Avicenna Alliance
Association for Predictive Medicine

AVICENNA ALLIANCE FEEDBACK TO THE EUROPEAN HEALTH DATA SPACE ROADMAP

The European Health Data Space (EHDS) covering the exchange and access of primary and secondary use of good quality health data is eagerly awaited by the Avicenna Alliance to pursue scientific research and innovations, including the use of computer modelling and simulation (CM&S) in healthcare.

The Avicenna Alliance recognises the importance of privacy protection and security measures for health data and the need for harmonising the processing and sharing of health data, by requiring robust data integrity checks and interoperable data formats/standards. Besides, there is a need to boost data-driven R&D and innovations (e.g., in silico clinical trials) at industrial scales and address the unsolved challenge around the sharing of health data in a lawful GDPR-compliant way.

When considering the use of privacy protection measures, the Avicenna Alliance invites the Commission to consider the options offered by the so-called “visiting mode” and the generation of synthetic data as alternative data access-models preserving privacy.

About the interoperability of data, the Avicenna Alliance stresses the need to take into account the existing rules of international organisations (e.g., ICH, IMDRF, ISO, IHE, , IEEE and HL7/FHIR) to limit disparities in the use of health data globally.

While technical developments, including in silico and AI techniques, enable us to turn the health data into actionable information, it is necessary to ensure the availability of as large as possible, high-quality data sets. This is of critical importance for cases such as rare diseases and paediatric diseases for which limited data is available and for which the use of in silico clinical trials can dramatically reduce the number of real patients involved.

When considering options for the support for training and testing of AI applications, the Avicenna Alliance asks the Commission to not only focus on ‘AI’ applications as a wide range of other technical developments, including in silico and modelling technologies, exist in healthcare.

The EHDS should not only have an important impact on the development of in silico technologies built on phenomenological models (e.g. purely data-driven such as AI) but also on mechanistic (e.g. hypothesis-driven) and hybrid models as they can drive health policies. More mechanistic in silico models have a major impact on the risk assessment and overall safety of the treatments and contribute to making more affordable new drugs and medical devices available by reducing their development, time and cost. The Avicenna Alliance calls the Commission to seize the establishment of a governance framework to support the training, testing, validation and exploitation of all in silico technologies.

The Avicenna Alliance welcomes the ambition to enhance the development, deployment and application of trustworthy digital health products and services, including those incorporating AI. While it is important to consider the options offered by AI, the Avicenna Alliance stresses the need to enhance technical developments including CM&S, digital twins, in silico clinical trials and high-performance computing.

As the Commission wants to support public authorities for accessing health data and supporting evidence-based decision-making, the Avicenna Alliance asks the Commission to encourage the use of Real-World Evidence and data produced by CM&S as part of Health Technology Assessments and the EMA’s evaluation process.

In addition to the Commission's cautious approach to regulating the use of AI-based tools, in terms of safety, robustness, algorithm bias, accountability and fundamental rights, there is a need to regulate digital evidence produced by new techniques, including in silico medicine.

The Avicenna Alliance calls on the Commission to consider how Good Simulation Practice (GSP) could offer the regulatory guidance that industry and researchers need to ensure the robust quality and working of computer models used in health applications.