ACTIONABLE RECOMMENDATIONS FROM THE
EIT HEALTH THINK TANK ROUND TABLE SERIES

Regulation and policymaking

Regulation and policymaking are considered significant challenges for the implementation of AI in healthcare, although, if developed and implemented in a flexible and future-oriented manner, they can also serve to enable innovation whilst protecting individuals' rights.

Whilst the EU Medical Device Regulation (MDR; update expected in May 2021) and EU IVDR (In-vitro Diagnostic Medical Devices Regulation) in combination with the GDPR (General Data Protection Regulation) are already in place, Round Table participants in all countries considered that guidance is needed from the EU regarding common standards, specifically focusing on development and regulation of AI and how the MDR should be applied to different AI applications. Whilst Member States do require a certain degree of flexibility for AI implementation into their healthcare systems, clear and simple directives regarding regulation are required. This ensures that the regulatory framework will not suffer from fragmentation and that innovation can be exploited across Europe for the benefit of society.

One proposal from the Round Table in Spain was for a quality certification standard for algorithms confirming that each one adheres to three basic characteristics: it should have no bias, be predictable, and be explainable.

Another often mentioned line of approach is that outlined in the Ethics Guidelines from the European Commission's High Level Expert Group, which suggests seven key requirements that AI systems should meet in order to be trustworthy:

- **Human agency and oversight**
- **Technical robustness & safety**
- **Privacy and data governance**
- **Transparency**
- **Diversity, non-discrimination and fairness**
- **Societal and environmental well-being**
- **Accountability**

Evaluation based on these seven key requirements would cover the entirety of the AI lifecycle. Indeed, it has also been mentioned as one approach to create a voluntary labelling scheme across Europe in the European Commission's White Paper on Artificial Intelligence labels could equally be introduced and might serve to both steer competition towards trustworthy harnessing of AI and data. Standards and certification will play a crucial role in supplementing any legal framework. At the same time, the approach to achieving regulation must be consistent and the manner in which the AI systems are assessed be clear, in order to ensure that no undue barriers are created.

The field of AI is moving fast and, in accordance, regulatory strategies need to be agile, not only to allow more rapid implementation of AI solutions but also because AI algorithms are continually learning and evolving. Strategies will need to be adapted so that applications can be reviewed and assessed periodically.

One approach suggested at the Round Table in France was for a 'Temporary Authorisation for Use' for AI applications that evolve over time, which could be monitored in a similar manner to Phase IV post-marketing authorisation trials for medicines.

Regulation and policymaking are considered significant challenges for the implementation of AI in healthcare

> *"We need to make sure that citizens and patients feel protected [by regulation], but that innovation and transformation isn't stifled."*

Farzana Rahman, Co-Chair of the 2020 EIT Health Think Tank Round Table Series

Another approach suggested across multiple Round Table Meetings made use of the concept of regulatory sandboxes for AI.

These would allow for a range of activities relevant to regulation and policy, such as for the testing and exploration of novel AI systems, to inform metrics and benchmarks as well as case studies, and to ensure that systems are safe prior to deployment.

Nevertheless, once deployed, AI systems should still be reviewed and retested periodically given the sensibility of the application sector. Auditability of AI systems and their development process will play a crucial role too, as well as future investigative powers for questions of liability, safety and security.

Participants at the Round Table Meeting in the Netherlands stressed there was an urgent need for more data spaces across the EU to allow companies to gain access to data in order to test and validate AI algorithms, as well as to encourage the development of more precise and suitable AI systems. Access and use of these data would need to be curated and regulated, and users would need to be GDPR compliant.

Notably, the creation of a European Health Data Space is currently one of the priorities of the European Commission for 2019-2025 and might help address some of these challenges. The initiative is intended to promote better exchange and access to a range of health data to support healthcare delivery and research, and to inform policy. It will be built on three fundamental pillars: a strong system of data governance and rules for data exchange, data quality, and strong infrastructure and interoperability.

At a Member State level, initiatives are also underway to create platforms that allow sharing and use of health data for research purposes.

Furthermore, Round Table participants suggested that the development of an EU-wide data donation scheme could be considered.

Overall, it will be important to cooperate and to coordinate across country borders to harness the full potential.

Case studies:

Shared data spaces for AI research and validation

The Health Data Hub in France is an example of a national data-sharing platform. It is a single platform for all citizens' health data, facilitating the use of these data for research projects, by both private and public entities.

Health-RI, a non-profit foundation in the Netherlands, is currently aiming to build an integrated health data research infrastructure accessible for researchers, citizens and care providers.