Medical Informatics Initiative
Supporting Project – Central Office of the National Steering Committee

Data Sharing Working Group Audit Approach in Connection with the Medical Informatics Initiative

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DISCLAIMER: The official document has been adopted in German language.

Summary

The audit scheduled for the last year of the setup and networking phase of the Medical Informatics Initiative will determine by means of systematic and independent investigations whether the quality-related activities of the organizations established and the associated results are in compliance with the guidelines planned, whether they put those guidelines into practice efficiently, and whether the guidelines are suitable for achieving the MII's goals. The discussions in the *Data Sharing* Working Group established that it should be obligatory for the audit to include three essential points:

1. *Audit of the audit use case [AUC] defined by a consortium*: This audit allows for an examination of the product quality, process quality, and structural quality of the consortium's workflow of a specific project. Consortia are to formulate statements of objectives for their AUCs in the application, using aspects of structural quality, process quality, and product quality for orientation purposes.

2. *System audits* in the data integration centers [DICs] set up: These examine the entire quality management system of a DIC or components thereof. Structural, process, and product audits can be integrated into them. System audits provide clear indications of measures to be taken to improve the existing structure of a DIC after the setup phase.

3. *Handling of preset queries to a shared, preset data structure*: An examination of process quality and product quality set up uniformly across all of the consortia.

The development of quality indicators for the specific audit forms should be made a component of the MII Roadmap. These indicators will be developed by the *Data Sharing* Working Group in consultation with the *Interoperability* Working Group and fleshed out by Q1 2018.

Furthermore, it is recommended that a working group be established in the monitoring body to deal with quality management [QM], which will develop the general structures for a QM system and for corresponding standard operating procedures [SOPs].

Introduction

The external audit process during the last year of the setup and networking phase of the Medical Informatics Initiative (MII) serves to verify "that, firstly, the organizational and technical solutions established offer measurable added value for research and/or patient care, and secondly, that data sharing is possible across all of the consortia" (the "Medical Informatics Initiative Funding Scheme" brochure from Germany's Federal Ministry of Education and Research (BMBF)). In this vein, whether the organizational forms established accomplish this mission efficiently and professionally based on a quality-yielding structure should also be verified.

The discussions in the Medical Informatics Initiative *Data Sharing* Working Group established that it should be obligatory for the audit to include three essential levels:

1. *Audit of the use case defined by a consortium [use case audit,* UCA*]*: The added value for research or patient care is to be proven based on a catalog defined in the application by the respective consortium for a use case audit. For this purpose, the consortia are to formulate statements of objectives for their AUCs in the application, focusing on aspects of structural quality, process quality, and product quality for orientation purposes.

2. *System audits of the data integration centers*: This part of the audit examines the entire quality management system of a DIC or components thereof. Structural, process, and product audits can be integrated into them. System audits provide clear indications of measures to be taken to improve the existing structure of a DIC after the setup phase.

3. *Handling of cross-consortia queries to a shared, preset data structure*: An examination of process quality and product quality set up uniformly across all of the consortia for the exchange of predefined queries using a defined (multi-level) core data set. In this context, all established DICs are to satisfy the queries.

An audit is the comparison of whether a specified "actual state" in an organization has in fact met the intended goal. It comprises a systematic and independent investigation that determines whether the quality-related activities of the organization and the associated results are in compliance with the guidelines planned, whether those guidelines are being put into practice efficiently, and whether the guidelines are suitable for achieving the MII's goals. As part of the process, the planned guidelines and objectives will be defined as audit criteria. There are various audit forms that are relevant to the following pages: system audit, process audit, and product audit. The development of quality indicators for the specific audit forms should be made a component of the MII Roadmap. Issues and criteria will be fleshed out by the *Data Sharing* Working Group in consultation with the *Interoperability* Working Group by Q1 2018.

Furthermore, it is recommended that a working group be established in the monitoring body to deal with quality management [QM], which will develop the general structures for a QM system and for the standard operating procedures required [SOPs].

The three elements of the mandatory audit identified above are described in more detail on the following pages.

1. Use Case Audit (UCA)

The use case audit as referred to above will be able to be used in connection with a process and product audit. Corresponding guidelines and audit criteria are to be formulated by each consortium. The application documents demand of the audit process "that the organizational and technical solutions established offer measureable added value for research and/or patient care". The added value is to be verified by means of the audit use case defined by the respective consortia. This element of the audit extends across the entire consortium and its criteria are to be defined in the general section of the consortium's setup and networking application.

When filing applications, it is essential in this regard that the individual consortia define objective, measurable criteria for success that are verifiable by way of an external audit. The consortia are responsible for implementing the audit use case. Documentation of the added value achieved, e.g., a comparison of the "actual state" prior to and after the setup of the data integration centers as relates to the specific AUC, is essential for a successful audit. This added value can be generated either for patient care or for research (or both). Because the goal of the Medical Informatics Initiative is data sharing between various institutions, how this added value was achieved – owing to data use being shared both within the data integration centers of the individual locations and then among the locations – also needs to be verified. The use case audit is a process and product audit (see below for an explanation of this audit form).

2. System Audit of the Data Integration Centers

The system audit investigates a complete system and examines appropriate functionality of an organization or specific components thereof. As a general rule, this is accomplished by auditing the entire quality management system of an organization or components thereof. This system audit is to be performed separately for each of the data integration centers set up within a consortium and covers structural quality, process quality, and product quality.

Structural quality examines the general parameters and capabilities of an organization, the characteristics of the human and material resources employed, and the components and systems of the IT infrastructure. The following aspects are relevant in this regard:

- Existing expertise in the DIC: verified by means of the staff members' résumés, and training and continuing education certifications

- Organization of the responsibilities required: verifiable by means of the organization's org chart
- Description of relevant processes with identification of the responsible individuals involved
- Sufficient coverage of the activities of relevance for the DIC: In this regard, criteria are to be developed that make it possible to evaluate the QM system of a DIC, that describe the implementation of data protection aspects, that quantify the capability for technical interoperability, that depict the quality and quantity of data sharing, and that evaluate standards for interoperable metadata.
- Appropriate implementation of the general legal requirements in the structures and processes of the DIC.
- Establishment of risk management

Required preparations

Audit criteria have been developed in connection with clinical studies and research for the organizations involved with such research (study sites, clinical research organizations [CROs], …). The content of the MII Roadmap should contain similar development.

The foundation of the DIC process audit is an SOP system for the DICs. And outline for these kinds of SOPs can be put together by all of the consortia acting jointly in an upper-level working group. On this point, analogous to the example, the development of SOPs for clinical research could be pursued by the Network of the Coordinating Centers for Clinical Trials (http://www.kks-netzwerk.de/). The development of corresponding templates for SOPs in the DICs should also be made part of the MII Roadmap. The *Data Sharing* Working Group will kick off this work.

Process audit

Process quality examines activities carried out: technical, conceptual, and administrative activities, and the execution of project developments. The process audit relates to the auditing of these processes. This is accomplished by auditing the quality management system in which the relevant processes and their execution are documented (for instance in standard operating procedures [SOPs]). The performance of the process audit can be targeted toward a *system* or a *project*. When a system-based audit is performed, only the directly affected processes are audited, not the entire production process. When a project-based audit is performed, audits are carried out at specific times in a development and planning process in order to promptly avert deficiencies in the anticipated outcome. This aspect is relevant for the audit use case.

Product audit

The *product quality* relates to measurable objectives. It is measured against parameters that track the quality of patient care and/or medical research and display proof of improvement. It concerns indicators that point to improvement in the process quality of the collection and refinement of data, or that describe the re-use of processes and structures in various projects.

The product audit examines the quality of the results (products) of an organization. Some sources also call this a quality audit. During this audit, the conformity of product quality with the requirements, the technical specifications, and the testing and process documentation are assessed, as are the effectiveness, suitability, and consistency of the documentation. In other words, the product audit is much more extensive than an inspection of product quality and also applies to relevant system elements.

There are two possible strategies for conducting a product/quality audit: (1) the *audit use case* (AUC) defined by the consortium for its work during the setup phase; (2) general queries that place fundamental, consortia-spanning demands on the services to be provided by a DIC.

3. Inter-Consortia Data Queries

In addition to the criteria for an AUC for specific consortia, minimum, consortia-spanning requirements for the product quality of a DIC should also be formulated. On this point, the prep work by the Data Sharing Working Group identified five task areas:

1. *Queries relating to the body of data*: Which basic module data are available? This comprises a determination of case figures based on a global example, or the release of data based on a global example. For this purpose, the office will define specific queries, which will become part of this document as an attachment.

2. *Queries relating to attributes and metadata*: Which vocabulary is used? Which mapping rules? Which access requirements exist? What is the current consent status? *Data Use Access Committee* [DUC] vote, the data generator's requirements, ...

3. *Queries relating to data accessibility* (e.g., phenotype vs. OMICS data)

4. *Queries relating to the traceability of data to the source and quality*: Origin (patient care, research data, biobank, publicly accessible data), disclosure, information on data and process quality (who, when, where, how, ...) data traceability (retrospective: where did the data come from? prospective: to which projects were the data contributed?)

5. Ability to use or exchange algorithms and models, e.g., in the context of a use case crossover. Can the (technical and organizational) infrastructure for a UC developed in a consortium be implemented in the DICs of other consortia? Are there guidelines stating how this transfer to other DICs can be accomplished[1]?

[1] Reference is made here to the papers on the core data and data provenance.

The following aspects will be audited with these task areas as a foundation of data sharing in a shared (multi-level) *core data set* with standards applied:

i. Harmonized conceptual data representation
ii. Harmonized representation of relevant attributes including metadata
iii. Harmonized query language, including options to express complex algorithms
iv. Harmonized data format, in particular for the return of data

The following questions are to be clarified by Q1 2018: (1) At what level is a centralized identity management system and/or record linkage necessary? (2) What are the requirements for this approach (rights/roles of the party making the query, existence of votes, etc. end point(s) at which the query is made, with/without *data use agreement* [DUA]); (3) How should the data be made available (safe data, safe setting, distributed processing)?

Answers to the open questions will be developed by the *Data Sharing Working Group* in consultation with the *Interoperability Working Group* and fleshed out by Q1 2018.