CAN GDPR WORK FOR HEALTH SCIENTIFIC RESEARCH?
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EXECUTIVE SUMMARY

Despite many actors' good intentions, the health research sector has so far survived GDPR rather than being strengthened by it. This is the opposite of what was hoped for by industry, researchers, patients and legislators. Cross-border research has been particularly disadvantaged. The workshop highlighted multiple issues ranging from fundamental human rights ("why can a citizen not give broad consent for the use of their data for scientific research") to legal theory ("is data processing in a clinical trial subject to the detailed provisions of GDPR") to the operational reality of legal uncertainty. Opportunities to re-use data for valid research projects are being lost, clinical trial sponsors, subjects and regulators are confused about the new rules of the game. In this context, the workshop particularly highlighted the need to address any transition to a new legal basis in an inclusive way, involving all stakeholders, and taking into account applicable laws in the health sector.

The solutions are not easy to find or simple. The legitimate actions of Member States in using the GDPR's open clauses contribute to the complexity of doing research. At the same time, there are clear limits to the harmonization powers of the Commission, although the actions being taken are very welcome. It is clear something more is needed. The European Data Protection Board has a key role to play in working together with the research sector towards the achievable objective of reconciling the needs of research with the rights of individuals to exercise choice and to understand how their data is being used.

WORKSHOP REPORT

- Although GDPR was intended to bring more harmonization, there is still a lack of consistency in its application to the health research sector in the post-GDPR era. In fact, it seems that post-GDPR there is less harmonization in the health research sector than pre-GDPR because of significantly different guidance provided to organizations in this space on how to apply the new law in different Member States. This has a huge impact on research in both private and public sector and, thus, ultimately, on patient welfare.

- Health research is a large scale activity and clinical trial studies are often organized across borders. Health data research, including the use of big data and artificial intelligence carries a lot of potential in terms of research, societal benefits and innovation, as we enter an era or personalized medicines and evidence-based care. Europe has a unique opportunity to become one of the experts and leaders in this area and needs to keep this position by creating a legal framework that enables digital health to advance. In this context, harmonization of laws and regulatory approaches is critical.

- After GDPR, it appears that it is more difficult to recruit patients, people are unclear what the rules are and it takes longer to review contracts and documents. One of the reasons for this is that regulators in Member States are taking different approaches to what lawful grounds for processing can be used, some of them not allowing consent, others encouraging consent as lawful ground. This is the opposite of what the GDPR aims to achieve, namely harmonization with all patients and research actors being treated the same way.

- Existing safeguards ensure that health research activity is carried out responsibly. There is now also a need to ensure that GDPR obligations and Subjects' expectations are met in a way that is protective of personal data. At the same time, health research activity must be seen also in its function for the public good. Indeed, the right to data protection is not an absolute right and needs to be balanced against other rights and interests (see recital 4 of GDPR), in particular, EU (and universal) public interests, such as the aim to advance science in the health sector.

I. Clinical Trials ("CT")

- Many actors are involved in the CT: Sponsor, CRO, Physician, Subject, etc. The physician has the closest relationship with the patient and conducts the CT. Good Clinical Practice (GCP) standards, which are a legal duty in the EU (and in other regions), require that only the physician holds the code to the personal data of the participants to the trial and keeps the conversion table in confidence. The Sponsor and the CRO only receive pseudonymized data. The duties of each of these parties are regulated in the clinical trial regulations.

- In addition to the GDPR, the CT regulatory ecosystem is very complex and well-established at EU and international level: the national clinical trial regulations, national laws on biosamples, other national laws on patients' rights, obligation of insurance, GCP, ICH guidelines. In particular, the national clinical trial regulations will be replaced in 2020 by the Clinical Trial Regulation (CTR), when the IT European exchange portal is expected to be ready. Its objective is to foster CT and simplify multi-country CT (only one country approval is necessary).

- CTR requires informed consent of patients to participate in the CT. It is provided on the basis of an Informed Consent Form (ICF), approved by regulatory authorities and ethical committees.

- Under the GDPR, a lot of room is left to the member states to determine the processing rules for health data and other special categories of data, such as biometric data and genetic data, as well as for implementing measures specific to conducting scientific research (see article 89(2) GDPR). This may directly affect the conduct of CT. There is a need to ensure that aligned approaches exist that address all Member states requirements or research in Europe will be compromised.

- As provided for in the GDPR, scientific research must be broadly construed since it is linked to EU public interests (e.g., achieving a European Research Area as per art. 179(1) TFEU): article 9.2.j) GDPR provides for specific rules to facilitate 'scientific research', a notion which is broadly defined in other EU regulations, and some examples of which are contained in Recital 159 GDPR providing a specific legal basis to use health data for scientific research without consent; article 5(1)b on scientific research being a compatible purpose for reusing data; article 17(3)d on right to erasure not always applying for scientific research; article 21 (6) on limiting the right of objection in case of

public interest; article 89 on setting forth safeguards for scientific research as well as enabling the Member States to provide for exceptions to data subject rights to enable scientific research.

- There is a lack of consistency in the guidance provided to controllers engaging in scientific research across Member States on the GDPR legal base(s) applicable to process personal data for CT:

    1. The relationship between the GDPR and the Clinical Trial Regulation has not been clarified regarding the personal data processing in a CT.

    2. It is unclear whether controllers are required to comply with both articles 6 and 9 GDPR when processing personal health data, or article 9 alone. In any event, the GDPR enables the use of different alternatives, which may be summarized as follows:

Art. 6 (alternatives)	**Art. 9 (alternatives)**
• **Compliance with a legal obligation** (Art. 6(1)c)), understanding that the legal obligation is the clinical trial regulations (currently, national laws and the CTR in the near future). • **Legitimate interests in conducting scientific research** (art. 6(1) f)), which can be used by the private sector but not by public sites and public sponsors. • **Performance of a task in the public interest or in the exercise of official authority** (article 6(1)(e)), which can be used by public sites. • **Necessary for the performance of a contract** (art. 6(1)b), being this contract the acceptance by the patient to participate in the CT, as signified in the ICF.	• **Public interest in public health (**article 9(2)(i). • **Scientific research according to local/EU law, with safeguards** (Art. (9)(2)(j)), understanding that the law could refer to clinical trial regulations or any other that regulate biomedical research or scientific research studies.
• **Consent** (Art. 6(1)a).	• **Consent** (Art. 9(2)a)).
(in relying on consent, it must be taken into account that the withdrawal of a data protection consent in this context cannot entail the deletion of the data in order to comply with the GCP, safety laws and art. 17(3)d) GDPR)	

    3. There is not a clear understanding that conducting a CT encompasses different kinds of activities and therefore, more than one legal basis may be applicable.

- National Data Protection Authorities (DPA), Health Authorities and Ethical Committees provide differing advice on the different GDPR legal bases to use. These stakeholders do not always take into

account the GDPR specific rules for scientific research or the health related regulations. This situation harms research, in particular, pan-European research, which ultimately harms patients' welfare. As a result of this lack of consistency, the information that a Swedish patient is receiving is different from the one provided to an Italian patient for the same study. This creates a lot of confusion and uncertainty for the industry, public researchers and patients. An opinion of the EDPB, after consultation with the health research sector, is necessary to clarify the situation and foster health scientific research in the EU.

- The choice of the legal bases is not only an academic discussion: it must be disclosed to any patient across the EU in a meaningful manner and defines whether the rights of portability or objection exist (assuming that the Member States at hand have not limited them according to art. 89(2) GDPR).

II. GDPR and secondary use of data for scientific research

- Secondary use of health data for health scientific research purposes (public and private) is indispensable to achieve the EU public interests in this regard. For example, data is needed to build algorithms to support correct dosing of medicine, to examine biomarkers and to support legitimate scientific inquiry. The re-use of such data can be ethically justified relative to the alternatives of the research not taking place or taking place in a new study with the associated privacy risks when the necessary data is already available. However, patients, as well as the private and the public research sectors, should be able to trust the process and have legal certainty on the conditions to reuse health data already collected, including the safeguards to be applied.

- The divergent approach regarding the legal basis described above also applies to the secondary uses for scientific research, where the situation is worse than for primary uses. Indeed, DPAs, Health Authorities and Ethical Committees are ignoring Article 5(1)(b), which provides for an *ex lege* compatible use of data for research if safeguards as per article 89 are put in place. GCP is one of the most important safeguards in this respect and impose, among others, the codification of the data, which entails that the starting point for any sponsor is always coded data.

- Since the field of research or the purpose of secondary processing cannot be anticipated in the ICF, a narrow consent for data processing would always restrict the advancement of science, unless the competent authorities construe that "health scientific research" shall not be limited by diseases to be sufficiently specific and work with the private and public sector to better understand the specific safeguards that already exist in the health scientific research field. Despite Recital 33 and the other GDPR provisions fostering scientific research, the Article 29 Working Party, in its Guidelines that have been endorsed by the EDPB, has suggested a restrictive interpretation of both the concept of scientific research and the breadth of consent which limits data use unless other legal bases are applicable.

- The "apparent" limitation of Art. 28(2) of the CTR, approved before the GDPR (and therefore, before art. 9.2.i) and j) existed), must also be construed taking into account the scientific research provisions of the GDPR and the EU Treaties goals regarding the European Research Area.

- The application of relative anonymisation should also be explored in this area: From a perspective of risk, it is not the same to share fully identifiable health related data (i.e., non protected data) in an open platform without any control (regarding, in particular, who accesses the data and for which

purpose) as to share coded data among scientific researchers with traceable access controls in order for them to conduct health scientific research, that must be conducted according to the Helsinki Declaration and the GCP (and approved by a health authority and an ethical committee when the law so requires).

Conclusion

Personal Data is essential for health research. However, lack of legal and regulatory harmonization is preventing the EU from taking the opportunities available from digital health. In particular, there is a current lack of harmonization regarding the GDPR legal basis and the role of the parties involved for GDPR purposes that is harming EU public interests in this field, which ultimately harms patients' health opportunities.

DPAs, Health Authorities and Ethical Committees hold disparate views regarding the interpretation of both the scientific research provisions of the GDPR (which enable different alternatives regarding the legal basis) and the health related regulations (which impose the integrity of the dataset and thus prohibit data deletion, which determines the different activities involved in a CT and the duties vested on each of the parties involved therein, in particular, the codification of the data before the data leaves the site to be provided to the Sponsor). There is also confusion regarding institutional responsibilities; the role of ethical committees in particular needs to be clarified.

Any discussion on the legal basis (consent and other alternatives) needs to be addressed in dialogue with the industry, with researchers and other stakeholders, in particular patients. The definition of further processing for secondary scientific research purposes is challenging, given that science is enquiry-driven and future data uses cannot be always anticipated in advance. An opinion of the EDPB, with the consultation of the health research sector, would be welcome to clarify the situation, and foster health scientific research (which is public and private) in the EU, aligning the patients' rights and interests, the research sector's needs and the EU public interests.