Systematic Review Article

**Artificial intellegence in Medical Research: Ethical and Regulatory Challenges in Developing Economies**

**ABSTRACT**

**Introduction**

Clinical research is a key area in which the use of AI in healthcare data seen a significant increase, even though met with great ethico-legal and regulatory challenges. Artificial Intelligence (AI) concerns the ability of algorithms encoded in technology to learn from data, to be able to perform automated tasks without every step in the process being explicitly to be programmed by a human. AI development relies on big data collected from clinical trials to train algorithms, that requires careful consideration of consent, data origin and ethical standards. When data is acquired from third-party sources, transparency about collection methods, geographic origin and anonymization standards becomes critical. While consent forms used in clinical trials can offer clearer terms for data use, ambiguity remains about how this data can be reused for AI purposes after the trial ends. There are very few or no laws on the use of AI especially in developing countries. Also, there are a lot of misconceptions on the global use of AI.

**Statement of objectives:**

Artificial intelligence as an innovative technology has contributed to a shift in paradigm in conducting clinical research. Unfortunately, AI faces ethical, and regulatory challenges especially in limited resource countries where the technology is still to be consolidated. One of the main concerns of AI involves data re-identification, in which anonymized data can potentially be traced back to individuals, especially when linked with other datasets. Data ownership is also a complex and often controversial area within the healthcare sector. AI developers needs to clearly explain the value of data collection to hospitals and cybersecurity teams to ensure that they understand how the data will be secured and used ethically

**Methodology**

The World Health Organization (WHO) recognizes that AI holds great promise for clinical health research and in the practice of medicine, biomedical and pharmaceutical sciences. WHO also recognizes that, to fully maximize the contribution of AI, there is the need to address the ethical, legal and regulatory challenges for the health care systems, practitioners and beneficiaries of medical and public health services. In this study we have pulled data from accessible websites, peered reviewed open-access publications that deal with the ethical and regulatory concerns of AI, that we have discussed in this writeup. We have attempted to place our focus on the development of AI and applications with particular bias in the ethical and regulatory concerns. We have discussed and given an insight on whether AI can advance the interests of patients and communities within the framework of collective effort to design and implement ethically defensible laws and policies and ethically designed AI technologies. Finally, we have investigated the potential serious negative consequences of ethical principles and human rights obligations if they are not prioritized by those who fund, design, regulate or use AI technologies for health research.

**Results:**

From our data mining and access to multiple documentations, vital information has been pooled together by a systematic online search to show that AI is contributing significantly in the growth of global clinical research and advancement of medicine. However, we observed many ethical and regulatory challenges that has impacted health research in developing economies. Ethical challenges include AI and human rights, patient’s privacy, safety and liability, informed consent and data ownership, bias and fairness.

For the legal and regulatory challenges, we observed issues with data security compliance, data monitoring and maintenance, transparency and accountability, data collection, data storage and use. The role of third-party vendors in AI healthcare solutions and finally AI development and integration into the health systems has also been reviewed.

**Conclusion**

The advancement of AI, coupled with the innovative digital health technology has made a significant contribution to address some challenges in clinical research, within the domain of medicine, biomedical and pharmaceutical products development. Despite the challenging ethical and regulatory challenges AI has impacted significant innovation and technology in clinical research, especially within the domain of drug discovery and development, and clinical trials studies.

**Key words**- ethical, regulatory, clinical research, Artificial intelligence, big data, health systems

**INTRODUCTION**

“Artificial intelligence (AI), generally refers to as the performance by computer programs of tasks that are commonly associated with intelligent human beings” [1]. “The basis of AI is algorithms, which can be translated into computer code that carries instructions for rapid analysis and transformation of data into conclusions, information or other outputs” [2,3]. “Big data and the capacity to analyze such data are the test batteries that rapidly drives AI. The specific definition of AI as recommended by the Council on Artificial Intelligence (CAI), of the OECD” [3, 4] “states that: The various types of AI technology include machine-learning applications such as pattern recognition, natural language processing, signal processing and expert systems” [5-7]. “Machine learning, which is a subset of AI techniques, is based on use of statistical and mathematical modelling techniques to define and analyze data. The learned patterns can then be applied to perform or control certain tasks and make predictions. Artificial intelligence (AI) cannot fully replace human intelligence. While AI excels at specific tasks like data processing and pattern recognition, humans remain irreplaceable for complex reasoning, creativity, emotional intelligence, and genuine innovation. AI is more accurately seen as a tool to augment human capabilities, not a replacement for them” [5].

**Machine Learning**.

“Machine learning can be grouped based on how it learns from data into the following categories; supervised learning, unsupervised learning and reinforced learning [8]. In supervised learning, data that are used for the training of the model are labelled, as the outcome variable is known, and the model infers a function from the data that can be used for predicting outputs from different inputs” [9]. “Unsupervised learning does not involve labelling data but involves identification of hidden patterns in the data by a machine. Reinforcement learning involves machine learning by trial and error to achieve an objective for which the machine is either rewarded or penalized, depending on whether its inferences reach or hinder achievement of an objective [9]. Deep learning, also known as deep structural learning, is a family of machine learning based on the use of multi-layered models to progressively extract features from data. Deep learning can be supervised, unsupervised or semi-supervised. Deep learning generally requires large amounts of data to be fed into the model” [9,10].

“Many machine-learning approaches are data-driven. They depend on large amounts of accurate data, referred to as big data, to produce tangible results. Big data are complex data that are rapidly collected in such unprecedented quantities like that of **terabytes** (one trillion units [bytes] of digital information), **petabytes** (1000 terabytes) or even **zettabytes** (one million petabytes) of storage space may be required as well as unconventional methods for their handling. The unique properties of big data are defined by four dimensions: volume, velocity, veracity and variety. AI could improve the delivery of health care, such as prevention, diagnosis and treatment of disease” [9], and is already changing how health services are delivered in several high-income countries (HIC), notwithstanding the impact at a slow pace in developing economies, through a North-South collaboration research effort [10]

“The possible applications of AI for health and medicine are expanding continually, although the use of AI may be limited outside HIC because of inadequate infrastructure. The applications can be defined according to the specific goals of use of AI and how AI is used to achieve those goals (methods). In health care, usable data have proliferated as a result of collection from numerous sources, including wearable technologies, genetic information generated by genome sequencing, electronic health-care records, radiological images and even from hospital rooms” [10, 11].

Currently, healthcare sector faces multiple and complex challenges, such as the increased cost of drugs and therapies which calls the communities and society to need more specific significant changes in addressing their health needs [3,11]. With the advent of AI in the manufacturing of pharmaceutical products, personalized medications with the desired dose, release parameters, and other required aspects can now be manufactured based on individual patient needs [5, 12]. With the application of innovative AI-based technologies there has been reduction of the time needed for the products to come to the market, as well as improvement of the quality of products and the overall safety of the production process, providing a better use of the available resources at a cost-effective level. The increase importance of automation with the advert of AI is significant at all level of the drug development process. [12, 13].

**Artificial Intelligence (AI) and Ethical Research**

There is also consideration analysis of the ethical challenges of AI in healthcare. Four ethical challenges have been widely exploited such as; informed consent, safety and transparency, algorithmic fairness and biases, and data privacy [14]. Within the regulatory framework, there is great focus on safety and effectiveness, liability, data protection and privacy and finally cybersecurity as shown in table 1.

**Table 1 Ethical and Legal debates in AI. [1]**

|  |  |
| --- | --- |
| **Ethical Challenges** | **Legal Challenges** |
| Informed consent to use | Safety and effectiveness |
| Safety and transparency | Liability |
| Algorithmic fairness and biases | Data protection and privacy |
| Data privacy | Cybersecurity |
|  | Intellectual property law |

Digital technologies and artificial intelligence (AI), particularly machine learning, have transformed clinical research and medicine practice to an innovative level. Technologies based on AI are now used in health services both in the Northern and southern hemisphere, and its utility is being assessed in low- and middle-income countries (LMIC) [15, 16]. It is important to note that safe use of new technologies, including AI, can bring about a global achievement of the United Nations Sustainable Development Goal 3, dealing with health- related objectives [1] AI can contribute in meeting the global commitments of achieving universal health coverage [17]..

Use of AI for clinical research has raised a global ethical-legal, regulatory, socio-cultural and commercial concerns, even though most of these concerns are global and not targeted only to AI [18]. The use of software and computational technology in clinical research has challenged developers, governments and health care providers for many decades, and AI poses new ethical challenges that extend beyond the confines of traditional regulators and participants in health-care systems. These ethical challenges must be adequately addressed if AI is to be widely used to improve human health, to preserve human autonomy and to ensure equitable access to such technologies [19].

The sse of AI technologies for health holds great promise and has already contributed to important advances in fields such as drug discovery, genomics, radiology, pathology and prevention. AI could assist health-care providers in avoiding errors and allow clinicians to focus on providing care and solving complex cases. The potential benefits of these technologies and the economic and commercial potential of AI for public health management with respect bigger global application [6, 20].

The performance of AI depends mainly on the nature, type and volume of data and associated information, and the conditions under which such data are generated [21]. The search for research data could compromise privacy and autonomy at the service of state or private institutional surveillance and commercial interest. If privacy and autonomy are not guaranteed, the effect of limitation of the ability to exercise the full range of human rights, including civil and political rights (such as freedom of movement and expression) and social and economic rights (such as access to health care and education), might have a wider global implication [22].

AI technologies used in clinical research, are normally designed by companies or through public–private partnerships (PPPs), and many governments also develop and use these technologies, most of the world’s largest tech-companies are developing new applications and services over which they have the intellectual property rights or for which they have done the sole investment. Many of these companies have already stored large amounts of data, including health data, and have a significant control in society and the economy [1, 23]. Although these companies may offer innovative approaches, there are big concerns that they might may take control of the state, health care providers and patients

Currently, there is limited comprehensive international guidance on use of AI for health in accordance with ethical norms and human rights standards. Most countries do not have laws or regulations on the use of AI technologies for health care, and their existing laws may not be adequate or specific enough for this purpose [22]. WHO recognizes that ethical guidelines based on the shared perspectives of the different entities that develop, use or oversee AI technologies are crucial to build trust in these technologies, to guard against negative effects and to avoid the development of many contradictory guidelines. Harmonized ethical guidelines are a welcome factor necessary for the design and implementation of AI for global health management most especially within the framework of ‘One Health’ [23].

The Ministries of health are the principal actors of health management and therefore they are responsible to determine how to introduce, integrate and harness the AI technologies to be introduced into their country, and regulating, restricting or prohibiting inappropriate use. The development, adoption and use of AI requires an integrated, coordinated approach among government ministries beyond that for health. The stakeholders also include regulatory agencies, that are in charge of validating and to define how and when the AI technologies can be used. The Ministries of Education are responsible for educating health personnel the digital health technologies on the functioning of these technologies and its integration to routine practices [24].

The ministries of information technology can facilitate the appropriate collection and use of health data and narrow the digital divide and then the countries’ legal systems can ensure that population exposed to AI technology are protected legally for any negative effects cause by AI [25].

**METHODOLOGY**

Our study strategy was to access and search the source documents from organizations, access to websites and google search to assemble our information, through data mining. The google search gave us information on AI, big data, regulations and ethical issues on digital health technology and AI tools related to clinical research. Vital web information, scientific reports of organizations were accessible for easy navigations. WHO recognizes that AI holds great promise for clinical health research and in the practice of medicine, biomedical and pharmaceutical sciences. WHO also recognizes that, to fully maximize the contribution of AI, there is the need to address the ethical, legal and regulatory challenges for the health care systems, practitioners and beneficiaries of medical and public health services. We pulled data from accessible websites, peer-reviewed open- access publications that deals with the ethical and regulatory concerns of AI that we have discussed in this writeup. We have also focused on the development of AI and applications with the ethical and regulatory concerns [22]. We have given an insight on whether AI can advance the interests of patients and communities within the framework of collective effort to design and implement ethically defensible laws and policies and ethically designed AI technologies. Finally, we investigated the potential serious negative consequences if ethical principles and human rights obligations are not prioritized by those who fund, design, regulate or use AI technologies for health and discuss on link between AI’s opportunities and ethical and regulatory challenges [2].

**RESULTS:**

**Applications of AI to Clinical Health research**

“This section identifies AI technologies developed and used in developed countries, although examples of such emerging technologies are being pilot-tested or used in developing economies. Digital health technologies are already widely in use in some LMIC, including data collection, dissemination of health information by mobile phones and extended use of electronic medical records on open-software platforms and cloud computing” [11]. Schwabe and Wahl [12] have identified four uses of AI for health in LMIC: diagnosis, morbidity or mortality risk assessment, disease outbreaks and surveillance, and health policy and planning.

**AI in the health care sector for disease diagnosis and prediction.**

“The use of AI in medicine raises notions of AI replacing clinicians and human decision making. The prevailing sentiment is, however, that AI is increasingly improving diagnosis and clinical care, based on earlier definitions of the role of computers in medicine” [14] and “regulations in which AI is defined as a support tool (to improve judgement) . AI is being considered to support diagnosis in several ways, including in radiology and medical imaging. Such applications, while more widely used than other AI applications, are still relatively novel, and AI is not yet used routinely in clinical decision-making. So far, AI has been evaluated for use in radiological diagnosis in oncology (thoracic imaging, abdominal and pelvic imaging, colonoscopy, mammography, brain imaging and dose optimization for radiological treatment), in non-radiological applications (dermatology, pathology), in diagnosis of diabetic retinopathy, in ophthalmology and for RNA and DNA sequencing to guide immunotherapy” [15]. In LMIC, AI may be used to improve detection of tuberculosis in a support system for interpreting staining images [16] or for scanning X-rays for signs of tuberculosis, COVID-19 or 27 other conditions [17].

“AI might be used to predict illness or major health events before they occur. For example, an AI technology could be adapted to assess the relative risk of disease, which could be used for prevention of lifestyle diseases such as cardiovascular disease” [25, 26] and diabetes [27]. “Another use of AI for prediction could be to identify individuals with tuberculosis in LMIC who are not reached by the health care system and therefore do not know their status” [28]. “Predictive analytics could avert other causes of unnecessary morbidity and mortality in LMIC, such as birth asphyxia. An expert system used in LMIC is 77% sensitive and 95% specific for predicting the need for resuscitation” [11].

**AI in Clinical care**

“Clinicians might use AI to integrate patient records during consultations, identify patients at risk and vulnerable groups, as an aid in difficult treatment decisions and to catch clinical errors. In LMIC, for example, AI could be used in the management of antiretroviral therapy by predicting resistance to HIV drugs and disease progression, to help physicians optimize therapy” [28]. “Yet, clinical experience and knowledge about patients is essential, and AI will not be a substitute for clinical due diligence for the foreseeable future. If it did, clinicians might engage in “automation bias” and not consider whether an AI technology meets their needs or those of the patient. The wider use of AI in medicine also has technological challenges. Although many prototypes developed in both the public and the private sectors have performed well in field tests, they often cannot be translated, commercialized or deployed. An additional obstacle is constant changes in computing and information technology management, whereby systems become obsolete (“software erosion”) and companies disappear. In resource-poor countries, the lack of digital infrastructure and the digital divide will limit use of such technologies” [5].

**Ethical and regulatory laws governing health research and Digital health technology in Cameroon**

To have an insight into the ethical and regulations laws of health research in Cameroon, and on a global scale, we have put together laws, decrees and ministerial circulars that regulates health research in Cameroon as illustrated in Table 1. International Regulation guide line on health research is outlined in table 2.

|  |  |  |  |
| --- | --- | --- | --- |
| **Table 2. National laws, decrees and ministerial circulars that regulate health research in Cameroon and International Regulation and guide lines on global health research** | | | |
| No | **National Laws/Decrees/Orders** | **National Decisions/Guidelines** | **International/Regional regulations** |
|  | Constitutional Law N° 96/06 of 18 January 1996  Law No 2024/017/23 December 2024 relating to the protection of personal data in Cameroon.  Law No 2024/018 of 23 December 2024 relating to the practice and organization of traditional medicine in Cameroon.  Law No 2022/008/27AVR 2022 relating to Medical Research involving human subjects in Cameroon.  Law No 2016/007 of 12 July 2016 relating to the Penal code of Cameroon.  Law No 2010/012 du 21 Dec 2010 relating to cybersecurity and cyber-criminality in Cameroon.  Cameroon Civil Code (Code Civil 2007, Yaoundé-Cameroun)  Law N° 2003/003 of 21 April 2003 relating to phytosanitary protection.  Law N° 2000/011 of 19 December 2000 relating to authors and neighbors’ rights in Cameroon.  Law N˚ 96/12 of 5 August 1996 law in the management of the Environment in Cameroon  Law No 90/035 of 10 August 1990 relating to the organization of the Pharmacy profession in Cameroon.  Law N° 90-36 of 10 August 1990 relating to practice and organization of the medicine profession in Cameroon.  Presidential decree No 2005/091 of March 2005 relating to the organization of Ministry of Scientific Research.  Presidential decree N˚ 2005/117 of 14 April 2005 relating to organization of Ministry of Environment and Nature Protection  Presidential decree No 2002/209 of 19 August 2002 relating to organization of the ministry of Public Health.  Presidential decree N˚ 2005/142 of April 2005 relating to the organization of the Ministry of Higher Education.  Decree No 98-405/PM of 22 Oct 1998. Fixing modalities for homologation of marketing authorization procedures of pharmaceutical products in Cameroon.  Decree n˚ 83-166 of 12 April 1983 Fixing the code of ethics and deontology of Doctors in Cameroon.  Order N˚ 079/A/MSP/DS of the Minister of Public Health of 22 October 1987 relating to the creation and organization of National ethics Committee for research in human subjects.  Order N˚ 0977/A/MINSANTE/SESP/SG/DROS of 18 April 2012 relating to the creation, organization and functioning of National ethics Committees for research in human subjects under the framework of the ministry of public health. | Decision No/2051/D/MINSANTE/SESP/SG/DROS/ of 10 May 2023 Appointing members of the national ethics committee for research in human subjects in Cameroon.  Ministerial Circular of Public Health (MSP) No 36-13/LC/MINSANTE/SG/DROS/YC of 03 February 2011 relating to conducting health research in Cameroon.  Decision N° 0689 /D/MINSANTE/SG/DROS of 29 July 2009 fixing condition for administrative authorization of health research in Cameroon.  Ministerial Circular N° 07 du 13 July 1981 of Ministry of Public Health fixing regulation and approval of pharmaceutical products.  Decision N˚0674/D/MSP/CIRCB of 13 October 2006 fixing the composition of ethics committee of Chantal Biya International Reference Centre (French acronym *CIRCB*) for research in Prevention of HIV/AIDS.  Revised Standard Operating Procedures for Research Ethics Committees (RECs) in Cameroon, 2023.  Guide on good practice for the creation, organization and functioning of the national ethics committee for research in human subjects, Minsante 2013. | Convention on Biological Diversity, 1992.  Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity, 29 Oct. 2010.  The African Union Convention on Cybersecurity and Personal Data Protection of 27 June 2014.  The Bangui Agreement Relating to the Creation of an African Intellectual Property Organization, Act of Bamako of 14 December 2015.  Regulation No 5/13-UEAC-OCEAC-CM-SE-2 on the Referential for the Harmonization of Approval Procedures for Medicinal Products for Human Use within the CEMAC. CEMAC Regulation No. 4/13-UEAC-OCEAC-CM-SE-2 adopting the procedures manual for pharmaceutical inspection. Directive No. 07/08-UEAC-133-CM-18 on the legal framework for the protection of the rights of users of electronic communications networks and services within the CEMAC.  Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.  WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Participants 2024 And By The 75 WMA General Assembly, Helsinki, Finland, October 2024.  Referential directives for harmonization of the homologation procedure of medicines issued from traditional pharmacopoeia in OAPI countries, OAPI, 2024.  European Medicines Agency EMA/212507/2021 of 18 June 2024: Guidance document on how to approach the protection of personal data and commercially confidential information while using the Clinical Trials Information System (CTIS) Version 2  The European Medicines Agency scientific guidelines on human medicines that are harmonized by the International Council for Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).  Good Clinical Practice: Integrated Addendum to ICH E6(R1) Guidance for Industry. U.S. Department of Health and Human Services,  Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), March 2018.  Council for International Organizations of Medical Sciences (CIOMS), International Ethical Guidelines for Health-related Research Involving Humans, Geneva 2016. |

From our data mining vital information has been pooled together by a systematic online search to show that AI is contributing significantly in the growth of global clinical research and advancement of medicine. However, we observed many ethical and regulatory challenges that has impacted health research in developing economies. Ethical challenges include AI and human rights, patient’s privacy, safety and liability, informed consent and data ownership, bias and fairness [29]. For the legal and regulatory challenges, we observed Data security compliance, Data monitoring and maintenance, transparency and accountability, data collection, data storage and use. The role of third-party vendors in AI healthcare solutions and finally AI development and integration into the health systems. Laws and regulations on artificial intelligence in clinical research. Several ethical challenges associated with the use of AI for resource allocation and prioritization [30].

**Laws and regulations on artificial intelligence in clinical research**

“Laws, policies and principles for regulating and managing the use of AI and specifically use of AI for health are fragmented and limited. Numerous principles and guidelines have been developed for application of health research and data security/criminality and personal in a country like Cameroon for AI in the private and public sectors and in research institutions” [31, 32]. There is no consensus on the definition AI, best practices or ethical requirements, and different legal regimes and governance models are associated with each set of principles. Other norms, rules and frameworks also apply to use of AI, including human rights obligations, bioethics laws and policies, data protection laws and regulatory standards. These are summarized below and discussed elsewhere in the report. Section 5 provides a set of guiding principles agreed by the WHO Expert Group by consensus, on which this analysis and these findings are based.

**Artificial intelligence and human rights**.

There are many laws, regulations and guidelines for the regulation of clinical research. WHO working in collaboration with many governments and country representatives has advanced the regulation of clinical research on a global scale. The laws, decrees and guidelines regulating clinical and health research has been summarized in table 1, and other international regulation has been elucidated. “Efforts to enumerate human rights and to fortify their observance through explicit legal mechanisms are reflected in international and regional human rights conventions, including the Universal Declaration on Human Rights, the International Covenant on Economic, Social and Cultural Rights which defines the right to health, the International Covenant on Civil and Political Rights and regional human rights conventions, such as the African Charter on Human and People’s Rights, the American Convention on Human Rights and the European Convention on Human Rights” [33]. Not all governments have acceded to key human rights instruments; some have signed but not ratified such charters or have expressed reservations to certain provisions. In general, however, human rights listed in international instruments establish a baseline for the protection and promotion of human dignity worldwide and are enforced through national legislation such as constitutions or human rights legislation.

“Machine-learning systems could advance human rights but could also undermine core human rights standards. The Office of the High Commissioner for Human Rights has issued several opinions on the relation of AI to the realization of human rights. In guidance issued in March 2020, the Office noted that AI and big data can improve the human right to health when new technologies are designed in an accountable manner and could ensure that certain vulnerable populations have efficient, individualized care, such as assistive devices, built-in environmental applications and robotics. The Office also noted, however, that such technologies could dehumanize care, undermine the autonomy and independence of older persons and pose significant risks to patient privacy – all of which are contrary to the right to health” [34].

**Data protection laws and policies**

“The European Union’s AI Act presents a compelling model for regulating AI by adopting a risk-based approach. Under this framework, healthcare data falls into a high-risk category, necessitating stringent quality controls and ethical standards. This approach emphasizes data accuracy, fairness and robustness, addressing many concerns surrounding the ethical implications of using AI in healthcare. The risk-based model is particularly well-suited to managing the complexities of health data, ensuring a high standard of data quality without impeding innovation” [35]. “Cybersecurity is another critical issue, as health data is particularly vulnerable to breaches, which can lead to identity theft, fraud and other risks. Ethical concerns also come into play, as improper use of health data can result in negative public reactions and erode trust in both healthcare providers and AI technologies” [5]. “Data protection laws are rights-based approaches that provide standards for regulating data processing that both protect the rights of individuals and establish obligations for data controllers and processors. Data protection laws also increasingly recognize that people have the right not to be subject to decisions guided solely by automated processes. Over 100 countries have enacted data protection laws. One well-known set of data protection laws is the General Data Protection Regulation (GDPR) of the European Union (EU); in the USA, the Health Insurance Portability and Accountability Act, enacted in 1996, applies to privacy and to the security of health data” [37].

**Data sharing**

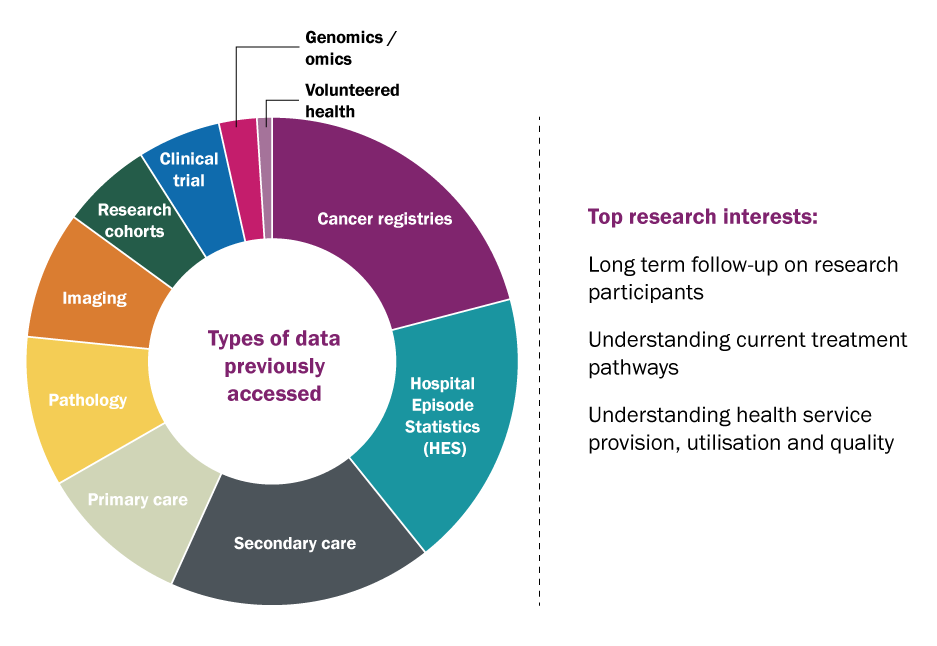
“Clear ownership rights allow responsible data-sharing. Developing clear data ownership frameworks is essential. Establishing precise guidelines around data ownership, particularly for clinical trials and healthcare provider data, will promote transparency and reduce conflicts over data usage. Clear ownership rights can provide a foundation for responsible data-sharing practices. Enhanced communication with healthcare providers is equally crucial. AI developers should engage in open communication, explaining technical and regulatory terms in a way that is accessible to hospital staff and cybersecurity teams” [38]. “Adopting a risk-based regulatory approach, similar to the EU AI Act, would create a flexible yet high-standard regulatory environment. This approach would classify health data use as high-risk, enforcing stringent controls while still fostering technological advancements” [39]. “Public education on data security and ethics is also vital. Educating the public on data security practices and ethical AI use can help build trust and address common concerns about data privacy and AI. Public awareness initiatives can clarify why certain data is collected and how it is protected, further reinforcing confidence in these technologies” [5, 38].

**Existing laws and policies related to health data**

“Several types of laws and policies govern the collection, processing, analysis, transfer and use of health data. The Council of Europe’s Committee of Ministers issued a recommendation to Member States on the protection of health-related data in 2019” [40-42] and “the African Union’s convention on cybersecurity and personal data protection (2014)” [41-43] requires that personal data involving genetic information and health research be processed only with the authorization of the national data protection authority through the Personal Data Protection Guidelines for Africa [44]. “Generally, the African continent’s digital transformation strategy [45] encourages African Union Member States to have adequate regulation; particularly around data governance and digital platforms, to ensure that trust is preserved in the digitalization. Laws that govern the transfer of data among countries include those defined in trade agreements, intellectual property (IP) rules for the ownership of data and the role of competition law and policy related to the accumulation and control of health data” [46].

**Approaches to reduce barriers to data access**

“Several solutions to existing barriers to use of data for AI have been exploited and reports show that there are opportunities for data owners or custodians to provide more support throughout the health data access process. There is a strong push for clear and efficient data access guidelines to address the apparent lack of clarity around who owns the data, what data is accessible and how much it will cost to access the data and maintain access” [47]. “Researchers and clinicians are advised to seek guidance on their projects early to ensure the quality of the proposal is sufficient and the data request is reasonable, but it is not always clear who to contact or what constitutes a reasonable request. It seems often researchers feel left ‘in the dark’ regarding health data, which is probably also why ‘support through data access process’ was the most listed response when researchers were asked where they felt more help was needed” [48]. Enabling secondary use of health data is the cornerstone of creating an open health ecosystem as illustrated in figure 1.



**Figure 1: Types of data and data access [2]**

**Major challenges on data accessibility**

There has been less information flow on how to apply the European General Data Protection Regulation (GDPR) to enable secondary use of health data while maintaining strong data privacy and protections [48]. Fragmented initiatives and approaches have hindered most country’s ability to support each other or encourage widespread participation in data sharing. The lack of concrete agreement on common data models and open standards have created barriers for interoperability and reuse of health data Limited focus and priority on identifying opportunities to use secondary health data to reduce health inequalities is also a strong negative factor for the AI technology innovation for big data management [49]. These challenges have been elaborated in Figure 2 with the secondary use of health data in the European regions.

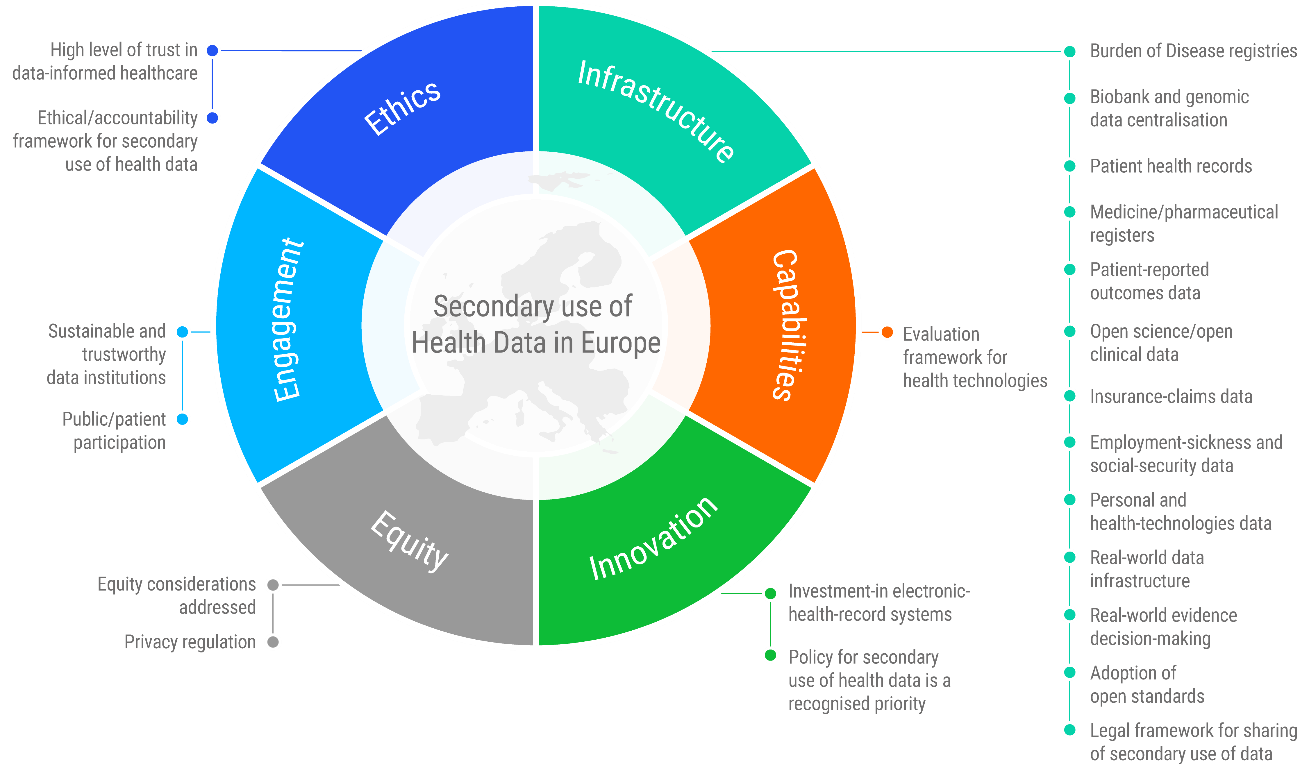


Figure 2. Secondary use of health data in European regions [40]

**Bioethics laws and policies on AI**

“Bioethics laws and policies play a role in regulating the use of AI, and several bioethics laws have been revised in recent years to include recognition of the growing use of AI in science, health care and medicine The French Government’s most recent revision of its national bioethics law” [49], which was endorsed in 2019, “establishes standards to address the rapid growth of digital technologies in the health-care system. It includes standards for human supervision, or human warranty, that require evaluation by patients and clinicians at critical points in the development and deployment of AI. It also supports free, informed consent for the use of data and the creation of a secure national platform for the collection and processing of health data” [50].

**AI Regulatory considerations**

“Regulation of AI technologies is likely to be developed and implemented by health regulatory authorities responsible for ensuring the safety, efficacy and appropriate use of technologies for health care and therapeutic development. A WHO expert group that is preparing considerations for the regulation of AI for health has discussed areas that should be considered by stakeholders, including developers and regulators, in examining new AI technologies” [49, 50]. They include documentation and transparency, risk management and the life-cycle approach, data quality, analytical and clinical validation, engagement and collaboration, and privacy and data protection. Many regulatory authorities are preparing considerations and frameworks for the use of AI, and they should be examined, potentially with the relevant regulatory agency. Governance of AI through regulatory frameworks and the ethical principles that should be considered

**Major ethical challenges of AI in clinical research**.

“AI is transforming the future of healthcare from discovery to diagnosis to delivery. However, AI ethics is a complex and multidimensional issue with considerations that include” [51]

“AI heavily influences many industries and fields, including agriculture and farming, manufacturing and production, autonomous vehicles, fashion, sports analytics and activities, healthcare, and the medical system. This technology has the power to impact the future of the industry and human beings, but it is a double-edged sword.AI applications in healthcare have literally changed the medical field, including imaging and electronic medical records (EMR), laboratory diagnosis, treatment, augmenting the intelligence of the physicians, new drug discovery, providing preventive and precision medicine, biological ex-tensive data analysis, speeding up processes, data storage and access for health organizations” [52].

“However, this field of science faces various ethical and legal challenges. Despite tremendous strides made in the field of AI in communities, and its role in improving the treatment process, it is not accessible to all societies. Many low-income and developing countries still do not have access to the latest technologies. It should be noted that the ethical dilemmas, privacy and data protection, informed consent, social gaps, medical consultation, empathy, and sympathy are various challenges that we face in using AI” [53]. “Therefore, before integrating artificial intelligence with the healthcare system, practitioners and specialists should consider all four medical ethics principles, including autonomy, beneficence, nonmaleficence, and justice in all aspects of health care” [53-56].

**Privacy and Data Protection**

“General Data Protection Regulation (GDPR) was first enacted by the European Union (EU), as it amended the privacy legislation in other countries, such as the US and Canada. According to these regulations, all personal data and the activities of foreign communities and companies are processed by the union-based data processor or controller in order to protect the information of natural persons with sufficient protection” [54]. “In the United States, the Genetic Information Non-discrimination Acts (GINA) is an organization that prohibits employers from discriminative decisions according to the genetic health information of individuals” [55]. In fact, the role of AI in healthcare is to analyze consumer health data and medical device images, improve diagnoses and outcomes, as well as a helpful role in accelerating health research activities.

In addition, social media, as part of AI, play a vital role in disseminating health news or medical advice, especially in pandemics. However, these can be ostensible positive aspects of AI, and ensuring the safety of the patients' data is still a significant concern when using robots

The challenges are that;

In healthcare, current laws are not enough to protect an individual’s health data. Clinical data collected by robots can be hacked into and used for malicious purposes that minimize privacy and security. Some social networks gather and store large amounts of users’ data, for instance, individuals’ mental health data, without their consent, which can be helpful in the marketing, advertising, and sales of these companies [52]. Also, some genetics testing and bioinformatics companies, which are not legal or closely monitored, sell customer data to pharmaceutical and biotechnology companies.

Informed Consent and Autonomy

“Informed consent is a process of communication between a patient and health care provider, which includes decision capacity and competency, documenting informed consent, and ethical disclosure” [56]. “According to the definition of ethical responsibility, patients have the right to be in-formed of their diagnoses, health status, treatment process, therapeutic success, test results, costs, health insurance share or other medical information, and any consent should be specific per purpose, be freely given, and unambiguous. Concerns about this issue also increased with the rise of AI in healthcare applications” [57].

Based on the autonomy principle:

“All individuals have the right to get in-formation and ask questions before procedures and treatments. Patients should be able to be aware of the treatment process, the risks of screening and imaging, data capture anomalies, programming errors, the privacy of data and access control, safeguarding a considerable quantity of the genetic information obtained through genetic testing. Patients may refuse treatment that the health care provider deems appropriate” [52, 58]. Patients have the right to know who should be responsible when these robotic medical devices fail or errors. The answer is essential for both patient rights and the medical labor market.

Social Gaps and Justice

“Another problem that threatens societies following the development of AI is the social gap issue. In all countries around the world, with every development, discovery and invention, people face greater social inequality and less social justice. Although AI improves the accessibility to more information about science and technology, world events, climate changes, and politics around the world, it exacerbates social inequality”[58]. “Automation and advanced economies have widened the gap between developing and advanced countries. Many people lose their jobs as robots grow and develop. Bookkeepers and managers in different communities could lose their jobs with the increase of automated systems, and there will be a considerable decrease in salaries. The rise of surgical robots and robotic nurses in healthcare environment, operating instead of surgeons and caring for patients instead of nurses, threatens their future job opportunities” [52, 58].

Medical Consultation, Empathy, and Sympathy

“Integrating artificial intelligence (AI) with all are-as of health care seems difficult and impossible. Due to uniquely human emotions, human and medical robots might not evolve together in a short time. Physicians and other care providers should seek consultation from or provide consultation to their colleagues, which is not possible in autonomous (robotic) systems. On the other hand, it seems unlikely that patients will accept machine-human medical relations instead of human-human. Doctors and nurses are expected to provide treatment in an empathetic and compassionate environment, which will significantly affect the healing process of patients” [52]. “This will not be achieved with robotic physicians and nurses. Patients will lose empathy, kindness, and appropriate behavior when dealing with robotic physicians and nurses because these robots do not possess human attributes such as compassion. This is one of the most significant negative aspects of artificial intelligence in medical science. For example: In Obstetrics and Gynecology, any clinical examination requires a sense of compassion and empathy, which will not be achieved with robotic doctors. Children usually experience fear or anxiety as they engage in healthcare settings and meet professionals. Their behavioral manifestations are lack of cooperation, withdrawal, and aggression that could be uncontrollable with the new robotic medicine system. The use of medical robots in psychiatric hospitals may adversely affect patients who have severe psychiatric disorders” [59].

**Safety and Liability**

“AI has the potential to reshape healthcare operations, making them safer and more reliable. However, AI can be prone to errors, and determining liability can be complex due to multiple parties involved in creating these applications” [60]

**Patient Privacy and informed consent**

“AI systems rely on vast amounts of data, raising concerns about how patient information is collected, stored, and used. Healthcare providers should inform patients about the use of AI in their care. Patients should additionally have the right to consent or opt out if they are uncomfortable with AI involvement in their diagnosis or treatment” [61].

**Data Ownership, bias and fairness**.

“Determining who owns and controls healthcare data used by AI systems can be an ethical issue with competing interests among healthcare providers, application developers, and data aggregators. Data used to train AI algorithms may result in biased healthcare decisions. This can lead to ethical dilemmas where AI systems possibly perpetuate or exacerbate disparities in healthcare outcomes among different demographic groups” [32].

**Focus on data transparency use**

Some state organizations that are collecting data for use in in commercial and public sector interventions have established principles for data collection and use. In the case of Cameroon, a law has been enacted in 2024 for data protection of individuals. Data protections establishes principles for the framework in which data can be used in health innovation. A notable commitment under these principles is transparency, that any commercial arrangements should be transparent, clearly communicated and not undermine public trust or confidence [32]. However, many agreements between the public and the private sector are not transparent, which raises serious concern if there are also financial conflicts of interest. Other forms of transparency could be required such as the transparency of sources and methods of obtaining and processing of data, how and why certain types of data are excluded, the methods used to analyze the data and open discussion in publications of data bias. The element of data transparency use has been summarized in fig. 3.



Figure 3. Elements of transparent use of data [60]

Healthcare professionals and patients need to understand how AI systems make decisions. Promoting transparency in AI algorithms and ensuring that developers and providers are accountable for their decisions is essential to building trust in AI systems.

**Patients Data collection, Storage, and Use**

“Patient health data is collected, stored, and used through a combination of manual and digital processes. Manual Data Entry occurs when Healthcare professionals record patient information during in-person visits. This can include basic demographic data, medical history, symptoms, and diagnoses” [62, 63]. Electronic Health Records (EHRs): Many healthcare facilities use EHR systems to record and store patient data electronically. These systems allow for the efficient input and retrieval of patient information.

**Data Storage**

“EHRs store patient data, including clinical notes, test results, and medication records. The Health Information Exchange (HIE) in some cases, patient data may be shared among healthcare organizations using HIE networks, allowing for the exchange of information between different providers. For Cloud Storage: Some healthcare organizations choose to store patient data in secure cloud servers, often with strong encryption and data security measures” [64].

**Data Use**

**Patient Care**: Healthcare providers review medical history, test results, and medication information to make informed diagnosis and treatment decisions.

**Research and Innovation**: Patient data sets can be used in medical research and clinical studies to advance industry knowledge and improve treatments.

**Billing and Insurance**: Organizations use patient data for administrative purposes, including generating bills, processing insurance claims, and managing payments.

**Quality Improvement**: Healthcare organizations may analyze patient data to assess the quality of care and identify areas for improvement.

**Public Health**: Public healthcare organizations use aggregated and anonymized patient data to monitor disease outbreaks, track health trends, and plan public health initiatives. Healthcare organizations and providers are legally and ethically responsible for protecting patient data and ensuring it is used for authorized and legitimate purposes. Unauthorized access or improper handling of patient data can result in legal consequences, including fines and penalties.

**Data Security and Compliance**

“Third-party vendors typically ensure that their AI solutions comply with healthcare data security regulations, such as the Health Insurance Portability and Accountability Act of 1996 (HIPAA) in the United States or the General Data Protection Regulation (GDPR) in the European Union. Compliance with these regulations requires that vendors implement strong security measures to secure data systems when handling patient data during collection, transmission, and storage” [63].

**Monitoring and Maintenance**

“Vendors typically offer continuous monitoring and maintenance services to ensure the reliability and accuracy of AI systems. Regular updates and improvements to algorithms and models are essential to keep the solutions effective and up-to-date”. [65]

**DISCUSSION**

“AI systems require human input and oversight to perform appropriately and make decisions in ambiguous situations. Ultimately, AI is not a replacement for human intelligence, it's a tool that can help us achieve our goals, but we need to ensure that we use it responsibly and ethically” [5]. “The most significant worry regarding the incorporation of AI technologies is the job losses that would follow and the strict regulations needed for the implementation of AI. However, these systems are intended only to make work easier and not to completely replace humans” [66-68]. AI can not only aid quick and hassle-free hit compound identification, but also contribute to suggestions of synthesis routes of these molecules along with the prediction of the desired chemical structure and an understanding of drug–target interactions and its SAR.

There is the need to understand how to ensure patient privacy when using AI. Ensuring patient privacy and security when utilizing AI in healthcare settings is critical to leveraging the full potential of the technology while minimizing risks [69,70]. Some key ways to enhance patient privacy and security in AI applications in healthcare include. Rigorous due diligence before entering into partnerships with third-party entities.

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**Recent Changes to the Regulatory Landscape that can influence AI**

“The White House released the Blueprint for an AI Bill of Rights in October 2022, emphasizing rights-centered principles for addressing AI-related risks. Concurrently, the US Department of Commerce's National Institute of Standards and Technology (NIST) introduced the Artificial Intelligence Risk Management Framework 1.0 (AI RMF) to guide responsible AI development with some insights applicable to healthcare” [71]. “The Health Insurance Portability and Accountability Act of USA, 1996 mandates data protection in the United States. Malicious actors using AI may expose covered entities and related associates to potential liability under the HIPAA. Applications of AI used by threat actors include the development of malware and deceptive phishing email templates designed to deceive recipients into opening dangerous attachments or clicking malicious links” [71].

“Ethical principles for the application of AI for health and other domains are intended to guide developers, users and regulators in improving and overseeing the design and use of such technologies. Human dignity and the inherent worth of humans are the central values upon which all other ethical principles rest. An ethical principle is a statement of a duty or a responsibility in the context of the development, deployment and continuing assessment of AI technologies for health. Additional moral requirements can be derived from this list of fundamental moral requirements” [72]. “For example, safeguarding and protecting individual privacy is not only recognized as a legal requirement in many countries but is also important to enable people to control sensitive information about themselves and self-determination, the respect for their autonomy and to avoid harm. These ethical principles are intended to provide guidance to stakeholders about how basic moral requirements should direct or constrain their decisions and actions in the specific context of developing, deploying and assessing the performance of AI technologies for health. These principles are also intended to emphasize issues that arise from the use of a technology that could alter relations of moral significance. For example, it has long been recognized that health-care providers have a special duty to advance these values with respect to patients because of the centrality of health to individual well-being, because of the dependence of patients on health professionals for information about their diagnosis, prognosis and the relative merits of the available treatment or prevention options, and the importance of free and open exchange of information to the provider–patient relationship” [73]. If AI systems are used by health-care workers to conduct clinical tasks or to delegate clinical tasks that were once reserved for humans, programmers who design and program such AI technologies should also adhere to these ethical obligations.

“Machine-learning systems could advance the protection and enforcement of human rights (including the human right to health) but could undermine core human rights such as non-discrimination and privacy. Human rights and ethical principles are intimately interlinked; because human rights are legally binding, they provide a powerful framework by which governments, international organizations and private actors are obligated to abide” [74]. “Private sector actors have the responsibility to respect human rights, independently of state obligations. In fulfilling this responsibility, private sector actors must take continuous proactive and reactive steps to ensure that they do not abuse or contribute to the abuse of human rights. The existence of a human rights framework does not, however, obviate the need for continuing ethical deliberation. Indeed, much of ethics is intended to expand upon and complement the norms and obligations established in human rights agreements. In many situations, multiple ethical considerations are relevant and require weighing up and balancing to accommodate the multiple principles at stake. An ethically acceptable decision depends on consideration of the full range of appropriate ethical considerations, ensuring that multiple perspectives are factored into the analysis and creating a decision-making process that stakeholders will consider fair and legitimate” [75].

**Challenges on the principles of autonomy.**

“Adoption of AI can lead to situations in which decision-making could be transferred to machines (automation). The principle of autonomy requires that any extension of machine autonomy not undermine human autonomy” [76]. “In the context of health care, this means that humans should remain in full control of health-care systems and medical decisions. AI systems should be designed demonstrably and systematically to conform to the principles and human rights with which they cohere; more specifically, they should be designed to assist humans, whether they be medical providers or patients, in making informed decisions. Human oversight may depend on the risks associated with an AI system but should always be meaningful and should thus include effective, transparent monitoring of human values and moral considerations. In practice, this could include deciding whether to use an AI system for a particular health-care decision, to vary the level of human discretion and decision-making and to develop AI technologies that can rank decisions when appropriate (as opposed to a single decision). These practices can ensure a clinician can override decisions made by AI systems and that machine autonomy can be restricted and made intrinsically reversible” [77]

“Respect for autonomy also entails the related duties to protect privacy and confidentiality and to ensure informed, valid consent by adopting appropriate legal frameworks for data protection. These should be fully supported and enforced by governments and respected by companies and their system designers, programmers, database creators and others. AI technologies should not be used for experimentation or manipulation of humans in a health-care system without valid informed consent. The use of machine-learning algorithms in diagnosis, prognosis and treatment plans should be incorporated into the process for informed and valid consent. Essential services should not be circumscribed or denied if an individual withholds consent and that additional incentives or inducements should not be offered by either a government or private parties to individuals who do provide consent.” [78]. Data protection laws are one means of safeguarding individual rights and place obligations on data controllers and data processors. Such laws are necessary to protect privacy and the confidentiality of patient data and to establish patients’ control over their data. Construed broadly, data protection laws should also make it easy for people to access their own health data and to move or share those data as they like. Because machine learning requires large amounts of data – big data – these laws are increasingly important

**The challenge to promote the wellbeing of human safety and public interest.**

“AI technologies should respect the fundamental ethical principles of beneficence and maleficence, justice and fairness. They should satisfy regulatory requirements for safety, accuracy and efficacy before deployment, and measures should be in place to ensure quality control and quality improvement. Thus, funders, developers and users have a continuous duty to measure and monitor the performance of AI algorithms to ensure that AI technologies work as designed and to assess whether they have any detrimental impact on individual patients or groups” [79]. Preventing harm requires that use of AI technologies does not result in any mental or physical harm. AI technologies that provide a diagnosis or warning that an individual cannot address because of lack of appropriate, accessible or affordable health care should be carefully managed and balanced against any “duty to warn” that might arise from incidental and other findings, and appropriate safeguards should be in place to protect individuals from stigmatization or discrimination due to their health status

**Transparency, understanding of intelligence capabilities**

“AI should be intelligible or understandable to developers, users and regulators. Two broad approaches to ensuring intelligibility are improving the transparency and explain ability of AI technology. Transparency requires that sufficient information (described below) be published or documented before the design and deployment of an AI technology. Such information should facilitate meaningful public consultation and debate on how the AI technology is designed and how it should be used. Such information should continue to be published and documented regularly and in a timely manner after an AI technology is approved for use” [80]..

“Transparency will improve system quality and protect patient and public health safety. For instance, system evaluators require transparency in order to identify errors, and government regulators rely on transparency to conduct proper, effective oversight. It must be possible to audit an AI technology, including if something goes wrong. Transparency should include accurate information about the assumptions and limitations of the technology, operating protocols, the properties of the data (including methods of data collection, processing and labelling) and development of the algorithmic model. AI technologies should be explainable to the extent possible and according to the capacity of those to whom the explanation is directed. Data protection laws already create specific obligations of explainability for automated decision-making” [80]. Those who might request or require an explanation should be well informed, and the educational information must be tailored to each population, including, for example, marginalized populations. Many AI technologies are complex, and the complexity might frustrate both the explainer and the person receiving the explanation. There is a possible trade-off between full explainability of an algorithm (at the cost of accuracy) and improved accuracy (at the cost of explainability)

**Subject inclusivity and equity.**

“Inclusiveness requires that AI used in health care is designed to encourage the widest possible appropriate, equitable use and access, irrespective of age, gender, income, ability or other characteristics. Institutions (e.g. companies, regulatory agencies, health systems) should hire employees from diverse backgrounds, cultures and disciplines to develop, monitor and deploy AI. AI technologies should be designed by and evaluated with the active participation of those who are required to use the system or will be affected by it, including providers and patients, and such participants should be sufficiently diverse. Participation can also be improved by adopting open-source software or making source codes publicly available” [80, 81]. “AI developers should ensure that AI data, and especially training data, do not include sampling bias and are therefore accurate, complete and diverse. If a particular racial or ethnic minority (or other group) is underrepresented in a dataset, oversampling of that group relative to its population size may be necessary to ensure that an AI technology achieves the same quality of results in that population as in better represented groups” [81-83].

**Adaptability, responsiveness and sustainability**.

“Responsiveness requires that designers, developers and users continuously, systematically and transparently examine an AI technology to determine whether it is responding adequately, appropriately and according to communicated expectations and requirements in the context in which it is used. Thus, identification of a health need requires that institutions and governments respond to that need and its context with appropriate technologies with the aim of achieving the public interest in health protection and promotion. When an AI technology is ineffective or engenders dissatisfaction, the duty to be responsive requires an institutional process to resolve the problem, which may include terminating use of the technology” [82]

“Responsiveness also requires that AI technologies be consistent with wider efforts to promote health systems and environmental and workplace sustainability. AI technologies should be introduced only if they can be fully integrated and sustained in the health-care system. Too often, especially in under-resourced health systems, new technologies are not used or are not repaired or updated, thereby wasting scare resources that could have been invested in proven interventions” [83] “Furthermore, AI systems should be designed to minimize their ecological footprints and increase energy efficiency, so that use of AI is consistent with society’s efforts to reduce the impact of human beings on the earth’s environment, ecosystems and climate. Sustainability also requires governments and companies to address anticipated disruptions to the workplace, including training of health-care workers to adapt to use of AI and potential job losses due to the use of automated systems for routine health-care functions and administrative tasks” [84].

**Data colonialism**

“A fourth concern with biomedical big data is that it may foster a divide between those who accumulate, acquire, analyze and control such data and those who provide the data but have little control over their use. This is especially true with respect to data collected from underrepresented groups, many of which are predominantly in LMIC, often with the broad ambition of collecting data for development or for humanitarian ends rather than to promote local economic development and governance” [84]. Insufficient data from underrepresented groups affect them negatively, and attention has focused on either encouraging such groups to provide data or instituting measures to collect data. Generating more data from LMIC, however, also carries risks, including data colonialism, in which the data are used for commercial or non-commercial purposes without due respect for consent, privacy or autonomy. Collection of data without the informed consent of individuals for the intended uses either, commercial or otherwise undermines the agency, dignity and human rights of those individuals; however, even informed consent may be insufficient to compensate for the power dissymmetry between the collectors of data and the individuals who are the sources.

**Artificial intelligence challenges on climatic oscillation**

“Use of deep learning models in AI has been scrutinized for its impact on climate change. Researchers at the University of Massachusetts Amherst, USA, found that the emissions associated with training a single big language model were equal to approximately 300 000 kg of carbon dioxide or 125 round-trip flights between New York City and Beijing [83]. A single training session for another deep-learning model, GTP-3, requires energy equivalent to the annual consumption of 126 Danish homes and creates a carbon footprint equivalent to travelling 700 000 km by car”[84]. All the infrastructure required to support use of AI has an additional carbon cost [85-86].

“WHO considers climate change to be an urgent, global health challenge that requires prioritized action now and, in the decades, to come. Between 2030 and 2050, climate change is expected to cause approximately 250 000 additional deaths per year from malnutrition, malaria, diarrhea and heat stress alone. The cost of direct damage to health by 2030 is estimated to be US$ 2–4 billion per year. Areas with weak health infrastructure – most in developing countries – will be the least able to cope without assistance to prepare and respond” [87-90]

“Reducing emissions of greenhouse gases through better transport, food and choices of energy, particularly reducing air pollution, results in better health” [88, 91]. “Extending the use of AI for health and in other sectors of the global economy could, however, contribute directly to dangerous climate change and poor health outcomes, especially of marginalized populations. Thus, the growing success and benefits for health outcomes of AI, which will predominate in HIC, would be directly linked to increased carbon emissions and negative consequences in low-income countries. AI technologies, for health and other uses, should therefore be designed and evaluated to minimize carbon emissions, such as by using smaller, more carefully curated data sets, which could also potentially improve the accuracy of AI models” [89-94]. Otherwise, the growing use of AI might have to be balanced against its impact on carbon emissions.

**Conclusion**

AI is best suited for handling repetitive, data-driven tasks and making data-driven decisions. However, human skills such as creativity, critical thinking, emotional intelligence, and complex problem-solving still need to be more valuable and easily replicated by AI. The advancement of AI, along with its innovative technology within the framework of digital health technology has made a significant contribution to reduce challenges encountered in clinical research, be it in medicine, biomedical and pharmaceutical companies. AI has contributed in the drug development process along with the overall lifecycle of the product, which could explain the increase in the number of start-ups in this sector.

The current healthcare sector is facing several complex challenges, such as the increased cost of drugs and therapies, and society needs specific significant changes in this area. With the inclusion of AI in the manufacturing of pharmaceutical products, personalized medications with the desired dose, release parameters, and other required aspects can be manufactured according to individual patient need. Using the latest AI-based technologies will not only speed up the time needed for the products to come to the market, but will also improve the quality of products and the overall safety of the production process, and thus providing a better utilization of available resources along with being cost-effective, thereby increasing the importance of automation

The most significant worry regarding the incorporation of these technologies is the job losses that would follow and the strict regulations needed for the implementation of AI. However, these systems are intended only to make work easier and not to completely replace humans.

**Perspectives.**

The rapid advancement of Artificial intelligence (AI) in the clinical and biomedical fields is considered a great approach in many communities that may augment professionals in the healthcare system. Nevertheless, despite the great potential and advancement of AI in the field of medical and health care, this achievement has imposed new requirements in the field of medical ethics. Consequently, we should be aware that its negative aspects might outweigh its benefits. To overcome this problem, experts must consider humanity and ethics in this regard. Although there are no drugs currently on the market developed with AI-based approaches and specific challenges remain with regards to the implementation of this technology, it is likely that AI will become an invaluable tool in the pharmaceutical industry in the near future. For the AI technology to be sustainable, and impactful clinical research there is the need for stakeholders to address and implement the ethical and regulatory challenges governing the sector.

**DISCLAIMER (ARTIFICIAL INTELLIGENCE)**

Author(s) hereby declare that NO generative AI technologies such as Large Language Models (ChatGPT, COPILOT, etc) and text-to-image generators have been used during writing or editing of manuscripts.

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