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Portal of Medical Data Models: Application in Federated Data Capture

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Abstract. So far, the portal for medical data models allows its users to download medical forms in a standardized format. Importing data models into electronic data capture software involved a manual step of downloading and importing the files. Now, the portal was enhanced with a web services interface to allow electronic data capture systems to automatically download the forms. This mechanism can be used in federated studies to ensure that all partners are working with identical definitions of study forms.

Keywords. Medical Data Models, Case Report Forms, Federated Data Capture

1. Introduction

The portal for medical data models (MDM) is a repository that provides access to standardized medical data models and related resources [1]. Currently, it contains more than 24,000 forms from different medical areas including health record forms or case report forms (CRF) from clinical trials. Typically, MDM users download forms manually using a web browser in order to import the form definitions into an electronic CRF (eCRF) system of their choice later on.

In multicentric studies the participating sites often agree on a single installation of CRF software that is made available over the Internet to all partners. However, since potentially sensitive patient data are transferred to institutions without a treatment context in this scenario, a central system has drawbacks in terms of data protection. A way to mitigate this problem is to install an instance of the eCRF software locally at each site. In this federated scenario it becomes essential to keep forms definitions synchronized across all sites to ensure generation of consistent high-quality data sets.

Federation of data management systems is a current topic in Medical Informatics research. For example, Liu et al. describe a federated architecture on medical data security [3]. Moshawrab et al. report on federated learning approaches for disease prediction [4].

We propose a novel interface for MDM that allows automated machine-to-machine access of form definitions within the portal. No personal data are exchanged in this step. In addition to individual systems, this interface can be used for metadata synchronization in federated data capture environments.

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2. Methods

The primary data format of MDM is Clinical Data Interchange Standards Consortium Operational Data Model (CDISC ODM), but export in other formats, such as Health Level Seven Fast Healthcare Interoperability Resource (HL7 FHIR) questionnaire is possible as well [2]. MDM portal is accessible via Hypertext Transfer Protocol Secure (HTTPS) for users. Consequently, a Representational State Transfer (REST) interface for machine access to ODM metadata was added. This interface allows to reference and download a specific form definition using the MDM identifier from the portal.

3. Results

For a proof of concept, MDM is now equipped with a REST interface. As a first consumer application of the interface we enhanced the electronic data capture (EDC) software openEDC [5] with a REST client interface. By entering the MDM identification number of a data model in openEDC, the corresponding form is automatically download via REST and made available as CRF. The software was tested in a federated test setting: four instances of openEDC located in German university hospitals referenced the same forms definition on MDM. Then, data for fictitious patients were manually entered into the openEDC instances to simulate a multicentric study without the restrictions introduced by data protection end ethics requirements for real patient data. Finally, study data were exported and sent to the study center and finally combined for analysis.

4. Discussion

We have demonstrated that MDM can be used as a central repository for EDC in federated scenarios. Using a single source for metadata definitions at all participating sites ensures that forms are in sync for the complete study. While the REST interface was tested with openEDC, its specification and access will be made available to the general public. Manufacturers of other EDC programs are encouraged to adopt the interface in their systems. To accommodate potential needs for adaption in specific study settings, we will investigate how customizing and synchronizing forms for specific study needs beyond the standard forms can be supported by MDM as well.

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