

Design Principles & Implementation of a Reporting System

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ABSTRACT

The GlaxoSmithKline merger in Dec 2000 highlighted the need for standardisation, which led to the development of a new in-house global standard reporting system called HARP (Harmonisation Analysis & Reporting Program).

This presentation will cover the design principles of the HARP Application and Reporting Tools.

It covers how the system has evolved over time to ensure standardisation across different functions and how enhancements have been implemented to benefit users.

Finally it covers the implementation process in more details focusing on successful UAT (User Acceptance Testing), training and support.

BACKGROUND

The merger between SmithKline Beecham and GlaxoWellcome in December 2000 highlighted the need for Standardisation across Biostatistics, and HARP is one of the outcomes of this standardisation. The first phase of HARP was to define the GSK Analysis & Reporting processes from start to finish. The second phase was to build the tools required help carry out these processes.

We currently have 4 major sites using HARP, two in the UK and two in the US. Our satellite companies in India, Verona and Canada are also using HARP. Eventually we will have approximately 400 users worldwide.

Within the legacy reporting environment each site was generally doing the same things but in slightly different ways. We had limited sharing of programming code, mainly due to the lack of consistency, and a lot duplication of effort because every team had their own code. We did have pockets of efficiency as most teams had their own set of macros to use. We also faced a considerable 'start up time' for newly assigned staff, which meant that it was very difficult to share projects across sites.

So why did GSK feel they need to create a Standard Reporting System? Well, Core standards were being developed for data capture (paper & electronic), databasing, right the way through to data displays (Tables, Figures, Listings). Therefore it made sense to take the process one step further and develop Standard Reporting System to generate these standard data displays. We also needed to get drugs to the market quicker, which meant we need to report studies faster, but with the same amount of resource. We wanted to improve security inline with GCP compliance, and have a way of making sure people were adhering to the new standards. A standard reporting system would enable use to achieve all these things.

HARP APPLICATION SUITE DESIGN

The inputs to HARP are raw SAS® datasets from data management system, and the outputs are Analysis & Reporting SAS datasets and data displays (Tables, Figure & Listings). The HARP Application Suite is made of two components, a library of SAS macros, referred to as the HARP Standard Reporting Tools and a Web-based application which is the user interface to the reporting tools, and is used to generate the Analysis & Reporting datasets and data displays.

Each of the major sites has its own UNIX server, so we don't have any performance issues. Any updates to the standard reporting tools, will be immediately replicated to each UNIX server.

Within the application we have three different levels of user, Basic User, Developer and Standard Tools Developer.

- Basic User – Limited SAS knowledge, will only run data displays through the application using standard reporting tools
- Developer – Programmers and Statisticians, who will be developing non-standard reporting tools
- Tool Developer – Same access as a Developer, but they can also make updates to standard reporting tools

There are also two administration roles, Compound Administrator and Standard Tools Administrator.

- Compound Administrators – Can carry out setup work for new compounds and studies
- Standard Tools Administrator – Grants access to new users, only after they have had the relevant training. They are also the only people who have the ability to check-in new or updated standard reporting tools into the HARP Application. This means that when a Tool Developer has made an update to a standard reporting tool, and the tool is ready to be checked back into HARP, they have to get the Standard Tool Administrator to do this.

The application also provides the user with notification about when jobs have been submitted and completed (ie) tells you if data has been imported successfully, or tells you when SAS jobs have been submitted and when they have finished running. Every operation within HARP can be tracked through the audit trail, so you can easily find out who has done what, and when.

Some of the major functions of the HARP Application Suite include:

UNIX file & directory creation of Development & Production Areas

Everything run in HARP is done in the production area, and only the HARP Application has write access to the production area, therefore if a user wants to write to the production area, then they have to do it via the HARP Application. The reason for this is so that we can have a full audit trail and are CFR 21 Part 11 compliant.

The development area is a mirror image of the production area, and is the place where non-standard macro development can take place. The idea is that you can develop and test your non-standard macro in the development area, and then once you are confident that it is doing what it should be doing, you can import the non-standard macro into production area and run it via the HARP Application.

SAS macro code management

All macros that are used in the HARP Application have to be checked into the system first. If a checked-in macro needs updating, you can check-out the macro (i.e. move it to the development area), make the necessary updates to the macro and then check the macro back in (i.e. move back into the production area).

Dataset creation & management

You can import your raw data, then plan your Analysis & Reporting datasets, then create your actual dataset and finally reconcile your planned dataset against your actual dataset to make sure they are the same. This reconciliation is very important, because the planned dataset metadata is used to generate the CRT package.

Data display creation & management

This is the user interface to the SAS macros. For each data display generated within the Application the user can edit all the macro parameters being passed to the Reporting Tools to generate that display. This means that user has a lot of flexibility when using the tools because they can control titles, footnotes, what summary statistics are being displayed in a summary table, or what variables are being presented in a listing.

CRT Package

You can add hyperlink for your Analysis & Reporting dataset variables to your annotated CRF, create you Data Definition Table (DDT) using the reconciled dataset specification that you produced for Analysis & Reporting datasets, and finally generate your SAS transport files.

Repository Loader

Loads the data displays, drivers, macros and CRT package into the output repository.

HARP REPORTING TOOLS DESIGN PRINCIPLES

The HARP Reporting tools are a cohesive collection of SAS macros, designed to integrate with the HARP Application that make up a standard, global reporting system.

The suite of macros follow a “building” block design :-

Utility macros - Code blocks that are designed to perform one job and do it well.

Package macros - A macro that contains a series of calls to utilities macros to perform a specific task (e.g. frequency counts, summary statistics)

Wrapper macros - Contain no coding. Pass default macro parameter values into the different package macros to create a specific display. (E.g. The standard displays for summary of adverse events and summary of concomitant medications will both use the same package macro).

HARP REPORTING TOOLS DOCUMENTATION AND VALIDATION

Documentation is created at each stage of the reporting tool development process.

- Business requirements
- System requirements
- Macro documentation – Unit Specifications – What the macro is designed to do.
- Test case documentation. – Specifies exactly what is to be tested and what the expected results are.

HARP REPORTING TOOLS MACRO DESIGN

The individual reporting tools all follow a set of defined programming standards in order to maintain quality tools and also to ensure integration with the HARP Application.

All macros have a fully documented header box containing version number, modification history, list of macros called directly, parameter information and example usage.

Extensive parameter validation is performed in all utilities and packages (For example to check if a required dataset exists and is not empty, to check that required parameters have a value and that this value is appropriate).

Any errors/warning are “captured” by the reporting tools and a meaningful message is displayed to the log and the macro is sensibly aborted.

Data display macros are coded so that it's possible for the user to re-run a data display just modifying the titles/footnotes and not have to re-perform the data analysis.

Data displays are programmed such that text can be produced on the displays in a localised language.

HARP ENHANCEMENTS

Since the first release of the HARP Application Suite, we had several new releases. These subsequent releases have included the following enhancements:

PK Utilities and WinNonLin Integration Application

Two new applications PK Utilities and WinNonLin Integration Application were added the HARP Application suite. These two new applications are used by Kineticists, and it provides a compliant environment for them to analyse drug concentration data for studies which collect and analyse PK data.

HARP Reporting Tools for pharmacokinetic data

Within Phase 1, Standards we developed for PK data, from data capture through to data displays (Tables, Figures and Listings). As a result new standard reporting tools were developed to produce these data displays.

A&R Dataset Transformation macros

The new data management deliverable for raw data is a System Independent (SI) dataset. These SI datasets are the same format and structure regardless to data source ie) paper, electronic or CRO. Transformation macros were then developed to transform the SI datasets into Analysis & Reporting datasets.

Bug fixes and Enhancements

As a result of feedback from users, enhancement and bug fixes were made to both the HARP Application and Reporting Tools.

IMPLEMENTATION OF ENHANCEMENTS

In order to implement these enhancements the following tasks are undertaken

- Updates to the Business Requirements during the planning and design stage.
- System testing – Testing performed by the developers in order to test that the product is doing what it was designed to.
- User Acceptance Testing (UAT) – Testing performed by the product users in order that the end users are satisfied that the changes/updates are appropriate and work as designed.
- Deployment – Releasing the updated version of the tools and/or application. Communication of enhancements to the users.
- Training/Support - the training material and user documentation are updated to reflect any changes

USER ACCEPTANCE TESTING (UAT)

We had a global UAT team, and testing was based on the Analysis & Reporting process from start to finish. UAT focused on positive testing, as the negative testing was done during the system testing phase. At the end of each round of UAT, the change control team met to determine which anomalies should be fixed prior to the next round of testing, and which should be deferred to a future release of the application.

TOP TIPS FOR ACCEPTANCE TESTING

In order to get the best out of your UAT, make sure you involve expert users with a thorough knowledge of the business process and requirements. Work in partnership with the system developers and provide input into the look and feel of the system on an ongoing basis, otherwise you might find that business requirements haven't been interpreted correctly, and UAT phase may be too late to fix them or it may lead to delays, while the system is fixed. The key objective is to test against the business process, not break the system.

TRAINING

Initial training was provided as classroom training (2-3 days in total for all aspects of HARP). The majority of training is now web-based, although two 1-day workshops are available to cover the HARP Reporting Tools in more detail.

Users must complete the prerequisite web-based training classes in order to have access to the HARP Application

SUPPORT

Upon first release of the application and the tools dedicated support from the expert users was provided to teams that required it.

Subsequently support for the application/tools is provided by:-

- User feedback – A database is available to all users containing useful reference material plus the opportunity to submit feedback. The users may also submit a Q/A for a particular aspect of HARP and this will be sent to experts in that particular area.
- Communication – Users are informed of forthcoming updates/new macros. Useful hints and tips are sent out via a Reporting tools newsletter.

CONCLUSION

One of the benefits of HARP is the harmonization of Biostatistics operations through standardisation, which means that we have consistency across sites, as everyone is following the same processes and working practices. This in turn will help reduce reporting, support and maintenance costs. HARP also allows flexible resourcing, as it is much easier to move projects between sites, or move staff between projects, as people will not require any additional training. The use of common tools for analysis, reporting and delivery will eliminate the duplication of effort. Finally HARP is a fully validated, secure, GCP compliant reporting environment.

CONTACT INFORMATION

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