Stakeholder Analysis for Digital Preservation in Biomedical Research

Frank Dickmann, Sabine Rey

Department of Medical Informatics, University Medical Center Göttingen, Göttingen, Germany

Abstract and Objective

This poster describes the implications of digital preservation on biomedical research from a national perspective. Preserving digital research data for long-term durations is an issue for every area of contemporary science. Looking for recommendations for a digital preservation infrastructure for research sites in Germany a stakeholder analysis was conducted. A stakeholder analysis describes the relevant environment aspects of a contemplated object: biomedical research extended by a digital preservation infrastructure. The results are prepared as an UML use case diagram and reflect requirements for biomedical research. These results are fundamental for a national solution for digital preservation. Legal requirements regarding privacy, retention times, and contractual relationships are of major concern. However, a concrete implementation is presently not available.

Keywords:

Digital preservation, Biomedical research, Stakeholder analysis, Confidentiality, Data privacy protection.

Methods

The stakeholder analysis produces a model of the relevant use cases within an evaluated environment. This includes factors of influence, stakeholders, and their relationships [1]. The Unified Modeling Language (UML) is applied as a graphical description language [2].

Results

Digital preservation comes from the librarian area and considers the archiving process from a generic lifecycle perspective to keep digital data accessible over long periods of time [3].

The area of biomedical research is closely related to clinical care and contains two sub-domains: 1. clinical research - fundamental approach, 2. clinical trials - applied approach.

Due to its direct contact with patients, tight data privacy regulations and retention periods apply for clinical trials derived from legal requirements. Retention periods in Germany vary between 5 to 30 years. Furthermore, good scientific practice recommends a retention period of 10 years of research data in any scientific area. Clinical research is less restricted because patients are not directly involved.

Another issue in digital preservation is dealing with intellectual property rights (IPR). IPR apply only if substantial intellectual efforts are added to primary research data.

The research data is commonly derived from investigations on patients. Thus, the patient is an important stakeholder and congruent access rights according to given informed consent are necessary. Further stakeholders are universities, university clinics, pharmaceutical industry, private organizations and further institutions of the area of healthcare services. These are nowadays organized in research networks based on co-operational contracts. At present the data sharing between the research networks is limited or simply not existing due to separate data archive implementations.

Conclusion

Research in a multi-institutional context is becoming a standard. In order for scientists of multiple institutions to be able to use and share research data in the future it is necessary to implement a sustainable infrastructure layer. Also preserved biomedical research data requires to be connected to scenarios of medical care for more comprehensive treatment e.g. for adjusting therapies according to longitudinal data sets.

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Address for correspondence

Frank Dickmann, University Medical Center, Dpt. of Med. Informatics, 37099 Goettingen, Germany