FEAM EUROPEAN BIOMEDICAL POLICY FORUM

FEAM
Federation of European Academies of Medicine

International Transfer of Health Data

Cross-sectoral roundtable - Summary report

16 October 2020

Online event

About FEAM, The Federation of European Academies of Medicine (www.feam.eu)

FEAM is the European Federation of National Academies of Medicine and Medical Sections of Academies of Sciences. It brings together under one umbrella 22 National Academies representing thousands among the best scientists in Europe.

FEAM's mission is to promote cooperation between National Academies of Medicine and Medical Sections of Academies of Sciences in Europe; to provide a platform to formulate their collective voice on matters concerning human and animal medicine, biomedical research, education, and health with a European dimension; and to extend to the European authorities the advisory role that they exercise in their own countries on these matters.

About the FEAM European Biomedical Policy Forum

The FEAM European Biomedical Policy Forum provides a platform for discussion on key policy issues for the biomedical community.

The Forum is an initiative from the Federation of European Academies of Medicine (FEAM). It aims to bring together representatives from academia, research charities, industry, European and national trade associations and professional bodies, regulators, public health bodies, and patient and consumers groups. If you would like further information on the FEAM European Biomedical Policy Forum or becoming a partner, please contact info@feam.eu

Disclaimer

Opinions expressed in this report do not necessarily represent the views of all participants at the event, the Federation of European Academies of Medicine (FEAM) and its Member Academies, or the FEAM European Biomedical Policy Forum partners.

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Report of the event

For the biomedical research, pooled data from individuals is often needed to identify complex pathways and obtain replicable results. Optimal use of data for research can support healthcare professionals and policy makers in improving the health and well-being of citizens. At the same time, protecting the privacy of individuals and empowering them to look after their health well-being are key objectives enshrined in the EU General Data Protection Regulation 2016/679 (GDPR) and embedded in the current European Data Strategy. While the GDPR has harmonised legislation on the processing of personal data within the European Economic Area (EEA), substantial challenges remain for data sharing outside of the EEA. In particular, there are few alternative mechanisms to share health data for research with public institutions in countries such as the USA, and substantial questions remain with regard to the interpretation of the GDPR also in light of the recent decision by the European Court of Justice in the "Shrems II" case. This situation presents challenges as well as opportunities for researchers collaborating with peers outside and within the EEA in crucial areas of health research. Against this background, the FEAM European Biomedical Policy Forum convened a cross-sectoral round-table discussion to explore challenges and opportunities related to sharing health data with a particular focus on the transfer outside the European Economic Area (EEA)[1].

Giske Ursin, Director of the Cancer Registry of Norway and member of the ALLEA-EASAC-FEAM Working Group on International Transfer of Health Data for Research, discussed the importance of sharing health data safely, while protecting the privacy of individuals. Sharing health data is crucial to collaborate with researchers within and outside the EU. However, a large amount of data generated by cohort studies and registries are so detailed that cannot be considered anonymous. There are about 5,000 ongoing collaborative projects across the EEA and with USA institutions. During the COVID-19 pandemics, data were shared within national and international organisations. Transfer of data has also affected cancer data being shared at the World Health Organization (WHO) level within the International Agency for Research on Cancer for public health purposes. Within the GDPR's layered approach to protecting data, some countries outside of the EEA, have received an adequacy decision. However, appropriate safeguards are needed for most data transfers (article 46 in the GDPR). Alternative mechanisms of protection include Standard Contractual Clause (SCC) for transfers outside of EU/EEA countries. Nonetheless, the lack of legal mechanisms for transferring data to researchers in the USA - both at Federal, public, and private institutions - remains an important challenge. Many institutions across Europe are working on agreements - in accordance with the article 46 of the GDPR - and on the identification of additional measures to be implemented, following the recent Schrems II judgment from the Court of Justice of the European Union (CJEU), in July 2020. The revision of the SCC might be the best option for the resolution of

[1] This discussion will also feed the ongoing working group project on International Transfer of Health Data – jointly developed by FEAM, EASAC and ALLEA, https://www.feam.eu/international-transfer-of-health-data-for-research/

GDPR limitations. Even though, the EPDB should be encouraged to provide clear guidelines for public research institutions. Ultimately, this challenge affects European citizens that would benefit from such research.

Alisa Vekeman, from the Directorate General Justice and Consumers, provided the perspective of the European Commission. International cooperation in health research area is crucial and the current COVID-19 pandemic has further evidenced this. The European Commission understands that there is a need to provide further guidance on the application of certain provisions of the GDPR in the context of scientific research and is collaborating with the EDPB on its upcoming guidelines to assist controllers and processors in this area. One of the objectives of the GDPR is to facilitate international data transfers, while ensuring a high level of protection While the GDPR has replaced rules established more than 20 years ago, it has not led to substantial changes with respect to the rules on international transfers, and even provided new tools. The European Commission is working with the EDPB on further guidelines for the transfer of data between public authorities. The EDBB issued a first draft early this year followed by an open consultation; and work on a final version of these guidelines is ongoing. The feedback on the draft guidelines that was provided during the public consultation by research bodies has been helpful to raise awareness about the health research sector. The EDPB is also working on guidelines on Codes of Conduct, which could be a very useful tool also for the research sector, as they allow sectors to develop data protection safeguards that are adapted to their specific type of cooperation. The Commission is also finalizing its work on modernised SCCs, in close consultation with stakeholders. The new SCCs will, inter alia, take into account some of the clarifications provided by the CJEU in the Schrems II judgment, which confirmed the validity of the existing SCCs, but also clarified the conditions under which they should be used. Increasing attention to GDPR is also linked to individuals' increasing awareness about their rights. In this context, strong data protection safeguards and privacy rules are essential to ensure public trust. The European Commission is ready to further engage with stakeholders.

Laura Drechsler, researcher at the Vrije Universiteit Brussel, provided a data protection law perspective. Data protection law in the health data transfer space is facing three major issues. The first is the need for a legal definition of data transfer in the GDPR itself that would allow to clarify its application to a wider range of repository spaces (icloud, websites, etc). The second is the complexity of GDPR transfer mechanism, which do not readily work for health data. There is for example a need for clarification how controllers can achieve the high level of protection demanded by the EU for data transfers. Additionally, the use of derogations needs to be further studied. Potentially the should not anymore be seen as exceptions of limited applicability, but rather as tools that could be more widely used, at least for health data transfers. Thirdly, the position of research including with health data in the GDPR is complex due to the combination of national law and EU law regulating the space.

Brendan Barnes, Director of Data Protection and IP at the European Federation of Pharmaceutical Industries and Associations (EFPIA), provided the industry perspective.

In its July 2020 Schrems II judgment, the CJEU declared the European Commission's Privacy Shield Decision invalid on account of invasive USA surveillance programmes. The Court also stipulated stricter requirements for the transfer of personal data based on the SCCs, while ensuring an adequate level of protection essentially equivalent to that guaranteed by the GDPR and the EU Charter of Fundamental Rights (CFR). If those standards can't be covered, operators must suspend the transfer of personal data outside the EU. The USA protection rules must therefore be adapted to maintain future collaborations with private companies in the EU. European research-based pharmaceutical industries expressed considerable concern about the Schrems II judgement positioning the private sector data flows in doubt. The judgement had reflected EU concerns about US mass surveillance for national security purposes rather than any issue for the health sector. Health data, for example from clinical trials, regulatory submissions, "real-world" studies, are vitally important for public health and are already regulated by multiple safeguards such as research ethics approval and Good Clinical Practice frameworks, as well as contractual standards. The current law is now limiting those vital data flows. As exporters of data, pharmaceutical industries are requested to carry out assessment on adequacy while complying with GDPR. This is a heavy obligation, given the severe penalties applied when failing the requirements to meet the standards under GDPR.

Gozde Susuzlu, Project Coordinator at the European Patients' Forum (EPF), presented some statistics showing that nearly 92% of patients are willing to play an active role in managing their own conditions and sharing their health data, while 60% of those patients would be supporting a cross-border sharing. These data outline the general willing of European citizens to share data, especially when supporting progress in health research. At the same time, protecting the privacy of individuals and empowering them to look after their health well-being are key objectives enshrined in the GDPR and embedded in the current European Data Strategy.

Carlos Luis Parra Calderón, Head of Technological Innovation at the Virgen del Rocío University Hospital and Board member of the European Federation of Medical Informatics (EFMI), described experiences, including recently with COVID-19, in transferring data within Europe and with the USA. Advances in informatics can help to increase the security of data and the GDPR requirements can help to stimulate advances in technologies enabling data sharing. Such advances may overcome some of the present limitations of privacy enhancing technologies, e.g. for detailed analysis of federated data. This context presents challenges as well as opportunities for researchers collaborating with peers outside and within the EEA in crucial areas of health research. GDPR's limitations can still represent an opportunity to search for new tools and new informatic technologies. Data sharing leads to the development of new research questions, with the potential to support research progress and promoting growth of science, unless privacy and confidentiality of data are maintained.

Key messages highlighted during the open debate:

- There is significant value in sharing health data across the EU and outside of the EU/EEA. International transfer rules within the GDPR must ensure sufficient protection in the international context. It is now important to find a balance between facilitating the transfer of health data, while ensuring a high level of protection for personal data.
- The implementation of GDPR has been complex. On the side of international transfers outside of the EEA, some panelist suggested that the GDPR posed additional challenges compared to previously existing rules. Nonetheless, there are differing perspectives on the extent to which GDPR implementation has actually given raise to new obstacles.
- The GDPR has increased public awareness' about data protection rights. Strong privacy rules are essential to gain trust and trust is a key element for patients.
- The European Data Protection Board is currently working to develop new guidelines on several tools for international transfers that are also relevant for the research sector. There is a need for examples, and concrete contractual tools and the research sector could assist by providing concrete input and examples (e.g. on existing best practices).
- The potential interpretation for public interest derogations was discussed as a potential opportunity to address international transfers of health data justified by public interest. However, the exceptional nature of derogations was also highlighted.
- New technologies offer possibilities to enhance the protection of personal data, for instance, by limiting direct access to data as data federations and distributed data mining algorithms. Such technologies are evolving very rapidly but at the moment, provide only limited solutions to the challenges of transferring personal health data outside of the EEA.

Additional material available:

1. General information and programme of the event
2. Full recording of the event
3. Publication on the Research Professional News

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