

Managing SAS/PH-Clinical in a Multiple Instance Environment

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Abstract

Companies using SAS/PH-Clinical to support multiple clinical development projects often implement separate instances of PH-Clinical. Maintaining consistency among instances can be a complex system management task. This paper discusses a multiple instance model for deploying and managing PH-Clinical in which a separate PH-Clinical instance is created for each project. Consistency and compatibility of project instances is maintained by building each instance from a single 'standards' instance. Global standards for the PH-Clinical dictionary, PH-Clinical study definition, PH-Clinical variable group and PH-Clinical templates are maintained in the standards instance. Modifications to these 'standard' PH-Clinical objects are made only in the standards instance and distributed to project instances. Design considerations, implementation issues and configuration management will be discussed.

Overview

This paper discusses the key points of using a multiple-instance model for deploying and managing SAS/PH-Clinical in which a separate SAS/PH-Clinical instance is created for each project. The focus of this paper is the standard PH-Clinical study definition and PH-Clinical variable group definition. A similar methodology can be used for standard PH-Clinical objects such as templates and format libraries. The key topics are:

- Multiple instance model
- Standard data model
- Standard Data model components
- Replication
- Updating the standard data model

Multiple Instance Model

In a multiple instance model for deploying and managing PH-Clinical a separate PH-Clinical instance is created for each project. An instance is defined as the PH-Clinical product library, user defined PH-Clinical libraries, user defined PH-Clinical objects and study data. Multiple instances may be used for several reasons, for example:

- The company has several physical locations and PH-Clinical is installed at each location.

- To simplify security and user administration where one instance is used for each therapeutic area or compound.

In our model a single standards instance is used for developing and maintaining a PH-Clinical dictionary, PH-Clinical study definition and PH-Clinical variable Group. These standard objects are then replicated to each project instance and used when developing PH-Clinical studies.

Standard Data Model

The most challenging and time-consuming task in deploying PH-Clinical is developing a standard data model. Most companies store clinical data using a data model that facilitates data entry and data cleaning. This data model is generally not optimal for browsing and reporting within PH-Clinical. Usually, this model is transformed and value-added fields are derived to produce a standard "Reporting" data model.

The standard data model usually contains definitions for demographic datasets (i.e. entrance criteria, demographics), patent characteristics datasets (i.e. medical history, medications, dosing) and safety datasets (i.e. adverse events, vital signs, laboratory). Usually a "driver" dataset is created containing key study dosing information, sub-setting information, endpoints and outcomes. Efficacy is usually not included, as it is often compound or indication specific.

The standard data model should be documented in a user-friendly format. There should be a section describing the fixed and common keys. For each dataset, there should be a general information describing the type of data and the record structure. For each variable dataset the following information is described:

- Dataset name
- Dataset label
- Variable name
- Variable label
- Variable description
- Variable type
- Variable length
- Format name
- Key level
- Derivation description

The standard data model is then used to create the data model components. Additionally, this data model can be used as the basis for using a data-warehousing tool such as the SAS Warehouse Administrator.

Standard Data Model Components

Once the standard data model is developed on paper several components are required to implement the data model in the PH-Clinical environment. The components include:

- SAS datasets
- SAS format library
- PH-Clinical dictionary
- PH-Clinical study
- PH-Clinical variable group

The standard SAS datasets can be created using the information in the standard data model. We usually create the datasets containing one observation. Additionally, sample standard studies can be created using completed clinical studies. The standard SAS format library needs to accompany the standard SAS datasets. These two components can be used to create the sample PH-Clinical study and sample PH-Clinical variable group. To facilitate PH-Clinical study definition the PH-Clinical function names and function labels are created using the SAS variable names and labels.

After creation, the standard PH-Clinical dictionary, standard PH-Clinical study and standard PH-Clinical variable group are exported and stored in a directory where the PH-Clinical Instance Administrators can access them.

Replication

Replication is a two step process. The first step, described above, is to export the standard PH-Clinical objects to a directory where the PH-Clinical Instance Administrators can access them. The second step is to import the standard objects into the instance.

At this point it is important to discuss the timing of when to import the standard objects. As we all know, standards evolve over time. So, how does this effect replication to the instances? The short answer is it depends on how the standard objects are changed.

In most cases updating the standard objects involves adding new datasets, variables or PH-Clinical functions. In effect nothing is being changed, therefore this type of change should not have any effect on the current data model in the instance. The types of changes that may effect the current instance are modifications to variable names, variable labels, PH-Clinical function names and PH-Clinical function labels. These types of standard data

model changes should be kept to a minimum and may have serious effects if replicated to an instance where there are many studies using the standard data model.

A simple and solution is to replicate into an instance when starting a new project, and then to freeze the data model in that instance for the duration of the project.

The second step of replication, importing the exported standard objects into a project instance, consists of several tasks:

- Copy the standard SAS datasets to a directory that is accessible by the project instance administrator.
- Copy the standard SAS format library to a directory that is accessible by the instance.
- Import the standard PH-Clinical dictionary.
- Import the standard PH-Clinical variable group.
- Import the standard PH-Clinical study. Edit the study and remap the data to the directory where the standard datasets are stored.

Updating the Standard Data Model

As discussed above, standards evolve over time. So how do you continuously update a standard data model without affecting all of the instances currently using the standard data model? First, you need to develop a robust data model, using a team of knowledgeable analysts, biostatisticians and clinical reviewers. After developing the model it should be prototyped and tested using several different compounds and types of studies.

Updating the standard data model should also be a team effort. The project instance users submit request to the standards team. The team evaluates the request and approves implementation. The types of changes may include:

- adding datasets and dataset functions
- adding variables and variable functions
- adding formats to variables and variable functions
- increasing variable and variable function lengths
- Modifying variable and variable function labels
- Never delete a dataset function or variable function

Conclusions

A multiple-instance implementation of SAS/PH-Clinical can be well maintained through the use of a single 'standards instance' in which critical structures and libraries are maintained in one master instance and

replicated to instances at other locations or instances which are project specific. 'One way traffic' for modifications to a company-wide data model is maintained by implementing changes only in the standards instance and by replication of the standards to the location or project instances. A comprehensive, robust data model is essential to successful implementation of this method.

Biographies

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