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Procedure Matrix: build the department assets of standardization

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ABSTRACT

The regulatory requirements, particularly the NMPA guidance, have undergone a gradual evolution and become increasingly stringent in response to the current state of domestic new drug R&D. Meanwhile, the emergence of domestic biotech and biopharmaceutical companies has intensified competition within the industry like never before.

This paper presents insights and solutions from the perspective of a statistical programming department on how standardization can enhance the competitive advantage of its organization.

Speaking of statistical programming tasks, many of them can be standardized to varying degrees. The depth of standardization is a key factor in the department's outstanding performance, which includes reduced training costs and improved workflow efficiency. Therefore, it is essential to package the most appropriate tasks into a matrix of feasible procedures that align with company policies.

INTERPRET THE HIGH-LEVEL REQUIREMENTS OF THE DEPARTMENT

No matter what you do for your business and how you do it, the company's policies or department's high-level requirements are always the fundamental roots which guide every aspect of the business activities, so the first step would be interpret the company's policies or department's high-level requirements of yours. Speaking of statistical programming department, the most fundamental roots would be CONSISTENCY and COMPLIANCE on which all other SOPs, WIs (work instructions), job aids etc. are built.

DIFFERENT APPROACHES TO FULFILL THE HIGH-LEVEL REQUIREMENT OF THE DEPARTMENT

Some frequently used approaches in most companies would include SOP, WI, job aids, guidelines etc. Among all kinds of approaches, they shared the mutual intention to fulfill the requirements while they serve different purpose and provide different functions (Figure 1).

SOPs are the most well-known approach, and it defines 'What' must be done and 'Who' is responsible.

Work instruction, on the other hand, tells you 'How' to do the job properly and provide step-by-step instructions to specific tasks so that SOPs can be correctly executed. WI focuses more on the output to be achieved to measure if the job is done 'well' and not just the requirement of the job.

A job aid could be a broader concept that include any materials that may assist a specific job. In this case, WI could also be treated as a kind of job aid. Other materials could be in a format like checklists, flowcharts, guidance files, and standard templates etc. A job aid focuses more on facilitating someone to complete a job effectively and efficiently.

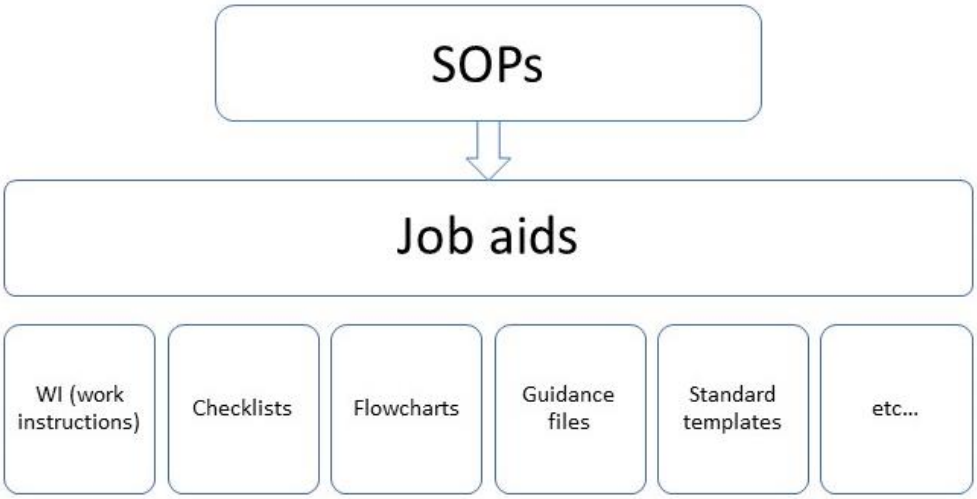

Figure 1. Relationship of SOP, Job aid, and others

A good SOP should state the roles and responsibility explicitly, a well-developed WI should be easy to follow, and a well-written job aid save time, increase accuracy, and improve job performance.

CREATE PROCEDURE MATRIX TO MEET THE EXPECTATION OF THE DEPARTMENT REQUIREMENTS

Choose which approach and how to best utilize them, different strategy will bring different results. Build a procedure matrix in your department is like a swimmer to strengthen his/her stroking techniques since one can swim very fast even when he/she doesn't know the correct swimming stroke and simply rely on his/her physical strength, however, the physical strength will ultimately have upper limit and restrict you from improving. The correct techniques will help you break the upper limit of the physical strength and make you even faster. Back to statistical programming, studies might be completed, and the package will be delivered even without procedures in place, however, the cost would be huge in a long run. That's why a department needs to create the procedure matrix.

The procedure matrix is a combination of the SOPs, WIs, and job aids etc. As discussed above, different approaches serve different purpose. Below are some high-level plan and design with some real examples when developing procedure matrix that suit for our department.

First, SOP will cover the basic requirement of the statistical programming work like the roles and responsibility when conducting program development and verification. This will be the big picture and provide a framework.

Second, a series of WI are in place to assist the jobs in detail like Good Programming Practice to assist Statistical Programmers in developing programs that meet regulatory requirement and improve programming efficiency and productivity; Statistical Programming Development Practices to describes the statistical programming development practices; General Reporting Guidelines for Tables, Listings and Graphs to describe the general reporting guidelines for Tables, Listings and Graphs and so on. This is an important component of the procedure matrix since these WIs describe almost every aspect of the work and clearly state how to do the job to get the required results.

Third, job aids in our department play a role that SOP, and WI cannot touch since they can closely pertain to the daily work and provide the most direct help and additional information to people no matter his/her previous experience. When needed, it will link to WI or SOP. People might not read SOP and WI every

day, but they will use job aid whenever there is a need to start a specific job. For example, we use Microsoft Visio to draw a flowchart for DBL activity named Data Flow Lifecycle from Database Lock to Table, Listing, and Graph Delivery (Figure 2). A DBL is a big day and it's like shooting a starting gun and then run as fast as you can. Even though we have all the SOP/WI there to describe who should do what and how, they do little help at this moment. Below is the thumbnail of the flowchart and intended to guide the programming lead step by step to go all the way through raw data extraction, SDTM/ADaM/TLGs generation and validation, compliance check to the final delivery etc. Even this is the first time for you to be a study lead and go through your first DBL, following this flowchart will leads you to a successful delivery with great efficiency and compliance.

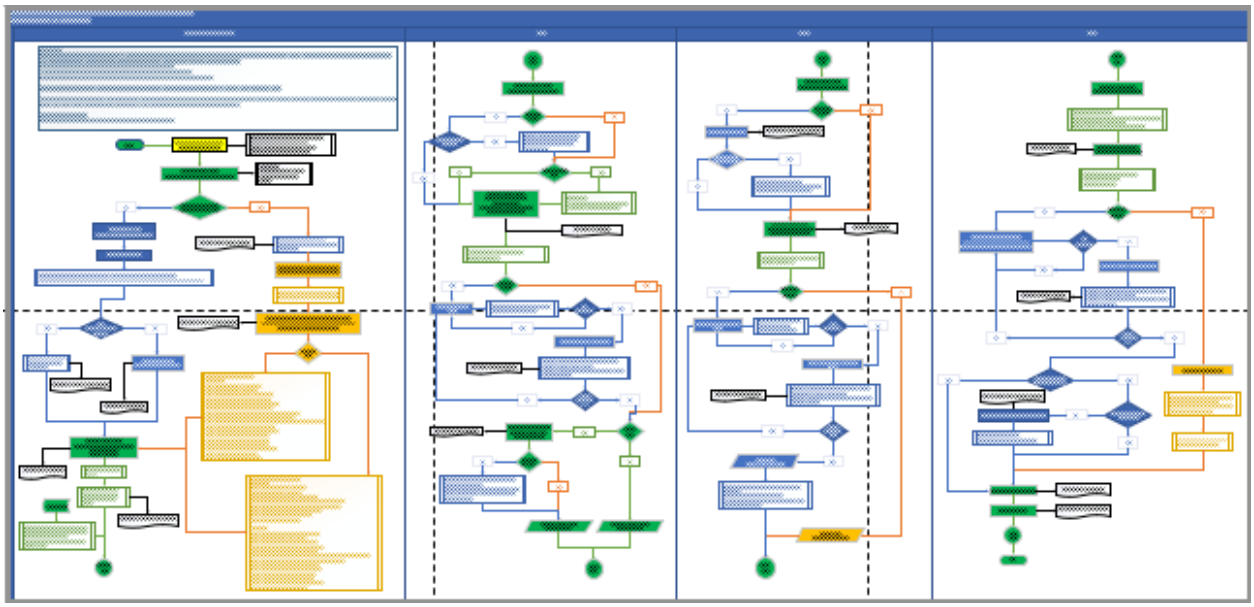

Figure 2. Data Flow Lifecycle from Database Lock to Table, Listing, and Graph Delivery

PROCEDURE MATRIX MANAGEMENT

Everyone want to read the procedure/work instruction/job aid that can aid a job rather than opening it and found it a chicken rib which is tasteless to eat but waste to throw away. In other words, the procedure matrix should be informative, understandable, and reliable. Otherwise, vague procedure/work instruction/job aid confuse employees, disrupt productivity, and result in costly errors. It is easy said than done. Creating a procedure/work instruction/job aid can be a bit overwhelming especially when there are multiple, detailed steps that need to be dissected. Some summarizations during our practice may help you and listed as below for your reference.

- The procedure/work instruction/job aid must reflect company's policy and department's high-level requirements correctly, as a result, it is better that the person who is responsible to create the procedure/work instruction/job aid be very experienced and familiarized with the overall statistical programming work process and had hands-on experience of the actual work.
- The contents should be clear without misunderstanding, and the way you put it should be simple and concise. Select the words, streamline the process, and avoid too short to lead to misinterpretation or too long to lost reader's attention. Technical writing skills will be helpful here.
- Make your procedure/work instruction/job aid well-managed and stored so that people who need them can easily accessed to them. Here is the lifecycle of a procedure materials (Figure 3):

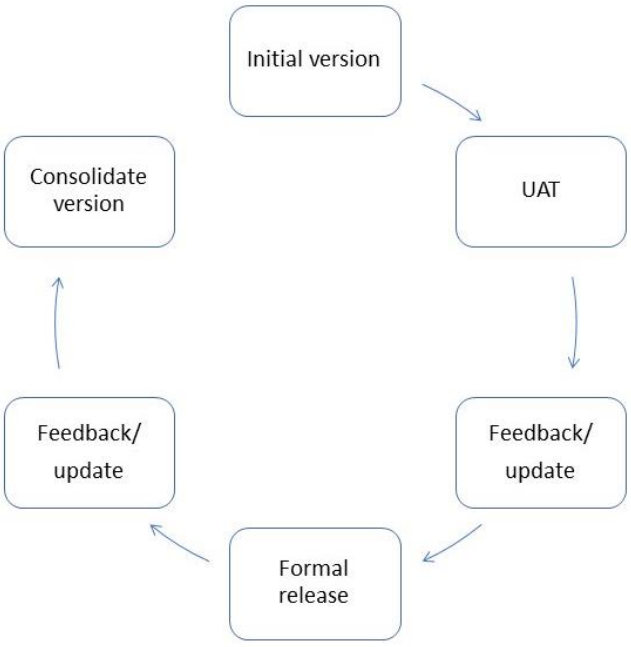

Figure 3. Lifecycle of a procedure

- Ensure the procedure/work instruction/job aid are consistent by themselves. For example, the terminology or the abbreviation used in any material within the procedure/work instruction/job aid should be the same and conform to the standard.
- Treat the project as an art, apart from the content, pay special attention to the display, especially for the job aids, training materials, and sometimes work instructions. The basic would be the format, like consistent font and font size through the materials. To be advanced, choose visual instead of textual display whenever possible. In a word, the procedure/work instruction/job aid are developed to serve people not people work for the procedures.
- Test the effectiveness of your procedure/work instruction/job aid before making them available to the whole department.

CONCLUSION

In current circumstance where many innovative biotech companies are founded and developing, most of the companies are facing the challenges of limited people resource and speedy pipeline strategy. At recent PharmaSUG meetings, similar ideas were also brought up by some big pharmaceutical companies1. This has been becoming a trend since SME (subject matter expert) of a department may leave but a perfect procedure matrix in place will become the assets of your company/department which will guide the work, improve efficacy, and create value to the company.

REFERENCES

Donna Hyatt, Brandy Cahill, and Yogesh Pande “Importance of Creating a Learning Portal for Statistical Programming End to-End Processes” PharmaSUG 2023 - Paper SD-109 Merck & Co., Inc., Rahway, NJ, USA

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