
Implementing a Data Sharing Agreement within a biomedical research consortium

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1. Background

Sharing research data is pivotal for efficient and successful biomedical research and a crucial aspect of open science. Although many researchers are aware of the potential to increase pace and transparency in science through sharing data, data sharing is still far from being common practice. This somewhat paradoxical situation is due to several hindering factors. One key factor is the researchers' fear of giving away opportunities by sharing data with other researchers in their field. Data sharing in medical sciences is reported to be less likely than in other disciplines. It has been argued that this might be the case due to the higher sensitivity of the data which often includes personal data from patients. However, if restrictions can be put on the possible use of data, the willingness to share increases. Some actions have already been taken to improve data sharing in biomedical sciences like requirements for publishing a medical trial in ICMJE-Journals or the release of new data sharing guidelines of funding organisations (EU Horizon 2020, NIH, MRC). There are some ideas how sharing of medical research data could be encouraged but most of them are of a theoretical kind. What is still missing, are use cases that may serve as best practice examples for the implementation of data sharing in the field of biomedicine.

The coNfirm project (Systems Medicine of a Heart Disease Network for improving multilevel heart health) is part of the e:Med funding program by the Federal Ministry of Education and Research which aims to establish systems medicine in Germany. Systems medicine is one among several current developments in biomedicine which are all based upon the gathering and processing of very large data sets (Big Data). The interdisciplinary coNfirm project consists of researchers in the areas medicine, bioinformatics and ethics from different German university hospitals and research institutions. While the biomedical subprojects mainly aim for understanding of cardiac health conditions, the ethical subproject organises, monitors, and evaluates data sharing between these researchers. The ethical subproject aims at implementation of data sharing concepts and processes in the consortium. The hands-on experiences will be useful to other researchers and consortia in the biomedical field as well. In this abstract we briefly illustrate the development and implementation of the data sharing agreement within the coNfirm consortium.

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2. Development of the Data Sharing Agreement

We started with a systematic online research on already existing guidelines for and studies on data sharing published by researchers and international research organisations. The results of this literature research informed the compilation of a survey that we carried out among the members of the coNfirm consortium using questionnaires with open and multiple-choice questions. Targeting both negative factors that impede and positive factors that facilitate data sharing we aimed at gaining insights into the motivational and organisational aspects of data sharing that could then be used as a starting point in developing a data sharing agreement within the consortium.

The results of our survey showed that the major issues a data sharing agreement would have to address are: authorship, questions about the publication of results, the kind of metadata needed to understand a dataset, and rules and guidelines for the sharing of data in general. Also, the members considered gathering and preparation of data at the one hand and analysis and evaluation of data on the other hand as the main work tasks to be valued in authorship decisions. “Agreement on authorships before the start of a project” and “mediation by the coordinator” were judged to be the most important factors for a successful process of data sharing within the consortium.

We then used the results of the literature review and the intraconsortial survey to develop a data sharing agreement for the consortium. We integrated paragraphs concerning authorship, metadata and the division/sharing of data and workload as mandatory parts to be addressed by every cooperation within the consortium. Among others, the data sharing agreement addresses the following issues:

- Introduction and background
- Underlying principles of data sharing (transparency, cooperation, mutual trust, FAIR data principles, good scientific practice, data protection)
- Hints to the Legal framework
- Principles of data protection
- Handling of data
- Recognition of data producers
- Regulations for the implementation of project-specific data usage agreements
- Legal liabilities
- The role of the data usage consultants
- Procedures to cope with conflicts among the consortium members

3. Development of the Data Sharing Agreement

The last step of the development of the data sharing agreement was already the first step of its implementation: In a consortium workshop dedicated to data sharing we discussed the first draft of the agreement with the consortium members. The data sharing agreement was revised according to the discussions and feedback loops, and then accepted in consensus and finally signed by all members of the consortium. The function of the data sharing agreement is to build a general framework to raise awareness and induce trust to enable and encourage safe and successful data sharing.

The general data sharing agreement determines that concrete research and data sharing undertakings within the consortium are being planned and outlined in specific data usage agreements. We thus developed a template for such specific data usage agreements that will serve as a way of applying and implementing the general principles of the data sharing agreement to concrete and individual research undertakings. We, as the data sharing consultants, accompany and moderate discussions and the elaboration of specific data usage agreements between the consortium members for every concrete research undertaking. While e.g. the data sharing agreement establishes that authorships should be distributed fairly among researchers according to their respective tasks and work load, the template for individual data usage agreements provides a concrete list of planned work contributions and authorship order. Once the participating researchers have reached consensus on a preliminary authorship list in accordance with their respective tasks and workload, the data sharing process can be initiated.

4. Conclusion

The development of a data sharing agreement bears the possibility to induce trust and awareness within a group of researches. By pro-actively addressing and moderating the main questions that could hinder the exchange of data (authorship, distribution of tasks, . . .) it aims to support data sharing and raise awareness for its substantial benefits. The publication of our hands-on experiences will help other researchers and research consortia share data and establish a culture of data sharing.