**TMF – Technologie- und Methodenplattform
für die vernetzte medizinische Forschung e. V.**

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Press release

Protecting citizens' data and enabling biomedical research: medical researchers comment on drafted legislation for a European General Data Protection Regulation.

Comment by TMF and the Network of Coordinating Centers for Clinical Trials supported by leading German research organisations.

29 July 2014. Medical researchers in Germany have welcomed the European Parliament's draft of a General Data Protection Regulation (GDPR) designed to standardise data-protection procedures in Europe. However, in a statement published today, the research community underlines that efforts must be made during development of the rules and regulations intended to protect citizens to ensure that biomedical research is not unnecessarily restricted or even prevented completely.

Protecting citizens' privacy and personal data is a central public concern across Europe. This applies to a broad range of fields, not least to medical research and the data of the patients and people involved in trials. Since the proposed European Regulation would have a significant impact on this area, TMF and the Network of Coordinating Centers for Clinical Trials have published an in-depth report endorsed and signed by a number of leading research organisations and associations in Germany, including the German Research Foundation (DFG) and the German Medical Faculty Association.

Individuals' rights concerning personal information versus freedom of research

For medical researchers, it is essential to maintain a good balance between the basic right of individuals to decide what happens to their personal data and the right to freedom of research. The proposed legislation, however, would endanger the concept of 'broad consent' which, following extensive public debate, has become the norm for medical research in Germany. This form of consent does not specify one or more pre-defined research purposes and, as such, is the only suitable way of carrying out long-term, innovative medical research projects that comply with all relevant legislation. Questions arising in future trials, that draw on data stored in infrastructures such as biobanks, registries and cohorts, cannot be anticipated today but only come to light as research progresses.

Non-commercial biomedical research

The statement issued by research institutions in Germany reflects the stance taken by non-commercial biomedical researchers with regard to the draft legislation from 12 March 2014, and also critically assesses the earlier draft published by the European Commission on 25 January 2012. It focuses on the sections of the proposed data-protection regulations that are directly relevant to biomedical research. The document reiterates previous comments issued by research organisations in Germany, in particular those published by the Europe-wide Wellcome Trust initiative, whose demands largely correspond with those of the signatories. However, the new document goes beyond previous statements in terms of its depth and detailed analysis of the draft legislation.

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TMF has published the statement in German and English. A short summary covering all pertinent points is included at the start of each document. Download the statement here: www.tmf-ev.de/News/Stellungnahmen.aspx

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