ICT Solutions for Brilliant Minds

CSC

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Regulation on the European Health Data Space
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CSC strongly agrees with the need to make better use of electronic health data both in primary healthcare and secondary uses, such as research and policy-making, as this will bring tangible benefits to all Europeans in the form of more efficient healthcare systems, development of new treatments and personalised medicine as well as better informed decision-making in the health sector. Therefore, CSC warmly welcomes the Commission's proposal for a Regulation on the European Health Data Space (EHDS) and urges using its rules, common standards and practices, infrastructures and governance framework as a basis for the development of the other sector-specific data spaces in order to pave the way towards the ultimate goal of creating one unified European data space.

CSC is particularly pleased with the strong emphasis of the proposal on interoperability as this is a key element of a functioning federated health data space, that connects various existing data repositories. Attention must be paid to advancing interoperability at all its levels (legal, organisational, semantic and technical, as per the European Interoperability Framework[1]) with particular emphasis on interoperability of metadata which is key for the findability of data from data users' perspective. As the same data is often used for both primary and secondary purposes, interoperability between the infrastructures for primary and secondary use must be ensured as a first priority.

It must also be acknowledged that it will require a lot of time and other resources to bring all datasets in all data repositories in compliance with the interoperability requirements of the EHDS. This must be taken into account when setting the deadlines for the application of the EHDS Regulation and allocating funding to the implementation of the Regulation. Sufficient funding is key for ensuring that the data users will not end up paying the undoubtedly large costs of managing the data permits and processing environments as this would create a tangible barrier for beneficial use of health data in Europe.

When choosing the funding instruments to be used for supporting EHDS implementation, it must be kept in mind that many public sector actors cannot participate in tenders but require grant-based funding. It is also important to ensure that funding will be made available not only to public administrations but also to the various data holders that have to comply with the requirements of the Regulation.

The implementation of the EHDS must be done making use of existing projects, practices, policies and infrastructures related to cross-border use of health data. For example, the infrastructures and

[1] https://joinup.ec.europa.eu/collection/nifo-national-interoperability-framework-observatory/european-interoperability-framework-detail

standards for data governance that are created in the implementation of the 1+MG Declaration[2] can serve as a starting point for the EHDS. Also, existing processing environments must be fully leveraged and their technical and organisational measures and security and interoperability requirements (Art. 50) set based on the existing practices, striking an appropriate balance between security and functionality.

In order to be able to draw on the expertise of those involved in the existing projects and infrastructures, a functional structure for stakeholder engagement must be created. This must be taken into account when establishing the European Health Data Space Board (Chapter VI), perhaps by further incentivising expert and stakeholder involvement. A diverse and balanced representation of different stakeholders must be ensured, with particular emphasis on including the views of the research community.

The EHDS Regulation and its implementation must aim to remove all unnecessary barriers to the secondary use of health data for research purposes. For example, the implications of the anonymisation and pseudonymisation requirements (Art. 44(3)) for research must be assessed carefully. At the same time, it is important to ensure that all data access applications are processed with due attention. Therefore, CSC is critical of the suggestion to issue data permits automatically in case a health data access body fails to provide a decision within the time limit set in the Regulation (Art. 46(3)).

From the point of view of open science, CSC welcomes the obligation for data users to make public the results or output of the secondary use of electronic health data (Art. 46(11)). However, this obligation must be further specified to ensure that publication behind a paywall will not be considered sufficient for reaching the intended level of openness.

Data altruism (Art. 40) is an excellent way to improve availability of health data, especially for research and other common-good purposes. This must be facilitated by creating the necessary tools for its implementation in practice. For example, a comprehensive and harmonised method is needed for making it easy for data subjects everywhere in Europe to give consent to the secondary use of their data. Ideally this should be done via a machine-readable Europe-wide consent form.

Digital infrastructures must be developed in convergence, aiming at synergetic data ecosystems, which can pave the way for world-class research and innovation. This means for example, that linkages of the EHDS with the other data spaces as well as the high-performance computing capacities and high-speed digital connections that the EU is currently developing must be ensured. Such ecosystems, along with the necessary competence development efforts, will be key to ensuring the excellence of European RDI, the cornerstone of Europe's future competitiveness, wellbeing and strategic autonomy.

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[2] https://digital-strategy.ec.europa.eu/en/policies/1-million-genomes