

Chapter 3

Application of Metadata Repository and Master Data Management in Clinical Trial and Drug Safety

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ABSTRACT

This chapter talks about metadata repository, and master data management in clinical trial and drug safety. The chapter begins with the definition of metadata repository and gives an explanation around the same, It talks about a well designed metadata repository and the characteristics associated with the same. A brief around why we need metadata and the reasons for the using the same has also been mentioned. The benefits of a well structured metadata repository was also mentioned in detail. The chapter then gives a detailed explanation on master data management and the usage of MDM in clinical trials. MDM solutions for clinical trials management is also explained in detail.

INTRODUCTION

Metadata Repository

A *Metadata repository* is a database created to store metadata. Metadata itself is information about the structures that contain the actual data. Metadata is often said to be “data about data”, but this is misleading. Data profiles are an example of actual “data about data”. Metadata is one layer of abstraction removed from this - it is data about the structures that contain data. Metadata may describe the structure of any data, of any subject, stored in any format. Thus Metadata becomes the crux of the data in varying structure, subject or format.

DOI: 10.4018/978-1-4666-8726-4.ch003

A well-designed metadata repository typically contains data far beyond simple definitions of the various data structures. Typical repositories store dozens to hundreds of separate pieces of information about each data structure.

Comparing the metadata of a couple data items - one digital and one physical - will help us understand what metadata really is.

First, digital- for data stored in a database we may have a table called "Patient" with many columns, each containing data which describes a different attribute of each patient. One of these columns may be named "Patient_Last_Name". What is some of the metadata about the column that contains the actual surnames of patients in the database? We have already used two items: the name of the column that contains the data (Patient_Last_Name) and the name of the table that contains the column (Patient). Other metadata might include the maximum length of last name that may be entered, whether or not last name is required (can we have a patient without Patient_Last_Name?), and whether the database converts any surnames entered in lower case to upper case. Metadata of a security nature may show the restrictions which limit who may view these names.

Second, physical- for data stored in a brick and mortar library, we have many volumes and may have various media, including books. Metadata about books would include ISBN, Binding_Type, Page_Count, Author, etc. Within Binding_Type, metadata would include possible bindings, material, etc.

Definition

The metadata repository is responsible for physically storing and cataloging metadata. The physical storage and sequential catalogue is best done in a metadata repository. Data in metadata repository should be *generic, integrated, current, and historical*. Each of the terms, generic, integrated, current and historical is explained with respect to metadata as follows. *Generic*: meta model should store the metadata by generic terms instead of storing it by an applications-specific defined way, so that if your data base standard changes from one product to another the physical meta model of the metadata repository would not need to change. Thus a change in the database standard across various products would not change the metadata model repository. This is one of the important characteristic of the data in a repository. *Integration* of the metadata repository allows all business areas metadata in an integrated fashion covering all domains and subject areas of the organization. The overall coverage of the domains and subject areas function in the integrated approach of the repository. The metadata repository should have accessible *current and historical* metadata. Metadata repositories used to be referred to as a data dictionary.

With the transition of needs for the metadata usage for business intelligence has increased so is the scope of the metadata repository increased. Business intelligence has been an important aspect in the industry. That being requiring the need of metadata, has increased the scope of the repository proportionally. Earlier data dictionaries were the closest place to interact technology with business. Data dictionaries are the universe of metadata repository in the initial stages but as the scope increased business glossary and their tags to variety of status flags emerged in the business side while consumption of the technology metadata, their lineage and linkages made the repository, the source for valuable reports to bring business and technology together and helped data management decisions easier as well as assess the cost of the changes. The metadata thus impacted the data management decisions proportionally and assessed the change in case inversely, making easier decision as well as changes in cost.

Metadata repository explores the enterprise wide data governance, data quality and master data management (includes master data and reference data) and integrates this wealth of information with

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