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Importance of Creating a Learning Portal for Statistical Programming End-to-End Processes

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ABSTRACT

In a highly regulated pharmaceutical industry, there are multiple Standard Operating Procedures (SOPs) written with respect to the mandatory processes that a clinical/statistical programmer need to follow/practice in their day-to-day programming activities. Multiple SOPs/processes can cause confusion and lead to non-compliance with the processes followed within the Statistical Programming Department (SPD). To avoid this situation, the statistical programming leadership team produced an idea of creating a site/portal that contains important topics listed in one place, as hyperlinks with each topic explained from start to end. For this very reason, the statistical programming end-to-end (SP E2E) learning portal gained a lot of popularity within SPD among junior, new hires, and even the senior programmers. The goal of understanding which process should be followed and when it should be followed was achieved. This idea of developing a learning portal also ensured that details for each process/topic have reached the right audience and that the expectations are understood by every programmer within SPD. The paper is written explaining details on the specific format used for each topic, and the review process followed for each topic, before publishing the topic in SP E2E portal.

KEYWORDS

Statistical Programming process, SOPs, Programming Activities and Deliverables

INTRODUCTION

This paper is introducing new idea in term of creating a learning portal that can give a better understanding to junior/senior statistical programmer on the topics that they need to know from start to end and how they can remain compliant with the SOPs set by the company leadership team. Another advantage of having such portal is, the SPD can jump to a topic that they need immediate help to understand before contacting a Subject Matter Expert (SME).

GOALS

Material will aim to promote:

- high quality deliverables
- greater consistency across the department
- increased efficiency (less time focused on figuring out what to do or things that should not be focused on)
- increased knowledge sharing (have those that know this information best – the SMEs – share their knowledge with the rest of the department)

EXPECTATIONS FOR TOPIC CONTENT

Material must be:

- Clear and concise
- Readable, even for recent hires

- Comprehensive (one stop shop)
- Provide the foundation for being successful in that space (common practices, pitfalls, etc.)

CLASSIFYING TOPICS UNDER A COMMON HEADER.

It is important to classify topics under a broader title or header. This will give the end user an understanding about the topic categorization. This is essential because this end-to-end portal will provide the end user with information about each topic, when it should start and end, and helps them understand the broader category.

Below screenshot displays the main page of the portal/site with a common header within which multiple topics can be listed. As you can see, this creates a systematic approach and clarifies to a programmer junior and/or senior on what stage they are in while checking the details on the given topic.

Figure-1: Main Categories in SP E2E Portal

TOPIC SELECTION UNDER ABOVE MAIN CATEGORIES

This is the core space within SP E2E portal in which topics were listed under each of the above main categories. The planning and selection of the topics listed in below screenshot (Figure-2) was done after the discussion with Statistical Programming Leadership team (SPLT) and then these topics were carefully categorized within each of the main categories shown in Figure-2. Each topic displayed below, once it gets internally published, will be a hyperlink to which programmer can click and get the answers on the points listed below.

1. Actions programmers need to take.
2. List of required training programmers need to complete to get familiar with the topic.
3. Tools, if any, are available for the programmer that can be downloaded and how the tool needs to be used.
4. List of available SMEs, for the topic, that the programmer can email or call.

Each topic, when published, can clarify the above points. It is easy to confirm that a common format was followed for each topic by the topic authors who were also acting as SMEs. Next section will give details on the format that was used for each topic.

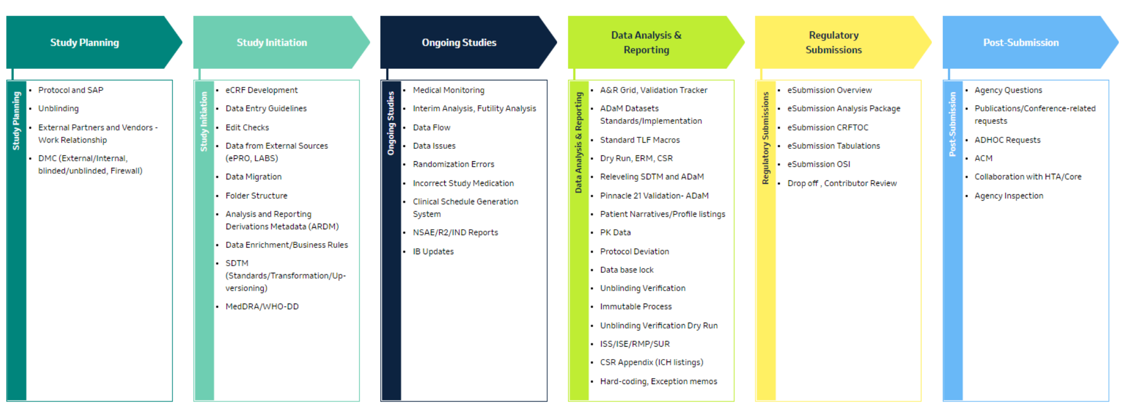


Figure-2: Topics Selected within Main Category

DOCUMENT FORMAT DESIGNED FOR EACH TOPIC

Standard format for each topic was followed because the goal for designing this portal is to make new hires, junior programmers, and senior programmers, become familiar with each topic that are listed in Figure-2. It can also serve the purpose of letting individuals know if there are any updates on the current process.

Each document will have the sections below, as shown in Figure-3.

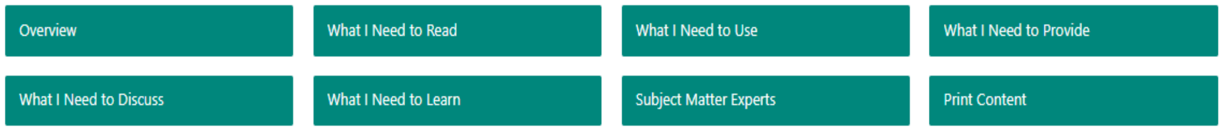


Figure-3: Various section titles within each Document for a topic

Overview: This section is dedicated to giving a high-level introduction on what the topic is and the purpose for the topic. Any relevant high-level background material can be included here. It can include link(s) that can directly go to the SOP (Standard Operating Procedure) page giving the official overview of the topic. The link(s) enables the author/SME of the topic to remain up to date/current with the process that is going to be explained in the subsequent sections of the document. Out of scope details can also be specified here.

What I Need to Read: This section contains links to material that should be read related directly/indirectly to the topic. Awareness is always a key and given that there are multiple links, SOPs, documents etc. which may exist in various places for a given topic are important for the programmer to understand what documents they must read. Along with the SOPs, this section may also contain internal published links that can help better understand the importance of this topic.

What I need to Use: This section contains things that need to be used for the topic. It could be a template (most common), specific software, or tool that is needed to be used for fulfilling the activities described in the topic. These tools either are available without any need to download or there can be tools that need to be downloaded/installed from the company's official software repository called 'software center.' This section within the document will share details with the user on what software, if any, needs to be installed.

What I need to Provide: This section summarizes the key deliverables involved for the topic. This section will outline not only what needs to be provided, but the timing as well relative to other deliverables/events. It becomes important for a programmer to understand what they need to provide or what the programmer should expect the outcome or deliverable that they will generate. The section 'what I need to provide' will share information on what a programmer is expected to deliver as final product. This section can have screenshots for the programmer (junior/senior) for better understanding of the expected deliverables.

What I need to Discuss: This section summarizes what input is needed from other functional areas to ensure success with the topic/deliverables. There is always a need to pre-plan and discuss when the process/topic described by the author needs to get started. This section provides details to the reader/programmer regarding when they should start the pre-planning discussion, who the programmer should contact for the discussion purpose and other functional area's responsibility, if applicable.

What I need to Learn: This section summarizes any training that needs to be completed. Differentiation should be given on what training is required and what is recommended. In addition to the SOP link(s), shared in section "What I Need to Read?" This section will also share the link(s) on the company's internal training, if any, that the user needs to take to get familiar with the topic.

Subject Matter Experts: This section provides the SME/SME team contact details for additional questions/clarifications in the process/document.

Print Content: If programmer wants to download the topic into pdf format, once section title clicked a pdf of the entire topic is created for the user.

Once the author(s)/SME(s) completes the final draft of the topic it goes through a rigorous review process, involving a team of selected individuals from the below groups, before the document goes for publishing into SP end-to-end portal.

1. Review-1 group: Senior programmers.
2. Review-2 group new hires and junior programmers.
3. Review-3 group: Individual(s) from Statistical Programming Leadership Team.

Details on the review process are given in the next section.

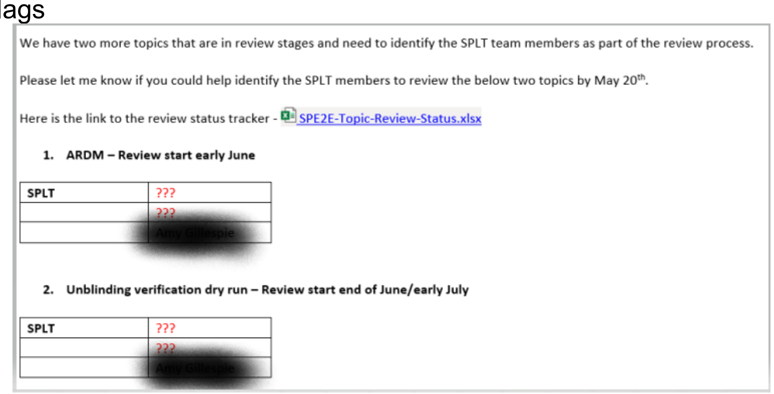
REVIEW PROCESS

The review process begins once the identified topic has been drafted by the development team and consists of three steps or rounds. The first round is completed by Senior Programmers, or your veteran programmers having been with the company for more than two years. Once all feedback is received, incorporated, and/or addressed by the development team, the second round of review can begin. Those less seasoned or newly hired statistical programmers having two years or less experience with the company review the topic next. If applicable, the topic is also sent to any ad hoc team members. Ad hoc team members are identified by the development team and may include those programmers having expertise in other areas such as SDTM (Study Data Tabulation Model (CDISC (Clinical Data Interchange Standards Consortium))) where their input would be beneficial to the current topic. The development team is again tasked with incorporating and/or addressing all feedback received from the second round. The final version of the topic is reviewed by individuals from the Statistical Programming Leadership Team (SPLT) and SP E2E Sponsor. SP E2E Review & Publishing Lead requests these members from the SP E2E Sponsor during round one.

To maintain consistency and fluency during each round of review, template emails, tracking spreadsheets, standard review times, and all versions of the document are retained for future reference.

The template email to review teams include the following items:

- Topic
- Link to document
- Due date
- Link to tracking spreadsheet to track review status
- Follow Up flags



We have two more topics that are in review stages and need to identify the SPLT team members as part of the review process.

Please let me know if you could help identify the SPLT members to review the below two topics by May 20th.

Here is the link to the review status tracker - SPE2E-Topic-Review-Status.xlsx

1. ARDM – Review start early June

SPLT	???
	???
	[redacted]

2. Unblinding verification dry run – Review start end of June/early July

SPLT	???
	???
	[redacted]

Figure-4: Example - template email to SP E2E Sponsor

The tracking spreadsheet includes the following items for each topic:

- Document Link
- Review Team
  - Team 1

    - Team 2
    - Ad Hoc (SDTM)
    - SPLT
- Reviewer Name
- Review Start/End Dates
- Status
    - Complete
    - Complete with comments
    - Complete without comments
- Reviewer Comments
- Development Team Comments
- Development Team Response
- Development Team Addressing Comments End
- SP E2E (SP End to End) Review Process Lead Comments

The standard review time is two weeks for each review period. An updated version of the document is created after every review cycle. One week after the review start date, a reminder email is sent highlighting the upcoming review end date. This is to keep the reviewers engaged and aware should they be on vacation, have other pressing priorities, or even other topics to review.

If necessary, the development team should meet with the reviewers or review group to discuss feedback that cannot be easily communicated via email.

The topic is ready for publishing once the clean version of the topic is available.

PUBLISHING PROCESS

The publishing process begins after all review rounds are complete and there are no further updates to the topic document. SP E2E Review and Publishing Lead provides a clean version of the topic to the publishing team. The publishing team uploads/copies the contents from the topic document to the portal. Like the review process, the standard publishing turnaround time is two weeks. If the standard format was followed, publishing is completed effortlessly. If the standard format was not followed such as changing the order of the sections, publishing can take more time to complete. SP E2E Review and Publishing Lead then notifies the development team once the topic contents are available on the portal. The standard review time for this step is only one week.

A tracking spreadsheet is used to log any issues, comments, updates needed to the published topic on the portal. The SP E2E team members should meet with the publishing team to discuss feedback that cannot be easily communicated via email. The available topic is communicated via email and/or departmental newsletter.

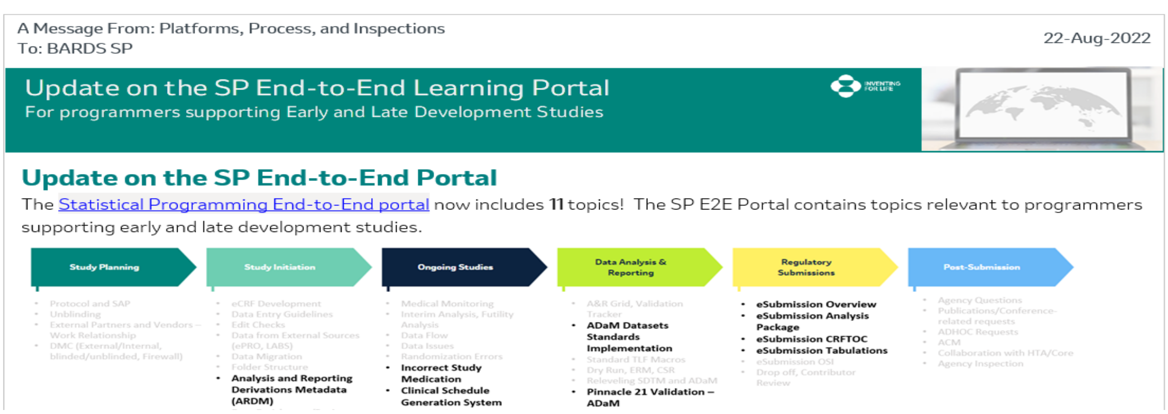


Figure-5: Screenshot showing Email Template on Published Topics

CONCLUSION:

The purpose of writing the documents such as SOPs, execution resources, instructions, etc. by SMEs and SPLT members within statistical programming department is for make sure that all programmers working in the department consistently follow the processes and there is common understanding on what is expected from statistical programmers while they do their day-to-day activity. There will be challenges to check whether the programmer understands the expectation set by the leadership team. To overcome this challenge and ensure all programmers within the department are compliant with the processes this paper tried to introduce an idea that can be implemented or practiced.

REFERENCES:

SAS Institute Inc. 2011. SAS/OR 9.3 User's Guide: Project Management. Cary, NC, USA: SAS Institute Inc.

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