REGULATING AI
AND BIG DATA DEPLOYMENT
IN HEALTHCARE

Proposing Robust and Sustainable Solutions for Developing Countries' Governments

Dr. Miriam Stankovich

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Proposing Robust and Sustainable Solutions for Developing Countries' Governments

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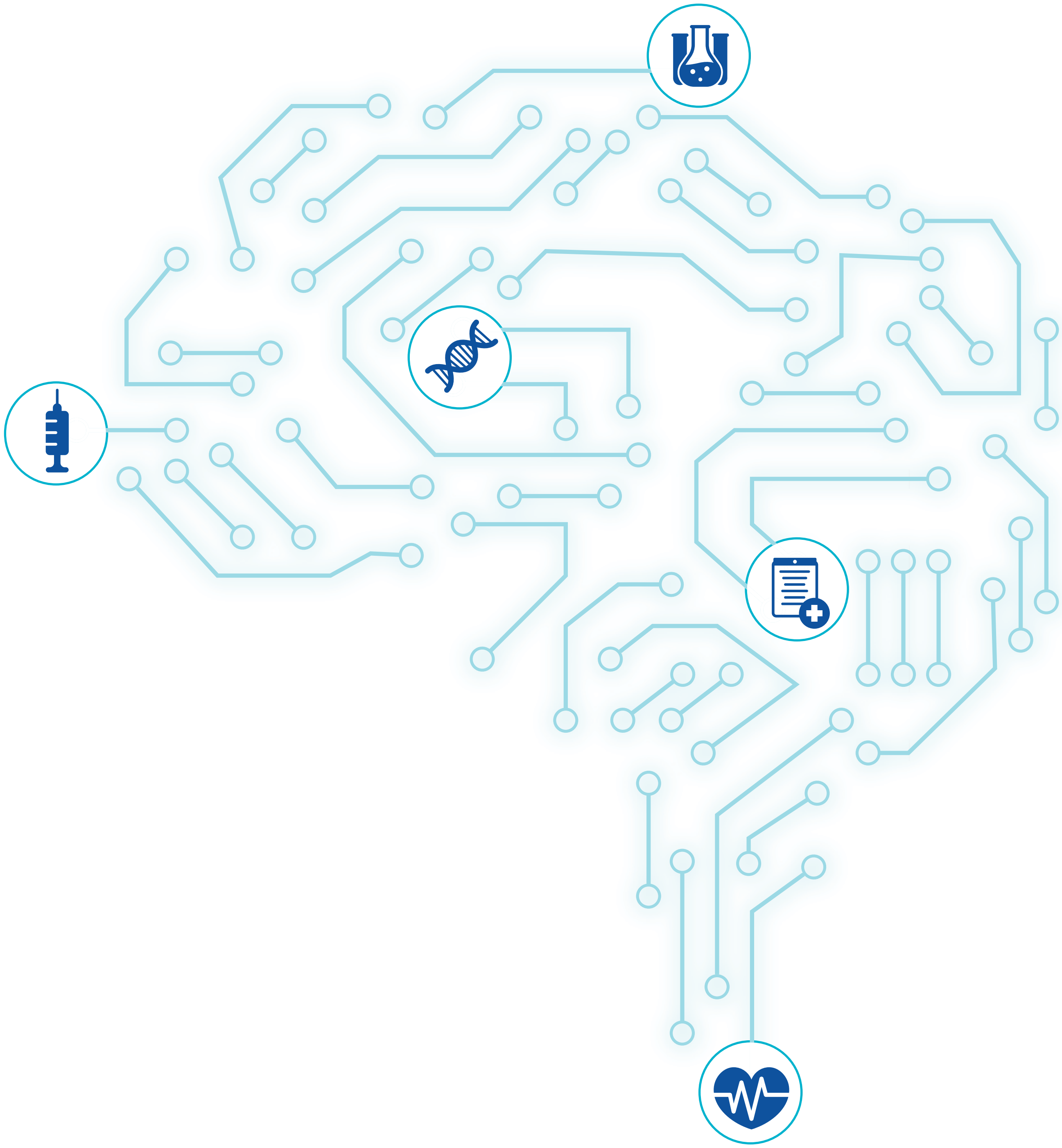


I. Introduction

Merely a generation ago, interest in "artificial intelligence" (AI) was confined to academic computer science, philosophy, engineering research, and science fiction. Today the term AI is broadly understood to include not only long-term efforts to simulate the kind of general intelligence humans exhibit but also fast-evolving technologies (such as convolutional neural networks) that affect many facets of modern society, such as health care, national security, social media, agriculture and a variety of other fields.[2]

The sweeping changes caused by AI have significantly increased the gap between government policy and innovative business models that rely on AI deployment. AI is changing norms and business models throughout society, demanding new and effective policy responses from governments on subjects with little real precedence. While governments struggle to adapt to the rapid pace of change, AI brings new solutions and offers the potential to change how policy is made by providing new tools and methods of policy development.

As a result of the COVID-19 pandemic, policymakers across the globe have started focusing on implementing policies and regulations to ensure that possible long-term effects on inequality, exclusion, discrimination, and global unemployment do not become the "new normal." In particular, vulnerable groups, such as older persons, people living in poverty, persons with disabilities, youth, and indigenous peoples, have been disproportionately affected by the harmful impacts of the pandemic and risk staying behind in the global recovery from the pandemic.[3]

In an increasingly digital economy, AI solutions can play an essential role in addressing these issues. If deployed correctly and with human-centric values at the core, AI can be a vital tool in improving global health, sustainability, and well-being and contributing to bridging the inequality gap. However, not all countries around the globe are equally prepared for the impact of AI in healthcare.[4]

Regulation of AI in healthcare is still in its infancy. Many countries have just issued their national plans, guidelines, or codes—which often highlight essential principles for developing ethical AI—without having passed much substantive law. Notable examples include the European Parliament's resolution on Civil Law Rules on Robotics (February 2017), the European Union's Ethics Guidelines for Trustworthy AI (April 2019), the European Commission's Proposal for a Regulation on a European approach for Artificial Intelligence (April 2021) and OECD's Council Recommendation on Artificial Intelligence (May 2019).

AI deployment in healthcare potentially drives game-changing improvements for underserved communities and developing countries in general. From enabling community-health workers to better serve patients in remote rural areas to helping governments in developing countries prevent deadly disease outbreaks, there is growing recognition of

2 Stanford University Explore Courses. https://explorecourses.stanford.edu/search?view=catalog&filter-coursestatus-Active=on&page=0&catalog=&academicYear=&q=LAW+4039.
3 UNICRI (2021) Bridging Inequality in a Post-Pandemic World: How Can We Leverage Emerging Technologies?, http://old.unicri.it/News/Bridging-Inequality-Post-Pandemic-How-Can-We%20Leverage%20Emerging%20Technologies%3F.
4 https://repository.library.georgetown.edu/bitstream/handle/10822/557892/Han_georgetown_0076M_11870.pdf.

the potential of AI tools to improve health access, quality, and cost. Health systems in many developing countries face obstacles, including shortages of health care workers, medical equipment, and other medical resources. AI tools have exciting potential to optimize existing resources and help overcome these workforce resource shortages and significantly improve healthcare delivery and outcomes in low-income settings in ways never previously imagined.

However, the deployment of AI in resource-constrained settings has been surrounded by a lot of hype; and more research is needed on how to deploy best and effectively scale AI solutions in health systems across developing countries. It is challenging to take disruptive technology innovations from developed countries and replicate them to address the unique needs of the developing world.

The quality and availability of healthcare services in developing countries lag behind developed countries. This leads to disparate health outcomes. According to the WHO, more than 40% of all countries have fewer than ten medical doctors per 10,000 people, and over 55% have fewer than 40 nursing and midwifery personnel per 10,000 people. Only one-third to half of the global population could obtain essential health services as of 2017. Not having adequate digital and data infrastructure in developing countries impedes the prospects of AI deployment in healthcare settings.[5]

In 2019, only 19,1% of people in the least developed countries were online, compared to 86,6% of people in the developed countries. A similar trend was shown in the "readiness for frontier technologies index" created in 2021 by the United Nations Conference on Trade and Development (UNCTAD). According to the UNCTAD, North American and European economies are the most prepared to use, adopt and adapt frontier technologies. Developing countries, and particularly those in Sub-Saharan Africa, Northern Africa and Latin America, and the Caribbean, on the other hand, are the least prepared, scoring significantly below the average index score. Policies ensuring the improvement of access to the internet and the development of technological skills in these countries are thus paramount to bridge the global digital divide by ensuring digital inclusion and development across the world.

Source: UNCTAD (2021) Technologies and Innovation Report 2021, https://unctad.org/system/files/official-document/tir2020_en.pdf.

Data provides the quantitative basis for the deployment of AI and digital resources. Data is the lifeblood of the digital economy and essential input for AI technologies. Many developing countries have been grappling with providing efficient delivery of essential healthcare services. To achieve this, health agencies need data about their populations to understand better the needs they must fill. The need for data to ensure efficient management and delivery of health services in low-resource environments has become increasingly important.

Unlike developed countries, which have abundant and readily available data that have driven healthcare decisions, governments, and organizations in developing countries lack reliable data collection, verification, and aggregation systems. Considering that developing countries are deprived of the necessary systems that generate and maintain robust, accurate, and relevant health data, the use of data to address issues related to disease prevention, intervention assessment, and community education has become challenging.

No single country or stakeholder has all the answers to these challenges. International cooperation and multi-stakeholder discussion are crucial to developing responses to guide the development and use of trustworthy AI for broader public health.[6]

5 Verma et al. (2020) Building a collaborative ecosystem for AI in healthcare in Low and Middle Income Economies, https://www.atlanticcouncil.org/content-series/smart-partnerships/building-a-collaborative-ecosystem-for-ai-in-healthcare-in-low-and-middle-income-economies/.

6 OECD (2020) Trustworthy AI in health, Background paper for the G20 AI Dialogue, Digital Economy Task Force, https://www.oecd.org/health/trustworthy-artificial-intelligence-in-health.pdf.

The principle of "leave no one behind" is a core principle of the 2030 Agenda for Sustainable Development and its 17 Sustainable Development Goals. As the United Nations Secretary-General António Guterres stated: "Technology can turbocharge the recovery from COVID-19 and the achievement of the Sustainable Development Goals".

This paper is intended to identify both barriers to AI deployment at scale in developing countries and the types of regulatory and public policy actions that can best accelerate the appropriate use of AI to improve healthcare in developing countries' contexts. **While AI technologies hold great potential for improving healthcare around the globe, these technologies cannot be considered a panacea for solving global health challenges. Scaling AI technologies has risks and tradeoffs.** Therefore, adoption, acceleration, and use of AI should strengthen local health systems and be owned and driven by the needs and priorities of developing countries' governments and stakeholders to help them best serve their populations.[7]

The paper starts with a landscape assessment of AI and big data analytics deployment in developing countries, where it considers three fields of AI deployment in diagnosis and clinical care, in health research and drug development, and in health systems management and planning. Then, the paper outlines the key challenges that need to be addressed by regulators in governing AI in healthcare, such as data access, data quality, data privacy and ethics. Lastly, the paper outlines the key governance mechanisms for AI innovation in healthcare in developing countries, such as data collection and management, data sharing and open source solutions for data de-identifications, open source data banks and data annotation.

7 Artificial Intelligence in Global Health – USAID. https://www.usaid.gov/sites/default/files/documents/1864/AI-in-Global-Health_webFinal_508.pdf.

II. Landscape assessment of AI and big data analytics deployment in developing countries

It is estimated that 2314 exabytes of space are needed to store the total volume of global healthcare data produced by 2020.[8] If the 2314 exabytes of data were stacked on top of each other, they would reach 82 000 miles high or circle the earth 3.2 times.[9]

AI is creating a seismic shift in the way people interact with technology. If deployed ethically, it stands to help address critical global challenges and deliver considerable benefits to developing and least developed countries. AI's cognitive, learning and reasoning capabilities might improve industrial productivity and result in new added value across industries by maintaining an optimal environment for production and predicting and managing obstacles. In addition, greater use of AI-based precision diagnosis and real-time risk-detection functions will significantly contribute to solving social problems such as caring for the elderly in the context of an aging population, preventing crime, and strengthening public safety. As AI exploits data to drive innovation, a critical contemporary source of growth and well-being, its transformative effects are bound to expand further in a wide array of domains. *However, the main question remains how developing countries will deal with these seismic changes and how prepared they are for them*.

The Global AI in Healthcare Market size is expected to grow from USD 6.1 Bn in 2021 and reach USD 39.5 Bn by 2026; it is projected to grow at a CAGR of 45.3%. The increased advances in AI and big data, and interest and activity from innovators, provides opportunity for developing countries to solve some of their existing challenges in providing appropriate healthcare to a large section of their population. AI combined with robotics and Internet of Medical Things (IoMT) could address healthcare problems and help developing countries' governments in meeting SDG 3 Good Health and Well -Being (see Figure 1).

Source: Global AI in Healthcare Market (2021-2026) by Sections, Diagnosis, End-user, Geography, Competitive Analysis and the Impact of COVID-19 with Ansoff Analysis.

The vision of big data and AI in healthcare is comprehensive and evidence-based, personalized, stratified precision medicine, which combines the best available scientific knowledge with the professional experience of health professionals for the benefit of the individual patient.[10] Hence, the application of AI to healthcare and pharmaceuticals can be used to aid in detecting health conditions early, deliver preventative services, optimize clinical decision-making, and discover new treatments and medications.[11] Therefore, AI can facilitate personalized healthcare and precision medicine while simultaneously powering self-monitoring tools, applications, and trackers. Many benefits can be attributed to big data and AI in healthcare as they can potentially offer higher quality and lower costs of care.

8 EMC Digital Universe, The Digital Universe Driving Data Growth in Healthcare: Challenges and Opportunities for IT (2014).

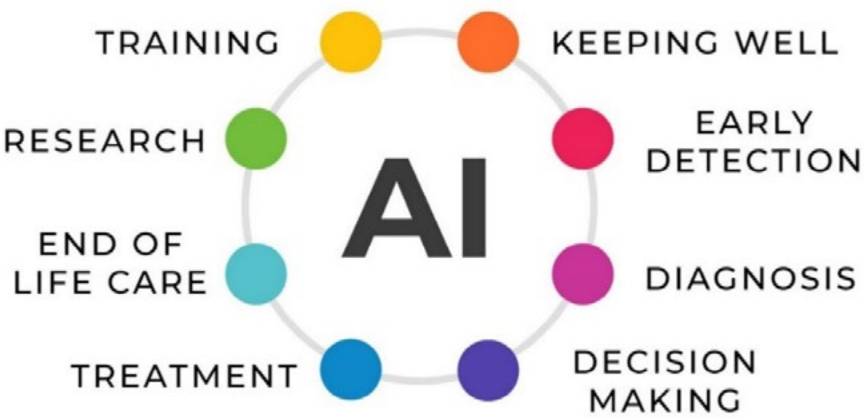
9 ITU, How to Unleash the Enormous Power of Global Healthcare Data: Opinion (2019).

10 UNESCO (2017) Report of the International Bioethics Committee on Big Data and Health, https://unesdoc.unesco.org/ark:/48223/pf0000248724.

11 OECD (2019) Artificial Intelligence in Society, at https://www.oecd-ilibrary.org/science-and-technology/artificial-intelligence-in-society_eedfee77-en.

AI can be deployed in health training, keeping well, early detection of diseases, diagnosis, decision making, treatment, end of life care and health research (Figure 1).

FIGURE 1. Potential use cases of AI in healthcare



II.1. DEPLOYMENT OF AI IN DIAGNOSIS AND CLINICAL CARE

Diagnosis

AI can support medical diagnosis in radiology and medical imaging, and several other medical areas. While more widely used than other AI applications, such applications are still relatively new, and AI is not yet used routinely in clinical decision-making. Currently, AI is being 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 diagnosing diabetic retinopathy, ophthalmology, and RNA and DNA sequencing to guide immunotherapy. In the context of developing countries, AI may be used to improve the detection of tuberculosis in a support system for interpreting staining images or for scanning X-rays for signs of tuberculosis, COVID-19, or other conditions.[12]

> In Nigeria, Ubenwa is using signal processing and machine learning to improve the diagnosis of birth asphyxia in low-resource settings. Bellemo et al. deployed AI to diagnose diabetic retinopathy in Zambia which showed significant and promising results when compared with human assessments. It showed clinically acceptable performance in detecting referable diabetic retinopathy. The Delft Institute's CAD4TB software has been employed in pilot studies examining the use of a computer-aided diagnosis of pulmonary tuberculosis from chest radiographs in Tanzania and Zambia. The performance of CAD4TB compared well with that of human experts.
>
> *Source:* https://www.frontiersin.org/articles/10.3389/fdgth.2020.00006/full.

Clinical care

Clinicians might use AI to integrate patient records during consultations, identify patients at risk and vulnerable groups, aid in difficult treatment decisions, and catch clinical errors. In developing countries, AI can manage antiretroviral therapy by predicting resistance to HIV drugs and disease progression to help physicians optimize treatment. Yet, clinical experience and knowledge about patients are essential, and AI will not 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.

12 WHO (2021) Ethics and Governance of Artificial Intelligence for Health, WHO Guidance, 9789240029200-eng.pdf (who.int).

II.2. DEPLOYMENT OF AI IN HEALTH RESEARCH AND DRUG DEVELOPMENT

Uses of AI in drug development

AI is already being used to simplify and accelerate drug development. This could change drug discovery from a labor-intensive to capital- and data-intensive process using robotics and models of genetic targets, drugs, organs, diseases, and their progression, pharmacokinetics, safety, and efficacy. AI could be used in drug discovery and throughout drug development to shorten the process and make it less expensive and more effective.

For instance, AI was used to identify potential treatments for Ebola virus disease. However, as in all drug development, identifying a lead compound may not result in a safe, effective therapy. In December 2020, DeepMind announced that its AlphaFold system had solved what is known as the "protein folding problem." The system can reliably predict the three-dimensional shape of a protein. Although this achievement is only one part of a long process in understanding diseases and developing new medicines and vaccines, it should help speed the development of new drugs and improve the repurposing of existing medicines against new viruses and new diseases. While this advance could significantly accelerate drug discovery, there is ethical concern about intellectual property ownership and control of an AI technology that could be critical to drug development. This problem is even more accentuated in developing countries' settings where the use of AI may be contingent upon restrictive contractual licensing terms that may even further limit its diffusion and use.

The question of ownership of AI for drug development is relevant in current times i.e., how appropriate is it for a few major private sector players to control intellectual property rights for technologies that have the potential for widespread public good? Often, these technologies have been funded by public grants or other public funding mechanisms.

The COVID-19 pandemic has exemplified the vulnerability of our societies to infectious agents. The danger to our health, our lives, our livelihoods, and even to political stability has been underappreciated until this pandemic. Some estimates consider that it typically takes about ten years[13] for a new medicine to complete the journey from initial discovery to the marketplace and the cost on the order of 2.6 billion dollars.[14] On the other hand, the societal value of a drug could be much higher, as we see with COVID-19 vaccines.[15] In addition, drug discovery has shifted from simple chemical entities that treat common conditions affecting large populations to more complex biological molecules that treat particular conditions, often associated with specific mutations or genetic profiles, for smaller populations, making it more difficult for developers to recover their investments. Therefore, current and future public health needs, e.g., in respect of infectious diseases and pandemics, are often unmet by the current drug discovery ecosystems due to increasing costs and market failures (e.g., with antibiotics, neglected diseases, or dealing with pandemics too late).

13 Pharma, Biopharmaceutical Research & Development: The Process Behind New Medicines, http://phrma-docs.phrma.org/sites/default/files/pdf/rd_brochure_022307.pdf.

14 Gardner (2020) New estimate puts cost to develop a new drug at $1B, adding to long-running debate, https://www.biopharmadive.com/news/new-drug-cost-research-development-market-jama-study/573381/.

15 Ahuja et al. (2021) PREPARING FOR A PANDEMIC: ACCELERATING VACCINE AVAILABILITY https://siepr.stanford.edu/sites/default/files/publications/21-003_0.pdf.

The use of AI to speed up and reduce those costs is a huge opportunity but would be much more likely to succeed in an open-science and data-sharing governance framework. The specific research and innovation challenges involved with these unmet public health needs at the global level would thus be better served (at a lower cost per country and more significant positive global impact) through international governmental and philanthropy coordination of shared funding and incentive policies. One such international endeavor is the Global Partnership on Artificial Intelligence, which is a multi-stakeholder initiative with 19 member nations, guided by the principles that informed the OECD's recommendations on Artificial Intelligence.[16]

It, therefore, seems imperative to explore new technologies like AI and associated data governance with the potential to drastically speed up and reduce costs of drug development, especially where the industry lacks incentives.[17] As we have seen with COVID-19, the danger of such emerging infectious pathogens can quickly reach a global scale and is best addressed with a coordinated international effort. While humanity is at risk (and we can even talk of existential threat), the poorer countries often suffer the most from infectious agents.

Two recent developments could help us change the nature of the AI game in drug development:

- the proliferation of biological and robotics technologies to measure and collect relevant data at a growing scale and
- the development of machine learning algorithms that can take advantage of that data to help us better capture the appropriate causal mechanisms and more efficiently search in the space of new therapeutic agents.

In 2020, Halicin, a new class of antibiotics, was identified through AI-based in-silico screening of chemical structures of molecules and their activity on bacteria.[18] A second recent example is the discovery of novel antibiotics using generative AI.[19] Another notable recent success, more on the side of understanding targets than searching for new therapies, is the breakthrough achieved by DeepMind with AlphaFold2,[20] hailed as "transformational" and "solving a 50-year-old biology challenge": predicting the most likely 3-dimensional configuration of a protein, given its sequence. This is the first step in the ambitious goal of predicting if a given protein (characterized by its sequence) will bind to a given drug molecule.[21]

Although we are seeing the early evidence of the potential of AI in drug discovery, many basic research and applied research questions require significant efforts to bring this potential to fruition. Many of these questions will require highly multi-disciplinary efforts and a scale of funding which pose societal challenges. Some leading examples of how AI can accelerate the drug discovery process are shown below.

16 https://gpai.ai/.
17 McKenna (2020) The antibiotic paradox: why companies can't afford to create life-saving drugs, https://www.nature.com/articles/d41586-020-02418-x.
18 Stokes et al. (2020) A Deep Learning Approach to Antibiotic Discovery, https://www.sciencedirect.com/science/article/abs/pii/S0092867420301021.
19 Das et al. (2021) Accelerated antimicrobial discovery via deep generative models and molecular dynamics simulations, https://www.nature.com/articles/s41551-021-00689-x.
20 https://en.wikipedia.org/wiki/AlphaFold.
21 Callaway (2020) 'It will change everything': DeepMind's AI makes gigantic leap in solving protein structures, https://europepmc.org/article/med/33257889.

- *Estimating the properties of a candidate drug from data.* A supervised learning system can be trained with the appropriate data associating candidate molecules (represented by their molecular structure) with properties of interest, such as drug-likeness (is the molecule small enough and with the suitable properties to get into the right places in the body), toxicity, low production price, easy storing, long shelf life, easy transportation, easy manufacturing and of course, affinity to one or more protein targets of interest.

- *Improving relevant biological, chemical, and physical models so they can be simulated.* With limited amounts of costly experimental data, or simply to obtain better generalization, one can take advantage of appropriate causal knowledge, either in the design of the machine learning predictors introduced above or to generate cheaper approximate data regarding the expected associations between drugs and proteins, which can be crucial when very little experimental data is available. These models can benefit from other kinds of data to tune some of their parameters or machine learning can approximate and accelerate their computation. Recent advances in causal machine learning could help combine existing biological knowledge with these observations and experiments, leading to progress in target identification (potentially multiple targets at once). Such models could also potentially help to predict side-effects or preventing resistance or dependence.[22]

- *Active learning iterating between expensive experiments and machine learning.* This is necessary to go from the approximate knowledge in computational models to decisions based on real experiments. Knowing that the machine learning predictors will generate candidates not just once but multiple times means that a form of exploration can be beneficial in selecting these candidates (by opposition with only picking the best guess). The algorithms can be set up and optimized to take advantage of this interactive context. The learning system can ask questions and propose experiments to acquire relevant knowledge, capture causal structure, and efficiently explore the vast space of molecules or drug combinations.

- *Learning to search in the space of molecules.* Combining all of the above advances, the question of learning a search policy for controlling the sequence of data acquisitions can be framed in the context of reinforcement learning, and raises additional questions like figuring out the suitable abstract action space (how to move in the space of candidate molecules, e.g., moving or adding atoms, or larger blocks?), and discovering the appropriate abstract area for representing molecules and planning such a search. Extending such studies to cover a range of emerging viruses broadly shall enable us to dramatically improve readiness against future pandemics and possibly create a stockpile of vaccines targeting specific predicted proteins.

- *High-throughput screening technologies.* The speed at which experimental data can be acquired is going to be the key to success and mainly relies on research done outside machine learning, for example, in biological and chemical technologies enabling the simultaneous screening of hundreds of thousands or more candidates

22 Yong (2018) A Bold New Strategy for Stopping the Rise of Superbugs, https://www.theatlantic.com/science/archive/2018/11/anti-evolution-drug-vs-antibiotic-resistant-superbugs/575929/.

at once, e.g., with DNA Encoded Libraries,[23] robotic chemistry platforms,[24] synthetic biology screening, and similar ideas.

- *Incorporating patient-specific information, real-time monitoring.* The choice of treatment can be personalized by conditioning the machine learning models on patient data, such as gene expression, ethnicity, vital signs (possibly from new devices, like wearable sensors) and patient history (immunity history). This is important because the appropriate treatment may depend on the stage of the disease and the patient's particulars. This requires a very different kind of data, from health records or medical measurements from patients. Patient-specific combinations of drugs could also be considered, using machine learning to predict which variety is more appropriate given patient data. Anti-virus drugs that aim to inhibit virus replication are most effective when the virus actively replicates during the incubation period and early symptomatic period. In contrast, inhibitors of inflammation are best used later to properly control inflammation. This requires continuous and real-time monitoring to detect the disease stage and anomalies at the earliest possible time point, as was found for COVID-19. One pioneering example of such attempts is seen in the Watch Warrior Study at Mount Sinai.25

- *Improving and scaling up trial designs.* Machine learning could also take advantage of data arising of new trial designs aiming at reducing the cost and duration of clinical trials, while making them more representative, by targeting volunteers from the larger population of infected patients using digital technology to report the effects of treatments, potentially with randomized cross-trials and models trained on the background population as control (synthetic arm). Such trials could at least eliminate the need for unnecessary but costly classical clinical trials, for which the treatment is not working in the cheaper general population. Machine learning could also be used as part of adaptive clinical trials, to extract more useful information faster.[26]

Application of AI for health research

An important area of health research with AI is based on the use of data generated from electronic health records. Such data may be challenging to use if the underlying information technology system and database do not discourage the proliferation of heterogeneous or low-quality data. AI can nevertheless be applied to electronic health records for biomedical research, quality improvement, and clinical care optimization. From electronic health records, AI that is accurately designed and trained with appropriate data can help to identify clinical best practices before the customary pathway of scientific publication, guideline development, and clinical support tools. AI can also assist in analyzing clinical practice patterns derived from electronic health records to develop new clinical practice models. A second application of AI for health research is in the field of genomics.[27]

23 Goodnow Jr (2016) DNA-encoded chemistry: enabling the deeper sampling of chemical space, https://www.nature.com/articles/nrd.2016.213.
24 Schwaller (2020) Predicting retrosynthetic pathways using transformer-based models and a hyper-graph exploration strategy, https://doi.org/10.1039/C9SC05704H.
25 Mount Sinai, Warrior Watch Study, https://www.mountsinai.org/about/covid19/warrior-watch-study.
26 Pallmann et al. (2018), Adaptive designs in clinical trials: why use them, and how to run and report them, https://bmcmedicine.biomedcentral.com/articles/10.1186/s12916-018-1017-7.
27 Davenport (2018), The potential for artificial intelligence in healthcare, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6616181/.

II.3. DEPLOYMENT OF AI IN HEALTH SYSTEMS MANAGEMENT AND PLANNING

Data collection and analytics

Data collection and AI analysis programs to gather vital information, have been deployed frequently in developing countries. For instance, in Cote d'Ivoire, Data for Development (D4D) makes large datasets of healthcare data or telecommunications information available to the public, thus allowing opportunities for disseminating large quantities of data and drawing essential conclusions on populations.[28] In The Gambia, a probabilistic decision-making system was used to assist rural health workers in identifying life-threatening conditions in outpatient clinics. The medical AI performed tolerably well in detecting 88% of cases. Furthermore, Computerized Aid To Treat (CATT) was used in drug prescriptions in South Africa by nurses based on a cost-and-effectiveness algorithm. More recently, application of AI for healthcare in Africa has seen a few pilots and test cases. For example, in South Africa, applying a multinomial logistic classifier-based system has been tested in human resource planning to predict how long health workers might stay in public service.[29]

Vezeeta, an Egyptian-based start-up with a leading digital healthcare platform in the Middle East and North Africa, connects patients and healthcare providers through state-of-the-art technology, allowing patients to search, compare, and book the best doctors in private clinics and hospitals. In addition to this, patients can also book lab tests, scans and services, and operations.

Another notable mention is Altibbi, a digital health platform that offers telemedicine consultation services, allowing patients to connect directly with a database of doctors via audio calls and chats.

A Dubai-based start-up – Dimension14 – uses an AI engine for scheduling patients and doctors by mapping out personalized journeys for both parties.

Source:
https://www.vezeeta.com/en
https://magnitt.com/startups/2921/altibbicom
https://www.dimension14.com/

Maternal and new-born deaths have long plagued the African continent as the right lifesaving interventions rarely can reach the right person at the right time. Nevertheless, a vast majority of these deaths can be prevented with relatively simple and inexpensive tools. This is where AI could play a crucial and transformative role, particularly in more impoverished and remote areas, by providing critical intelligence to help community health workers prioritize and triage care and resources to those most at risk.[30]

Even in a single-payer, government-run system, health systems may be overly complex and involve many actors who contribute to, pay for, or benefit from the provision of healthcare services. The management and administration of care may be laborious. AI can assist personnel in complex logistical tasks, such as optimizing the medical supply chain, assuming mundane, repetitive tasks, or supporting complex decision-making. Some possible functions of AI for health systems management include identifying and eliminating fraud or waste, scheduling patients, predicting which patients are unlikely to attend a scheduled appointment, and assisting in identifying staffing requirements.[31]

28 Bram, T., et al (2015) Utilization and Monetization of Healthcare Data in Developing Countries, at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4605478/.
29 Owoyemi, A., et al (2020) Artificial Intelligence for Healthcare in Africa, at https://www.frontiersin.org/articles/10.3389/fdgth.2020.00006/full.
30 Rao, N. (2019) Big Data Can Improve the Health of the World's Most Vulnerable: Mothers and Children, at https://time.com/5708751/big-data-maternal-health/#:~:text=Mothers%20and%20Children-,Big%20Data%20Can%20Improve%20the%20Health%20of,Most%20Vulnerable%3A%20Mothers%20and%20Children&text=They%20report%20their%20tallies%20to,work%20they%20do%20each%20day.
31 WHO (2021) Ethics and Governance of Artificial Intelligence for Health, WHO Guidance, 9789240029200-eng.pdf (who.int).

AI could also be useful in complex decision-making and planning. For example, researchers in South Africa applied machine-learning models to administrative data to predict the length of stay of health workers in underserved communities. In a study in Brazil, researchers used several government data sets and AI to optimize the allocation of health-system resources by geographical location according to current health challenges. Allocation of scarce health resources using AI has raised concern, however, that resources may not be fairly allocated due, for example, to bias in the data.

Health promotion

AI can be deployed for health promotion or to identify target populations or locations with "high-risk" behavior and populations that might benefit from health communication and messaging (micro-targeting). AI programs can use different forms of data to identify such populations, with varying accuracy, to improve message targeting.

However, micro-targeting can raise concern, such as that for commercial and political advertising, including the opaqueness of processes that facilitate micro-targeting. Furthermore, users who receive such messages may have no explanation or indication of why they have been targeted. Micro-targeting also undermines a population's equal access to information, can affect public debate and can facilitate exclusion or discrimination if misused by the public or private sector. [32]

Disease prevention

AI has also been used to address the underlying causes of poor health outcomes, such as environmental or occupational health risks. AI tools can identify bacterial contamination in water treatment plants, simplify detection and lower costs. Sensors can also be used to improve environmental health, such as by analyzing air pollution patterns or using machine learning to make inferences between the physical environment and healthy behavior. One concern with such use of AI is whether it is provided equitably or if such technologies are used only on behalf of wealthier populations and regions with the relevant infrastructure for its use.

Public health surveillance, emergency preparedness and outbreak response

AI has been used in public health surveillance for collecting evidence. Technology is changing the data collected for public health surveillance by adding digital "traces," which are not generated specifically for public health purposes (such as blogs, videos, official reports, and Internet searches). Videos (e.g., YouTube) are another "rich" source of information for health insights. New developments in AI could, after rigorous evaluation, improve the identification of disease outbreaks and support surveillance.

Several concerns about the use of AI for public health surveillance, promotion and outbreak response must, however, be considered before the use of AI for such purposes, including the tension between the public health benefits of surveillance and ethical and legal concern about individual (or community) privacy and autonomy.

32 Ibid.

Characterization of digital traces as "health data" raises questions about the types of privacy protection or other safeguards that should be attached to such datasets if they are not publicly available. For example, the use of digital traces as health data could violate the data protection principle of "purpose limitation." Individuals who generate such data should know that their data will be used for at the collection point.[33]

Magic Box, built by UNICEFs Office of Innovation, is a big data program developed in response to the 2014 Ebola crisis in West Africa. It uses real-time data to inform decision-making in emergency situations such as epidemics.

Magic Box's AI uses real-time aggregated data from public sources and private sector partners to generate actionable insights and a better understanding of complex and changing situations. It builds on machine learning, network analysis and complex systems research to provide decision-makers and relevant frontline health workers with disease spread predictions, key counter measures, and population level insights.

It considers precipitation and weather data, high-resolution population estimates, air travel data, aggregated and anonymized mobility data from mobile phone records, geotagged social media traces, temperature data, and case data from WHO reports to build better models and understanding of epidemics and other humanitarian and development contexts affecting children.

Magic Box has benefited from partnerships with Amadeus, Google, IBM, Vodafone and Telefonica, further increasing its capabilities and allowing its application to other mosquito-borne diseases like Zika, dengue, and yellow fever, new Ebola outbreaks and the current COVID-19 crisis.

Source: Working Group on Digital and AI in Health
Reimagining Global Health through Artificial Intelligence: The Roadmap to AI Maturity
September 2020

Such use also raises questions of accuracy. Models are helpful only when appropriate data are used. Machine-learning algorithms could be more valuable when augmented by digital traces of human activity, yet such digital traces could also negatively impact an algorithm's performance. Google Flu Trends, for example, was based on search engine queries about complications, remedies, symptoms, and antiviral medications for influenza, which are used to estimate and predict influenza activity. While Google Flu Trends first provided relatively accurate predictions before those of the US Centers for Disease Control and Prevention, it overestimated the flu prevalence between 2011 and 2013. The system was not re-trained as human search behavior evolved.

Although many public health institutions are not yet making full use of these data sources, the surveillance itself is changing, especially real-time surveillance. For example, researchers could detect a surge in cases of severe pulmonary disease associated with the use of electronic cigarettes by mining disparate online sources of information and using HealthMap, an online data-mining tool. Similarly, Microsoft researchers have found early evidence of adverse drug reactions from weblogs with an AI system. In 2013, the company's researchers detected side-effects of several prescription drugs before they were found by the US Food and Drug Administration's warning system. In 2020, the US Food and Drug Administration sponsored a "challenge," soliciting public submissions to develop computation algorithms to detect adverse events from publicly available data automatically. Despite its potential benefits, real-time data collection, like collecting and using digital traces, could violate data protection rules if surveillance was not the purpose of its initial collection, which is especially likely when data collection is automated.[34]

Before the COVID-19 pandemic, WHO started developing EPI-BRAIN, a global platform that will allow data and public health experts to analyze large datasets for emergency preparedness and response. AI has been used to assist in both detection and prediction during the COVID-19 pandemic. However, some consider that the techniques and programming developed will "pay dividends" only during a subsequent pandemic. HealthMap first issued a short bulletin about a new type of pneumonia in Wuhan, China, at the end of December 2019. Since then, AI has been used to "now-cast" (assess the current state of) the COVID-19 pandemic, while, in some countries, real-time data on the movement

33 WHO (2021) Ethics and Governance of Artificial Intelligence for Health, WHO Guidance, 9789240029200-eng.pdf (who.int).
34 WHO (2021) Ethics and Governance of Artificial Intelligence for Health, WHO Guidance, 9789240029200-eng.pdf (who.int).

and location of people has been used to build AI models to forecast regional transmission dynamics and guide border checks and surveillance. To determine how such applications should be used, an assessment should be conducted of whether they are accurate, effective, and valuable.

AI can also assist public health authorities in tracking, monitoring and managing pandemic outbreaks. AI and big data can also facilitate social distancing. AI has been used to map the movements of individuals to approximate the effectiveness of government-mandated orders to remain in confinement. In some countries, AI technology has been used to identify individuals who should self-quarantine and be tested. The deployment of AI in this context has raised legal and ethical concerns about privacy and risk of discrimination and possibly unnecessary restriction of movement or access to services, which heavily impact the exercise of a range of human rights. As for all AI technologies, their actual effectiveness depends on whether the datasets are representative of the populations in which the technologies are used, and they remain questionable without systematic testing and evaluation. The WHO issued interim guidance on the ethical use of proximity-tracking applications in 2020.

Robots have also begun to replace clinicians in hospitals, as they have found their application in helping disinfect rooms, providing telehealth services, and processing and analyzing COVID-19 test samples.

In this regard, the most notorious example is the Canadian health surveillance start-up called BlueDot that accurately identified the spread of COVID-19 and its risk among the first in the world.[35] The start-up's AI software discovered a cluster of unusual pneumonia cases in Wuhan, China in late December 2019, and predicted where the virus might spread. It used geographic information system (GIS) data and flight ticket sales to create a dispersion graph based on the airports connected to a city and where passengers are likely to fly. It also used anonymized location data from 400 million mobile devices to track flows from the outbreak epicenter to other parts of the world. BlueDot applied this methodology to identify many of the cities among the first to receive the coronavirus, such as Tokyo, Bangkok, Hong Kong, Seoul, and Taipei.[36] The South Korean government released an app that allows users to self-report symptoms, alerting them if they leave a "quarantine zone" to curb the impact of "super-spreaders" who otherwise infect large populations.[37]

Leveraging AI-powered sensors to support triage in sophisticated ways

Florida's Tampa General Hospital deployed an AI system in collaboration with Care.ai at its entrances to intercept individuals with potential COVID-19 symptoms from visiting patients. The technology conducts a facial thermal scan and picks up other symptoms, including sweat and discoloration, through cameras positioned at entrances to ward off visitors with fever.

Another such example is the Israeli company Diagnostic Robotics, an AI-based triage platform that gives public health officials continuous monitoring of the virus's patterns. The platform has been adapted to tackle the current pandemic, offering an analytics tool that produces risk assessment and predictive models, thus allowing a quicker and better targeted medical response.

Source: Venture Beat, How people are using AI to detect and fight the coronavirus, https://venturebeat.com/2020/03/03/how-people-are-using-ai-to-detect-and-fight-the-coronavirus/.

WSJ, Hospitals Tap AI to Help Manage Coronavirus Outbreak, https://www.wsj.com/articles/hospitals-tap-ai-to-help-manage-coronavirus-outbreak-11584696601.

Forbes, Israeli Innovators Harness Artificial Intelligence Technologies To Curb The Global COVID-19 Pandemic, https://www.forbes.com/sites/startupnationcentral/2020/04/13/israeli-startups-artificial-intelligence-covid19-coronavirus/#5520e13f4567.

35 Panjabi (2020) The promise of data in difficult times, https://towardsdatascience.com/the-promise-of-data-in-difficult-times-428d9619714d.

36 How AI Predicted the Coronavirus Outbreak with Kamran Khan, https://twimlai.com/twiml-talk-350-how-ai-predicted-the-coronavirus-outbreak-with-kamran-khan/.

37 Shendruk, South Koreans are using smartphone apps to avoid the novel coronavirus, https://qz.com/1810651/south-koreans-are-using-smartphone-apps-to-avoid-coronavirus/.

III. Priority challenges that need to be addressed by regulators in governing AI in healthcare

The current COVID-19 pandemic has exacerbated the deployment of AI in healthcare. Making AI tools available to overcome a fast-moving pandemic effectively requires government officials, developers, and health organizations to observe the fundamentals of regulation and focus on use cases and models with good data sets that have been validated. This poses challenges, such as access to quality and accurate data, data protection, sharing and privacy (health data is sensitive information), identity (public health crisis could enable the swift passage of regulations for identification without public debate or transparency), and bias (the use of AI and big data analytics in health also carries inherent bias, such as gender, racial, poverty-based bias).

Many developing countries' governments lack the technological capabilities and resources to create suitable policies and regulations for the deployment of AI technologies in healthcare.

There is a lack of consistent regulation, which is often highly dependent on the discretion of local officials and can change quickly. This variability creates an uncertain regulatory environment that generally impedes the scale-up of AI technologies. Clear guidance from multilateral bodies and governments on when and where regulation on AI tools is needed, would be helpful for AI companies operating across developing countries' healthcare markets.

In addition, many developing countries have limiting regulations on what health services or advice can be given to patients outside of health facilities or without the presence of a physician. For instance, the laws in India, China, Brazil, and other markets require physicians, and not algorithms, to make diagnoses and highly trained health workers to carry out specific medical tests. On the other hand, some AI tool companies have not confronted regulatory issues because they are categorized as providing "educational health information" and are not regulated to provide care guidance. But as health regulations in developing countries become more robust, this is likely to change–with a risk, regulations will become more complex and inconsistent across countries.

Other critical challenges associated with regulation of AI generally include the following:

- AI's technological capabilities could result in potential breaches of human rights from sources of risk that did not exist before (e.g. remote biometric surveillance or facial recognition technology).
- Bias and discriminatory outcomes may result from decisions taken or supported by AI systems that may remain completely unperceived and not understood.

- AI may create safety risks for users and third parties that are not expressly covered by current product safety legislation.

- Due to the nature of AI technologies, it may be difficult to assign liability to a particular human action or omission.

AI deployment in healthcare has raised legitimate concerns and anxieties:

- The deployment of AI in standard health care delivery and administration is still minimal. There are difficulties in scaling up projects and questions about the quality of health data.

- Algorithmic bias and black boxes. AI can be used to accentuate existing inequalities and unwarranted variation in care. However, there is a danger that, without proper control, AI could codify and reinforce biases and exacerbate inequality.

- AI and big data deployment in healthcare create a novel set of ethical challenges that must be identified and mitigated since AI technology has tremendous capability to threaten patient preference, safety, and privacy. For instance, machine learning algorithms might not provide equally accurate predictions of outcomes across race, gender, or socioeconomic status. Another example is facial recognition technologies (FRT) tools that assist with identification, monitoring, and diagnosis. As FRT is increasingly utilized in health care settings, informed consent will need to be obtained to collect and store patients' images and for the specific purposes for which FRT systems might analyze those images. Patients might not be aware that their images could be used to generate additionally clinically relevant information.[38]

This paper analyzes the following key challenges to regulating AI in the healthcare sector of developing countries: (i) data access, (ii) data quality, and (iii) data privacy and ethics.

III.1. DATA ACCESS

Data fuel digital health; they are the basis of research and discovery of new treatments, empowering the personalization of medicines, and demonstrating the value of treatments to powering AI and machine learning algorithms. Data also enable healthcare providers and policymakers to make informed decisions about allocating resources.

Health data constitute 30% of the globally stored data.[39] For health data to make decision making better the datasets need to be more diverse and robust. However, data access and data quality barriers still prevent innovators from using data more efficiently and effectively in health. The COVID-19 crisis has exposed these data gaps even further.[40]

Often, health data in developing countries are incomplete or of low quality, which leads to inefficient allocation of resources by policymakers. As a result of insufficient or low-quality

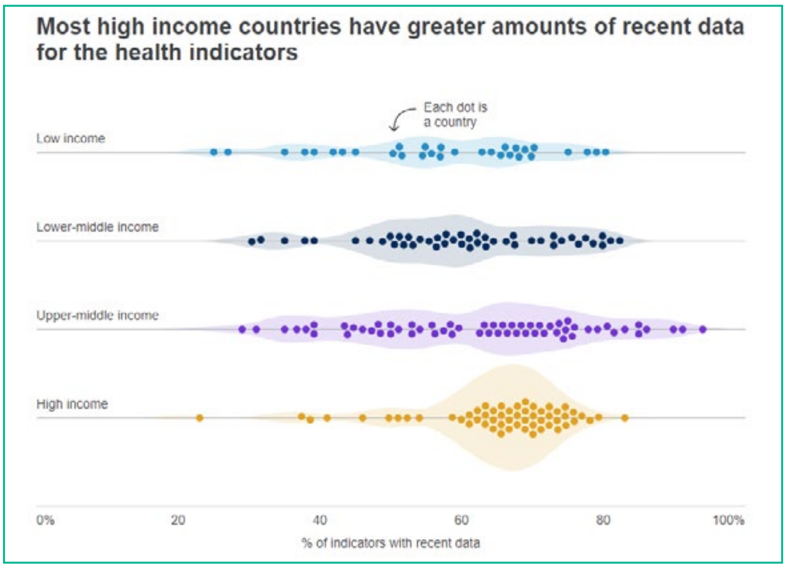
38 Martinez-Martin (2019) What Are Important Ethical Implications of Using Facial Recognition Technology in Health Care?, https://journalofethics.ama-assn.org/article/what-are-important-ethical-implications-using-facial-recognition-technology-health-care/2019-02.

39 https://datasaveslives.eu/.

40 Gwee (2021), The importance of increasing access to high-quality health data, https://www.oecd-forum.org/posts/the-importance-of-increasing-access-to-high-quality-health-data.

data, policymakers may be misled in their attempts to allocate resources effectively. Health datasets are siloed and locked within institutions, and countries are grappling with linking different data sources and using the data for secondary research. See Figure 2.

FIGURE 2. Source: WHO[41]



According to the OECD, many countries still cannot extract and harness the information they need to deliver better public health outcomes. Interoperable and good quality health record data would inform better care delivery and support more significant national health research goals.[42]

Apart from data access, data interoperability is another challenge. Often, health datasets are not interoperable and are not portable among institutions. This leads to less diverse health datasets that might not represent the patient population at the national level. Moreover, interoperability and standardization affect the building of regional and global health datasets and impede AI and machine learning solutions across boundaries. COVID-19 has demonstrated the need for data interoperability and standardization.

Another challenge is that much of the healthcare data is unstructured, which impedes uniformly compiling and analyzing health datasets. The proliferation of wearables and digital health devices provides the ability to capture and leverage real-world data as a supplement to clinical data.

III.2. DATA QUALITY

One of the key impediments to the effective deployment of AI in healthcare is access to FAIR (findable, accessible, interoperable, and reusable) data. In developing countries, this problem is exacerbated because data are not always digitized and not easily accessible due to private sector capture. It has been suggested that "data quality issues are critical when building AI for clinical settings. It is, therefore, incumbent on the regulators of AI models to also ensure that the data used adheres to the FAIR principles and is collected ethically before certifying the model as fit for the market. This could be further supplemented by organizational quality assessment in pre-market checkpoints. These conditions can signal to the industry that data integrity and ethical collection is of paramount importance to be eligible for the market, and lead to positive structural changes in how enterprises function."[43]

41 https://www.who.int/data/gho/data-availability-a-visual-summary.

42 OECD, Readiness of electronic health record systems to contribute to national health information and research, https://www.oecd-ilibrary.org/docserver/9e296bf3-enpdf?expires=1579621095&id=id&accname=guest&checksum=99410E022DB8401F52C48C7A7B224539.

43 Verma et al. (2020) Regulating AI in Public Health: Systems Challenges and Perspectives, https://www.orfonline.org/research/regulating-ai-in-public-health-systems-challenges-and-perspectives/.

Data representativeness is another problematic issue related to data quality. AI's output is shaped by the data that is fed into it. Computer-based recommendations are often taken at face value, assuming that whatever result an AI algorithm portrays is objective and impartial. Humans choose the data that goes into an algorithm, and these choices can embed human biases, which in turn might negatively impact underrepresented groups. These biases might occur at any phase of AI development and deployment. The most common source of bias is data that does not sufficiently represent the target population, which can have adverse implications for specific groups. For example, women and people of color are typically underrepresented in clinical trials. If algorithms that analyze skin images were trained on images of white patients and then are applied more broadly, they could potentially miss melanomas in people of color. Or, the use of an algorithm designed to prioritize care for COVID-19 patients could put populations lacking access to COVID-19 testing at a disadvantage because the algorithm may fail to factor in their needs and characteristics, if those populations are underrepresented in the training data.[44]

III.3. DATA PRIVACY AND ETHICS

Any regulatory framework should consider providing for both health and privacy rather than forcing a choice between them. The AI technology will serve the welfare and well-being of developing countries only if certain safeguards, such as human in the loop and privacy by design, are introduced.

Several existing frameworks might serve as a base for the checks and balances necessary for such a regulatory framework: the European Social Charter that clearly states the "right to health" in Article 11, the Oviedo Convention, and the Convention 108+ that ensures protection of personal data and privacy,. However, there is a need for a "dedicated legal instrument" with a global reach governing AI, one that considers its specific characteristics, and that would lay down benchmarks in privacy, confidentiality, data safety, informed consent, and liability.[45]

Data privacy and ethical use of data raise significant concerns among many developing countries' governments, and other stakeholders—not only for those working on AI specifically but also for those involved in digital health and other sectors more broadly. For instance, data privacy issues are significant for digital health and AI solutions since health data is generally government-owned, raising concerns about private companies gaining access to the data and potentially profiting by leveraging it for their uses. Many developing countries already have regulations prohibiting private companies from taking health and other data types outside their borders. In addition, many local stakeholders are concerned about AI tools requiring access to large amounts of health data because they fear this would increase the risk for monopolistic behavior if a single private player assumes such a significant role within a country's health system.[46]

44 Siwicki (2021) How does bias affect healthcare AI, and what can be done about it?, https://www.healthcareitnews.com/news/how-does-bias-affect-healthcare-ai-and-what-can-be-done-about-it.

45 Selin Sayek Böke (2021) Artificial Intelligence and Health Care in Light of COVID-19: Ensuring a human-rights perspective, https://www.oecd-forum.org/posts/artificial-intelligence-and-health-care-in-light-of-covid-19-ensuring-a-human-rights-perspective?channel_id=722-digitalisation.

46 Artificial Intelligence in Global Health - USAID. https://www.usaid.gov/sites/default/files/documents/1864/AI-in-Global-Health_webFinal_508.pdf.

Tech companies and health systems have trained AI to perform remarkable achievements using health data. Startups like K Health source from databases containing hundreds to millions of EHRs to build patient profiles and personalize automated chatbots' responses. IBM, Pfizer, Salesforce, and Google have also attempted to use health records to predict the onset of conditions like Alzheimer's, diabetes, diabetic retinopathy, breast cancer, and schizophrenia. And at least one startup offers a product that remotely monitors patients suffering from heart failure by collecting recordings via a mobile device and analyzing them with an AI algorithm.

The datasets used to train these systems come from a range of sources, but in many cases, patients have not been made fully aware their information is included among them. This situation is even more complicated in developing countries' settings where there is a lack of regulation and awareness among key stakeholders (regulators included) about the importance of preserving the privacy of health datasets that are harvested by AI and big data analytics.

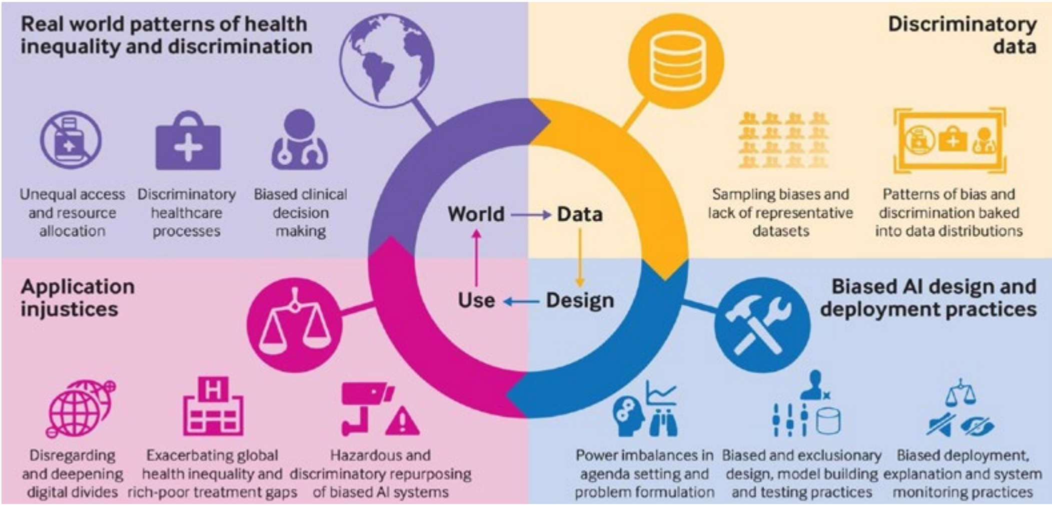
Source: https://venturebeat.com/2021/02/01/ai-in-health-care-creates-unique-data-challenges/

The concept of algorithmic bias, which implies that AI is as good as the data on which it is trained on, is an important factor in how AI and big data are used for development. Algorithmic bias has a more pronounced effect when AI applications are introduced to developing countries' setting. The preponderance of AI applications is being developed outside the developing world, and most datasets available are from people from developed countries. This might affect the sensitivity of AI systems. AI systems could also embed algorithms that contain specific beliefs and bias of the creators of the AI systems. This can lead to discriminatory outcomes if applied to low-resource settings without their developmental input and data.[47]

Given these constraints, regulators in developing countries should make sure that AI-powered tools can be applied equally to different groups of people. Information from specific population groups tends to be missing from the data with which these tools learn, meaning that the tool might work less well for those communities. For instance, a team of U.K. scientists found that almost all eye disease datasets come from patients in North America, Europe, and China, meaning eye disease-diagnosing algorithms are less certain to work well for racial groups from underrepresented countries.[48] Another example is that skin cancer-detecting algorithms tend to be less precise when used on Black patients because AI models are trained chiefly on images of light-skinned patients.[49]

Figure 3 gives an overview of global patters of health inequality and discrimination and related biased AI design and deployment practices.

Figure 3. Biased AI design and deployment practices



Source: https://www.weforum.org/agenda/2021/07/ai-machine-learning-bias-discrimination/

47 https://www.frontiersin.org/articles/10.3389/fdgth.2020.00006/full.

48 Knight (2020), AI Can Help Diagnose Some Illnesses—If Your Country Is Rich, https://www.wired.com/story/ai-diagnose-illnesses-country-rich/.

49 Lashbrook (2018), AI-Driven Dermatology Could Leave Dark-Skinned Patients Behind, https://www.theatlantic.com/health/archive/2018/08/machine-learning-dermatology-skin-color/567619/.

However, even if diverse data sets are generated, this might not translate into AI tools rolled out reliably in low-income countries, where disease profiles differ from those in developed nations. To illustrate this, in sub-Saharan Africa, women are diagnosed with breast cancer younger, on average, than their peers in developed countries, and their disease is more advanced at diagnosis. Diagnostic AI tools trained on mammograms from Europe are trained to identify disease early in older women. These results and AI training sets could have devastating results if/when deployed in sub-Saharan Africa.[50]

One way to solve this problem is to give AI developers access to low-income countries' data. However, this might raise concerns related to data protection for vulnerable populations. For instance, information such as HIV status could discriminate against specific populations.

Often, private companies offer to pay for such data, which might be tempting for cash-strapped national health systems or individual researchers to part with patient data, perhaps without thinking hard about the rights of those whose data they are sharing.

Data companies could also lure people into giving up their privacy in return for medical care or financial reward. Such practices could create a privacy divide between rich and poor.[51]

Since many tech companies offer AI tools as free products directly to their users (patients or physicians), the users often become the 'product' that is monetized by the tech companies. The companies that own these tools could sell their customers' sensitive health data. This issue highlights concerns around data privacy surrounding digital health and AI health solutions and will need to be addressed by local players and national governments.

AI deployment in healthcare also raises ethical concerns about whether private companies with access to patient and population health data should be required to disclose the data to individual patients, local populations, health workers, and other local constituencies. For the AI-enabled population health tools, a possible dilemma could arise when a private company analyzes data that indicates a potential outbreak of a highly contagious infectious disease in a given region. In this case, should that company inform health workers or communities within that region immediately? For an AI patient-facing platform, a dilemma might be whether AI tools should disclose a diagnosis to patients without appropriate counseling or other confidentiality measures that health providers would otherwise provide.

Limited access to healthcare for certain people is one way AI tools could widen the health gap globally. Patient virtual health assistant and physician clinical decision support AI-enabled tools face ethical and fairness issues; the distribution of benefits from these tools will likely be uneven across low-resource contexts and may not reach the most underserved populations in the near term. The digital divide across poverty and racial lines is likely to impact these tools on varying levels. For patient-facing tools, benefits will originally go to those with smartphones and 4G connectivity—most likely higher-income segments of the population.[52]

50 A fairer way forward for AI in health care - Nature. https://www.nature.com/articles/d41586-019-02872-2.
51 Ibid.
52 Artificial Intelligence in Global Health - USAID. https://www.usaid.gov/sites/default/files/documents/1864/AI-in-Global-Health_webFinal_508.pdf.

IV. Key governance mechanisms for AI innovation in healthcare in developing countries: recommendations

AI in health must support humans and seek to improve health outcomes, not simply replace humans in full automation. Expressed as a formula, this means: Humans + AI = Better outcomes. — Working Group on Digital and AI in Health Reimagining Global Health through Artificial Intelligence: The Roadmap to AI Maturity September 2020

Data and algorithms are an integral part of the ability of machines to learn. The outcome of AI depends on the quality of data and algorithms. Data should not be biased, data ownership should be clearly defined, and algorithms should be transparent enough to identify the stakeholders' liability. The responsibilities of all stakeholders need to be delineated to prevent damage and repair or compensate for harm in the worst-case scenario. A proper regulatory framework would ensure these properties for data, algorithms, and the whole of the AI process.[53]

The governance framework of AI in healthcare should be based on multi-stakeholder accountability, independent oversight, and adequate evaluation of socioeconomic and human rights impacts. Governance structures that will allow for screening, and certification of AI applications for health care services at the national level are critical to ensure their safety and rights compatibility. These processes should be handled by independent authorities that are neither politically nor commercially driven.

There is also a need to resist the commercial capture of public health through AI. For this reason, we should encourage national public healthcare authorities to adopt a strategic approach, coordinating digital transformation policies, research and investment, and management and exploitation of personal data. Seeking a healthy balance between individual, private, and public interests and will protect public health in developing countries.

Any regulatory framework of AI in healthcare should ensure multifaceted quality certifications about the composition of the teams, the nature of the data, and the operation of the algorithms. For the efficiency and safety of AI-driven health applications, developing countries' governments need to ensure that there is always human in the loop, i.e., that AI never fully replaces humans so that adequately trained professionals validate health care decisions. AI is only as good as the data, human capital, and expertise of the interdisciplinary team involved in the development of the AI solution. An adequate regulatory framework

53 Boke (2021), Artificial Intelligence and Health Care in Light of COVID-19: Ensuring a human-rights perspective, https://www.oecd-forum.org/posts/artificial-intelligence-and-health-care-in-light-of-covid-19-ensuring-a-human-rights-perspective.

should define the respective liabilities of all stakeholders. It should put in place the necessary conditions and guarantees to protect human rights while working towards the collective interest. This could be done by public certification of AI systems that would ensure that data and algorithm quality is guaranteed to prevent deepening existing inequalities. Public certification of AI applications would build public trust and allow users to give informed consent. Instead of only receiving information about an AI application, end-users would be empowered to understand the implications of their decision before they "click and consent."[54]

Regulators and policymakers would need to address concerns over the privacy and protection of sensitive health data. Adequate data protection systems for preserving data privacy will need to be put in place.

Legal and regulatory frameworks for AI in healthcare should be iterative, adaptable, and go hand in hand with the pace of AI development. Regulatory frameworks should be built on a foundation of mutual support and global solidarity. Only then will we not only overcome this pandemic but also be ready to tackle the next one.

Is informed consent possible in the age of AI?

Often, the standard consent form that patients sign at the point of care is not sufficient to justify the use of their data for commercial purposes, even in anonymized form. These documents, which ask patients to consent to the reuse of their data to support medical research, are often vague about what form that medical research might take. Often, the anonymized medical data is sold to commercial entities that use the datasets to train their AI and machine learning tools. Most of the times, patients are not aware of this. AI and machine learning make re-identification of data a reality. Hence, societies would need to come up with adequate health data sharing regimes that would preserve privacy and entice innovation at the same time.

Enabling an ecosystem for AI in healthcare requires developing countries with at least a minimum set of principles and standards for data governance. While there can be a range of comprehensive regulatory frameworks for data governance in healthcare, the leanest way to ensure a well-functioning AI ecosystem is by focusing on two elements of data infrastructure: (i) data collection and management (for ensuring quality, interoperable, and machine-readable data); and (ii) data sharing (in a way that preserves privacy).

IV.1. DATA COLLECTION AND MANAGEMENT

Developing countries' regulators should incentivize health data recording in adherence to a minimum set of national/international standards. A common set of standards will ensure semantic and technical interoperability between all players. FAIR data management practices should be prescribed for storing data in a findable, accessible, interoperable, and reusable manner while also emphasizing machine-actionability. This involves standardizing data structures (consistency in how data like health event summaries, prescriptions, care plans, etc., are stored) and standardizing common medical terminologies (using common language to describe disease, symptoms, diagnosis, such as WHO-ICD10, SNOMED CT, DICOM, etc.).[55]

54 Ibid.
55 Lashbrook (2018), AI-Driven Dermatology Could Leave Dark-Skinned Patients Behind, https://www.theatlantic.com/health/archive/2018/08/machine-learning-dermatology-skin-color/567619/.

IV.2. DATA SHARING

Suitable governance mechanisms in sharing of health data are built upon two considerations: (i) health data are considered data of public interest, and (ii) any health data sharing mechanisms should always incorporate privacy by design considerations. This also requires a policy consensus on key questions of how to ensure the consent of the patient and define ownership of data, especially to share it with AI developers for processing. This is where policies and standards around de-identification and anonymization can balance privacy and use health data for health innovation. There are experimental and novel models for data sharing, such as data trusts, sandboxes, and collaboratives, especially in developed countries. However, these experimental models might not be readily transferable to developing countries. Hence, the first and quickest step should be to define a standard model agreement for data sharing between all stakeholders that prescribes privacy and security measures to be undertaken by both the data fiduciary and the party requesting data access.[56]

Developed countries' governments have developed innovative approaches to regulating AI in healthcare sharing of health data, such as regulatory sandboxes, public policy labs, and fast-track programs. The main questions in the context of developing countries remain largely unresolved: Are these mechanisms readily transferable to the context of developing and least developed countries? How do governments stimulate AI innovation in the healthcare sector without overregulating and preserving privacy simultaneously?

One way to ensure that AI tools do not widen existing health inequalities is to incorporate equity into the design of AI tools. For instance, the UK's National Health Service was criticized for not giving enough attention to the potential for AI to widen health gaps in its updated Code of Conduct for Data-driven Health and Care Technologies, released in February. Likewise, the US Food and Drug Administration (FDA), which regulates and approves new medical technologies, has been urged by the American Medical Association to highlight bias as a considerable risk of machine-learning in its approval process for medical software. It has been argued that AI tools that continually improve their performance by learning from new data should come under increased scrutiny by the FDA.[57]

Some research funders are tackling the issue head-on by launching research programs to study how the introduction of AI tools affects access to care and its quality. Wellcome, a London-based biomedical charity, launched a £75-million (US$90-million), five-year program that will look at ways to make sure that innovations in the use of health data will benefit everyone — not just in the United Kingdom, but also in other parts of the world, such as East and Southern Africa and India, where Wellcome has a strong presence.

Medical studies initiated by partner institutions, like the Mount Sinai Asthma Health and Stanford Medicine's MyHeart Counts projects, can access 23andMe research services using a new ResearchKit app, through which customers can choose to share data. Customers of 23andMe's services can also choose to participate in other surveys to aid medical research, and provide data to 23andMe's industry, academic and non-profit partners. The data collaborative allows research partners to use 23andMe data to investigate over 1,000 diseases, conditions, and traits to identify new associations between genetic markers.[58]

56 Ibid.
57 A fairer way forward for AI in health care - Nature. https://www.nature.com/articles/d41586-019-02872-2.
58 Data collaborative, 23andMe Patient-Centric Research Portal, https://datacollaboratives.org/cases/23andme-patient-centric-research-portal.html.

In developing countries, building trust in AI solutions in healthcare is about ensuring that AI tools meet demand on the ground and build trust and buy-in from the communities they are intended to help. Rolling out healthcare AI tools in developing countries requires an in-depth understanding of the existing bottlenecks in the healthcare system. For example, the AI that can identify people with tuberculosis from chest X-rays, primed for use in India, could save time, money, and lives in South Africa, especially in rural areas where there are not specialists to examine such images. However, to obtain images in the first place, communities will need X-ray machines and people to operate them. Failure to provide those resources will mean that AI tools will simply serve those already living near better-resourced clinics.[59]

Data trusts

Data trusts are data sharing frameworks, which ensure that all parties involved have defined rights and responsibilities towards the data; and that individuals' personal data, and other sensitive data, is protected. Data Trusts allow two or more parties in any sector to partner in data sharing agreements, shape the agreements according to their needs and enable multiple organizations to work together to solve a common problem.

Data trusts are still experimental forms of data sharing piloted mostly in the developed world. Possible forms of data trusts that can be considered by developing countries governments include national and local public health data trusts and public data research trusts. National and local health data trusts can be charged with maximizing the public benefit from health data while respecting privacy and consent, for example around linking patient records, diagnoses, genomic and socio-economic and behavioral data. A public data research trust can act as the authorized guardian of a range of types of administrative and social data (from national and local governments etc.), providing this to authorized projects from authorized providers with built in audit of the data uses. Access could be provided via APIs and some commercial data could be added into these data pools. Individuals could be given the option to opt in and decide if their data would be part of the public data research trust. [60]

Data trust examples

The UK National Health Service (NHS) Digital's Independent Group Advising on the Release of Data has been deliberating over prospective uses of data on behalf of the organizations that hold it.

There are also 'bottom up' data trusts, such as LunaDNA, which support groups of individuals to contribute data to an entity that stewards it on their collective behalf. Some personal data stores and personal information management systems also already operate under this kind of delegated authority, where they enable people to contribute data about them and defer some rights to decide who can access and use the data. It happens for non-personal data too.

The UK Biobank, set up in 2006 to steward genetic data and samples from around 0.5m people, is a charitable company with a board of directors that 'act as charity trustees under UK charity law and company directors under UK company law'.

59 Ibid.
60 NESTA, The new ecosystem of trust, https://www.nesta.org.uk/blog/new-ecosystem-trust/.

Data trusts have been included in the Canadian Government's Digital Charter as a mechanism to support particular sectors, activities and technologies. The European Commission has also considered 'trusts' as a personal data intermediary with significant potential in their European strategy for data published in February 2020.

Source: Open Data Institute, https://theodi.org/article/data-trusts-in-2020/.
LunaDNA: https://www.lunadna.com/.
UK Biobank: https://www.ukbiobank.ac.uk/wp-content/uploads/2011/05/EGF20082.pdf.

Open health data banks in India

India has proposed a multilayered health information exchange for the creation of health data banks. Health data is stored in local databases while keys are stored in a centralized database, thus providing for enhanced data security and access control. While the delineated system is to maintain personal health records, an additional layer can be added to aggregate or de-identify the data to enable it to be shared openly without infringing on personal privacy. The Indian Government has also planned the creation of the National AI Platform (NAIRP), which is conceptualized to serve as an open data, knowledge, and innovation platform.

Source: India, Final Report on National Digital Health Blueprint, https://main.mohfw.gov.in/newshighlights/final-report-national-digital-health-blueprint-ndhb.

Data sandboxes

The term "data sandbox" is used to describe any isolated environment, through which data are accessed and analyzed, and analytic results are only exported, if at all, when they are non-sensitive. These sandboxes can be realized through technical means (e.g. isolated virtual machines that cannot be connected to an external network) and/or through physical on-site presence within the facilities of the data holder (where the data are located). Data sandboxes would typically require that the analytical code is executed at the same physical location as where the data are stored.

Compared to the other data access mechanisms presented above, data sandboxes offer the strongest level of control. Data sandboxes are therefore promising for providing access to very sensitive/personal and proprietary data. One such example is the Centers for Medicare and Medicaid (CMS) Virtual Research Data Center (VRDC), a virtual research environment that provides timely access to Medicare and Medicaid program data (such as beneficiary-level protected-health information). Access is provided over a virtual private network (VPN) and a virtual desktop to satisfy all CMS privacy and security requirements.[61]

Data philanthropy

The promise of big data for development will not be fulfilled if institutions—primarily private corporations—refuse to share data. The UN Global Pulse, for instance, has put forth the concept of "data philanthropy," where "corporations [would] take the initiative to anonymize their data sets and provide this data to social innovators to mine the data for insights, patterns and trends in real time or near real-time."[62]

61 CMS Virtual Research Data Center (VRDC) FAQs, https://www.hhs.gov/guidance/document/cms-virtual-research-data-center-vrdc-faqs.

62 Kirkpatrick, Robert. "Data Philanthropy: Public and Private Sector Data Sharing for Global Resilience." UN Global Pulse. 16 Sept. 2011.

IV.3. OPEN SOURCE SOLUTIONS FOR DATA DE-IDENTIFICATION; OPEN SOURCE DATA BANKS; DATA ANNOTATION

Establishing open source programs by collectives or governments in developing countries that collaborate with programs such as the United States Privacy Engineering Program under National Institute of Standards and Technology might help set a cohesive direction for a country's healthcare AI industry.[63]

Given that collecting representative health data is often cost-prohibitive, it frequently serves as an entry barrier to entities building AI health interventions. To make solution development economically feasible and avoid bias in the healthcare models being developed, developing countries need to build a robust repository of datasets representing their populations. Research institutions and non-profit organizations such as Child Health and Development Studies or OpenfMRI have created several health data repositories. A concerted institutional push for creating such databanks under a single platform in developing countries will be the first step in kick-starting a local healthcare AI hub.[64]

63 Lashbrook (2018), AI-Driven Dermatology Could Leave Dark-Skinned Patients Behind, https://www.theatlantic.com/health/archive/2018/08/machine-learning-dermatology-skin-color/567619/.

64 Ibid.

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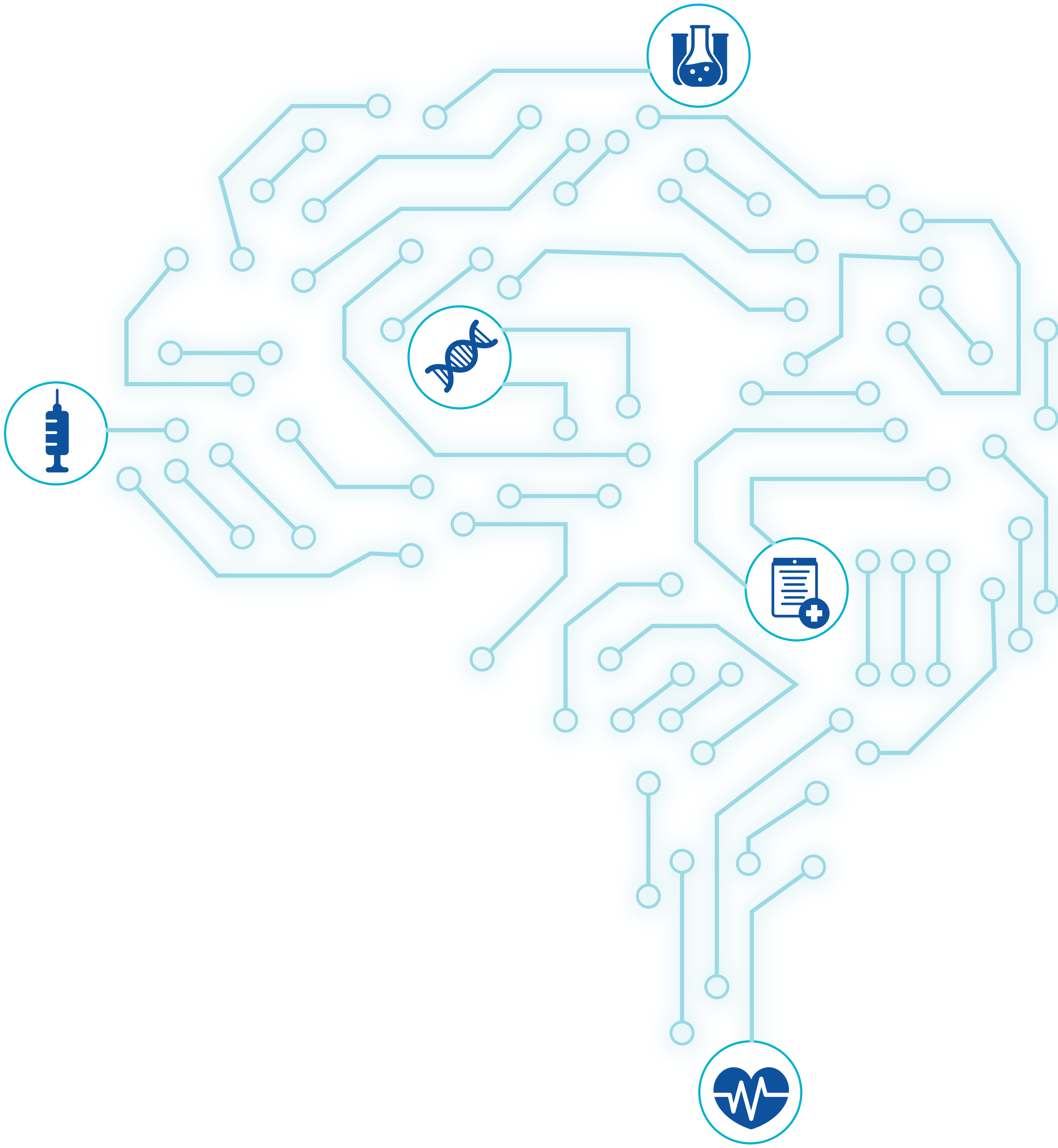

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