ACRO
ASSOCIATION OF CLINICAL RESEARCH ORGANIZATIONS

16 July 2020

In response to EMA Request for Comment on:

The General Data Protection Regulation (GDPR)
Secondary Use of Health Data
for Medicines and Public Health Purposes

Discussion Paper for
Medicines Developers, Data Providers, Research-Performing
and Research-Supporting Infrastructures

Introductory Comments

The Association of Clinical Research Organizations (ACRO) represents the world's leading clinical research and technology organizations. Our member companies provide a wide range of specialized services across the entire spectrum of development for new drugs, biologics and medical devices, from pre-clinical, proof of concept and first-in-human studies through post-approval, pharmacovigilance and health data research. In 2019, ACRO member companies managed or otherwise supported a majority of all biopharmaceutical-sponsored clinical investigations worldwide. With more than 150,000 employees, including over 60,000 in Europe, engaged in research activities in 114 countries the member companies of ACRO advance clinical outsourcing to improve the quality, efficiency and safety of biomedical research.

While we recognize that issues related to GDPR compliance do not, in general, fall within the remit of the EMA, we note that the agency is the pre-eminent source of guidance concerning research uses of health data by medicines developers and research-performing and supporting infrastructures and so we welcome this EMA project to develop Q&A on the secondary use of data within the context of the GDPR.

We hope that such Q&A guidance on secondary use of data for medicines and public health purposes will influence the thinking of Member State DPAs, as well as Ethics Committees; this point is important, as researchers are encountering highly varied interpretations of DPAs and ECs on the issue of sensitive, and even pseudonymous and anonymous health data for research and public health purposes.

Discussion Points

- In regard to the secondary use of health data (e.g., clinical trial data, clinical encounter and healthcare data in EHRs, insurance claims data, registry data, pharmaceutical consumption data, health status and health trend data, etc.) for purposes other than initially collected, Consent (or re-Consent) is a practical impossibility, especially at scale, (i.e., “big data”)

- In establishing the legal basis of secondary data use, medicines developers and research-performing and supporting infrastructures generally rely on legitimate interest; and purposes of research and public interest, providing that a privacy impact assessment is performed to assess and ensure minimal impact on the data subject

- Examples of public interest to support secondary use of health data are myriad, and include safety monitoring, public health tracking, health services research, comparativeness effectiveness research, and medicines development

- We appreciate that the research exemption is articulated in Article 89 and Recital 33, and support the application of appropriate safeguards such as data minimization, encryption, anonymisation, and the like

- We regret that the "guidelines on processing of data concerning health for the purpose of scientific research in the context of COVID-19" adopted by the EDPB 21 April 2020 has not led to meaningful harmonization regarding application of GDPR requirements by Member State DPAs

- Pseudonymisation should be central to consideration of secondary data use, given our view that in most instances the health data of which secondary use is made is invariably 'somewhere on the spectrum' between pseudonymous and anonymous and thus its use for secondary purposes should be permissible broadly under certain prerequisites. In fact, we would remind the EMA of the Draft Code of Practice on Secondary Use of Medical Data in Scientific Research Projects, (eTRIKS project supported by IMI, the European Union and EFPIA, final draft 27 Aug 2014) which stated that Personal Data that have been pseudonymised should not be considered Personal Data in the hands of the user who does not have access to the key, if: the process of de-identification complies with industry and regulatory standards; a binding agreement defines the conditions under which the data can be used; and appropriate technical measures have been taken to minimize risk of re-identification.

- Among the many reasons that pseudonymised data should not be considered Personal Data is that the very process of re-identifying key-coded data for the purpose of allowing the exercise of individual data subject rights creates meaningful risk to an individual's privacy and the potential for mis-attribution of the data of one individual to the data of another. Additionally, in clinical trials, good clinical practice (e.g., ICH E6(R2) GCP guideline) requires that the records identifying the subject will be kept confidential by the investigator.

- To the extent to which pseudonymised data is considered not Personal Data, then issues such as compatibility, transparency, the exercise of data subject rights, and the like, which in the context of secondary use of data are impracticable, if not impossible, are largely mooted.

- ACRO is interested in the issue of data retention in relation to secondary use of Personal Data (not pseudonymised or anonymized) by medicines developers and research-performing and supporting infrastructures, and we believe it would be helpful for the EMA to clarify a data retention period of 25 years, the same as for primary use data generated in a clinical trial, and consistent with GCP requirements for secondary use data that are used to support regulatory decision-making. In any event, it would be useful to have a specific industry wide benchmark to harmonize retention periods.

- In light of the recent retraction of publications on the study of chloroquine and hydroxychloroquine in the treatment of hospitalized patients with COVID-19 by The Lancet and the New England Journal of Medicine, ACRO also recommends that secondary use data should be made available in a form that allows for independent analysis.

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- Beyond the issue of a Q&A guidance, it may also be useful for the EMA to create a portal that could help educate data subjects on such issues as pseudonymisation, compatibility and transparency in relation to secondary use, and the like.

Concluding Remarks

Comprised of companies at the forefront of clinical and data research, ACRO has long been engaged with the issue of secondary data use. In fact, an ACRO delegation had an extensive discussion of the topic with then-European Data Protection Supervisor Giovanni Buttarelli and his staff in September 2017. Then, as now, our members recognize that duties of fairness and loyalty to the interests of the data subject must be observed and principles of necessity and proportionality must be followed. Simply, secondary use of health data – whether EHR data, claims data, registry data, outcomes data, etc. – is not an excuse to circumvent the principles of data protection and data subject rights; rather, it is a crucial mechanism for the pursuit of essential research to improve human health, a goal that the current public health emergency has made astonishingly important and immediate. We thank the EMA for its intention to provide a practical guidance for how such secondary use can be made in compliance with the GDPR, and look forward to a Q&A that will be helpful to data subjects, researchers, ethics committees, patient groups, regulators, and other stakeholders. We look forward to the virtual workshop on the topic of secondary use of data for medicines and public health purposes, which is scheduled for 29 September 2020.

Respectfully submitted,

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