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x4T-EDC: A Prototype for Study Documentation Based on the Single Source Concept

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Abstract. Data collection is essential in clinical studies. The single source approach aims to integrate Electronic Health Records (EHR) and Electronic Data Capture (EDC) systems. Due to the lack of EDC system with single source functionality, we intended to enhance our single source system x4T to a small-scale EDC system. x4T uses CDISC ODM as format for study documentation forms. Functional and non-functional requirements regarding EDC were identified through focus groups with IT and medical experts. User management and audit trail were identified as important EDC-features. To re-use data values of the EHR, study items have to be semantically matched. We have enhanced our x4T-system towards a small-scale EDC system.

Keywords. CDISC ODM, clinical studies, EDC, EHR, single source

1. Introduction

Data management in clinical studies is a major task in the study life cycle. In case of investigator initiated trials (IITs) the sponsorship is mainly covered by academic institutions. Thus, in such small-scale projects only limited resources are available for creating and maintaining study databases. Office software like Microsoft Excel® or simplistic database management systems are frequently used as case report forms (CRFs) for data capture in small-scale studies.

Electronic data capture (EDC) systems are used for the data collection mainly in clinical trials. Both commercial and open source EDC systems are available with functions for the entire process of study conduction. Small-scale studies and those which were funded by foundations were less likely to use an EDC system compared to those sponsored by industry [1], which is caused by high license fees as well as high cost for operations and maintenance, even in open source systems [2].

In our research group, we have developed and implemented the single source system x4T (exchange for Trials) [3] that enables the re-use of medical routine data for clinical research. Therefore, data from the Electronic Health Record (EHR) is transferred into the x4T-system to pre-populate CRF items. Because extensions to common EDC systems are cost-intensive or not possible at all, a lightweight data capture system compatible with the single source approach would be beneficial, in

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particular for IITs. Therefore our objective is to define the minimum requirements for a small-scale EDC system in a single source setting and to assess the technical feasibility of this approach with x4T.

2. Methods

Requirements for an EDC system in a single source setting have been identified by informal interviews with medical experts and local study initiators. Further requirements have been derived from the literature, in particular from the European Clinical Research Infrastructures Network [4]. Based on these requirements, the existing x4T-system [3] has been enhanced to a small-scale web-based EDC system. Initially x4T was developed to display forms and validate pre-population data. x4T applies the Operational Data Model (ODM) from the Clinical Data Interchange Standards Consortium [5] to represent forms. An eXist XML database [6] is used to store both metadata and data from each study.

3. Results

The x4T system was enhanced to an EDC system based on the functional and non-functional requirements shown in Table 1.

Table 1. Functional and non-functional requirements of an EDC system in a single source setting.

Functional	Non-functional
• Study administration • Basic edit checks • Audit trail • Backup / Export • Generic statistical functions • Update CRFs • Form completion tracking • Single source / pre-population	• Simple installation • Quick study setup • Stability • Usability aspects • Low purchase and operation expenditure

The x4T system was extended to a patient-centered framework for data capture. The display of web-based CRFs was enhanced to a patient record with visits, form status and the opportunity for data amendment including audit trail. A role and right management component allows upload and maintenance of studies and users. Figure 1 presents the study setup process. Studies in the ODM format can be uploaded into the x4T system and users are assigned roles regarding those studies. Access rights are tailored according to the needs of each user group. For instance, principal investigators are allowed to perform all functions except study insertion and deletion whereas statisticians can perform data exports and view statistical functions. x4T administrators manage user accounts for all studies while principle investigators are restricted to their corresponding studies.

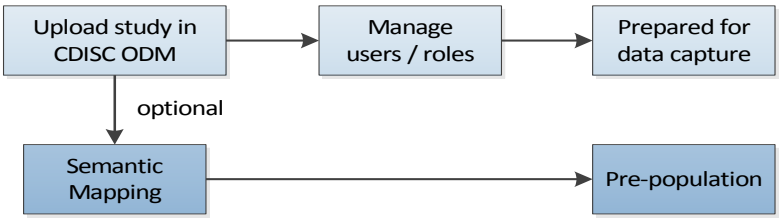

Figure 1. Workflow of study setup: ODM file is uploaded, users and roles are assigned and the system is prepared for data capture. If available, semantic matching of EHR and study items enables re-use of EHR data.

In accordance with the single source approach, physicians can pre-populate CRF items with EHR data through semantic matching between EHR data fields and study items.

4. Discussion / Conclusion

Our prototype demonstrates the technical feasibility of an EDC with single source functionality.

There are some limitations in this research work. First, study metadata needs to be available in ODM format. Appropriate ODM design or conversion tools are needed to provide this input for x4T-EDC. Second, EHR data fields need to be semantically annotated to enable pre-population of CRFs. Currently this is a work-intensive, manual process; also discussed in [7]. The x4T-EDC prototype will be evaluated in three clinical domains (dermatology, cardiology and vascular surgery). In particular, usability of the system will be analyzed and key functionalities will be validated.

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