Contribution to the discussion on the European Commission's Data Strategy and AI White Paper

Report by the EIT Health Consultative Group, 31st May 2020

EIT Health

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Introduction

EIT Health welcomes the European Commission's White Paper on AI and the Communication on a European Strategy for Data of 19 February 2020.

EIT Health is a network of approximately 150 partners, made up of leading organisations and institutions from academia, business, research and healthcare delivery brought together to answer some of the biggest healthcare and ageing challenges facing our society today. As a Knowledge and Innovation Community (KIC) of the European Institute of Innovation and Technology (EIT), EIT Health collaborates across borders via: innovation projects, entrepreneurship/business creation, and professional education incubation.

EIT Health has set up a small Consultative Group (CG) of senior leaders from some of its partner organisations to provide views on policy issues in health innovation raised by the European Commission or other European Institutions. The Group does not seek consensus, but rather intends to provide informed views to support policymakers with evidence and thoughtful reflections from the 'coal face' of innovation in the sector.

The EIT Health CG provides this document as a contribution to the related public consultations and, more generally, as input to EU-level policymaking. Separately from this document, the EIT Health CEO will propose EIT Health actions to advance the data and AI health innovation ecosystem in Europe.

Although the discussions of the CG began before the COVID-19 pandemic had made a significant impact in Europe, it has necessarily sharpened our reflections on issues of data and AI and the wider Digital Strategy. It has also allowed us to note the positive and fast change in the way in which policy and regulatory actors and experts from the clinical and front-line have collaborated as they have pulled together to respond to the challenges of COVID-19.

The sections below set out the key areas of input to EU policy makers in responding to the particular regulatory and policy needs of the use of AI and data-rich solutions in health and healthy aging innovation. They all relate to the themes of the Data Strategy and AI White Paper:

1. Securing access to data - clarity of data processing rules, security and availability of data
2. Building trust in AI - the transparency and explainability of AI
3. Risk management
4. Applicability and application of existing medical/health legislation, including liability
5. International dimension

A conclusion from our reflection is that we need to move towards health as a learning system in Europe, and step up the possibilities for innovators, regulators and policymakers, industry - small and large-, citizens, providers, practitioners, and insurers to learn from each other, to collaborate and to share data and AI tools, and to do so in trusted settings.

We also need, as the EU, to engage strongly internationally. The biggest players in health are global companies but there is no interest as close to the heart of individual citizens and national governments as health.

We urgently need to follow-up on these conclusions, in the interest of citizens, for economic opportunities and jobs in Europe, to sustain our public health systems, and to defend our sovereignty. EIT Health can and will play a role in this.

Securing access to data - clarity of data processing rules, security and availability of data

Innovation in the health and healthy aging sector, whether in pharmaceuticals, devices, software or processes, will almost always demand the use of sensitive data coming from patients' medical records, trials, ambient data collected in healthcare settings and data from everyday life recording movements, food intake, sleep patterns, moods and a myriad of other factors. Since 2018, the use of such data in Europe has been governed by the General Data Protection Regulation (GDPR), the purpose of which is to balance free movement of data in the internal market with the rights and interests of individuals.

The complexity of this balance has come into stark focus as the Member States respond to the COVID-19 crisis, and in particular as they begin to use smart phone applications for contact tracing as a means of managing the spread of infection. This begs questions not only of the ethics of the primary use of such data in the interest of public health, but also the re-use of patients' data for research into new medicines and a potential vaccine. The Guidance of the European Data Protection Board on the secondary processing of health-related data in the context of COVID-19 research noted that the GDPR should not hinder measures taken in the fight against the COVID-19 pandemic, and reminded data controllers that the GDPR should be seen as a tool to support innovation and research, not as a measure to be fought against. While EIT Health welcomes this reminder, it remains true that many questions concerning the application of the GDPR in the use of health-related data for research, innovation and healthcare delivery are still unanswered. Three issues of particular concern were discussed by the CG with respect to the clarity of the rules on data processing: the fragmentation of the way in which the GDPR is applied to data processing for research, the need for guidance on security of health data processing and health data availability. These concerns are outlined below:

i) Addressing the fragmentation of the GDPR and its wider challenges for research and innovation
Article 6(1) of the GDPR provides six legal bases for data processing, which must be complemented by one of the exceptions to the general rule prohibiting the processing of sensitive data set out in Article 9 (2)(a-j). Several, but notably not all, Member States (MS) currently state that consent per Article 6(1)(a) and explicit consent per Article 9(2)(a) are the appropriate legal bases to be used for health-related research purposes. Others, however, have chosen a different route, making public interest in public health or research (articles 9(2)(i) and (j) respectively) the preferred legal basis for such processing. This has led to a fragmented interpretation of GDPR across Europe, which in turn has a significant impact on research conducted over several MS.

In a MS where consent is used as the legal basis for health-related data processing, a further problem for research has arisen. The use of consent as the legal basis activates several other rights under GDPR: the right to withdraw consent, to demand erasure of the data and the right to receive a portable copy of any data processed. These rights can create many problems for researchers: withdrawal of consent to use data in research once research has started can cause significant disruption; and erasure of data from a study can undermine the integrity of the study. The rights of erasure and portability may also be very difficult for a researcher to comply with in practice, since the extraction of one person's data from a large study will often be logistically difficult, if not impossible. The GDPR provides that both these rights may be limited where the processing of data is necessary for a task carried out in the public interest, but as 'public interest' is a term interpreted variably across the EU this may too lead to fragmentation of the GDPR.

In addition to fragmentation in the interpretation of the GDPR, it should be noted that health and life sciences researchers will also have to comply with national level laws on confidentiality and where researchers are healthcare professionals, deontological codes will also set ethical demands which may vary significantly between countries.

As well as issues of fragmentation limiting cross-border research, the GDPR can itself also create challenges for researchers and innovators because despite creating a derogation to allow the use of health-related data for public interest scientific research purposes (Article 5(1)(b), it does not define the terms 'public interest' or 'scientific research'. The EDPB in its Guideline on Consent in GDPR of May 2020 noted that interpretation of 'scientific research' may not be stretched beyond its common meaning and recommended that it is understood to mean a research project set up in accordance with relevant sector-related methodological and ethical standards and conducted in conformity with good practice. Given that innovative research, notably using tools such as AI, will not necessarily benefit from well-established good practices and guidelines it is important for national and EU level bodies to work together to develop and promote such guidelines.

In addition to the lack of definition of the term 'research', the GDPR also lacks definition of concepts such as data minimisation, which is required as a core principle of data protection (Article 5 (1)(c). The concept of data minimisation is often diametrically opposed to an innovative research agenda and thus again to significant interpretation to balance the risks and benefits of including specific fields within a research dataset. As well as a lack of definition of the term 'research', the GDPR also lacks definition of concepts such as data minimisation, which is a core principle of data protection (Article 5 (1)(c)). The concept of data minimisation is often diametrically opposed to an innovative research agenda and thus significant interpretation to balance the risks and benefits of including particular fields within a research dataset. This has particular implications for healthcare data where highly sensitive data might also contain critical insights. While the use of safeguarding tools like pseudonymisation could be used to address this challenge to some extent, the de-identification of data at scale, particularly for unstructured data, is a technically non-trivial undertaking. The legal landscape for the use and re-use of data for research and innovation in health and healthy aging is, in some countries, therefore not only very difficult to negotiate, but is also variable across the EU, making cross-border and large-scale research difficult.

Recommendation: *EU or EDPB to adopt guidance that recommends MS to adopt legislation that harmonises the legal base to be used for the processing of health data for scientific research and innovation.*

Recommendation: *EU or EDPB to provide clarity to the terms 'scientific research' and 'public interest' in the research setting to create clarity on the interpretation of GDPR Article 5(1)(b).*

ii) Data Security

One of the primary purposes of the GDPR is to ensure that data are processed in a secure manner. Recognising digital security is a fast-moving science and that legislation could not keep pace with the developments in this sector, the GDPR calls for 'privacy by design' but is intentionally silent on how this should be technologically implemented. To address this, Article 89(1) requires MS to adopt rules to implement safeguards when data are processed for scientific research purposes. As in other aspects of the GDPR, the call for national level guidance has the potential to cause fragmentation of interpretation of the law. Here again, EU level guidance to drive uniformity would be highly beneficial.

Given the highly technical nature of security, it is recommended that such guidance is developed in close co-operation with technical advisory bodies such as ENISA, and that the European Union provides support for the development of open-source security tools that can create a base for future cross-border data sharing initiatives for research.

The call for greater collaboration on security tools and standards is, however, not only to address the needs of researchers and innovators, but also to address the safety and sustainability of the healthcare and healthy aging sector itself. The recent spate of cyber-attacks on hospitals and research labs has heightened awareness of the need for a more co-ordinated strategy for security in research settings. COVID-19 has demonstrated beyond doubt the need for collaborative research across EU borders, but those efforts and the funds invested in them are severely undermined when research is misappropriated or compromised due to organised hacking.

Recommendation: *The guidance of ENISA should be used to develop EU level recommendations on core data security requirements and further investments should be made to develop common security tools and methods that MS may reference in the context of legislation adopted pursuant to Article 89(1).*

Recommendation: *EU Institutions, MS and third countries should collaborate to develop new models to allow for timely access to data for international research and innovation initiatives.*

iii) Data availability (interoperability, quality and altruism)

Both the Data Strategy and the White Paper on AI underline the importance of the availability of data as the fuel for a wide range of innovations, including AI. Both documents also highlight the health sector as a significant but also high-risk user of data. For a European Health Data Space to flourish, and for AI tools to be trained, the issue of availability must be addressed, which includes technical issues such as data interoperability and quality as well as novel concepts such as data altruism.

A significant body of standards for interoperability of digital health systems have been created by both general standards development organisations such as IEEE and ISO as well as health sector specific organisations, such as Health Level Seven (HL7) and the Clinical Data Interchange Standards Consortium (CDISC) HL7 and CDISC to ensure the ability to share and manage information between devices and information systems within and across organisational boundaries. European funds have been used extensively in developing and promoting these standards, but interoperability remains a significant challenge and standards are not implemented as widely as they could be. A key step to ensuring wider use of standards, and thereby driving up interoperability, is that health sector procurers mandate adherence to common standards in their technical specifications. The European Commission, in setting the requirements for public procurements above a certain monetary value, could do much to increase the use of such mandates.

The development of good digital health systems also requires that data are of good quality, not least when data are used to build, train and validate AI tools. Standards for data quality are fragmented across Europe and demand action at EU level to ensure that a high common standard for health data quality can be achieved, a crucial element in building the trust of clinicians and patients in the capacity and value of digital health. The percentage of valid data in datasets is only around 60% (due to incompleteness and wrong data).[1]

One of the objectives set out in the Communication on Data Strategy is to make it easier for individuals to allow the use of the data they generate for the public good, if they wish to do so (known variably as, 'data altruism' and 'data donation'). While data altruism could serve as a useful tool to drive greater data solidarity in Europe and could address the need for more health-related data to be available to researchers and innovators, an over-reliance on donated data or data altruism should be carefully examined. When data are obtained through such mechanisms, this may impact negatively on the representativeness of data, as data will come from a self-selecting group.

1. FAIR related work, see https://www.fair4health.eu/storage/files/Resource/15/D23%20Guidelines%20for%20implementing%20FAIR%20Open%20Data%20policy%20in%20health%20research.pdf

The focus of EU level initiatives to facilitate more data flow should therefore be on developing trust and robust governance in the way in which data are handled, rather than focusing primarily on obtaining data directly from data subjects. A key tool in doing this could be the adoption of a Code of Conduct which is developed in co-operation between data subjects (patients), data users (researchers and innovators) and data controllers who will have ultimate responsibility for the safe and proper handling of data.

Recommendation: *The European Commission should explore fuller use of public procurement guidelines to ensure greater uptake of health data standards to build trust in data interoperability and quality.*

Recommendation: *In the context of the European Health Data Space, the European Commission should explore a range of approaches, including controlled access to disease registries, to ensure better availability of aggregated heath data for research.*

Recommendation: *Any system to develop data altruism should be supported by clear legal guidance and, where appropriate, Codes of Conduct as set out in Article 40 GDPR to ensure that the perspective of all stakeholders can be addressed.*

International developments

The GDPR is being seen as a global example of best practice and is being followed in many other jurisdictions. However, it remains true that the European stance on data privacy and access to data for research is stricter than that in force in our major global competitors such as USA and China. The fragmentation in GDPR interpretation outlined above as well as strict reliance on consent in some EU countries could undermine European capacity to be global innovator. We must ensure that the right balance is struck between the protection of fundamental rights and the needs of innovation and research to ensure that Europe does not fall behind in the race to find innovative, affordable and sustainable solutions for healthcare and healthy aging.

Furthermore, new models of co-operation with respect to data sharing between researchers and innovators around the world must be addressed. Feedback from the US Mission to the EU[2] on the evaluation of the GDPR noted that since the implementation of GDPR, important joint health research between U.S. and EU based universities and research institutions has been impeded. The route of the impediments is seen both in the fragmentation of the interpretation of the GDPR noted above, as well as the complexity of reaching data sharing agreements between the USA and EU. The letter states that the U.S. National Institutes of Health has successfully negotiated only one data sharing agreement with a European counterpart since the enactment of GDPR, and calls for greater ease in carrying out longer term international cooperation on joint health, so that the objective of human health can be reached alongside the fundamental right to privacy.

While the GDPR does provide for international data transfers using rules of data protection law equivalence, binding corporate rules, Standard Contraction Clauses and devices such as the privacy shield, these will not always be sufficient to cover the needs of research and innovation. Article 49(4) recognises this by allowing for EU or national level legislation to provide for transfer to data outside of the EU if this is necessary for important reasons in the public interest. As research is very often in the public interest, the EU should seek to find an appropriate legal basis in order to facilitate better EU-International research while respecting European data protection rules.

2. https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12322-Report-on-the-application-of-the-General-Data-Protection-Regulation/F514088

Building trust in AI - the transparency and explainability of AI

The introduction of AI-enabled systems to support, or even make decisions autonomously, poses major challenges in critical domains where a close interaction with human agents takes place. This is particularly true in the health and healthy aging sector where Machine Learning is starting to acquire traction and relevance due to its potential to complement, or even improve, the diagnosis capabilities of medical doctors (e.g. radiological images analysis to detect tumours or to triage patients). It is also gaining in importance in medical logistics, where predictive algorithms can be used to forecast healthcare resources and staff needs. The coexistence of such intelligent software agents with the human medical experts demands a very high level of trust before the successful and definite adoption of AI to support clinical processes will be fully embraced. This demands a certain amount of transparency of AI systems and the capacity explain how the algorithms that underpin the AI work - the so called explainability.

The Guidelines of the High-Level Expert Group and the Communication on Building Trust in Human-Centric Artificial Intelligence call for the transparency on the way in which AI algorithms work and transparency of the data sets that were used to test, train, and validate algorithms of AI. While the sentiment behind this call is well accepted, the practicality of it should be carefully examined. The practicalities of enforcing full transparency in such a way that would allow a regulator to fully understand and assess the fairness and fitness for purpose of an algorithm is highly complex, and some would say impossibly complex. Data scientists with years of experience in developing AI, including some represented on the CG, insist that opening the 'black box' of AI is neither possible nor useful. The call for transparency should therefore not be confused with a capacity to explain how the algorithm works.

The key to building trust in AI is unlikely to be transparency of vast volumes of data, but rather robust explanations of how the algorithm is used to make a decision. Such explanations will have to be developed in such a way that it can easily be adjusted to several different stakeholders impacted by the use of AI. In a healthcare setting, this will include technical details suitable for a Chief Information/Technology Officer to validate a system, clinical details sufficient to allow a clinician to assess the value of an AI out-put to any given clinical situation, as well as a level of explanation accessible to a patient impacted by the care delivered on the basis of AI. Where such explanation is provided to regulators in the process of AI certification, the focus should be on ensuring that the system using AI can be demonstrated to be safe and appropriate for the task, rather than explain the process in which the algorithm works. This approach is reflected in the spirit of the wording of Articles 13 (2)(f) and 14(2)(g) GDPR, which impose on a data controller the duty to inform a data subject about the existence of automated decisions making and the logic involved in such decision making.

A risk exists that the requirement for transparency and explainability of AI in legislation or guidelines is not fully developed and as a result lacks any real capacity to build trust. As noted by bodies such as AlgorithmWatch and echoed in the Royal Society's Policy Briefing on Explainable AI, requirements of explainability in AI ethics guidelines are often poorly developed, lack enforceability and at worst are often no more that PR tools for companies and governments.

Recommendation: *Transparency and explainability of AI are complex and emerging concepts. If these concepts are used in guidelines or legislation, they should be developed in close collaboration with data scientists to ensure that requirements can be executed and have real value.*

3. https://ec.europa.eu/futurium/en/ai-alliance-consultation/guidelines#Top
4. COM(2019) 168
5. https://algorithmwatch.org/ai-ethics-guidelines-inventory-upgrade-2020/
6. https://royalsociety.org/-/media/policy/projects/explainable-ai/AI-and-interpretability-policy-briefing.pdf

International developments

Internationally, much work is being undertaken on explainability, transparency, and more generally ethics for AI in health innovation. The WHO and ITU have engaged in the development of an international framework for AI assessment and invited EU initiatives and EU policymakers to actively take part in this (see international dimension below). Europe must continue to play an active role in international collaborations to develop trustworthy AI in order that EU innovators can benefit from globally aligned ethical approaches, insofar as these are compatible with fundamental European values.

Risk management

Healthcare and life sciences in the EU are familiar with extensive quality and risk management processes, that are, to a large extent, set out in EU level legislation. This includes legal requirements on the way in which clinical trials are set up, undertaken and reported, ex-ante risk and ethical assessments, post-market surveillance, post-clinical trials and mandatory reporting of issues to competent authorities. With the Medical Device Regulation (MDR) and In-Vitro Device Regulation (IVDR), these processes have been extended and sharpened. On the one hand this implies greater costs and bureaucracy, on the other hand this demands better data collection and more use of data analytics (i.e. AI). It also requires closer collaboration between users/buyers and suppliers/manufacturers, and greater possibility for differentiation based on evidence about safety, data protection, and effectiveness.

Importantly, the changes introduced by MDR/IVDR are based on extensive experience in the field and seek to correct several shortcomings that have in the past led to medical device recalls. Also important is that extensive experience and corresponding formal governance exists to involve stakeholders - notably the end-users concerned, the patients. There is also a huge market-led, bottom-up informal reporting on devices, medication, treatments, etc., such as by patient groups, online platforms such as PatientsLikeMe, but also by medical device and medicines suppliers and intermediaries such as pharmacies. In addition, some guidance exists for device + service combinations, namely for mobile health (mHealth). These, however, may have to be updated for AI in mHealth.

Current evidence of timescales, flexibility and costs show a growing tension concerning the level of reporting required and the time and costs this implies. It is questioned if the level poses an unnecessary burden on product developers, and thus creates a delay in the capacity of industry to respond to urgent health needs. Certification costs are high except for low-risk products/services (such as MDR Class I); timescales for adaptation of existing certification are in the order of years whereas with self-learning software turnaround times of months are necessary; and flexibility is low due to lack of sense of urgency and, as is sometimes claimed, lack of skills in notified bodies.

Recently, however, under pressure to increase flexibility to cope with COVID-19, additional interpretation of the rules has been issued, such as skipping certain steps in clinical trials, post-delivery validation and parallelising steps in validation for certification (exemption in various forms from device regulations have been approved by the UK, Australia, Singapore or China).[7,8]

7. https://www.gov.uk/guidance/exemptions-from-devices-regulations-during-the-coronavirus-covid-19-outbreak
8. https://www.tga.gov.au/exemption-coronavirus-covid-19-medical-devices

Moreover, important complements to traditional certification procedures are emerging, notably the preCert and Algorithmic Change Protocol approaches of the FDA and the FDA's online tool to request feedback regarding the category and regulation that applies to a certain device and with an affordable cost, which simplifies the application process.

The above suggests that the field of health is rich with experience and is also experimenting with renewal while the main needs are to:

i. Adapt to the reality of AI
ii. Respond to the speed of digital developments
iii. Respond fast to emergency health challenges

Therefore, the focus of regulatory steps in AI and data policy should not do away with existing responsible risk management in health innovation, but rather follow a commensurate approach for this field, namely tuning existing approaches to the reality of AI, allow for rapid and responsible innovation, and raise the level of understanding and collaborate on common approaches and facilities.

Recommendations: *Ensure that the existing rules, procedures and processes are tuned to the reality of AI and data, while maintaining responsible risk management, - including accountability, reporting, auditability - by:*

i. Assessing timescales, flexibility and costs when applied to individual products
ii. Developing standardised and openly available risk management approaches for cyber-security, safety (in close cooperation with ENISA), and robustness issues related to AI in health; and learning from approaches such as pre-market clinical trials and post-market pharmacovigilance
iii. Promoting international EU cybersecurity work for health innovation and involve EIT Health experience
iv. Launching a standardisation mandate for AI risk management at process level (ex-ante, ex-post)
v. Speeding up collaboration with EMA and HMAs in EU level efforts on applicability/adaption of existing legislation and in the development of health dataspaces

International developments
Internationally a trend is to develop process-oriented risk management for AI-based solution, next to additional product/device-oriented certification for security. For cybersecurity, work being done in Europe by ENISA which itself is in support of the EU Cyber Act lends itself for internationalising. EIT Health can play a role in this, given that many of its members are active internationally and have insight in cybersecurity rules in several countries.

In comparison to the USA, where the FDA has issued guidance on AI, a similar guidance from the EMA does not exist in Europe. Nevertheless, the EMA has started work on AI (such as in a big data taskforce with the HMAs) and has identified AI and (big) data in its regulatory landscape for 2025. The EMA also prioritises international cooperation. Nevertheless, the timescales of progress with the EMA seem long compared to the USA (and possibly also other countries such as China or Canada).

Applicability and application of existing medical/health legislation, including liability

Existing legislation such as MDR and IVDR poses two problems for AI and data policy: these laws assume that the device is a fixed item and do not foresee it to be dynamically changing as the related AI software through self-learning changes the device's performance or even changes its functionality, and they do not address medical / health services whereas increasingly data and AI enable health-as-a-service. In relation to the first point, an additional issue is that the certification lead times of current legislation are very long compared to the speed of development of AI and big data analytics.

However, the COVID-19 crisis has shown ways to reduce lead times, such as by parallelising steps, working with rapid review panels, rapid iteration between manufacturer and certifying body, restricted use processes (without breaking the law, obviously). For example, the UK allowed for temporary placement in the market of under-certified devices, with the obligation to label them, track their performance, and remove them from usage and/or submit them to full certification once the COVID-19 crisis is over.[9]

The diagram below illustrates reducing approval lead-time:[10]

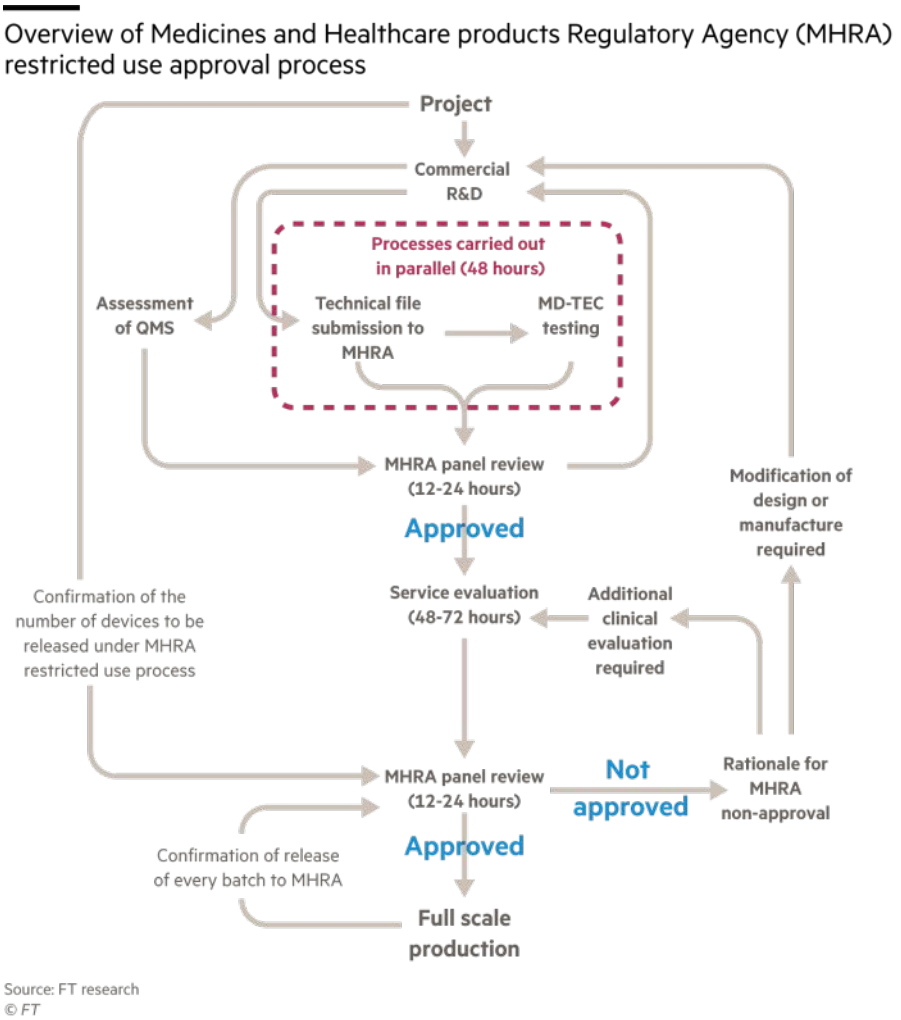


Figure 1: Accelerated medical devices approval by UK MHRA (source: Financial Times)

9. MHRA specification for Rapidly Manufactured Ventilator System, 10.4.20, https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/879382/RMVS001_v4.pdf

10. In this case from 6 months to 6 days in the UK, of course justified by the corona urgency. It is not suggested that such radical reduction should be the norm.

Recommendations:

i. *Speed up certification of AI-enabled[11] medical devices, applying lessons learned from the COVID-19 crisis; this should be open to address all steps of product/service development, validation and deployment.*
ii. *Develop approaches such as preCert and ACP and, once agreed upon, interpret class II and class III certification of the AI-part of devices as being adequately covered by compliance with these approaches; while doing so also keep in mind possible extension to non-AI software devices*
iii. *Clarify in these approaches the coverage of software-only devices (also non-AI ones) and consider software terms such as 'iterations' development and deployment and explain applicability (or not) of manufacturing terms in current legislation*
iv. *Clarify the demarcation between manufacturers and professional users of liability for AI-enabled medical devices in the application of current legislation*
v. *Clarify which AI-enabled devices are covered by existing human oversight obligations.*

CG members also stress improvements that should be made in medical device certification, namely:

- Reduce the costs for the certification process
- Create better and understandable documentation regarding the certification process
- Create mechanisms to facilitate the execution of clinical trials for startups, SMEs and research centers

Needs are also signaled beyond the current MDR: a new category for medical devices that are not used directly with humans or in critical/vital processes (e.g. surgeries, patients' control); and a single certification process for the whole European Union.

For the problem mentioned above, namely that AI/data-enabled health-as-a-service is not covered by EU legislation, there is no obvious solution. There are parallels, however, to the development of health websites and (data protection) issues raised on mHealth, where codes of conduct, labelling and benchmarking have been applied, rather than, for good reasons, EU legislation. Similar approaches can be pursued here, so, rather than aiming for EU legislation:

Recommendations:

i. *Extend Codes of Conduct such as previously developed for mHealth to also cover AI/data-enabled health services; with associated self-regulatory labeling (not for high-risk AI)*
ii. *Update health website guidance, labeling and benchmarking to address AI-enablement, with specific attention to AI transparency*

11. AI-enabled meaning that AI is part of the functionality of the device (i.e. AI during the device being in operational use), rather than AI in the development phase or post-market phase.

The wider international dimension

An important political framing of the recommendations related to international comparison is the sovereignty issue: Europe risks losing economic sovereignty by lagging behind others in in AI and data innovation in the health business and is already confronted with serious weaknesses in health sovereignty in the COVID-19 crisis, which has become a political hot topic.

The data issues (availability, access, interoperability, quality) are closely linked to data space initiatives. In international comparison the impression is that data space initiatives in the USA are quite limited, but they should be compared to the proposed EU level initiative and national initiatives, such as the Finnish MyData.

From time to time the view is expressed, by the pharma industry amongst others, that Europe is (still) attractive because it has high-quality and long-run, longitudinal data. However, EU policymakers would make a risky assumption if they take positive statements about Europe's current strengths in health data and health innovation at face value.

It is recognised that, in the USA, important instances of excellent data collection and data collectors exist, such as Kaiser Permanente, or, in the COVID-19 case as a global data collector, the John Hopkins University. It is also noted that deficiencies in data quality have emerged in some European countries during the COVID-19 crisis.

US-based firms dominate the market of health record management systems (EHR/EMR). Building on that strong position, they extend into AI-based solutions and data-analytics. Helped by favorable financial and regulatory environments they attract health and pharmaceuticals talent and research. Developments with similar effect, though different in governmental support, are happening in China. The consequence is a creeping erosion of Europe's sovereignty, which in the long run means loss of autonomy in industry and jobs, and already, painfully manifests itself during the current health crisis.

On AI explainability/liability an important link exists to medical device regulation, as software as a medical device (SaMD) has seen much regulatory development in the USA. These developments are often seen by the industry as very helpful even if the guidance is not considered to be flawless and complete. The EMA/HMA Big Data Taskforce has provided guidance but this is at a very high level and not yet concrete and usable for the practice of health innovation, in contrast to the FDA guidance. The same holds for EMA's 2025 regulatory perspective. As mentioned, the WHO and ITU have engaged in the development of an international framework for AI assessment of medical devices.

The EU urgently needs to connect to such international developments yet avoid getting stuck into long and unwieldy processes, procedures and requirements.[12] This suggests investigating a more generalised approach.

12. Some Group Members point out that current international standards such as ISO 13485 for medical devices are possibly not suitable to incorporate AI requirements because of these reasons.

Recommendations:

i. *FDA or similar (EU-adapted) AI guidance should be put to the test asap in Europe, such as by EIT Health in collaboration with EMA/HMA*

ii. *Launch a comparative study into current health data quality, addressing at least EU, USA and China*

iii. *Define and apply quality criteria and metrics for data and AI that can be used for international comparison*

iv. *Define other international comparison benchmarks for data, such as speed and costs of data access, data availability; and define targets for the EU*

v. *Pursue standardisation of AI benchmarking and AI-certification for health devices, products and services, also internationally Consider to do so with a more generic scope than health*

Conclusions

The issues discussed above suggest that to address the challenges raised in the EC's Data Strategy and AI White Paper, we need systematic and sustained learning, flexible experimentation, and education in the world of health and healthy ageing in Europe. We also and urgently need to reinforce and innovate in the collaboration and sharing of assets (such as Health Dataspaces) of all actors in health in Europe, in particular of innovators and regulators.

We believe that all oft hese issues provide an ideal opportunity to explore the potential of sandboxing or anticipatory regulation approaches.

The inclusion of industry partners, innovators and end-users in developing regulation through regulatory sandboxing or anticipatory regulation[13] is gaining traction for both horizontal issues, such as data protection[14] as well as in verticals such as financial services[15] and energy.[16]

Core characteristics of anticipatory regulation are set out in NESTA's report 'Renewing Regulation'.

Figure 2: Elements of anticipatory regulation approaches (NESTA)

13. https://www.nesta.org.uk/feature/innovation-methods/anticipatory-regulation/
14. https://ico.org.uk/for-organisations/the-guide-to-the-sandbox-beta-phase
15. ttps://eba.europa.eu/sites/default/documents/files/documents/10180/2545547/154a7ccb-06de-4514-a1e3-0d063b5edb46/JC%202018%2074%20Joint%20Report%20on%20Regulatory%20Sandboxes%20and%20Innovation%20Hubs.pdf
16. Singapore (energy) sandbox guidelines https://www.ema.gov.sg/cmsmedia/EMA%20Regulatory%20sandbox%20-%20Consultation%20Paper_final.pdf

Nevertheless, sandboxing is not a knight on a white horse. Such an approach should be carefully assessed and be part of a learning system approach itself. It needs to be monitored on time-to-market and risk management to ensure that it contributes to both fast and responsible innovation.

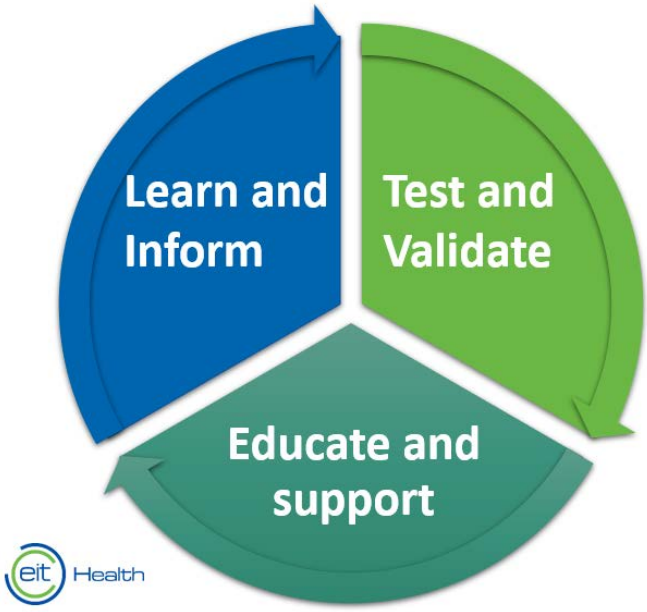
EIT Health can draw on its wide range of partners and build on its well-established experience as an innovation facilitator for product and service innovation, pioneer of professional education, and promoter of the health/aging entrepreneurship ecosystem. Within EIT Health, developers can test their capacity to comply with the wide range of new regulatory standards that digital innovation in healthcare demands, and regulators can test the user-friendliness of proposed regulatory tools.

In this context the Consultative Group considers that sensible innovation-regulation sandboxing in EIT Health may consist of an iterative and collaborative set of activities. These would support EU level policy with access to the real-life experiences of some the European Union's most innovative companies and researchers. The aim would be to support a new approach to policy and regulation development for innovative, sustainable, accessible and equitable healthcare and healthy ageing across the EU. This could be developed as a three-step process in which EIT Health could work with its partners to:

1. **Learn** from the health innovation community 'coal face' to **inform** policymakers and regulators about the needs of the community[17]

2. **Test and validate** support tools to existing legislation, such as codes of conduct, risk management procedures; and support initiatives to test 'pre-guidance and pre-legislation', that is, experimental rules that anticipate future codes of conduct, self-regulation or actual legislation, in areas where the policymakers foresee or anticipate possible future rule-making

3. **Educate and support** the health innovation community on the use of guidance and legislation, thereby continuously learning from the community where further policy and regulatory needs are perceived to exist



Such innovation-regulation sandboxing can be seen as a possible approach to complement and also to combine the rich set of innovation activities in EIT Health.

17. This exercise with the EIT Health Consultative Group is an example.

Disclaimer: The Consultative Group members did not seek consensus but rather intend, with this report, to provide informed views to support policymakers with evidence and thoughtful reflections from the 'coal face' of innovation in the health and healthy aging sector. Views expressed in this report should not be taken to represent the views of their respective organisations and companies.

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