

MOPP the SOP – Makeover of Programming Process Steps in the Standard Operating Procedure

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ABSTRACT

Our goal was to redesign our standard operating procedures and the corresponding tools and templates for defining, developing and validating programs to support analysis and reporting (A&R) performed by Biostatistics and Research Decision Sciences (BARDS). Current processes were evaluated and comprehensive documentation, templates and training materials were developed for each of the system development lifecycle stages – Define, Develop, Validate and Operations. This paper will provide insights into the planning, implementation and execution of a major procedure rewrite in order to streamline processes and align with industry best practices.

INTRODUCTION

The existing standard operating procedures and the corresponding tools and templates for the department had evolved over approximately six years. The existing policies and procedures allowed BARDS to successfully conduct highly reliable analysis and reporting (A&R). The main reasons for the makeover of the standard operating procedures were to streamline and reduce non-value added tasks and documentation, take advantage of new division wide templates and tools, and ensure compliance and traceability in our A&R processes. Another objective of the redesign was to empower staff to affect their work processes by being involved in the BARDS revised program development and validation process initiative. The initiative was kicked off in January of 2016 and culminated in the release of the revised processes and tools in December 2016.

BACKGROUND AND APPROACH

As BARDS developed and grew over the years, it no longer focused entirely on late development studies. Various subgroups were established to support other analysis such as early development studies, clinical safety and risk management, real world evidence, and health technology assessment. As a result, these subgroups often needed to develop specialized processes and steps to meet their needs, which were more semantic than functional due to the explicit wording in the original SOP. This complexity had the potential for adding confusion, extra work, and errors to the process. Since the BARDS organization is now comprised of more than 400 statisticians and statistical programmers located in North America, Europe, and Asia, the importance of a new process to yield a flexible and well-organized operating model across all BARDS functional areas was critical in order for staff to efficiently and consistently develop and generate high quality deliverables.

The purpose of the new standard operating procedure was to define a consistent approach for defining, developing and validating programs to support analysis and reporting (A&R) performed by BARDS and to ensure the traceability of the A&R process. The scope for the processes include *all* Analysis and Reporting programming conducted by BARDS staff (regardless of functional area and whether it's conducted by Statistical Programming or Statistics) including analysis for a single database as well as integrated analysis conducted across multiple databases.

In order to ensure we met the needs of all BARDS staff, representatives from the various functional areas were included in the re-write of the program development and validation process initiative. This helped to empower our staff to take ownership of the process, and to ensure that all facets of A&R were considered. This year-long effort began with focus groups that were conducted to identify the critical elements of the A&R process for each of the functional areas. Smaller groups reviewed existing processes and work instructions to identify commonalities. The revised SOP was drafted and reviewed by a team of representatives from the various areas within BARDS. Modifications were made until the

SOP met the needs of all groups. Once the SOP was revised, the team began working on stream-lining and consolidating the supporting tools, templates, and guidance documents.

TERMINOLOGY AND LIFECYCLE PHASES

The makeover of the SOP included global implementation of consistent terminology for departmental roles including customer, developer, authorized requestor, specification author, independent reviewer or tester, double programmer, and customer reviewer. Adopting this terminology, instead of using current job titles, to indicate who is responsible for each task allowed the SOP to remain flexible for all areas within BARDS and to minimize revisions when job titles change. For example, by indicating the customer is responsible for providing the specifications for a deliverable, it allows flexibility in who is acting in the role of the customer (i.e., clinical development scientist, modeler or a statistician).

The revised SOP follows the System Development Life Cycle (SDLC) used in the A&R process which includes steps for the 4 phases including Define, Develop, Validate and Operations as shown in Figure 1.

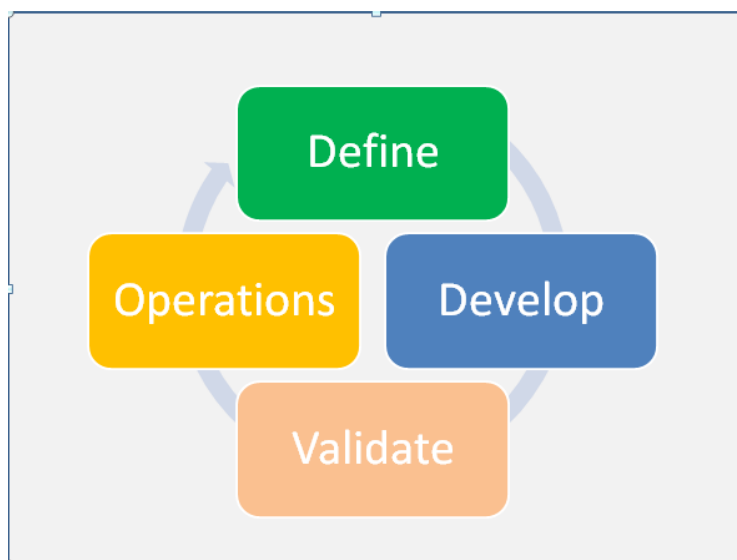


Figure 1. System Development Life Cycle (SDLC)

The SOP is subdivided into these 4 phases in order to clearly illustrate which steps belong to which phase of the SDLC.

The DEFINE phase is the most critical phase. It is the time where all requirements for the A&R package, and the programs needed to generate them, are gathered and documented. The DEVELOP phase is where programmers create programs or macros based on the requirements that were gathered in the Define Phase. Then programs are VALIDATED in the test area according to the validation plan. Finally, validated programs are promoted to the production area of the computing platform and executed using production data to produce analysis datasets, tables, listings and figures in the OPERATIONS phase.

DEFINE PROCEDURE

The purpose of the Define Procedure is to plan all A&R deliverables and the analysis programs required to support them. One of the first steps in the Define Procedure is for the customer to document the specifications for each deliverable in the A&R package. There is a specific template that is to be used, depending on the type of deliverable. Once the specifications are complete, and they are stored in the appropriate location for that computing platform, the developer must plan and track the development of both the deliverables and programs.

Two templates were developed for this purpose: The A&R Grid and the Program Development and Validation Tracker. Each project team will make a copy of these templates to track the information for their A&R package. The A&R Grid is used to track all deliverables for an A&R package, such as tables,

[illegible][illegible]

A line is entered on the Program Development and Validation Tracker for each program or macro that is used in the creation of an A&R deliverable. A validation category is selected based on the requirements for that particular program (i.e., developer testing, double programming, and/or independent review). The completion of specifications is tracked. If a program is being reused from a previous study with minor modifications, the location of the original validation documentation is noted.

Once the specifications for the deliverables are completed and approved, program development can commence. The purpose of the Develop Procedure is to develop programs and conduct developer testing for all A&R deliverables. The developer first identifies any existing validated standard programs from the Standards Library to ensure reusability and consistency across all protocols within a compound or therapeutic area. Where needed, the developer will create new programs or update existing programs in accordance with the requirements and specifications provided by the customer. The developer is expected to follow good programming practices and to comply with industry regulations. Developer testing is conducted in accordance with the validation plan. A high level description of validation activities and completion statuses are documented in the Program Development and Validation Tracker, including any exceptions to the prescribed process.

During the Validate Procedure, the programs and macros are tested and validated based on the validation plan that was previously agreed to by the project team in the define phase. In our previous version of the SOP we had over 40 validation categories for programs. Upon reviewing this information we determined that the criticality of the analysis and the inclusion of complex statistical analysis determined the degree of testing and validation required for a program, and this could be simplified to just 4 different situations (see Table 1. Required Testing). All programs require developer testing, but those with complex statistical algorithms also require independent review or testing by the statistician, and

critical programs with important analysis, such as those evaluating primary efficacy, require double programming.

Description of Program	Required Testing
Most critical - programs with important analysis (e.g. primary efficacy) as well as complex statistical algorithms needing independent testing.	Developer Testing Double Programming Independent Review/Testing
Critical programs with important analysis (e.g. primary efficacy)	Developer Testing Double Programming
Programs with complex statistical algorithms needing independent testing.	Developer Testing Independent Review/Testing
Non-critical programs without complex algorithms	Developer Testing

Table 1. Required Testing

Required activities that must be completed for each validation step are reviewed, and any exceptions are noted in the Program Development and Validation Tracker. By simply noting an exception to required steps, we can eliminate the need for detailed checklists for each program.

The SOP notes that results of the testing must be stored in the appropriate location for the computing platform being used. However, the specific location is not explicitly stated in the SOP. Separate resources for each computing platform specify the detailed location and folder structure that are to be used for that system. The completion status of each type of required testing is tracked in the Program Development and Validation Tracker.

If a customer review is required, this is also conducted during the validation phase. Finally, after all testing is completed, a dry run of all programs or macros is performed and the customer is sent a sample of the deliverables for review and approval.

OPERATIONS PROCEDURE

After all testing is complete and a sample of the deliverables has been approved, the development lead will promote the validated programs to production. Production data is obtained for the final execution of the deliverables; the executor will do a quality check of the deliverables and inform the customer when they are available.

IMPLEMENTATION AND TRAINING

In order to ensure the success of the revised SOP and supporting documentation, BARDS staff required appropriate training and support to implement the new process. To ease the burden on the staff, use of new SOP would begin with the assignment of a new A&R package. For projects currently under development, the old SOP would continue to be used. This prevented the need to retrofit any existing tools and templates already in use for a project into the new tools and templates.

Prior to the release of the new SOP, all of BARDS staff was notified of the 31 December 2016 effective date and were assigned to read and acknowledge the new SOP via our corporate learning management system. This allowed us to track that everyone who was impacted by this SOP was aware of the new process.

The next step was to provide training and answer any questions or concerns the staff may have had about the new procedures. Since our staff is distributed worldwide, the logistics in disseminating this information to everyone in a timely manner needed to be considered. Initially, we did not want to create an eLearning to provide this information because we knew that once people actually started using the tools and templates in production we may need to make some modifications, and we wanted to be available to address any questions or concerns the staff may have and provide clarification in real time. We therefore scheduled a series of web conferences to provide an overview of the new process as well

as the corresponding tools and templates at times that were convenient to the various audiences. Once the tools and templates stabilized, we created an eLearning to provide an overview of the process.

As groups began to use the new process, we provided targeted training for each of the new project teams to get them started with the updated tools and templates and ensure their understanding. This multi-tiered approach allowed for a successful implementation and adoption of the new A&R process and corresponding tools and templates.

CONCLUSION

Careful planning and detailed review of our existing processes allowed us to re-design an SOP to meet the Analysis and Reporting needs of all the diverse groups within BARDS and to ensure that we were providing improved traceability for our program development. Involving representatives from the various functional areas not only helped to ensure that all facets of A&R were considered, but it also empowered our staff to take ownership of the process.

We were able to create a flexible procedure by using generic terms for individuals performing the actions in the SOP (e.g., customer, developer, etc.) instead of using specific job roles. We further maintained flexibility by putting the details for different computing platforms that may be used in program development in a resource instead of directly in the SOP. For example, the SOP notes certain documentation that must be retained in order to promote compliance and traceability, however, the details of where that information should be stored for each computing platform is identified in a resource, not directly in the SOP.

As a result of this re-design, we now have a consistent approach for all Analysis and Reporting programming in BARDS. Following the same process not only helps to improve efficiencies by promoting greater use of standards and allowing staff to provide support to other areas when needed, it also creates an environment for enhanced compliance and traceability.

CONTACT INFORMATION

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