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ARTIFICIAL INTELLIGENCE IN HEALTH:

A EUROPEAN OPPORTUNITY

A White Paper prepared by the EUCOPE Digital Task Force.

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AI IN HEALTH: A EUROPEAN OPPORTUNITY

1. INTRODUCTION

As demonstrated by the fight against COVID-19, Artificial Intelligence (AI) has the potential to drive change and improve efficiency and accessibility in healthcare[1].

From compounds design[2] in medicines development to faster patient screening and diagnosis to hospital management (to name but a few applications), **AI-based solutions can help upgrade our healthcare systems towards more sustainability, while helping to address patients' unmet needs**. AI represents a historic opportunity to redesign healthcare in Europe, but realizing its full potential will require some structural, behavioural and societal adjustments. It is undeniable that digital applications and innovations in health have not experienced the massive uptake seen in other sectors (e.g. security, finance, automotive).

As AI's potential in health attracts interests and enthusiasm, its limitations due to its adaptive nature, data availability and appropriate regulatory framework have also come to the fore. In the EU, the COVID-19 pandemic has accelerated reflections about the role of policy in enabling companies to lead globally in digital health and innovation. Leaders need to ensure small to medium-sized companies (SMEs) can access **capital, data and skills** to develop AI-solutions in healthcare.

As a follow-up to its White Paper on Artificial Intelligence[3], the European Commission released its Data Strategy[4] which aims to boost healthcare data sharing and interoperability through the creation of a European Health Data Space[5] – which will enable – and further foster – the effective use of AI-related technologies in healthcare. Moreover, the European Medicines Agency explicitly highlights the value and need for enhanced regulatory clarity for AI in the Regulatory Science Strategy for 2025[6] and the HMA-EMA Joint Big Data Taskforce Recommendations[7]. Hence, it appears certain that a **fit-for-purpose regulatory**

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[1] Jin, C., Chen, W., Cao, Y. *et al.* Development and evaluation of an artificial intelligence system for COVID-19 diagnosis. *Nat Commun* 11**,** 5088 (2020). https://doi.org/10.1038/s41467-020-18685-1

[2] For example: screening of compounds, automatic design of chemical compounds, appropriate synthetic route to make compounds, models to predict efficacy / ADMET properties of compounds

[3] https://ec.europa.eu/info/publications/white-paper-artificial-intelligence-european-approach-excellence-and-trust_en

[4] https://ec.europa.eu/info/strategy/priorities-2019-2024/europe-fit-digital-age/european-data-strategy_en

[5] https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=COM:2018:0232:FIN

[6] https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/ema-regulatory-science-2025-strategic-reflection_en.pdf

[7] https://www.ema.europa.eu/en/documents/other/hma-ema-joint-big-data-taskforce-phase-ii-report-evolving-data-driven-regulation_en.pdf

framework that enables safe data-sharing, accelerates the rollout of personalised medicine and diagnostics solutions, and drives innovation in AI is essential in enabling Europe to lead this race.

AVAILABILITY – DRIVING INNOVATION

The recent months have seen numerous legislative proposals flourishing in the Member States to allow for the reimbursement of digital health solutions, including AI-based solutions. Pricing and reimbursement systems need to adapt to ensure the greatest availability of these new products for the benefit of patients in Europe. Similar to more traditional medicinal products, the systems for allowing reimbursement vary greatly from one country to another, creating disparities amongst European patients. With more and more AI-based solutions applying for reimbursement, it is essential Member States come together with stakeholders to find a coherent and balanced approach to reimbursement processes.

2. MAKING IT HAPPEN – BARRIERS TO ADOPTION

Moving to an environment in which AI-based solutions can deliver significant and consistent improvements in healthcare is a long road. Here are the biggest barriers and challenges we see.

DATA CHALLENGES

Access to data

AI relies critically on the availability of rich data. High quality, reliable and interoperable data is the sine qua non condition of any solution utilizing artificial intelligence. It is the key to training unbiased, robust and safe AI.[8] Despite the vast amount of data available in healthcare institutions, or generated in a non-medical context[9], the majority is either not **accessible**, or usable, making the development of AI healthcare solutions extremely challenging.

The other underlying challenge with data accessibility is the fragmented landscape the data providers operate in and the variability in data format. Very often, when data is available, the dataset is not viable, with systems not able to synthesise data, communicate with and use information from different systems. **Interoperability** and unified standard format are among the main barriers to the adoption of any digital health solutions for a long time, and the problem only exacerbates when applied to AI. The siloed environment resulting from the very different systems operating in the different countries of the European Union makes it very difficult for digital solutions to live up to the expectations.

Data quality

[8] The socio-economic impact of AI in healthcare, Report, October 2020, Eliana Biundo, Andrew Pease, Koen Segers, Michael de Groote, Thibault d'Argent, Edouard de Schaetzen.
[9] For example, a watch can record health pulse, applying AI to analyze those records can allow to predict/diagnose heart attack

Data quality issue is not unique to AI. It is a long-existing problem for any study. Some data collected using AI tools can have higher quality than those collected using standard techniques.

However, due to the fragmented landscape, the data, when available, can be of disparate quality and complexity. Curating this information and evaluating its appropriateness for an application in an AI-based solution requires a lot of skills, resources and time, which is beyond the scope for smaller biotechs or health solutions developers.

Healthcare data is a very particular type of data. It can influence diagnosis, treatment options, it can expand the span of research, it can assess the outcome of a treatment. **The quality of such data is paramount for the success of AI and even more critically for a patient's life**.

As for in any medical practice, data needs to be accurate, representative and interpretable to deliver meaningful insights[10]. A poor dataset can lead to misinterpretation, and in turn, influence another important step in patients' access: the evaluation of AI-based technologies.

Data disparity

Combining datasets from different sources, even when they are all high quality, is complicated because of their disparity. This disparity is two-fold:

1. Different entities may not measure the same thing. Studies led by different companies, with different objectives, do not necessarily collect the same, or even similar data. Having access to multiple datasets of this kind hardly provides any benefit over any single one.

2. Even when different datasets contain the same measurements, these measurements themselves might not be comparable, especially if they are subject to human subjectivity. Different researchers do not necessarily come to the same conclusions or scores when presented with the same sample.

In that perspective, EUCOPE recommends regulators at the EU level to establish a **standard set of data** to be collected and encourage the use of **automated tools** that allow reproducible data collection enabling combining existing datasets.

Recommendations

EU Level	National level
Define data collection standards[11]	Training healthcare professionals

[10] Ibidem.
[11] Including on data annotation and labelling

Establish a unified standard for data exchange Incentives for organizations/vendors that align with common data standards Promote data interoperability and exchange protocol, based on the experience of ERNs (Collaboration between several member states on the same topic)	Allow transfer of data between local centres Centralise data collection from regional data sets

REGULATORY CHALLENGES

Validation process and Reimbursement

Member States are slowly but surely adopting national legislatures allowing for digital health solutions to apply for **reimbursement**. While it is far from being general practice, the trend is growing, and regulatory agencies or Health Technology Assessment (HTA) bodies are adapting their pathways to include the assessment of digital health solutions, including AI-based solutions.

While AI providing health data based on continuous monitoring (both passively and actively) of daily activities has a greater potential for reimbursement, the solutions utilizing AI without immediate health benefits might find a more challenging process.

The data set used by the AI applications or used as secondary data (for instance, when an AI-based tool provides information on an internal decision point) in the application dossier for HTA, reimbursement process or post-marketing studies must be of the **highest standards of quality**. It is crucial to **demonstrate the relevance** of the data in a lifecycle approach: in the context of approval and, at a later stage, reimbursement. Should the regulator dispute the quality and/or the validity of the data used by the algorithm, the entire process could be severely delayed, henceforth, delaying **access to patients**.

While one can understand the challenge in adapting to an extremely changing world, as well as to the massive disruption AI is about to bring to healthcare, it is indisputable that regulators need to issue **clear guidance** on quality requirements for validation processes, reimbursement criteria, and post-marketing studies[12]. We also call for clearer visibility on the possible evolution of the regulatory framework, to take into account the coming development of technology (e.g.: adaptive AI).

[12] Be it for surveillance or studies in the context of real-world evidence generation.

International Cooperation

The immense value of international cooperation through forums like the International Medical Device Regulatory Forum (IMDRF) and ICH [13] helps driving the necessary convergence for global companies/access.

For the EU to close the gap with other important players – the United States of America, Japan or China – it needs to provide clearer guiding documents and risk-proportionate requirements so the sector can adequately prepare and act in consequence.

Further guidance is also required when it comes to the **flow of data** or data transfer for the purpose of research. In the case of many **rare diseases**, most often the patient population in one country, or even one continent is not enough to have a sufficient dataset to ensure proper clinical research. In that case, the **transfer of data** between research institutions has proven very efficient in bridging this deficit. The General Data Protection Regulation represents a proud asset of the EU's arsenal to safeguard personal data, and rightly so. The regulation offers some provisions in relation to data for scientific and research purposes, but more clarity, notably on the ability to transfer pseudonymized research data out of the EU, is absolutely crucial.

Another important aspect that would require more clarity is the question of **Intellectual Property** (IP). As an AI model itself and the data used to create that model are strongly related to each other, the owner, and therefore the ownership of IP rights of such AI model can become unclear. Clear definitions and potential adjustments to IP legislation should be produced to clarify the legal framework.

The European Commission is about to publish some ambitious legislative proposals in the field of AI, and EUCOPE and its members welcome such prioritization of AI, especially in the healthcare sector. It is imperative, however, that the **additional regulations or guidance documents do not represent a further barrier** to the adoption of AI services, but rather act as an **accelerator to stimulate innovation**, to the benefit of the EU competitiveness, and ultimately, to the benefits of European patients.

Recommendations

EU Level	National level
Ensure appropriate incentives to foster innovation Free flow of data for research purposes	Clear guidance on quality requirements for HTA Set of criteria enabling faster reimbursement

[13] International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use

Appropriate data-sharing framework to foster collaboration between academia and industry Clarify Intellectual Property rights Provision of regulatory support from EMA and, where appropriate, from ECDC	Provide specific training for regulatory and reimbursement professionals Ensure value-based assessment Harmonise regulations across the Member States

ORGANISATIONAL AND SOCIAL CHALLENGES

Digitalisation and AI inclusion will require **substantial investments** in many areas. Such an investment can prove to be burdensome and challenging for smaller biotechs and pharmaceutical companies. Without proper support from external actors (public sector, investors), some medical technologies developers might hesitate to make that effort, with an uncertain return on investment.

We, therefore, call for the European Institutions and regulatory bodies to urgently come up with unified data security standard across platforms, industries, countries, etc, such that the barriers in data transfer, storage and analysis can be minimized.

The European Union is home to leading technologies and excellence centres in the world, with supercomputers, AI sandboxes environments and testing centres available. The next European Health Data Space will aim to ensure data is easily transferrable and usable by many players, small and big.

On that basis, EUCOPE calls on the necessary collaboration between private and public stakeholders to **build trust for investment and ensure access to public infrastructures and capital to smaller developers or companies**.

Like any disruptive technology, the adoption of AI-based solutions very much depends on the **acceptance** and utilization by the end-users, be it the health institutions, the healthcare professionals, the payers or the patients themselves. **Trust** in data management, in its governance, its transparency, is paramount to full adoption by the larger public. Too often we have seen new technologies being overhyped and not living to the expectations because of lack of trust from the end-users. Let's learn from past examples and make sure proper training and education are in place.

Recommendations

EU Level	National level
Provide legal frameworks to ensure public trust	Provide specific training and education for the public

Allow access to public infrastructures Build a network of AI centres Ensure a balanced approach to favour ethics and governance without hampering innovation Provide a stimulus for investments in AI, including via small venture companies and academia	Include digital literacy in professional training and education Ensure coherence between local, regional fund structures and EU funding programmes.

3. CONCLUSION

AI-based solutions can help upgrade our healthcare systems towards more sustainability, while helping to address patients' unmet needs. To realise this potential, it appears certain that a **fit-for-purpose regulatory framework** that enables safe data-sharing, accelerates the rollout of personalised medicine and diagnostics solutions, and drives innovation in AI is essential.

Important hurdles remain for the EU to lead this race (data challenges, **clear guidance** on quality requirements for validation processes), but the plans from the European Commission indicate a strong ambition from policymakers. We believe it is paramount that any upcoming legislative steps act as an **accelerator to stimulate innovation**, to the benefit of the EU competitiveness, and ultimately, to the benefits of European patients.

EUCOPE – the European Confederation of Pharmaceutical Entrepreneurs

EUCOPE is Europe's trade body for small to medium-sized innovative companies working in the field of pharmaceuticals and medical technologies.

Based in Brussels, EUCOPE gives voice to more than 900 research-orientated innovative companies and associations active in research, development of pharmaceuticals, biotechnologies and medical devices. Many of its members are developing therapeutic solutions for persons living with a rare disease, who had little to no treatment available just a few years ago.

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