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on behalf of the DFG, the MFT, the KKS-Network and the TMF

Role(s):

- Researcher
- Clinician
- Clinical trialist
- Clinical trial sponsor / funder

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Requirement To Share Data

- I agree with this general approach

Comments: The German Research Foundation (DFG), the Association of Medical Faculties in Germany (MFT), the Network of Coordinating Centres for Clinical Trials (KKS-Network) and the TMF - Technology, Methods and Infrastructure for Networked Medical Research welcome the ICMJE's proposal as an important step to making the best use of clinical trial data. The intention of this proposal is in large parts in line with the DFG principle of open access to data from publicly funded research. Both, data sharing and reanalysis of clinical trial data need to be recognized as important scientific contributions. Especially in the context of clinical trials, however, competing interests between researchers, the public, and trial participants need to be carefully balanced. Any condition regarding data sharing needs to find broad acceptance within the scientific community and must comply with data protection regulations. Therefore, unrestricted public access to deidentified clinical trial data is most likely not appropriate in many cases. Authors are not to be barred from publication in ICMJE member journals if data sharing is not possible, e.g. in trials with very small numbers of patients (as in studies of rare diseases, safeguarding the confidentiality of trial participants), for ethical reasons or data protection regulation.

6 Month Time Frame

Comments: We support early data sharing and a timeframe of 6 months after publication is most likely suitable for the majority of published clinical trials. It offers the opportunity of independently validating the published results and generating additional knowledge from secondary analysis. However, a general 6 month timeframe does not adequately take into account individual circumstances that may preclude early data sharing. The original investigators should have the opportunity to extensively analyze and publish the data that sometimes took many years to generate. We propose that standards should be developed that take into account individual specificities of clinical trials as well as scientific, ethical, clinical, public health, intellectual property rights or policy implications.

Require a Data Sharing Plan

- I agree with this general approach

Comments: To ensure that data collected in clinical trials are useful for the wider research community and suitable for replication and secondary analysis, a data sharing plan needs to be developed before data are collected. The data sharing concept will have consequences on the ethical evaluation, on the informed consent process and on how clinical trials are conducted. For reasons of transparency, the data sharing plan should be published as a component of the clinical trial registration. Sufficient time needs to be given to clinical trial registries to implement this functionality as part of the registration.

Providing Credit

- I agree with this general approach

Comments: Conducting clinical trials requires an enormous effort in the preparation, conduct, and data analysis. Sharing clinical trial raw data should be based on a formal, contractual agreement of collaboration between those who generated the data and scientists wishing to reanalyze the data. A reanalysis plan clearly defining the use of data should be agreed on as the involvement of those who generated clinical trial raw data is crucial for the quality of data analysis. Even if a secondary data analysis is not based on a formal agreement, the work of the trialists who generated the data needs to be adequately acknowledged. It should be discussed whether the intellectual contribution of those who generated the data would justify co-authorship or whether a novel way of authorship needs to be established.

Other Comments: Sharing clinical trial data with a wider scientific community has enormous potentials but also comes with great responsibilities. The scientific community has to develop policies to ensure that the best use is made of shared data and that data is not used inappropriately. For the benefit of clinical care and the advancement of knowledge, sharing and reanalysis of data need to follow the highest quality standards. As a funder, the German Research Foundation acknowledges that costs are associated with data sharing and that appropriate technologies and infrastructures need to be developed. Therefore, the DFG provides funds for data processing necessary for data sharing and for the use and establishment of data sharing infrastructures. The need for additional resources to implement such measures should also be acknowledged by other funders and institutions.