EU GDPR: Views and Opinions

SCTO Regulatory Affairs Platform
April 2019

While developing appropriate laws to serve Switzerland, we can learn from and build on current EU experiences of how GDPR affects clinical research.

Exploring the broader EU setting

How will the new European data protection regulation affect clinical research? And what recommendations can be derived, to make it run more smoothly? These questions, among others, were addressed in a recently published article by Demotes-Mainard, Cornu, and Guérin (Therapie. 2019 February; 74(1), 31-42). It was published originally in French and translated into English.

The article is an outcome of a roundtable held in 2018 with French representatives from the European Clinical Research Infrastructure Network (ECRIN), clinical scientists from university hospitals and public research organisations, the industry, and authorities, on the topic of data protection. The objectives were to identify problematic areas, including those in the need for clarification, and to make related recommendations to promote clinical research, while ensuring a high level of patient protection. The authors outlined comprehensively all stages of clinical research affected by GDPR (see Table 1, reproduced with permission).

Table 1 Stages of clinical research impacted by the GDPR.

Point of impact	Explanation/types of database
Site selection, investigator selection	A site/investigator can be selected based on its past publications, its activity and its patient population
Agreement between sponsor and investigational site	Agreement needed between data controller (DC) and processor
Patient selection	Patients can be selected from healthcare databases: PMSI, data warehouses
Informed consent	GDPR information updated, broad consent, re-consent, evolving consent, dynamic consent, e-consent
Cohort/registry data Data from national databases	Specific studies or clinical trials using these databases
Electronic health records	Data on care is inserted into research databases and clinical trial CRFs
Electronic data capture	Connected objects, e-questionnaires
Data sharing (FAIR)	With medical journal reviewers, and made available to the community
Reuse of data	Access to existing databases

CRF: case report form; FAIR: findable, accessible, interoperable, reusable; GDPR: general data protection regulation; PMSI: program for the medicalization of information systems.

Table 1

The authors also made recommendations falling into three categories: the exercise of individuals' rights, streamlining administrative procedures, and a more open relationship with the international environment.

Recommendations for fostering international cooperation

The authors are calling for Europe-wide harmonisation of data protection regulations and procedures. It is difficult at present to ascertain to what extent the GDPR and the obligations of multinational clinical trial sponsors are being implemented in European countries.

Regarding their obligations to ethics committees, foreign sponsors should be told how to proceed, including by making the relevant documents available in English, so as to facilitate their international projects. Various European partners are preparing codes of conduct to help clarify how the GDPR applies to multinational data processing.

The authors concluded that, at this stage, the constraints of GDPR are still imperfectly defined. These constraints should, however, not compromise the opportunities available to clinical research: transparency and data-sharing according to the principles of open science, the possibilities afforded by big data, and the potential to reuse existing data (such as hospital data, health databases, study data cohorts, and registries).

From the EU to Switzerland within Europe

Euresearch, a Swiss non-profit association facilitating national participation in the EU Framework Programme for Research and Innovation, made "Ethics and Data Protection in Horizon 2020" a highlight of its February 2019 newsletter.

With the GDPR aiming to harmonise data privacy laws across Europe, those Horizon 2020 projects with sites in Switzerland often face related legal and ethical challenges. To obtain support with such a project, please contact the Euresearch office in your region, or the national contact point for health or ethics.