Object-oriented modular data dictionaries of reusable components based on registration and analysis of data in clinical trials

Speer R., Heller B.
Universität Leipzig
Institut für Medizinische Informatik, Statistik und Epidemiologie

Introduction

Planning and preparation of clinical trials require a considerable organizational expense. In particular it is necessary to invest a lot of time in structuring and programming the databases and the data-entry masks dependent on the size and the design of the clinical trial.

In most cases, similar or equal data are collected independent of the objectives and the design of a clinical trial.

Objectives

It is obvious that by taking reusable components the expense in the planning and preparation phases of clinical trials can be reduced. Therefore it is necessary to compile data dictionaries for planning and preparing clinical trails which provide such components with corresponding knowledge and methods. These data dictionaries should be enlarged according to new knowledge an new qualities of components. In addition to this, the data dictionaries should allow a dynamic adaptation of existing components.

Methods

The basis of such data dictionaries including reusable components is a fundamental analysis and a modular, dynamic structure of clinical data and documentation forms. Therefore it is possible to make following classification for data-entry and documentation forms:

1. a generic part which is identical for all data-entry and documentation forms
2. a documentation-form-specific part
3. a study-specific part

One has to distinguish two data dictionaries. The attributes of data for a clinical trial were build on the basis of generic classes (objects) in a data dictionary and the different data objects were deduced from these generic classes as sub-classes. The corresponding methods and rules were represented in the knowledge base. To examine the study-specific attributes of the data-objects the methods and rules of the knowledge base were dynamically linked to the objects

On the basis of the generated objects, the second data dictionary describes the representation design of these objects and allow the generation of data-entry masks and documentation forms

Results

Based on the object-relational database-system ORACLE8, a modular model of data-dictionaries was designed, which allows the dynamic definition and reuse of generic classes of knowledge and data for different clinical trials

Conclusion

A great advantage of reusable components in the field of clinical trials is a quick and easy generation of new data-entry masks and documentation forms. In addition, that help us in the standardization process of clinical trials.

Based on the object-oriented approach of our components we have the possibility to take the advantage of a Common Object Request Broker Architecture (CORBA) for a forms- and study-independent analysis of patient data in clinical trials.

References

[1]   Ben-Natan, R (1995). CORBA:a guide to common object request broker architecture. Mc-Graw Hill.

[2]   Berger, H. (1997). Konzeption und Implementierung eines Konsultationssystems zur Therapieplanung in der Erwachsenenonkologie. Institute for Medical Informatics, Statistics and Epidemiology, University of Leipzig. Master Thesis.

[3]   Haag, U. (1997). Knowledge Representation for Computer-Aided Planning of Controlled Clinical Trials: the PATriCIa Project. Methods of Information in Medicine (36): 172-178.

[4]   Heller, B. (1996). Modularisierung und Fokussierung erweiterbarer komplexer Wissensbasen auf der Basis von Kompetenzeinheiten. DISKI Bd.120. Infix Verlag, St.Augustin.

[5]   Object Management Group (1993). The Common Object Request Broker:Architecture and Specification. OMG Document Number 93.xx.yy.

[6]   Speer, R. (1997). Modellierung und Realisierung einer Client/Server-Datenbank zur Erfasssung und Auswertung medizinischer Studien. Institute for Medical Informatics, Statistics and Epidemiology, University of Leipzig. Master Thesis.