



Alliance for Biomedical Research in Europe

Statement by the Alliance for Biomedical Research in Europe on the European Commission's proposal for a European Data Protection Regulation

The Alliance for Biomedical Research in Europe (BioMed Alliance) is a non-profit organisation dedicated to the promotion of excellence in European biomedical and health research. It consists of 20 major professional societies in different areas and represents around 250 000 scientists and health professionals.

The BioMed Alliance welcomes the European Commission's proposal for a new Data Protection Regulation which aims at updating the existing framework dating from 1995 to address the fragmentation of national legislation and legal uncertainties.

The BioMed Alliance underscores that patient data and associated biobanks are vital for health research. Patient records provide the basis for observational studies of factors influencing human health and disease. Such studies have led to several breakthroughs in identifying factors including the associations between smoking, lung cancer and chronic lung diseases; between high blood pressure, kidney disease and cardiovascular disease to mention just a few.

Using patient data in research is therefore of vital interest to Society and their use improves our understanding of health and disease.

The Commission proposal to Parliament and the Council (COM(2012)0011) provides a number of derogations from particular requirements for the use of "personal data" for scientific research and identifies such conditions in Article 83. Personal data should not be used if anonymous data are sufficient and, if possible, identifying information should be kept separately from other information.

The BioMed Alliance strongly supports the derogations which facilitate the processing of personal data without consent if necessary and for such data to be held for extended periods for research purposes (for instance, disease registries and other eHealth records).

The BioMed Alliance also strongly supports the possibility to use pseudonymised/key-coded data without consent and based on national regulations. The Amendments proposed by the European Parliament (27, 327 and 328) restrict the use of such data without informed consent to cases of "exceptionally high public interest". Such restriction would markedly increase the regulatory burden of scientists and organizations and obstruct the use of such data with countries outside the EU.

Taken together, the BioMed Alliance supports Article 83 of the Data Protection Regulation and proposes that the associated derogations for research are maintained without the suggested Amendments by the EP.

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Ulf Smith
President

On behalf of the BioMed Alliance Executive Committee

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