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Portal of Medical Data Models: Stakeholder Feedback and Requirements

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Abstract. The Portal of Medical Data Models has been developed since 2011 by the University of Münster. Its main goals are transparency, standardization and secondary use of medical metadata. Via two online surveys feedback from stakeholders of German health research was collected regarding the portal's contents. The surveys confirmed great interest in secondary use of medical forms.

Keywords. Medical metadata standards, medical data models, secondary use

1. Introduction

The Portal of Medical Data Models (MDM Portal) [1] constitutes to our knowledge Europe's largest research infrastructure for publication, creation, analysis and reuse of medical data models. Currently (January 2021), it contains > 24,300 form-based data models in > 50 different languages. 589,866 items are available in system-independent CDISC ODM format (Clinical Data Interchange Standards Consortium, Operating Data Model) [2]. 91% of the items are semantically annotated with UMLS codes (Unified Medical Language System) [3]. 1,910 users have registered. Due to the portal's large content and user base, we decided to analyze stakeholder feedback and requirements.

2. Methods

Two online surveys have been conducted in 2019 and 2020. The first online survey based on a cross-sectional self-report questionnaire which was sent via email to relevant German networks and actors of health research (Principle Investigators listed in Clinicaltrials.gov, Coordination Centres for Clinical Studies, Association for Documentation and Information Management in Medicine, Federal Association of Contract Research Organizations and MDM users). 179 persons participated (estimated response rate < 3%). The questionnaire consisted of 31 closed-ended questions (9 in 5-point Likert scale) and 2 open questions. 10 questions assessed demographics and research background, 9 related to data management and the remaining to use and acceptance of open metadata registries such as MDM. In order to increase the response

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rate, the questionnaire in a reduced design (15 questions) was sent to the 79 participants of our last MDM workshop (40 participants, response rate = 51%). Answers to each question were analyzed with descriptive statistics.

3. Results

In the first survey, over 80% (n=144) of the respondents agreed or strongly agreed on reusing proven forms (responses 4 and 5 in 5-point Likert scale were grouped). Both surveys indicated relevance of almost all form categories. In the first survey group the ranking was: adverse event (51%), laboratory (49%), demography (47%) forms. The second survey revealed the following ranking: medical history forms (45%) and adverse event, demography, physical examination forms (38% each). Currently, a large part of MDM's content consists of eligibility criteria forms for clinical trials (> 10,900). Nearly all respondents were able to use one or more of the 18 export formats for their own electronic data capture system. The most frequently mentioned format was CSV. In terms of MDM's most interesting functions, the following ranking resulted from both surveys: optimization of eCRFs (electronic case report forms) (51%/58%), search and development of eCRFs (47%/63%), programming of plausibility and edit checks (39%/53%), quotable publication of eCRFs (33%/43%), coding of eCRFs (21%/48%). Many participants have conducted clinical studies funded by BMBF (Federal Ministry of Education and Research) or DFG (German Research Foundation). Although both organizations demand or recommend publication of eCRFs in their funding guidelines [4, 5], only a minority of the respondents could name a publication platform.

4. Discussion and conclusion

A large majority of the stakeholders surveyed would like to reuse tried-and-tested forms. Contents and functions of the MDM Portal are considered relevant. But currently, knowledge transfer in this field is not yet applied on a regular basis. Since many data models are not yet publicly available, MDM contents are still limited and standardized data collections rest a big challenge for the field of health informatics. Dissemination efforts for the MDM Portal should be enhanced. It provides citable and licensed publication of medical forms and analyzing tools to support metadata interoperability in health research. Further surveys are planned to collect feedback, specifically from international users.

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