Draft seminar report:

The impact of the General Data Protection Regulation on the use of personal data for science

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Science 14, Rue de la science 14b, 1040 Brussels

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1. Introduction

On 27 April 2017 in Brussels, ISC organized a seminar which examined the impact of the EU's General Data Protection Regulation (GDPR[1]) on science and R&D collaboration in the EU and globally, to raise awareness and sensitise policy makers on the likely implications of the new, complex data protection landscape for scientific research. The use of personal data for health-related research was a particular focus of the meeting.

Participants in the seminar included EU policy-makers, Member States representatives, representatives from research organizations, industry, associations and advocacy groups, legal experts, and other interested stakeholders. The seminar previewed the application of the GDPR and addressed how the scientific research community can prepare for compliance by the time the Regulation applies on 25 May 2018; how to approach data protection from the perspective of open science and rapid technological progress; how to reconcile data subjects' privacy and progress in (medical) research; and what are the potential impacts of the GDPR for global science collaborations. This report provides an overview of the issues identified and considered during the seminar.

2. Event proceedings and outcomes

In the opening session, it was stressed that the GDPR provides for more flexibility compared to the existing data protection directive and that it offers a privileged regime to scientific research[2]. The specific provisions, relevant to scientific research were then presented[3], underlining the overarching objective of the GDPR to protect personal data of individuals as well as to ensure the free flow of data in the EU. The scientific research community is still concerned that potential differences in the Member States' approaches to the processing of personal data for scientific research purposes could make collaboration on this area more difficult. Member States have been granted the power and are expected to specify, at national level, some of the provisions of the GDPR related to scientific research (including several paragraphs/points in articles 4, 5, 6, 9, 14, 17, 85, 89[4] and several recitals). The European

[1] The GDPR entered into force on 24 May 2016 and will apply from 25 May 2018. The GDPR entails a modernized, single set of data protection and privacy rules and is aimed at empowering the citizens as data subjects, as well as establishing legal certainty for business and innovation, based on clear and uniform rules. It will replace the data protection directive (Directive 95/46/EC) and will apply to all organizations in and outside the EU that deal with the personal data of EU individuals. Moreover, the reform of the data protection rules consists of, apart from the GDPR, the Data Protection Directive for the police and criminal justice sector (Directive (EU) 2016/680). While the Regulation will enter into force on 24 May 2016, it shall apply from 25 May 2018. The Directive enters into force on 5 May 2016 and EU Member States have to transpose it into their national law by 6 May 2018. The Official text of the GDPR is available here: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L:2016:119:FULL&from=EN

[2] Recital 159 of the GDPR states that scientific research should be "interpreted in a broad manner" and includes privately funded research, as well as studies carried out in the public interest.

[3] These include provisions regarding safeguards, further processing and processing of special categories of personal data, consent, storage, information obligation, (derogations to) data subject rights etc.

[4] These refer to pseudonymization, principles relating to processing of personal data including further processing and storage, lawfulness of processing, conditions for consent, processing of special categories of personal data,

Commission, amongst others, is currently conducting a dialogue with the Member States (and also stakeholders) to ensure the consistent implementation of the GDPR. At the Member State level, however, there seems to be clear differences in readiness and preparation for the application of the GDPR by 25 May 2018. To facilitate scientific research collaboration, (which often include cross-border research), coherence, harmonization, and coordination are needed. With the upcoming European Open Science Cloud and the 9th Framework Programme for research, as well as technological progress, the question is if the GDPR is future proof. Practical issues of big data management and data integrity and security were illustrated by the example of the Italian Institute for Astrophysics (INAF) which concerned non-personal data. The question and answers part of this session focused on the limited capacity and resources of data protection authorities (and also the WP Art. 29 and the future European Data Protection Board) to deal with future initiatives related to codes of conduct, amongst other issues.

The second session was dedicated to the potential impact of the new data protection rules on international and global scientific research collaborations and specific concerns and implications for data sharing. Switzerland, while not covered by the GDPR, participates in many EU research initiatives under the S&T cooperation agreement and therefore needs to comply with the EU data protection rules. Switzerland is currently revising its own data protection rules and plans to complete the revision before May 2018. The proposed new Swiss data protection law would offer sufficient protection for research, along the line of the GDPR. There are several other initiatives taking place, such as the Swiss Personalised Health Network[5]. Specific issues, such as interpretation with regard to consent, pseudonymization, and governance, were discussed in the context of collaborative settings and the European Open Science Cloud. The need for uniform understanding was stressed. Furthermore, the United Kingdom will be implementing the GDPR, as they will still be an EU Member State in May 2018. Therefore, the NHS is preparing to implement it to deadline, as well as feeding into national legislation on derogations and supporting development of guidelines; post-Brexit transition and the mode for data transfers, though, are still in question. Adequacy may be the most frictionless transition, but this is uncertain.

CERN provided an example of the ambiguity international organizations (referred to in the context of 'third countries') deal with, especially in demonstrating adequacy and compliance, and jurisdictional issues in regards to international organizations and subsequent requirements, implications, and liability, and how this would play out practically in global science collaborations. It was questioned whether international organization could be a signatory to a code of conduct and who would be the supervisory body, without prejudice to the privileges and immunities. The e-Privacy regulation[6] would be the 'lex specialis' in the field of electronic communications to the GDPR; "it would appear that provision of services to international collaborations would be subject to both regulations", adding an additional layer of complexity. This is to be considered when dealing for example with the European Open Science Cloud strategy. More communication and dialogue is needed; article 50 of the GDPR on international cooperation needs to be engaged now. INAF furthermore presented the data sharing in world's most collaborative institutions in the context of worldwide participation.

specific data subject rights such as for example information provided and the right to be forgotten, furthermore freedom of expression and information and processing for – among others – scientific research purposes, including safeguards and derogations.

[5] More information is available at this link: http://www.samw.ch/en/Projects/SPHN.html

[6] More information is available at this link: https://ec.europa.eu/digital-single-market/en/proposal-eprivacy-regulation

The third session dealt with the use of (sensitive) personal data for health research. Initially, specific issues for the use of personal data in health research were presented in relation to the GDPR application; specifically, this is the Member States' right to maintain or introduce further conditions, limitations, which, however, should not hinder the free flow of data. In the context of health research, pseudonymization/anonymization, further processing and purpose limitation, and the right to consent withdrawal were also discussed. It was stressed that only data which are of quality can be reused. Ensuring compliance would be achieved among others through discussions among the EU bodies/institutions and Member States with the scientific research community on guidelines. The development of the health and life sciences data protection code of conduct according to the article 40 of the GDPR (see below) was presented as a basis for collective engagement with an advantage to have recognized validity within the EU.

Furthermore, from the perspective of the pharma industry, the value of health data, which is a multiple source-multiple user environment, was discussed[7] and it was once again pointed out that the implementation of the GDPR is complex and there are other regulations, policies, guidance and standards, and various initiatives[8] to consider when navigating this landscape, both in terms of personal and non-personal data, as well as already mentioned recitals and articles in the GDPR providing some latitude to Member States to shape the GDPR in relation to research. The Innovative Medicines Initiative (IMI), public-private partnership working to improve health by speeding up the development of, and patient access to, innovative medicines, particularly in areas where there is an unmet medical or social need, was also presented. Their IP policy supports open innovation and data access. Data generated or collected within IMI research projects is available to all partners. At the IMI level, harmonized approach to consent form and data integration is requested from the start by the stakeholders. Education on use and reuse of data is necessary. Sustainability of valuable data-rich assets was addressed and other data challenges were also brought to attention, such as possible discrepancies at the national level in regards to pseudonymization, data interfaces, standards, as well as exemptions and the issue of cross-border collaborations and international data transfers. This session also introduced the patient perspective; the high level of data protection, which is commendable by civil society, is not necessarily desired by patients as they are willing to share their data for medical innovation[9], reminding to not forget "why we are using the data". The patients' frustrations lie in the effective control of their data and the issue of reciprocity. It was also noted that it is important to link clinical and research data with other datasets.

Concluding discussion emphasized the importance of engaging different stakeholders in dialogue and exchanging views to assure the GDPR will be properly understood and interpreted and thus effectively implemented. It was stressed that looking forward, it is necessary to create alignment at the level which benefits research; otherwise, the GDPR might be a missed opportunity.

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[7] Please see the RAND report Understanding value in health data ecosystems, which is available at this link: http://www.efpia.eu/mediaroom/390/43/Realising-the-benefits-of-health-data

[8] Such as the proposed ePrivacy regulation, the European Medicines Agency disclosure policy and other relevant standards by various initiatives, the mHealth code of conduct, investment in European Reference Networks, other Member States' health data initiatives, the OECD framework for governance in health data, Council of Europe guidance on research ethics and data protection etc.

[9] Please see the European Cancer Patient Coalition white paper on the Value of Innovation in Oncology, which is available at this link: http://www.ecpc.org/innovation.pdf

3. Presenters

The speakers[10] at the seminar were:

- Paulo Silva, European Commission, Directorate-General for Justice and Consumers
- Marie Timmermann, Science Europe
- Nicolò D'Amico, National Institute for Astrophysics, Italy (INAF)
- Martin Müller, SwissCore
- Sarah Collen, NHS European Office
- David Foster, CERN / Helix Nebula
- Corrado Perna, National Institute for Astrophysics, Italy (INAF)
- Mariann Karcza, European Commission, Directorate-General for Research and Innovation
- Brendan Barnes, European Federation of Pharmaceutical Industries and Associations (EFPIA)
- Francesco Florindi, European Cancer Patient Coalition (ECPC)
- Magali Poinot, Innovative Medicines Initiative (IMI)

4. Background information

The seminar on the 27 April 2017 was a follow-up meeting to the ISC GDPR seminar, organized on 18 October 2016[11]. One of the outcomes of this seminar was a wide support for developing code(s) of conduct. The implementation of the GDPR foresees in Article 40 the establishment of codes of conduct as one of the means contributing to the proper application of the Regulation. The seminar furthermore explored how will the EOSC accommodate the GDPR's provisions and create a secure and trusted environment for health data for research; the role of patients and their enhanced rights as data subjects; the issue of quality and integrity of data; the role of data analytics in capturing the value from the data; how the GDPR relates to other (recent) regulations, for example the clinical trials Regulation, etc. Finally, the scientific research community on 18 October 2016 expressed concerns in regards to the possibility of Member States' further conditions for the use of data for research that may pose challenges for research collaboration between and amongst Member States and globally.

The need to assure consistent and harmonized implementation of the new data protection rules was also highlighted in a commentary by Prof Jan-Eric Litton, Director General of BBMRI-ERIC, which was published by Nature early this year[12], stressing that the differences in understating across Member States "could seed doubts when scientists and research groups ask to share others' data". By way of information, to guarantee appropriate application of the Regulation and demonstrate compliance, BBMRI-ERIC embarked on developing a health and life sciences data protection code of conduct at a working meeting in February 2017[13].

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[10] The final agenda, speakers' bios, and their presentations are available at this link: http://iscintelligence.com/event.php?id=317
[11] See: http://iscintelligence.com/event.php?id=308
[12] The article is available at this link (Nature 541, 437, 26 January 2017): http://www.nature.com/news/we-must-urgently-clarify-data-sharing-rules-1.21350
[13] See: http://iscintelligence.com/event.php?id=310