



Alliance for Biomedical Research in Europe

Preserving health and scientific research in Europe

Statement by the Alliance for Biomedical Research on EU Data Protection Regulation

The BioMed Alliance welcomes the revision of the EU legal framework on the protection of personal data. The creation of a transparent, consistent legal framework by the EU institutions could further stimulate health research to the benefit of patients, as well as the European knowledge economy.

After a satisfactory proposal by the European Commission, the BioMed Alliance is concerned by the direction the debate has taken inside the European Parliament. Some of the amendments made are counterproductive to advance health and well-being and to protect EU citizens, as they do not take into account the vital role patient data and associated biobanks play in health research.

Especially the introduction of amendments 191 & 194 to articles 81 and 83 will have a strong negative impact. They implicitly force researchers, except in cases of “high public interest”, to re-contact all data subjects to obtain their specific consent for the reuse of their data. This despite the fact that their data has already been pseudonymised at this stage.

In practice this will mean unsustainable administrative costs, delay in research and waste of valuable data as not all data subjects will be reachable in a later stage. Moreover, crucial large scale data studies, often supporting larger breakthroughs in science (see Annex I), may not be feasible anymore on European territory.

The BioMed Alliance therefore strongly recommends the Council of Ministers and European Commission **to oppose the European Parliament’s amendments to articles 81 and 83 in triilogue negotiations** and calls on the EU institutions to **reintroduce the balance achieved in the original European Commission proposal between privacy and health research.**

Karin Sipido,

President of the Alliance of Biomedical Research in Europe

Executive Committee

President: Prof. K. Sipido
Past- President: Prof. U. Smith
President-Elect: Prof. C. O’Morain
Treasurer: Prof. L. Nicod

Board Members:
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Annex I: Case Study - the European Medical Information Framework (EMIF)

The Parliament's amendments to Articles 81 & 83 could undermine the European Medical Information Framework (EMIF), the largest European electronic health record database.

EMIF aims to link together existing health data from 40 million European citizens across seven EU countries and to assess data from a range of sources such as: hospital databases, cohorts and national registries.

The data will initially be used to tackle obesity, diabetes and Alzheimer's disease, but in a later stage also expected to be valuable for the study of many other European health threats. These also include less common side effects of pharmacological therapies requiring large data bases to early detection.

Why will the Parliament's amendments to articles 81 & 83 put this cutting edge research project under threat?

Participants to this study have given "broad" consent for the use of their pseudonymised¹, personal data. This allowed researchers to link and match the data about the same person from different databases.

The Parliament's amendments would hinder this innovative form of data collection as it forces researchers to ask the specific consent of subjects to reuse their data. Without this specific consent the data could not be linked and assessed by the researchers and hence loses its significance.

The Parliament introduced an exception to this rule in case of "high public interest"², but studies like the EMIF study will in practice most likely not be classified as falling under this category.

Hence, the only option left for researchers performing these data collection studies is to re-contact all participants for specific consent. However this will create an enormous administrative workload to the extent that the continuation of the study will no longer be feasible. Even in small data collection projects, the asking for re-consent will significantly increase the costs of the project, lead to the waste of valuable health data and delay the outcomes of the study.

All in all, the Parliaments' amendments would severely impact European research and endanger Europe's competitive advantage in research excellence and innovation.

¹ individuals' identities are masked, but could be retrieved if needed

² "High public interest" is the exemption used only in a very limited set of circumstances.

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About The Alliance for Biomedical Research in Europe

The Alliance for Biomedical Research in Europe (BioMed Alliance) is a consortium of 21 member organizations, representing over 400 000 researchers and health professionals.

The Alliance for Biomedical Research in Europe (BioMed Alliance) was founded by four major European academic medical societies namely the European Cancer Association (ECCO), the European Respiratory Society (ERS), the European Society of Cardiology (ESC) and the European Association for the Study of Diabetes (EASD).

The BioMed Alliance is committed through its actions to promote excellence in European biomedical research and innovation with the goal of improving the health and well-being of all European citizens.

BioMed Alliance's members:

European Association for the Study of Diabetes (EASD), European Association for the Study of the Liver (EASL), European Association of Nuclear Medicine (EANM), European Atherosclerosis Society (EAS), European CanCER Organisation (ECCO), European College of Neuropsychopharmacology (ECNP), Federation of European Biochemical Societies (FEBS), European Federation of Immunological Societies (EFIS), European Academy of Neurology (EAN), European Hematology Association (EHA), European League Against Rheumatism, (EULAR), European Respiratory Society (ERS), European Society for Paediatric Research (ESPR), European Society of Anaesthesiology (ESA), European Society of Cardiology (ESC), European Society of Hypertension (ESH), European Society of Radiology (ESR), European Society of Human Reproduction and Embryology (ESHRE), United European Gastroenterology (UEG), European Academy for Allergy and Clinical Immunology (EAACI), European Society of Pathology (ESP)

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