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Making Process Accessible: Process Roadmapping

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ABSTRACT

Establishing clear, well defined processes is critical to maintaining quality, compliance, and efficiency in the work we do in Biometrics. Our formal processes often consist of only high-level SOPs which lack broad buy-in, are disseminated by the read and understand method, and are difficult to access for reference when a process is being performed. This paper will present an approach to developing robust processes and documenting, organizing, presenting, and maintaining comprehensive documentation of those processes, including all relevant forms, templates, and training material, in a single easy to access portal. The portal is structured as an end-to-end roadmap, visually representing the spectrum of activities carried out by each function with links to detailed process maps for specific activities which are owned by functional SMEs. In our organization, this approach has led to greater buy-in and compliance and has created a culture of continuous improvement.

INTRODUCTION

The Process Owner Network (PON) concept is designed to implement truly cross-functional end-to-end business process management. The PON is made up of individuals (Process Owners) sitting within each functional area across the organization who are accountable for cross functional business processes and the associated procedural documentation that guides the execution of those processes.

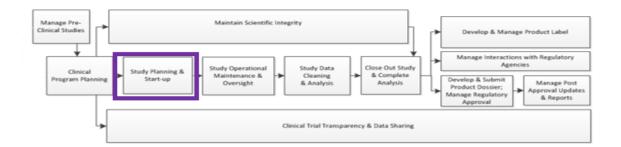
Some key responsibilities of the Process Owners include:

- Overseeing routine and regulatory-driven process updates
- Understanding how their process impacts and integrates with other processes
- Acting as a primary point of contact for all who execute the process to field questions, review process deviations and accept suggestions for improvements
- Performing process risk assessments and establishing Key Quality Indicators (KQIs)
- Monitoring process performance

A dedicated group called Business Process Excellence provides support to the PON in the form of Continuous Process Improvement consulting, process document specialists, and overall process strategy and governance. The product of all of this is a one-stop-shop portal with an end-to-end process road map which can be easily navigated to obtain all information about a process including process maps/flows with links to all pertinent SOPs, templates, forms, job aides/guidance, and training materials. This paper will describe the end-to-end process roadmap and how it is developed and maintained.

CROSS-FUNCTIONAL END-TO-END PROCESS ROADMAP

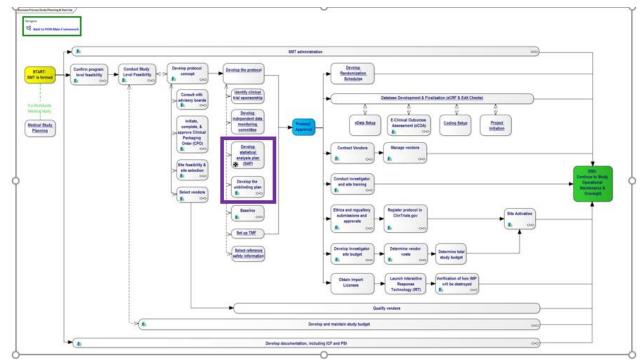
Developing the end-to-end road map is a truly cross-functional endeavor, with input from process owners and SMEs from across the organization, in this case Development Sciences. It takes a skilled leader to guide the team to a single vision of how to represent all of the processes at a high level, showing how they interconnect and ensuring that nothing is left out.



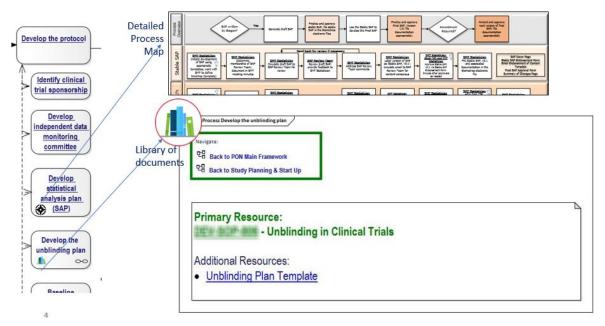
PV Data Anal		tem & Quality Oversight	PV Data Collection & Handling	Assess Safety & Benefit Risk
Records TMF Records Records Management Management Uifecycle				
Quality Oversight & Governance	Manage Inspections	Perform Audits	Governance Managem	
Process Management	Manage & Document Processes/Deviations	Business Develop Workflow	ment	
Vendor Management	Select & Contract Vendors	Oversee Vendor	5	
Learning & Training	Develop & Manage Training	Deliver Training	;	

PROCESS FLOWS

Once the roadmap is in place, process owners work to develop more detailed flows of their process area which are liked from the roadmap. The process flows contain links which drill-down to additional resources including more detailed process maps, SOPs, templates, forms, job aides/guidance, and training materials.

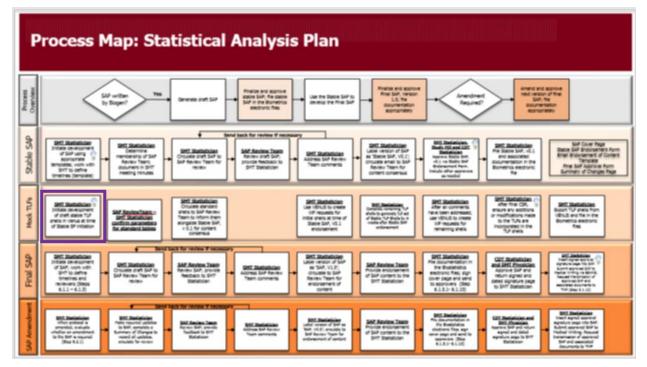


Resources are indicated by linked icons indicating either a detailed process map or a library of documents are available.

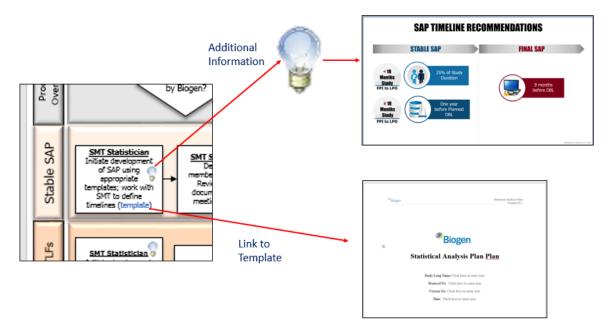


PROCESS MAPS

Process Owners work closely with SMEs to develop detailed process maps with step-by-step instructions for the process and access to other types of resources such as vendor documents, training slide decks, forms, and templates.

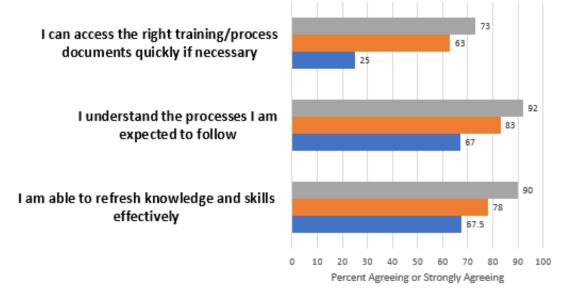


Resources on process maps are indicated by lightbulbs that contain more information or links directly to forms and templates.



IMPACT OF PROCESS ROADMAP

Mapping process helps to identify gaps in the process. This can help with the risk assessment and be an important part of the Quality Management System (QMS) which is needed to meet the recent ICH E6 requirements. In the two years since implementing the process roadmap and associated flows and detailed maps, there has been a meaningful improvement in process awareness. The improvement has been measured with a survey, benchmarked in 2015 before the implementation and then repeated annually since.





PROCESS ROADMAP OF THE FUTURE

The ultimate goal of the process maps is to increase quality and compliance in all our activities while at the same time increasing efficiency, so additional functionality is being added to tracking Key Quality Indicators (KQIs) to measure the impact on quality and compliance, as well as tracking productivity metrics to ensure we are seeing continuous improvement. To help tie in quality, compliance, and productivity, the next phase will be to create layers which surface this information in the process roadmap. Layers will include owners and subject matter experts (SMEs) for each process, training compliance for SOPs and modules related to the process, KQIs and their status, and metrics for cost, timeliness, and productivity. Surfacing this information in the roadmap will increase awareness and keep quality and compliance top of mind each time people access the roadmap to reference process information.



CONCLUSION

The Process Owner Network and the one stop shop process portal with the cross-functional end-to-end process roadmap are very effective ways to increase understanding and awareness of processes and to ensure people can easily access the information they need as they are carrying out a process. Process mapping presents the information in a more understandable format than simply writing it in an SOP. Furthermore, process maps bring all related resources including SOPs, templates, forms, job aides/guidance, and training materials together in a single, easily accessible location. Tying in training compliance, KQIs, and performance metrics, will have an even bigger impact in keeping these things front and center as work is performed.

CONTACT INFORMATION <HEADING 1>

Your comments and questions are valued and encouraged. Contact the author at:

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