Metadata registry and management system based on ISO 11179 for cancer clinical trials information system

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ABSTRACT

Standardized management of data elements (DEs) for Case Report Form (CRF) is crucial in Clinical Trials Information System (CTIS). Traditional CTISs utilize organization-specific definitions and storage methods for Des and CRFs. We developed metadata-based DE management system for clinical trials, Clinical and Histopathological Metadata Registry (CHMR), using international standard for metadata registry (ISO 11179) for the management of cancer clinical trials information. CHMR was evaluated in cancer clinical trials with 1625 DEs extracted from the College of American Pathologists Cancer Protocols for 20 major cancers.

Introduction

For Clinical Trials Information System (CTIS), "Entity-Attribute-Value" (EAV) model has been regarded as a common solution for the management of complex and heterogeneous clinical study data [1]. Entity is a subject (i.e. patient) who participates in a clinical trial; Attribute is a DE (i.e. question) in a Case Report Form (CRF); Value is a response of a subject to a specific question. To systematically manage common data elements (CDEs) of CRFs and to understand 'Value' in EAV model, most CTIS manages CDEs as metadata. Traditional CTIS, however, uses organization-specific definition method and data storage model for metadata. ISO 11179 is an international standard for formally and comprehensively expressing the semantics of metadata in a consistent manner [2]. Organization-specific metadata is not good to support data reusability, sharing and interoperability. In the present study, we develop a Clinical and Histo-pathological Metadata Repository (CHMR) system for structured DE management focusing on cancer clinical trials information system based on international standard for metadata registry, ISO 11179.

Methods and Results

Systematic management of DEs for CRFs and analysis of clinical trials data in EAV-structured CTIS require DEs to be defined at the level of metadata. Following the wisdom of NCICB's (National Cancer Institute Center for Bioinformatics) caDSR (cancer Data Standards Repository) [3] development effort, CHMR implemented ISO 11197 using relational DBMS, resulting a web-based repository for standard-based representation and management of metadata.

According to the basic structure of ISO 11179, CHMR is designed to have 54 relational tables, 22 for 'Administered items' and 32 for 'Common facilities'. 'Administered items' are registry items for which administrative information such as data element, value domain and conceptual domain is recorded in an administration record. 'Common facilities' are collections of administrative information like naming, definition and classification for administered items.

To evaluate the ISO 11179 functionality of CHMR system, we have extracted 1625 clinical and histo-pathological CDEs and formally defined them with metadata information from the College of American Pathologists Cancer Protocols for 20 among the 46 cancer types. The CDEs stored in CHMR are available through the web-based CHMR browser at http://chmr.snubi.org/. CHMR also allows user-defined DEs to be registered. The utility of CHMR in cancer clinical trials for reusable and sharable DE and CRF management was successfully evaluated.

Discussion

Providing methods for formal definition and management of DEs for CRF creation are essential in CTIS. CHMR based CTIS is suggested to be helpful for reducing data-input error by permissible-value control using metadata definitions and pooled comparison analysis of data from different clinical studies.

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References

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