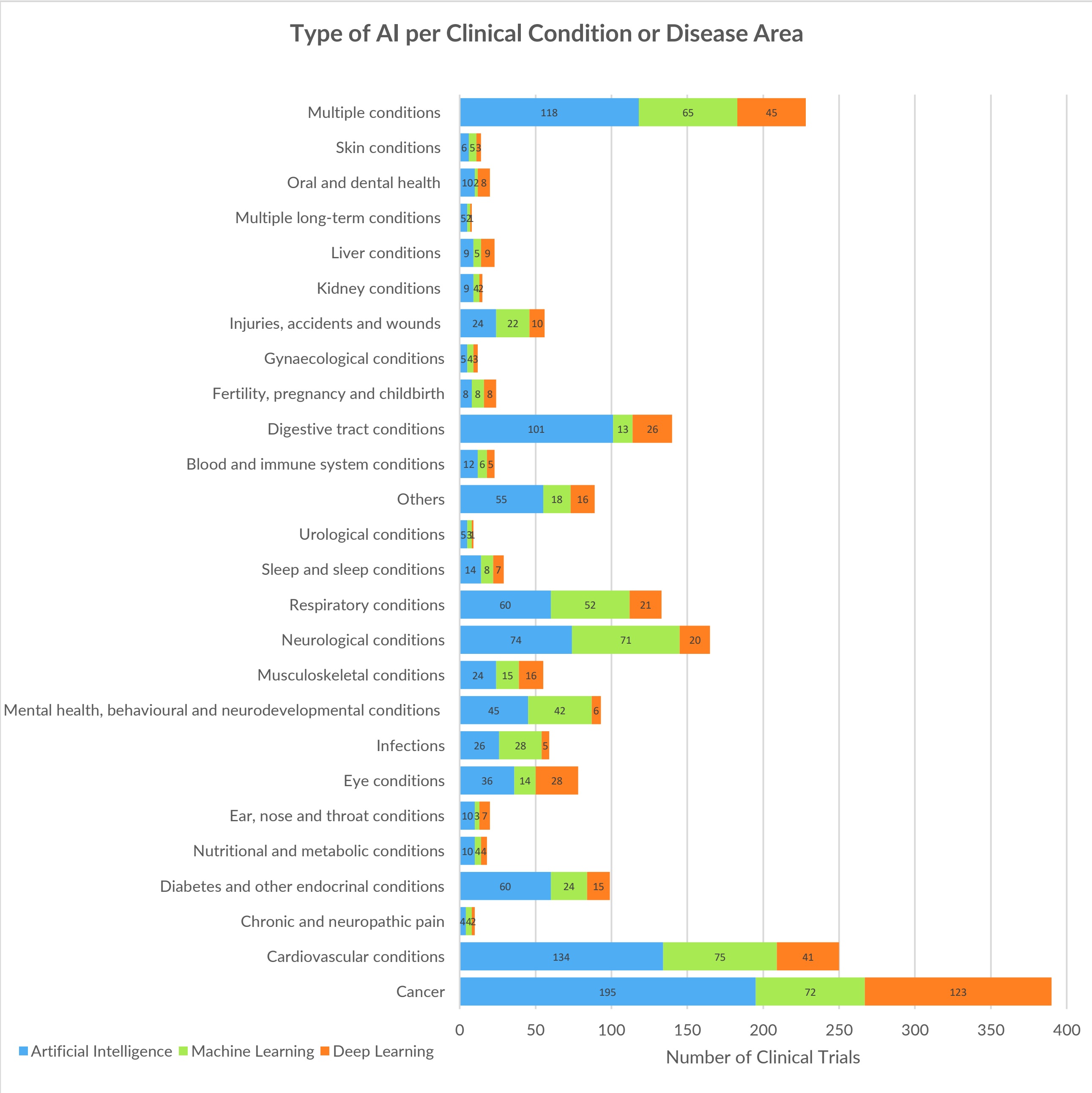


Figure 6: Number or AI type used across clinical condition or disease area

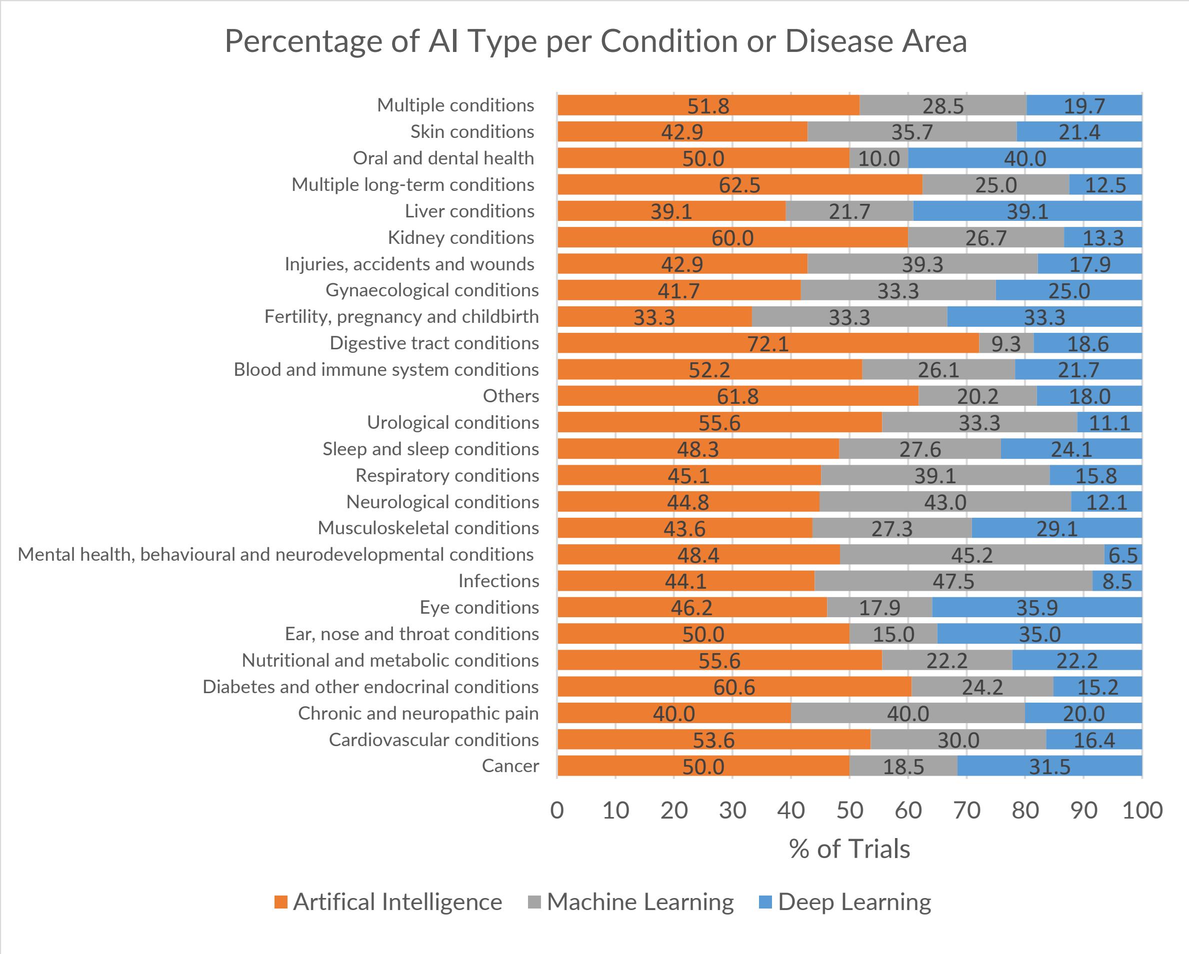


Figure 7: Proportion of AI type used in each condition or disease area

In most cases, artificial intelligence was the most common intervention in each condition. However, technologies used in liver conditions equally used artificial intelligence and deep learning (39.1%). In conditions relating to fertility, pregnancy and childbirth, artificial intelligence, machine learning and deep learning were used equally, each contributing a third. Another exception to artificial intelligence being used most frequently is in conditions of chronic and neuropathic pain in which artificial intelligence and machine learning were used equally (40%). The only condition in which artificial intelligence was used less than other AI subtypes was in infections in which machine learning was more commonly used (47.5% vs 44.1%). The reason for this could be that machine learning could be trained to learn certain biomarkers that present in different infections.

3.3 Clinical trial location analysis

Figure 8 illustrates the locations of the clinical trials. Most clinical trials were located in Asia (632). This was closely followed by Europe (530) and North America (491). Only 121 of the clinical trials were in the UK. Australia and the fewest number of clinical trials with only 7 out of the total 2060.

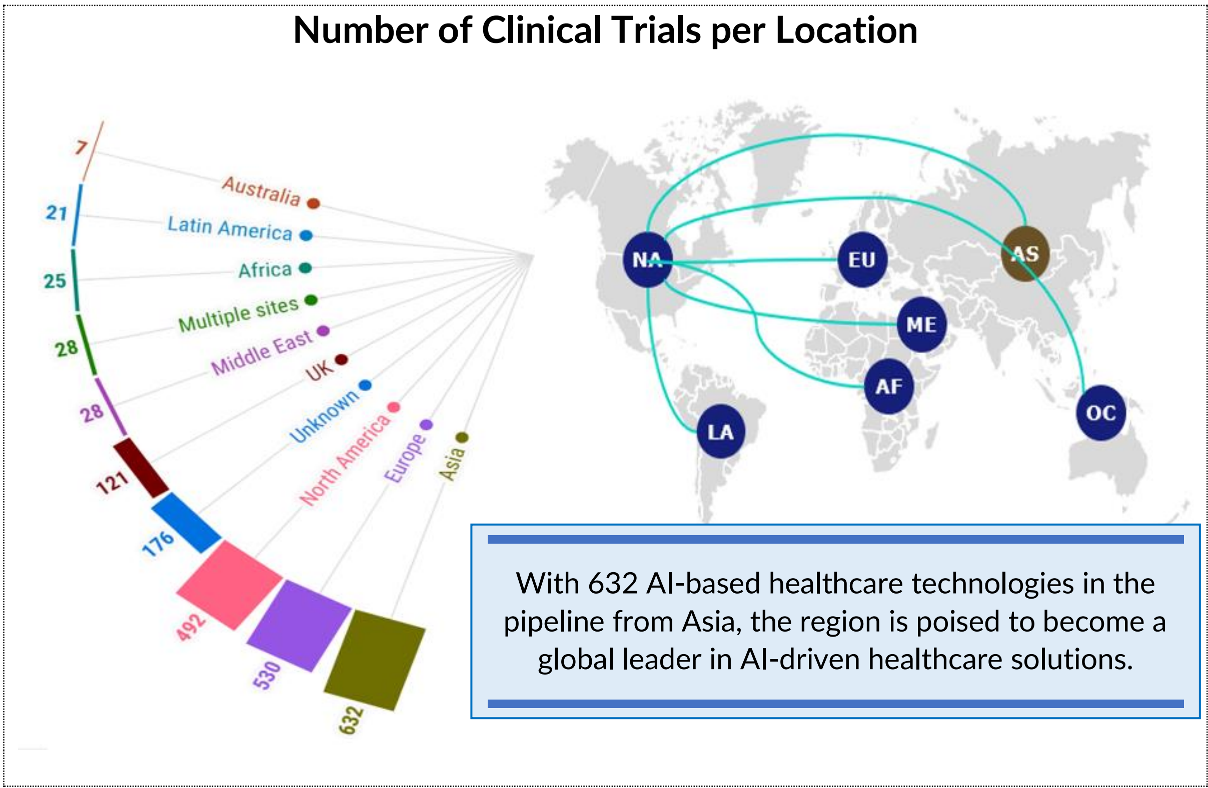
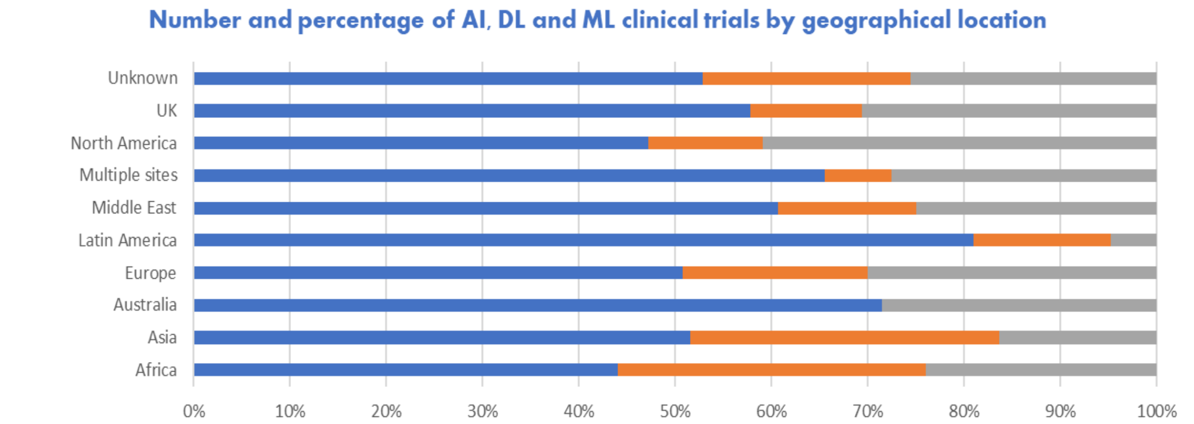


Figure 8: Number of clinical trials by geographical location

Figure 9 depicts the number and percentage of AI, DL and ML clinical trials by geographical location. In most of the locations looked at in this scan, over 50% of the clinical trials were those of AI-based category, followed by ML clinical trials which accounted for about 30% of the total. DL category had the least percentage in most of the locations except in Asia, Africa and Latin America.



	Africa	Asia	Australia	Europe	Latin America	Middle East	Multiple sites	North America	UK	Unknown
Artificial Intelligence	11	326	5	269	17	17	19	232	70	93
Deep Learning	8	203	0	102	3	4	2	58	14	38
Machine Learning	6	103	2	159	1	7	8	201	37	45

Artificial Intelligence Deep Learning Machine Learning

Figure 9: Number and percentage of AI, DL and ML clinical trials by geographical location

As shown in figure 9 above, the highest number of AI interventions in development were found to be in Asia (326), next was in Europe (269), and followed by North America which was the third largest (232). Similar trends were observed for the deep learning interventions with Asia having the largest numbers (203), Europe (102), and North America (58). A reverse in the trend was observed for the ML interventions in development, where North America was found to have the highest number (201), followed by Europe, and Asia was the third largest (103). The locations with the least number of AI, DL, and ML interventions in development were found to be in Africa, Latin America, and Australia. Australia had 5 AI, 2 ML, and no DL interventions. The UK was the 5th largest of all the locations included in the search with 70 AI, 14 DL and 37 ML interventions in development. Some of the factors which may be driving greater innovation in AI-based medical technologies in Asia may not be unique to the region, such as an ageing population and declining birth rates, which is also being seen in the Western world (i.e. Europe, North America, UK).[21] However, factors which are driving greater innovation specific to the region vary depending upon country due to the differences in economic status and challenges facing specific countries. For example, in China, large access to centralised databases and poor healthcare infrastructure is driving development of AI-based technologies, which may offer a solution to current burdens on the Chinese healthcare system.[22] This differs somewhat to factors driving development in other Asian nations, such as Japan, where an ageing, declining workforce and increasing patient burden is driving innovative automation solutions to keep up with rising demand for healthcare services.[23]

There is overlap in factors which may be driving innovation globally, such as the rise of chronic diseases in economically developed nations and ageing populations.[5] However, in Europe a unique factor which may be driving development of AI based health technologies could be pan-European collaboration and coordinated approach to regulation.[24]

Locations with lower levels of AI-based health technology development include Africa and Latin America (Figure 8). This is possibly due to many countries within these regions experiencing disproportional levels of poverty and inequality in comparison to other locations.[25,26] It is important to address the challenges these regions face which may limit innovation, to ensure equal development opportunities and access to new AI-based health technologies. Access to innovative AI based health technologies in these locations could address the barriers to healthcare in these regions such as lack of resources, corruption within healthcare systems and lack of education particularly regarding healthcare.[25,27,28]

3.4 Funding analysis

From the technologies included in our scan, we found that development was primarily funded by non-industry sources, as shown in Figures 10 and 11. (1743 [85%]) of total funding for AI-based medical technology development and deployment was from non-industry sources, (298 [15%]) of total funding was from industry, and only 1% of funding was from a combination of both non-industry and industry sources (Figure 10).

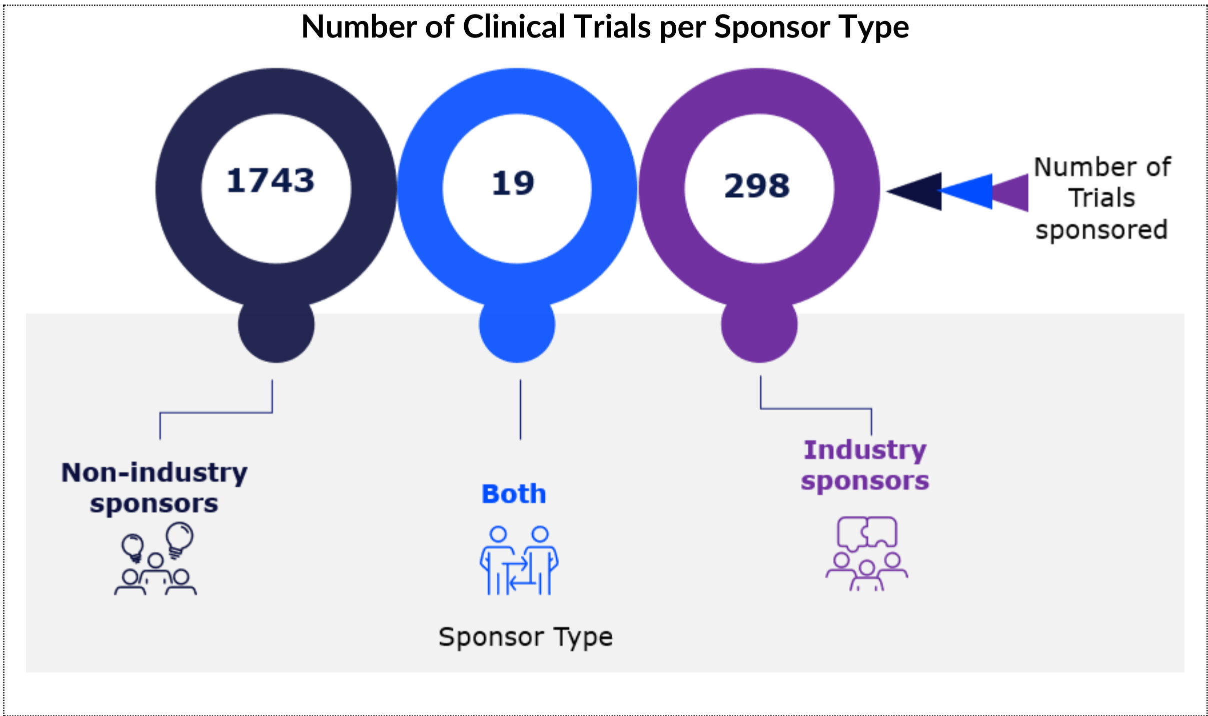
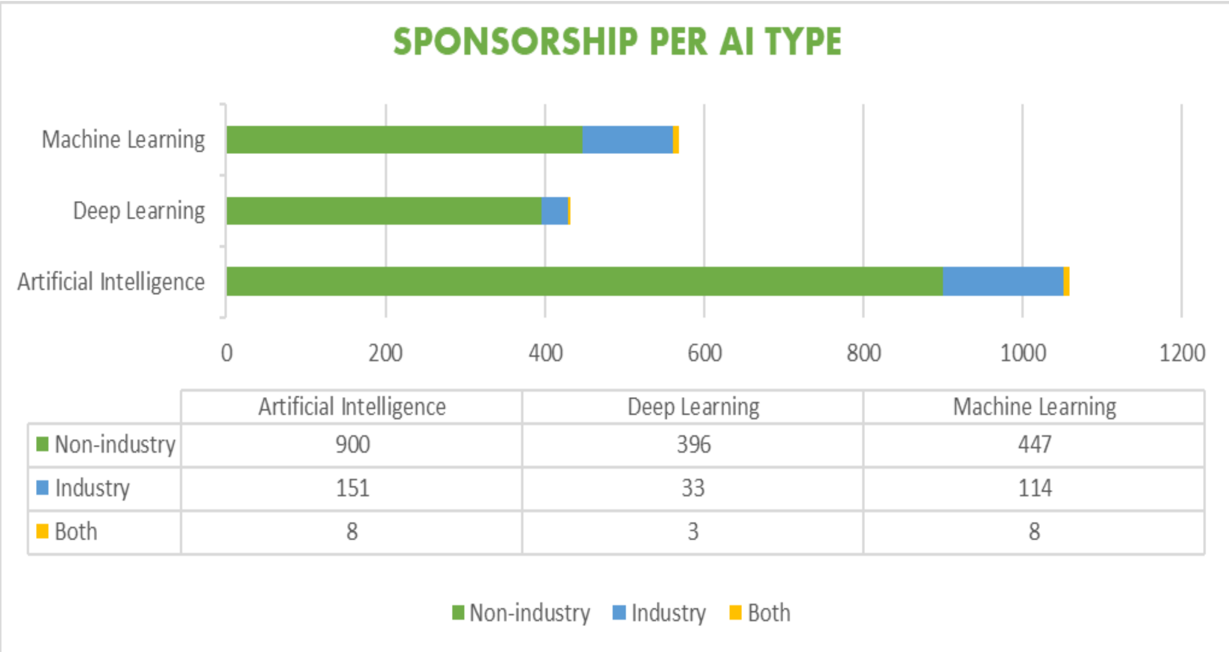


Figure 10: Number of clinical trials using AI categorised by sponsor type

1,743 of the trials had non-industry sponsors, 298 were sponsored by an industry and 19 trials had both industry and non-industry sponsors. Non-industry funders and sponsors have been found to be crucial to ensure research addresses not only treatments, but also prevention, diagnosis, and education questions.[29]

Non-industry funding can include sources such as government funding, charitable funding, and funding from academic institutions. Industry funding can include funding from companies within the private sector, venture capital funds, corporate venture capital and Special Purpose Acquisition Companies (SPAC) funding.[30]

There are numerous possible explanations for why funding is provided mainly by non-industry sources. Charitable organisations and state funding may have longer term vision and are more interested in improving public health, rather than being driven by profits. Another possible explanation is non-industry funding can be more flexible, allowing researchers developing AI-based medical technologies to respond more rapidly to emerging public health challenges and unmet needs.[31] There are numerous factors which may explain why industry funding constitutes a significantly smaller percentage of total funding. One limiting factor facing industry development and funding of AI-based medical technologies is technical and operational challenges. Development of these technologies requires a specialised and highly skilled team, access to high-quality data and advanced infrastructure. This can be expensive and difficult for some industrial sources to access, which may limit industry funding in this area.



	Artificial Intelligence	Deep Learning	Machine Learning
Non-industry	900	396	447
Industry	151	33	114
Both	8	3	8

Figure 11- Funding analysis of AI-based medical technologies, categorised by intervention type. This graph visualises funder type and the proportion of interventions funded by this source.

Figure 12 below shows the proportion of funding types in each geographical location. Of the top 4 locations, all AI-based medical technology development was primarily funded by non-industry sources. 99% of technologies produced in Asia were funded by non-industry sources, similarly, 87% of technologies produced in Europe and 81% of technologies produced in the UK were funded by non-industry sources (Figure 12). However, only 68% of technologies produced in North America were funded from non-industry sources, with 28% being funded by industry, and the remaining 3% funded by a combination of both industry and non-industry funding (Figure 12).

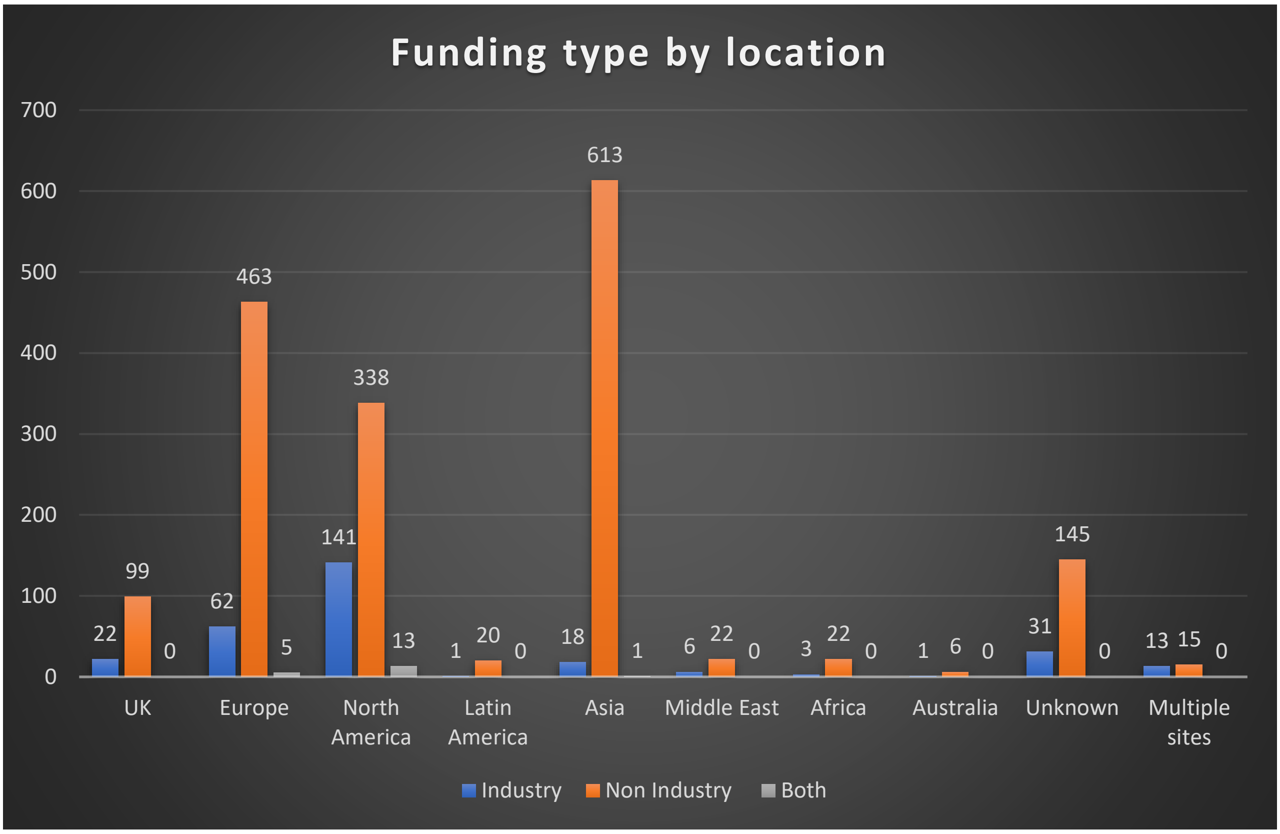


Figure 12 – Funding types in each geographical location.

Whilst most funding in North America was delivered by non-industry sources, the location did have a substantially lower percentage of non-industry funding compared with the other top 4 producers of AI-based medical technologies. This could be due to structural differences in healthcare systems. Healthcare systems within North America, particularly the USA, are privately owned, and have much greater involvement with the private sector and big pharma. In contrast, many Asian and European countries have greater state involvement with healthcare systems, with many countries providing state funded healthcare which may impact the funding landscape. UK healthcare is predominantly provided by the NHS and therefore, has greater levels of government funding driving innovation.

Specific factors driving innovation of AI-based medical technologies in the UK are closely linked the NHS. The NHSX AI Lab focuses on the development and deployment of AI-based medical technologies.[32] The NHSX AI Lab has £250 million in funding from the UK government, which will significantly drive innovation of new technologies, contributing to UK based development of AI-based medical technologies. Additionally, the industrial strategy challenge fund has provided £50 million to drive innovation at 5 key technology centres, where AI-based healthcare technologies.[33] This funding and UK government support and collaboration with the private sector may be a key factor driving UK AI-based health technology innovation.

3.5 FDA recently approved AI/ML-enabled devices

For all eligible AI/ML-based medical devices extracted from the FDA database, the following characteristics were collected: device name, manufacturer, approval date, medical specialty, and primary product code. Our search identified 691 AI/ML-based medical devices of interest, all of which were included in our analysis. The devices were approved between the years 1995 and 2023. Figure 13 illustrates the number of FDA approved AI/ML-based medical devices categorised according to their medical specialty.

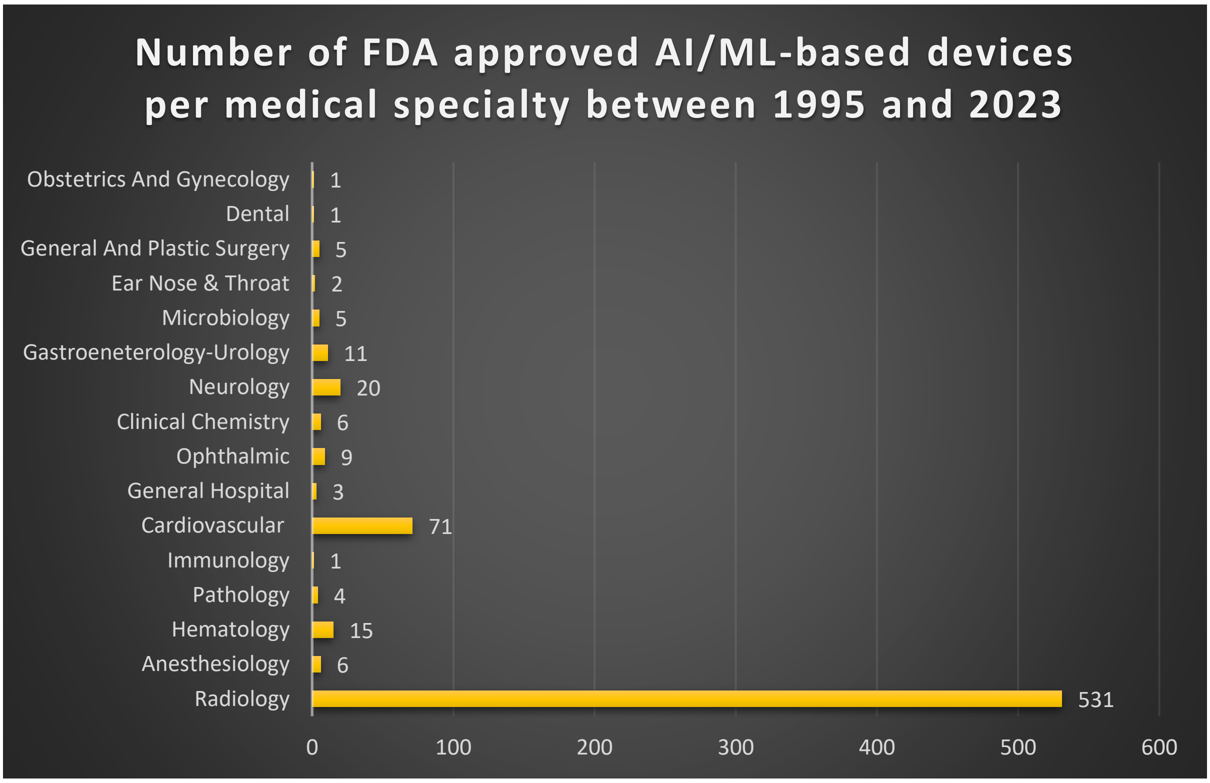


Figure 13: Number of FDA approved AI/ML-based devices per each medical specialty (1995-2023).
* *This data was obtained from an FDA database and was categorised using the FDA medical speciality classification ("Proportion of devices per medical specialty").*

The greatest number of approved devices were those aimed for radiological use (77% of total approved devices), such as devices with AI for image analysis (Figure 13). This radiology category is substantially greater than other medical specialties. A contributing factor for this might be that radiological imaging data are growing at a disproportionate rate when compared with the number of trained readers available to interpret them.

The next largest category was for devices targeting cardiovascular conditions (10%) (Figure 13). Cardiovascular disease was the leading cause of mortality in the USA (2016), which would explain high levels of development in AI/ML based devices to address this significant national health concern[34]. The World Health Organisation (WHO) identified cardiovascular disease as [i]the leading cause of death globally, meaning there is incentive for companies to develop innovative technologies to address this major health challenge.[19]

Device Approval Trends

An overview of the top 4 medical specialties in which AI/ML-based medical devices were approved by the FDA is presented in Figure 14-17. The top four medical specialties include radiology, cardiology, neurology, and haematology. These specialties have seen an increase in AI/ML-based medical devices due to their potential to improve patient outcomes.

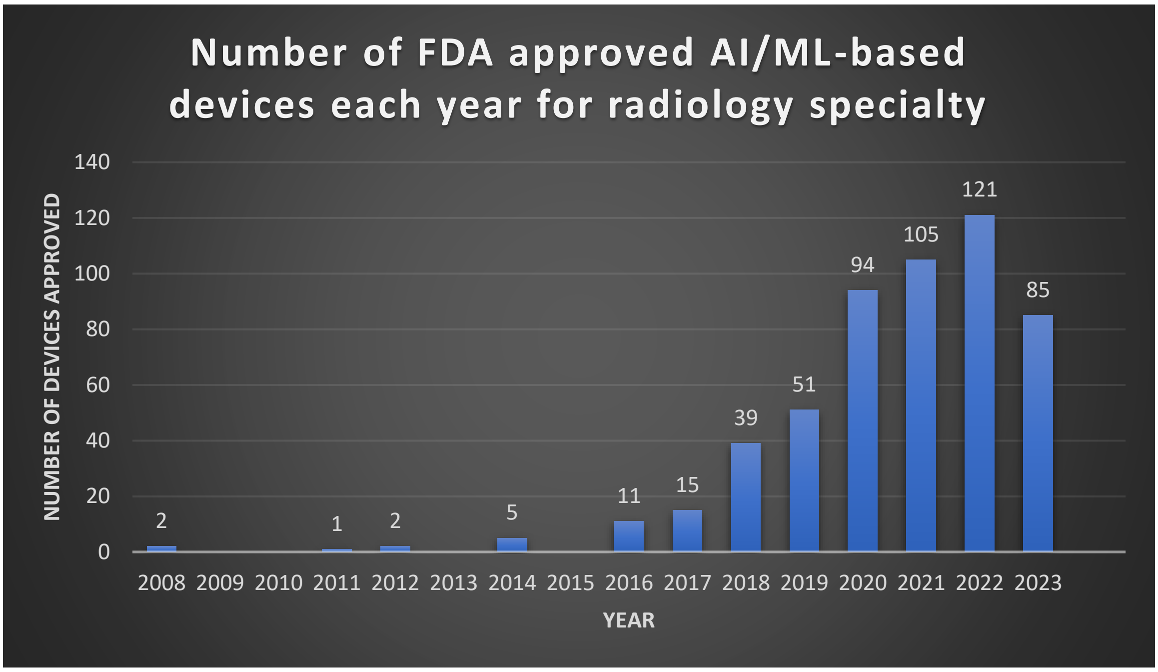


Figure 14: Number of FDA approved AI/ML-based medical devices for radiology specialty (2008-2023).

According to Figure 14 above, the majority of AI/ML-based devices approved by FDA were for use in radiology, with the highest number (121) being approved in 2022. There was sparse development between 2008 and 2014, followed by a rapid spike in development from 2014-2023. Figure 15 shows the number of approved AI/ML-based medical devices for cardiovascular specialty between 2008 and 2023.

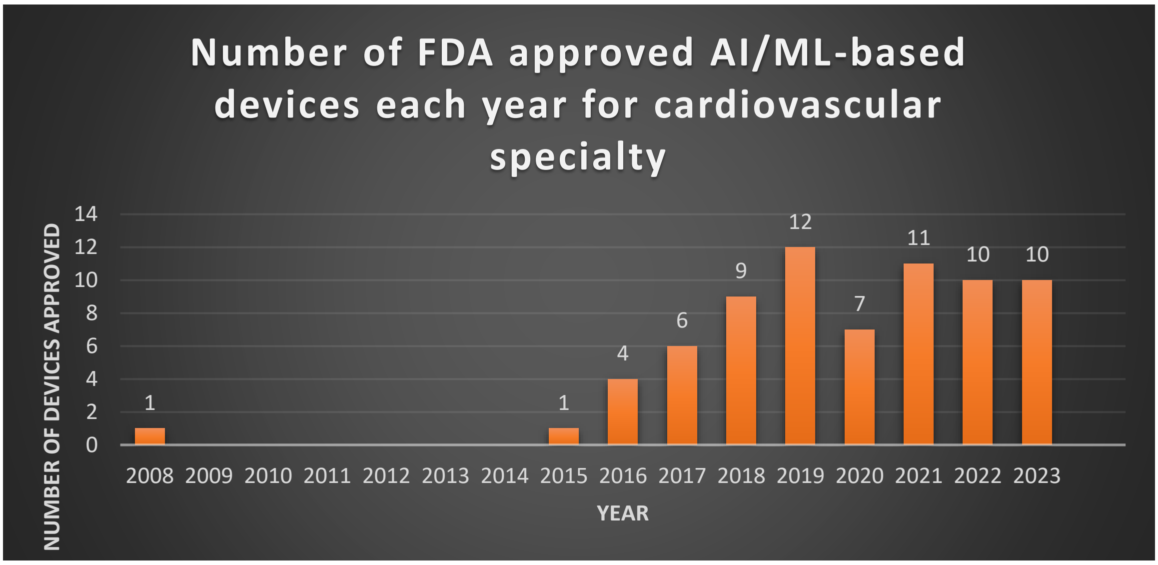


Figure 15: Number of FDA approved AI/ML-based medical devices for cardiovascular specialty (2008-2023)

From 2008 to 2015, there was a significant gap in development for the cardiovascular specialty (Figure 15). In part, this can be attributed to cardiovascular research being focused on alternative areas or to the fact that technology capabilities at the time were not able to match the requirements needed for AI/ML-based solutions. There was a sudden rise in approvals in 2016, which has since remained relatively constant suggesting AI/ML medical devices for cardiovascular disease is an ongoing area of interest for research and development. In Figure 16 below, we show how many AI/ML-based medical devices have been approved for use in neurology over the period of 2008 to 2023.

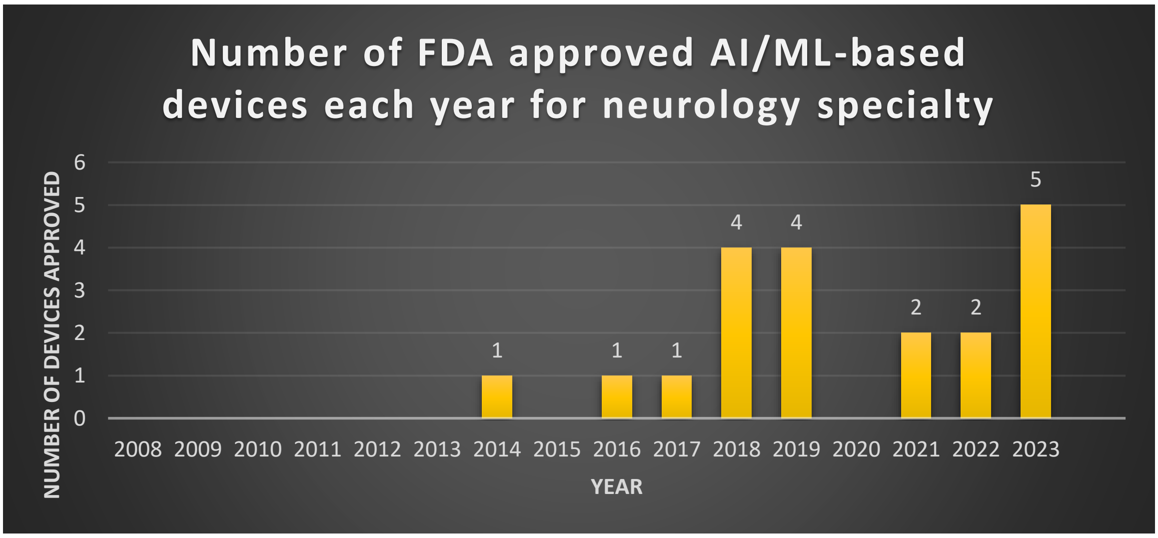


Figure 16: Number of FDA approved AI/ML-based medical devices for neurology specialty (2008-2023)

As shown in Figure 16 above, medical devices utilizing AI/ML for the specialisation of neurology were not approved until 2014. This may mean that research was not particularly focused on this specialty previously, or due to the complex nature of neurological conditions it may be that development in this area was hindered by limited understanding of pathophysiological factors in disease development until this point. A representation of the number of FDA-approved AI/ML-based medical devices for the haematology specialty is presented in figure 17.

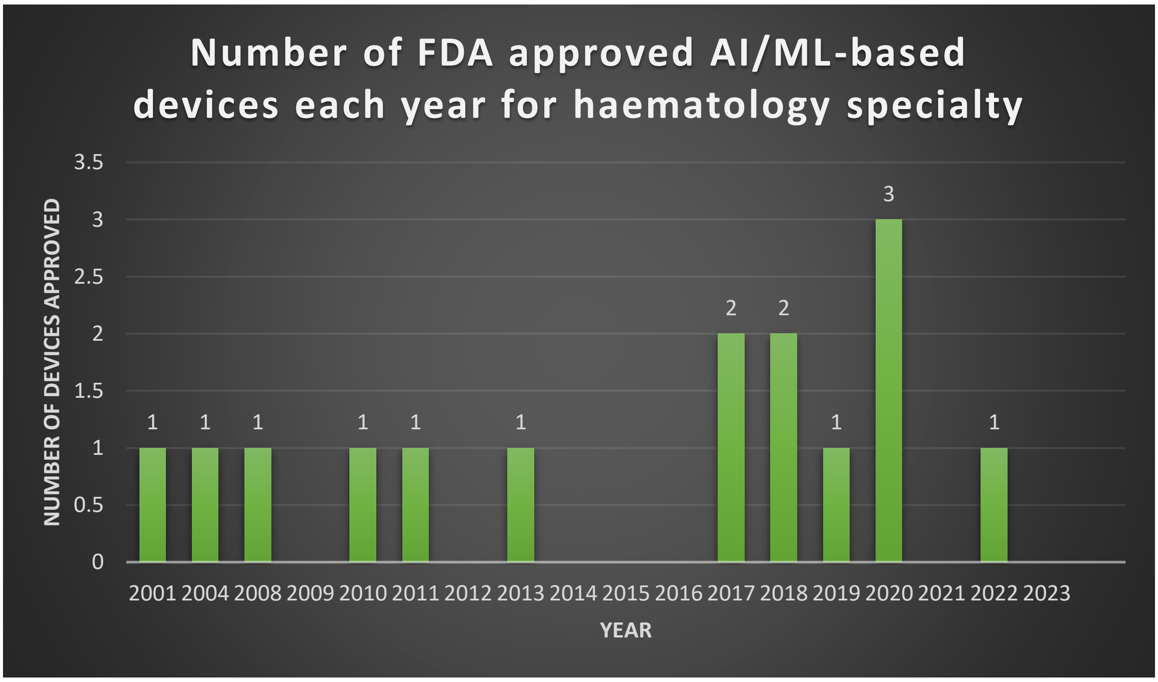


Figure 17: Number of FDA approved AI/ML-based medical devices for haematology specialty (2008-2023)

In Figure 17, we can see that device approvals for the haematology specialty began the earliest of all the top four specialties, with the first device coming to market in 2001, seven years before the first device approval for radiology (Figure 14) was granted). The reasons for this are unclear, however it could be as AI may play an important role in technologies identifying diagnostic biomarkers, or could also establish reliable quality databases for blood products, enabling efficient management of the manufacturing and clinical application of blood.[35]

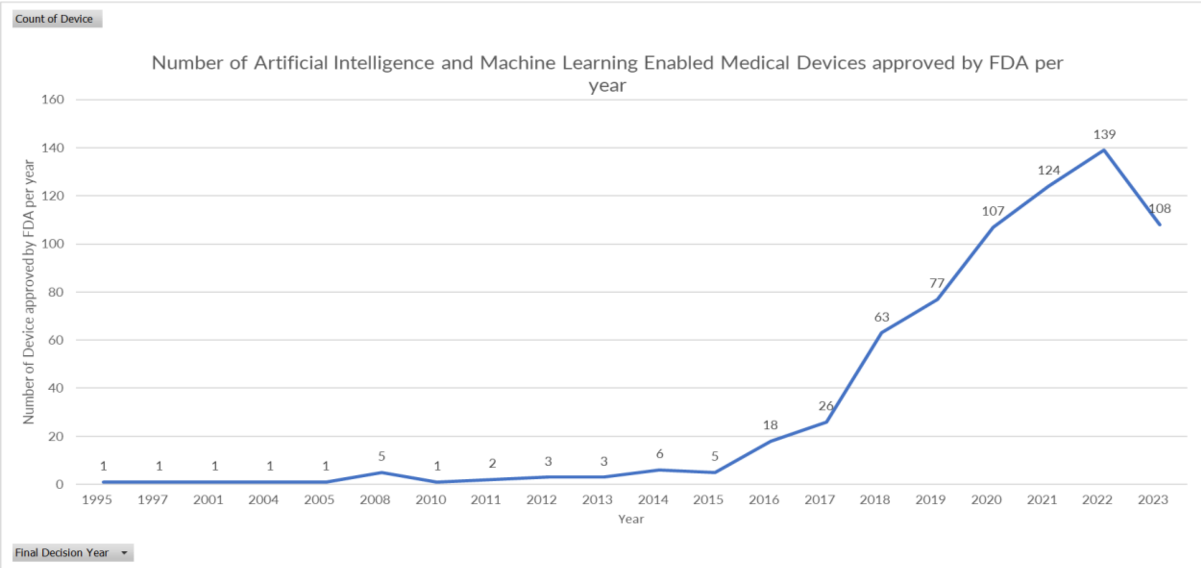


Figure *18*: Number of AI/ML- based health technologies approved per year by FDA

As shown in Figure 18, the trend in AI/ML enabled medical devices approved by the FDA from 1995 to 2023 is presented. In 2008, AI/ML enabled medical devices development experienced a temporary spike before returning to baseline levels until 2014, when it began to accelerate. This acceleration has continued and is expected to continue as AI/ML technology advances and becomes more accessible. AI/ML enabled medical devices are expected to play a critical role in the healthcare industry in the coming years.

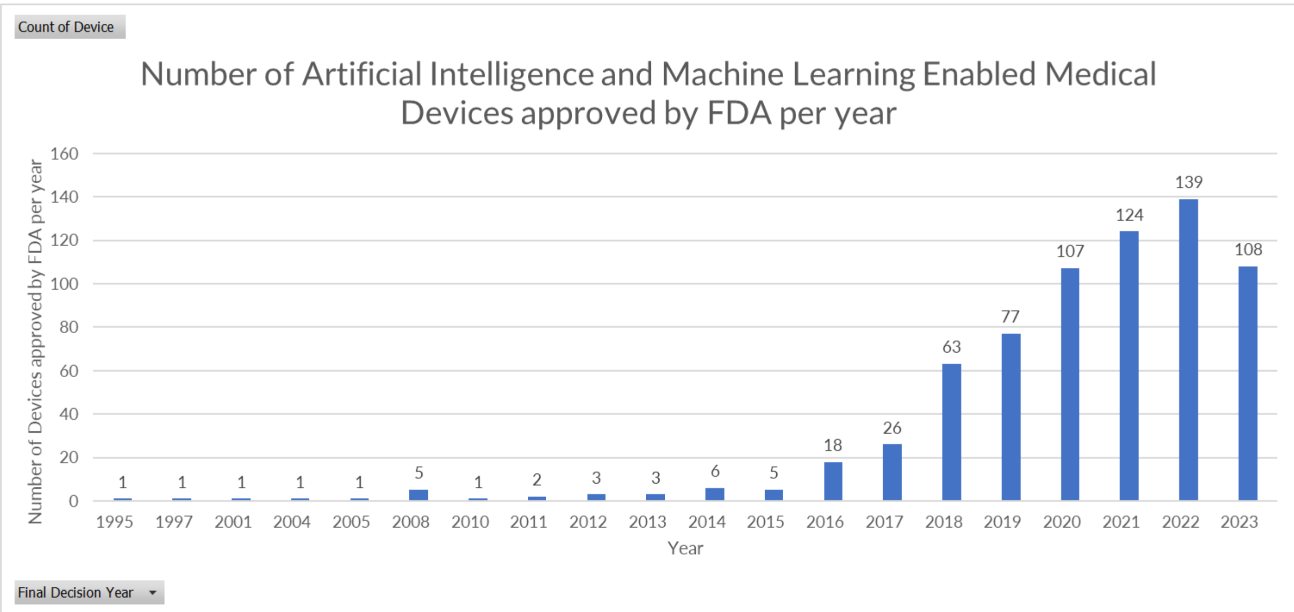


Figure 19: Number of FDA approved AI/ML-based medical devices between 1995 and 2023

A further visualisation of the trend in AI/ML enabled medical devices approved by the FDA from 1995 to 2023 is provided in Figure 19. There were 139 devices approved in 2022, which was the highest number ever. The number of AI/ML based health technologies approved by the FDA remained relatively constant until 2014, where it appears development began to rapidly accelerate (Figure 18 and 19). Reasons why AI/ML development began to accelerate during this time include increasing availability of multimodal datasets, advancements in cloud computing used with AI, and increasing innovation of AI based health technologies and AI technologies more generally. [8,36]

The rapid rise in development between 2020 and 2022 may be due to the COVID19 pandemic (Figures 18 and 19). There was an urgent need for remote monitoring and assessment of patients to limit in person appointments to prevent disease transmission, which may have fuelled rapid development and accelerated the use of these technologies in clinical practise.

There was a temporary spike in AI/ML medical technology development in 2008, before returning to base levels until 2014 (Figure 18 and 19). A possible reason for this spike was the H1N1 pandemic, which like COVID19 pandemic would have created a need to manage patients remotely to limit transmission. However, due to technology not being as advanced as by 2014, and limited availability of cloud computing and big data sets. This would have limited innovation, and potentially explains why development returned to base levels for a further 6 years (Figure 18).

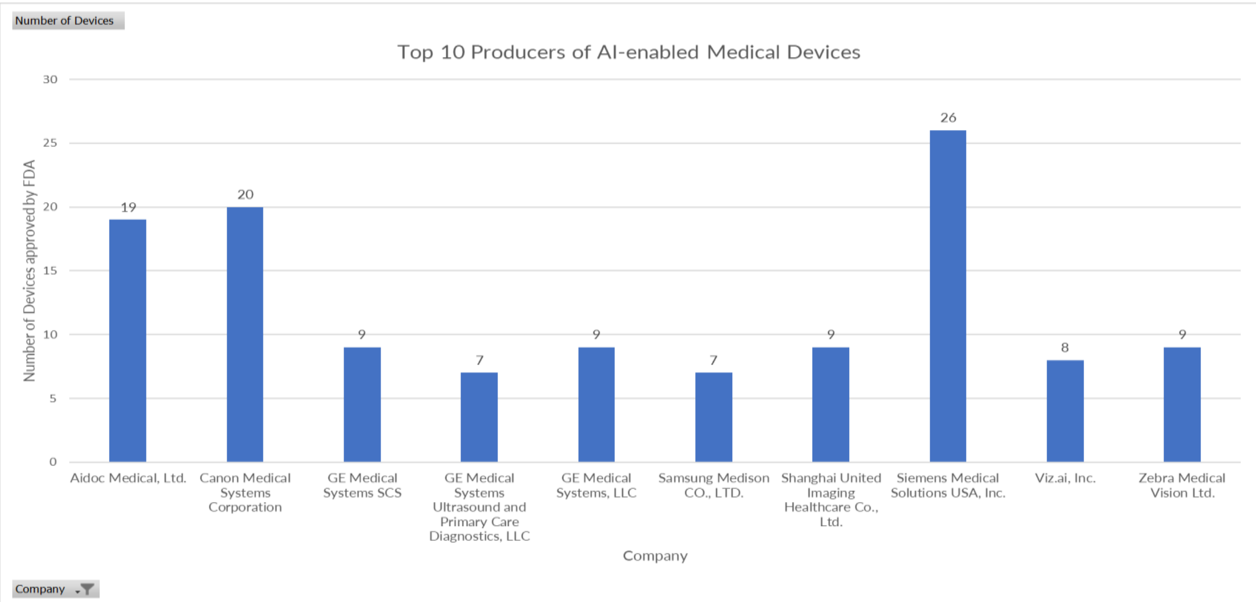


Figure 20: The top 10 producers of AI/ML based medical technologies.

Analysis was also undertaken to identify the top producers of AI/ML based medical technologies, as illustrated in Figure 20. Siemens Medical Solution US, Inc is the largest producer of these technologies. Further analysis showed the top 3 producers from these companies predominantly produced devices within the radiology category. This may be because this area is so diverse and includes many technology types, or that this area may have the greatest profit potential. The radiology device panel includes a diverse range of devices which could be used in diagnosis, management and treatment of multiple conditions. The types of devices included within this speciality (for example, CT scanners), would be excellent candidates for development with AI capabilities for tasks such as disease diagnosis.

4.0 Conclusion

The report shows that Asia is the region with the greatest number of clinical trials in development that employ AI, ML, and DL as part of their interventional or observational studies. About 650 AI-based healthcare technologies are currently in development both in Europe and the United Kingdom (Fig 9). Although this is a fair number, there is a need for more to ensure that many of these technologies will eventually be available for use in the EU/UK.

In order to improve collaboration between industry and academia, more industry sponsored clinical trials are required. These clinical trials would provide a direct benefit to the companies that sponsor them, as well as to the medical and scientific communities. They would allow for the industry to learn more about their products and to access the latest research in the field, as well as to provide funding for research. The development of AI, ML and DL technologies for use in the management of cancer and cardiovascular disease appears to be very significant, this study reveals other conditions such as neurological and respiratory conditions that could benefit from AI, ML and DL.

Advancements in AI have created new possibilities for addressing a variety of healthcare-related problems. AI, ML and DL innovations will continue to play a critical role in improving efficiency and diagnostic precision, enabling healthcare professionals to provide patient-centred care and eliminate variations in patient management. AI/ML/DL-based medical technologies may also address inequalities within both global and regional healthcare systems, improving patient outcomes. However, care must be taken to ensure further disparities in patient management do not arise as a result of unequal access to AI-based medical technologies. The substantial number of approved devices highlight the need to ensure rigorous regulation of these devices. Currently, there is no specific regulatory pathway for AI/ML/DL-based medical devices in the USA or Europe.

To our knowledge there is no comprehensive analysis of AI/ML/DL-based medical devices approved in the USA and Europe. Attempts to widely assess AI/ML/DL-based medical devices might have been hampered by the absence of a publicly available register of approved medical devices in Europe (by contrast to the USA), the confidentiality of information submitted to the Notified Bodies and regulators, and the decentralised nature of approval decisions.

Overall, our analysis shows a high number of promising innovations in the AI, DL and ML space which could be of significance in the diagnosis, management and prevention of varying health conditions and contributing positively to the economy.

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