

Pros and Cons of Standardisation – A user's dilemma

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ABSTRACT

HARP (Harmonisation Analysis & Reporting Program) is an in-house developed reporting system consisting of two main components; a library of SAS macros and a web based front-end application. HARP has captured various independent processes undergone during the life-cycle of a study and wrapped a shell around these processes to make it more standardised for everyone to use.

INTRODUCTION

HARP is a system that has been designed for a range of benefits that includes standardisation, compliance, reduced timelines in the reporting process, easy delivery of output and the reusability of resource. Underneath the system lies a set of highly intuitive SAS macro code all integrated together to give the HARP user an environment where the entire reporting process is a breeze to work with. But, has this really been the case for the end user?

What the end user saw in the change in process was a set of previously independent tasks done during the various cycles of a study, all combined within a standardised tool. The purpose of this paper is to talk about, in general, how standardisation of study reporting impacted the end-user. It shall detail a few key obstacles faced before and during the roll-out of the system and as these obstacles were addressed, how this benefited the user.

THE OBSTACLES

- The learning curve to be competent in using the system:

There are over 500 users within GSK who are currently using the standard reporting system. These users are based in the US, UK, India, Verona and Canada. At the time when we were using Legacy systems for reporting, each site had their specific methods, specific processes of producing validated SAS datasets and output (table's, listings and plots).

This reporting system was set out to revolutionise the whole approach of reporting studies and this meant that the various legacy processes and tools needed to be de-commissioned. The best tasks and processes for reporting were built into the new system, but this also had the overhead of having to train the immense number of users with the new approach to reporting. For an end user, adapting to the revolutionised system was a change in process.

Sufficient training was provided to the users to adapt to this new approach, but we are all aware, there is no better training then "hands-on" training or "on-the-job" training. However, as with anything new, the system took time to understand and get familiar with, to be used to its full potential.

- Over engineered or under engineered? – One user's interpretation of the system to another:

One of the principles for the new reporting system was re-usability. Initially, it seemed practical to develop package macros (macros that can perform a multitude of tasks based on various conditions), that would be used over and over again to create the necessary output when required. These macros were very detailed, with 1000s of lines of code, containing many parameters that enabled the flexibility for the system to produce several variations of the output. But, was this a friendly approach for the users?

During the legacy era, programs were written and designed for specific activities and included code applicable for particular tasks. With the revised approach to reporting, macros replaced these stand-alone programs. But this also meant that tasks or activities that were not required for a user's current study still had to be processed, as

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macros are generic. Although options were available to turn off specific tasks in these generic processes, users initially saw this as a negative aspect, simply because it was felt too much code could result in a greater chance of reporting issues.

Following user feedback various user guides, on-the-job training, a centralised database for users to ask questions regarding these macros have been improved and this has made the system easier to use.

- SAS code hidden beneath a series of nested macros – a debugging challenge?

The word 'macro' may seem frightening to users. Wiktionary (part of Wikipedia) describes a macro as "very large in scope or scale". A macro, with a number of nested macros was seen as a challenge to debug in cases where the user had to determine why the output did not meet the requirements. During the early releases of the system, users were faced with the calamity of having to trawl through 1000s of lines of code to identify "what went wrong!"

Once again, with the increased support for this system and taking onboard suggestions, the subsequent releases of the system have provided better debugging techniques and error messaging handling.

- Are we being replaced by a machine?

Before this system was rolled out and as we progressed towards automation, this question was perhaps the fundamental one raised. Tasks previously undertaken using standard programming were to be automated. Was this a good sign? A lot of users had concerns about job security.

With this automated process, this was NOT an issue and the reporting process turned into a blessing for all. Having the tedious task of producing tables, listings and plots now automated, users can concentrate on the more pressing issues such as standards, validation rules, developing code for non-standard output and macros that can be standardised for therapeutic areas.

THE MERITS

- Standardisation and a well defined audit trail:

There are now over 500 users, all producing output to the required ICH and FDA standards and all working with the same tools to produce the required output. Finally, from the user's perspective, the tasks of producing your tables, listings, plots and the analysis datasets has been standardised. Everyone is working with the end in mind. Standards have been set for the required output and tools are in place to produce them. This has resulted in a more efficient working practice and the output is produced with ease and minimal effort.

Within the reporting system, there is a well structured audit-trail in place. This provides the ability to monitor the reporting process from a GCP compliance point of view. Users are able to work securely and safely, knowing that every process undertaken using this system is tracked and logged. In the event of any mishaps, the source of this can be easily be identified.

- Flexibility and relatively easy to adapt process:

The system has been designed with a consideration for ease of use. A user can be anywhere in the globe, but as the system is a web based application using it has been very versatile. Your output is at hand with a touch of a button and information can be shared amongst users without having to consider alternate methods.

- Centralised approach to reporting – collaboration of various systems re-developed for HARP;

This system is designed to import data, define your output; select the tools (macros) required to produce the output; produce the output and submit your output for publishing. All these tasks when carried out using the legacy system required individual tools. From a user's perspective, adapting to this "all under one roof" solution has been very favourable as it not only lets you work faster, but enables you to be better at what you do.

- An all-in-one system – providing a better view on progress:

The output that is produced is clearly defined within the web application front-end. This helps monitor the study progress and ensure that timelines are being adhered to. There are also various flags available to track progression of output, for e.g. draft, QC Ready, final etc.

There are situations where various users, across the globe, work on the same study. The system has provided these users a way to easily manage sharing of resources and producing the output. Furthermore, as the macro code that is used, stored under a well audited system with read-only access folders, the accidental over-writing or deletion of code is prevented and changes can be easily tracked too.

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- A standardised – non standardised tool:

The system is not “limiting” but rather “progressive”. A merit to a user is that non-standardised code can be written and run via the system to produce the required output. Programs are run in a standardised manner and the process is fully logged for compliance. The ability to offer such flexibility ensures that you can quickly incorporate non-standard output for your clinical report and you are not restrained to saying “the system cannot do it”.

- Re-usability – a programmer’s heaven for using existing code:

Working together, sharing resources, basically highlights the point, “don’t do it yourself if someone else already has”. Everyone dislikes repetitive tasks. Producing the same standard output for various studies and having to write your own program each time is mundane. The users can now rely on these outputs to be produced using standard validated code and have more time to concentrate on the non-standardised outputs required for the study.

Furthermore, with a “standardised - non-standardised tool”, a user can easily copy over programs used in previous studies to the study they are working on and then tweak the code to suit the study’s requirement. Once again, this provides a valuable time-saving solution.

- A standardised system, a standardised QC process:

We all are aware that QCing of your programs and outputs can take as much time as writing the code to produce this. However the user now has the ability to greatly reduce this QC effort. This is because the standard output that is produced using the standard macro has gone through a strict validation process. The system uses validated macros, via a validated system and a GCP Compliant audit trail process. Validated and standardised code requires much less QC than a non-standardised macro or program.

THE CONCLUSION

The beauty with standardising the various processes is it’s flexible enough to give you added benefits over those you had previously. The obstacles faced by an end user were neatly captured and improvements made on further releases of the suite. From an end users point of view, as the obstacles were overcome, the merits of using this standardised system were greatly noticeable allowing their job to be done efficiently and effectively.

CONTACT INFORMATION

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