Author's response to reviews

Title: EsPRit: Ethics Committee Proposals for Long Term Medical Data Registries in Rapidly Evolving Research Fields - A Future-Proof Best Practice Approach

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Version: 1 Date: 07 May 2017

Author’s response to reviews:

The manuscript was thoroughly edited for proper English.

Comments on Reviewer 1 comments:

How can veracity of data be controlled in instances where a change in methodology alters the value of data already collected?

• At any point in time during the life cycle of a MDR-LT an ethics committee proposal compiled using EsPRit is a fundamental part of the documentation of the registry. If, for example, data collection methods change over time the adaption has to be reflected in the ethics committee proposal. Thus, a new decision covering the changes has to be made by the committee. Therefore, at any point in time and for each data item it is well documented how the data was collected and how the data was interpreted.

o Added to the manuscript within the “Lifecyle management” section

Can the system deal with different subjective opinions of ethics committees which can arise?

• The study designers describe the process on how to e.g. discover MDR-LT requirements to meet the goal of the study. The process should adhere to well proven and documented methods. If an ethics committee decision requires changes to the described process or methods the comments have to be analyzed and if feasible incorporated into the application. Since the process of compiling the application is iterative not all building blocks have to be reworked.

o Added to the manuscript within the “Lifecyle management” section

The system involved opinions from medical experts: What if these differ on a fundamental issue?
• If opinions of medical experts differ on fundamental issues like study goals or necessary data sets to answer the research question a consensus has to be reached. If a consensus cannot be reached the designers of the MDR-LT have to decide whether to proceed preparing the application or revise the initial goals of the study. Any concerns regarding the feasibility have to be documented in a comprehensible way.

- Added to the manuscript within the “Lifecycle management” section

Comments on Reviewer 2 comments:

The chart I have a copy of is difficult to read because it appears quite fuzzy.

• A high resolution image was uploaded.

It is difficult for me to determine, however, how the authors get to how this building block approach gets information to the ethics committee, if it does.

• The result of each block is taken as input of subsequent blocks. Thus, the final result of the process named „Architectural Concept“ is the sum of all information collected. In most circumstances this final result will be a document which is forwarded to the ethic committee for decision making.

- Added at the end of the initial description of the workflow (see EsPRit: Building Blocks and Methods)

The manuscript might read and flow better if the authors could reduce the number of abbreviations and simply the discussion of the building blocks.

• Abbreviations removed wherever possible. In general, the paper was thoroughly edited for proper, readable and understandable descriptions and language issues.

- Edits are marked within the revised document.