

The **A** of Managing a **B** Standards **C** Macro Library

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The Clinical Data
Science Conference

Introduction

1. Introduction
2. Review of Structure
3. The Key Point

Introduction

Review of Structure

The Key Point



Amit Bhaniani has been working in the BARDS-HTA team at MSD since May 2015 and managing the Standards Macro Library since July 2019.

Carl Herremans has been working in the BARDS team at MSD since 2004. He heads the steering committee of the BARDS-HTA Standards Macro Library since July 2019 and is leading many initiatives on standardization.

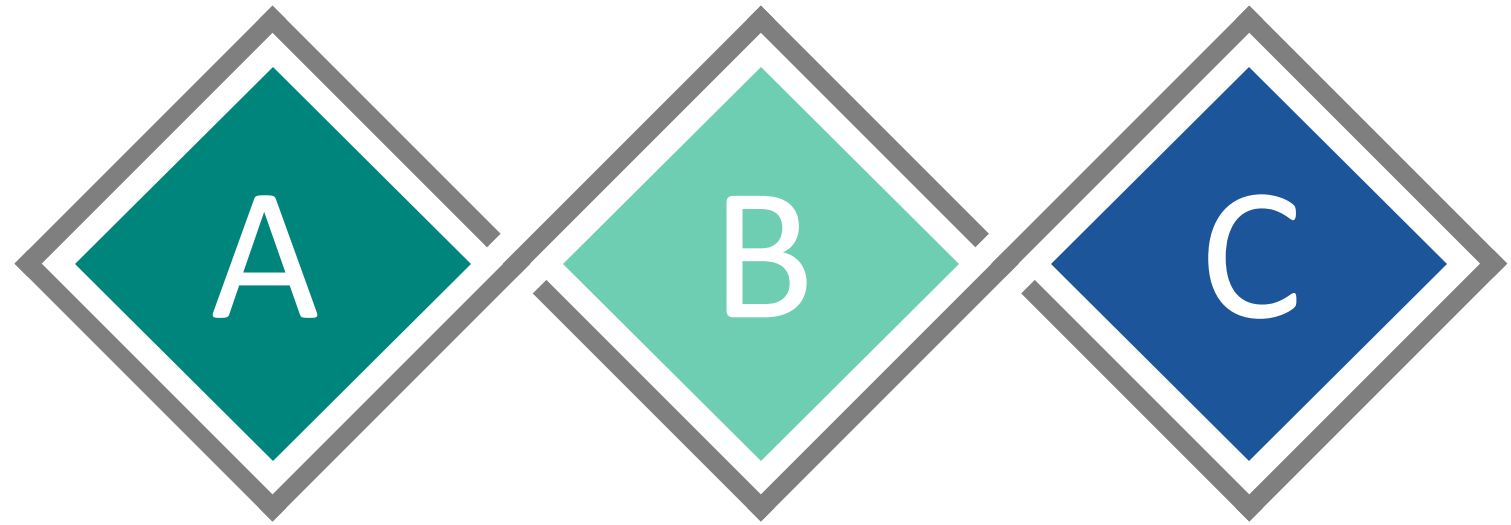


We acknowledge the contribution of our statisticians and statistical programmers who worked on the development and updates of the standard programs in our macro library. We also thank our stakeholders for their honest and regular feedback and sponsors for their guidance and continuous support.

Introduction

Review of
Structure

The Key Point



Active Roles & Responsibilities

Building the Standards Macro Library

Communication

Introduction

Review of Structure

The Key Point

Although developing and maintaining high quality macro programs as a standard macro library is a common practice in statistical programming, efficient management of this vital resource is not an easy task.

By clearly defining the structure of the macro library team and their roles & responsibilities; efficient execution of these responsibilities; and successful communication, we can build a robust standards library to address changing business needs.

A high-quality standards library is a resource intensive activity which pays itself back through high quality outputs and shorter turnaround times for projects. This is an invaluable business asset and a valuable learning experience.

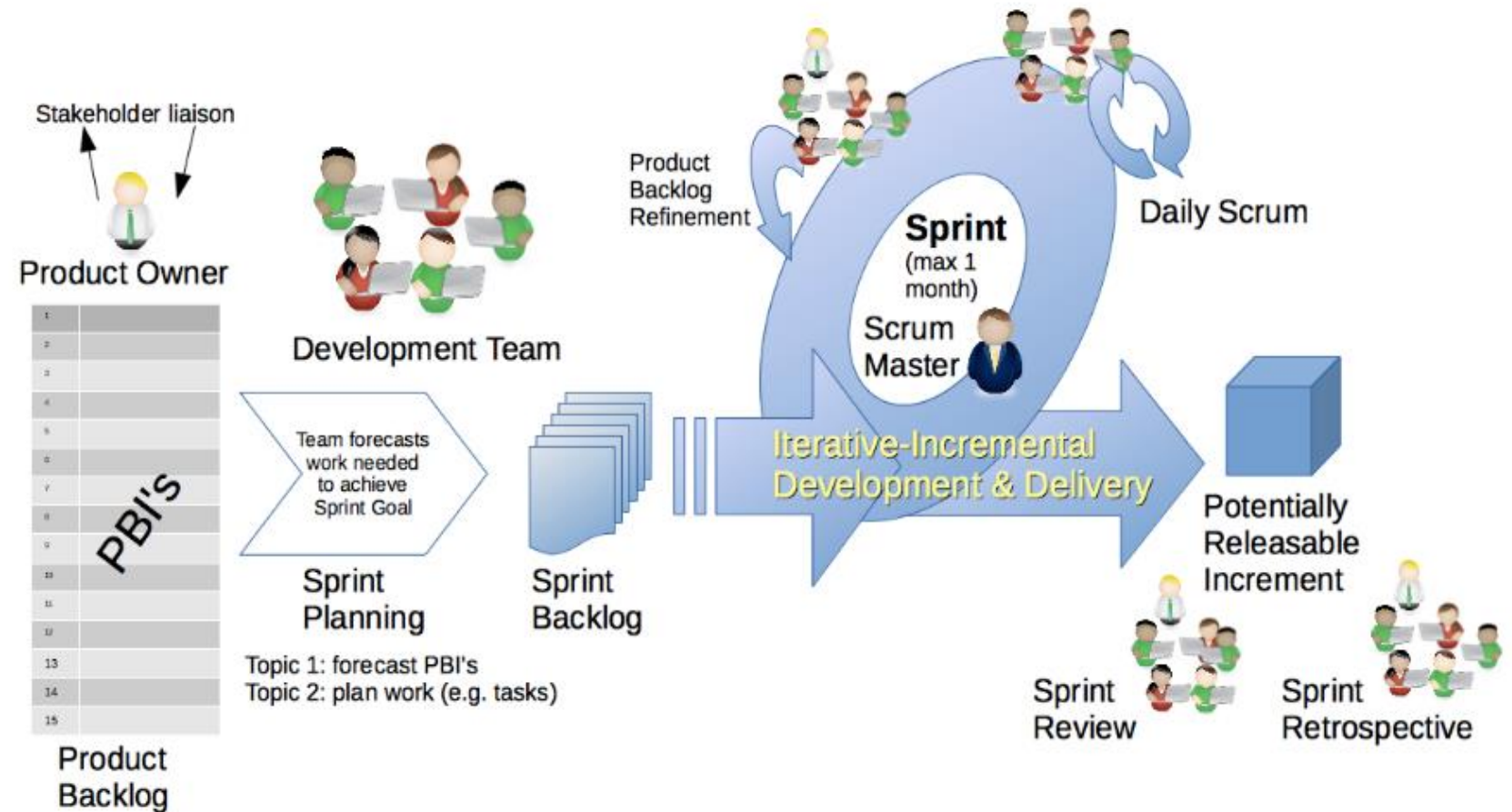
ABC

Active Roles & Responsibilities

1. The Framework
2. Roles and Responsibilities (RACI)
3. Macro Approval Process

ABC

The Framework

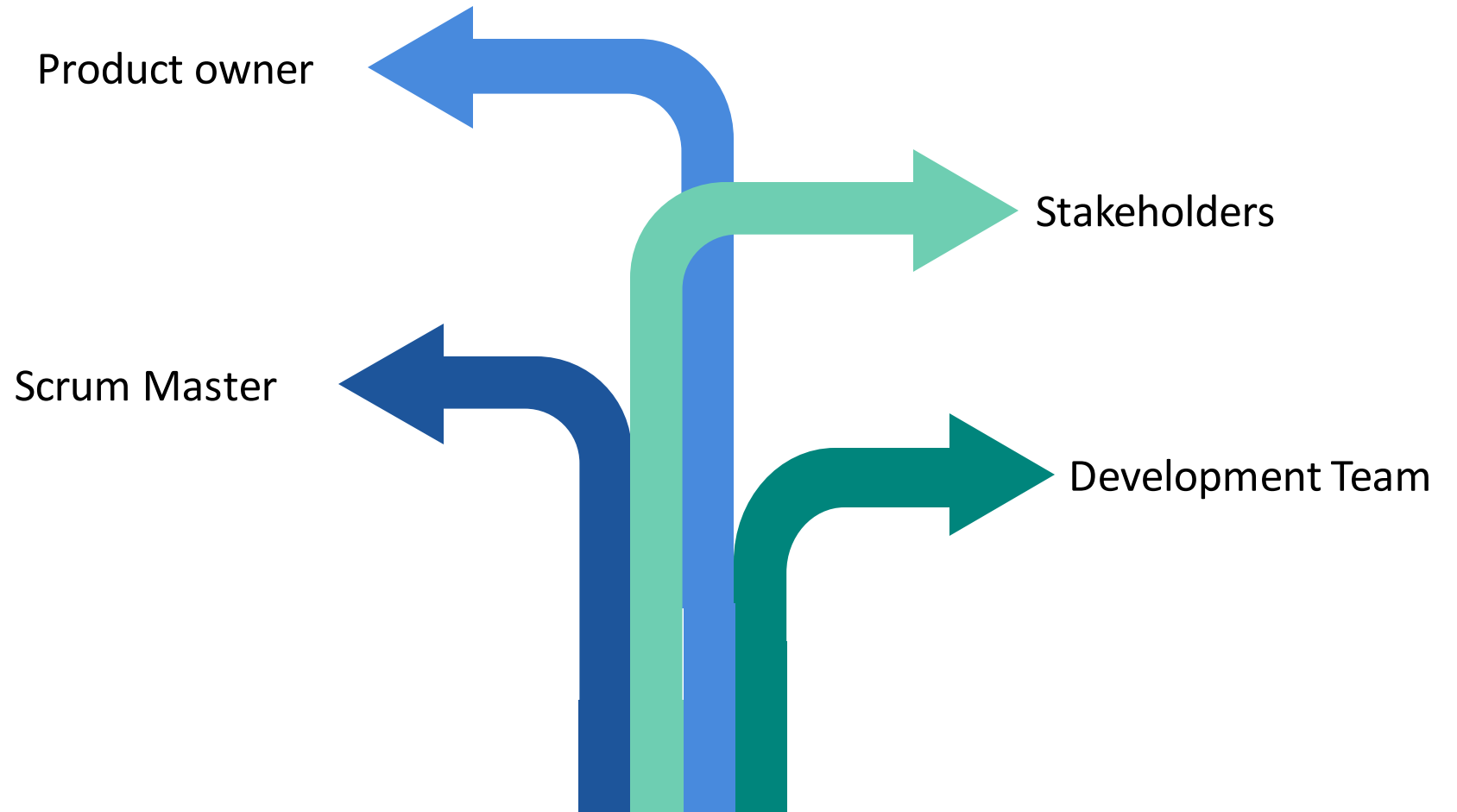


Scrum Framework

ABC

Roles and Responsibilities

Key Roles defined in Scrum Framework



ABC

Roles and Responsibilities

Responsibility Assignment Matrix (RACI)

	Stakeholders	Product Owner	Scrum Master	Development Team
Request for a new macro or update to an existing macro	A,R	I	I	
Work order approval	C	A,R	C	
Work assignment		I	A,R	I
Work order execution		C	C	A,R
Production deployment	I	I	A,R	R

- Responsible
- Accountable
- Consulted
- Informed

Macro Approval Process



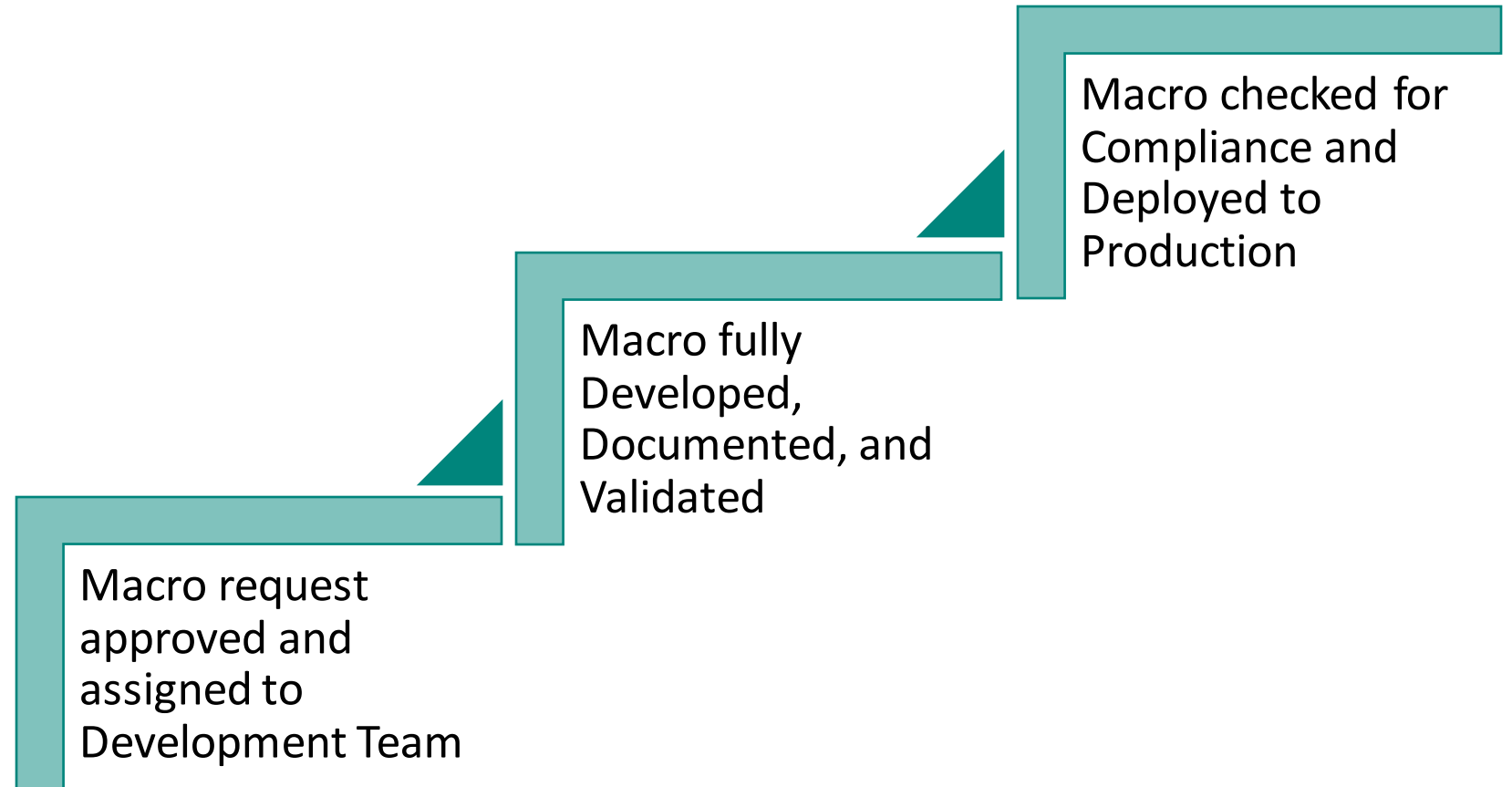
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Building the Standards Macro Library

1. Validation Process
2. Traceability of Macro Development
3. Promotion of Standard Macros

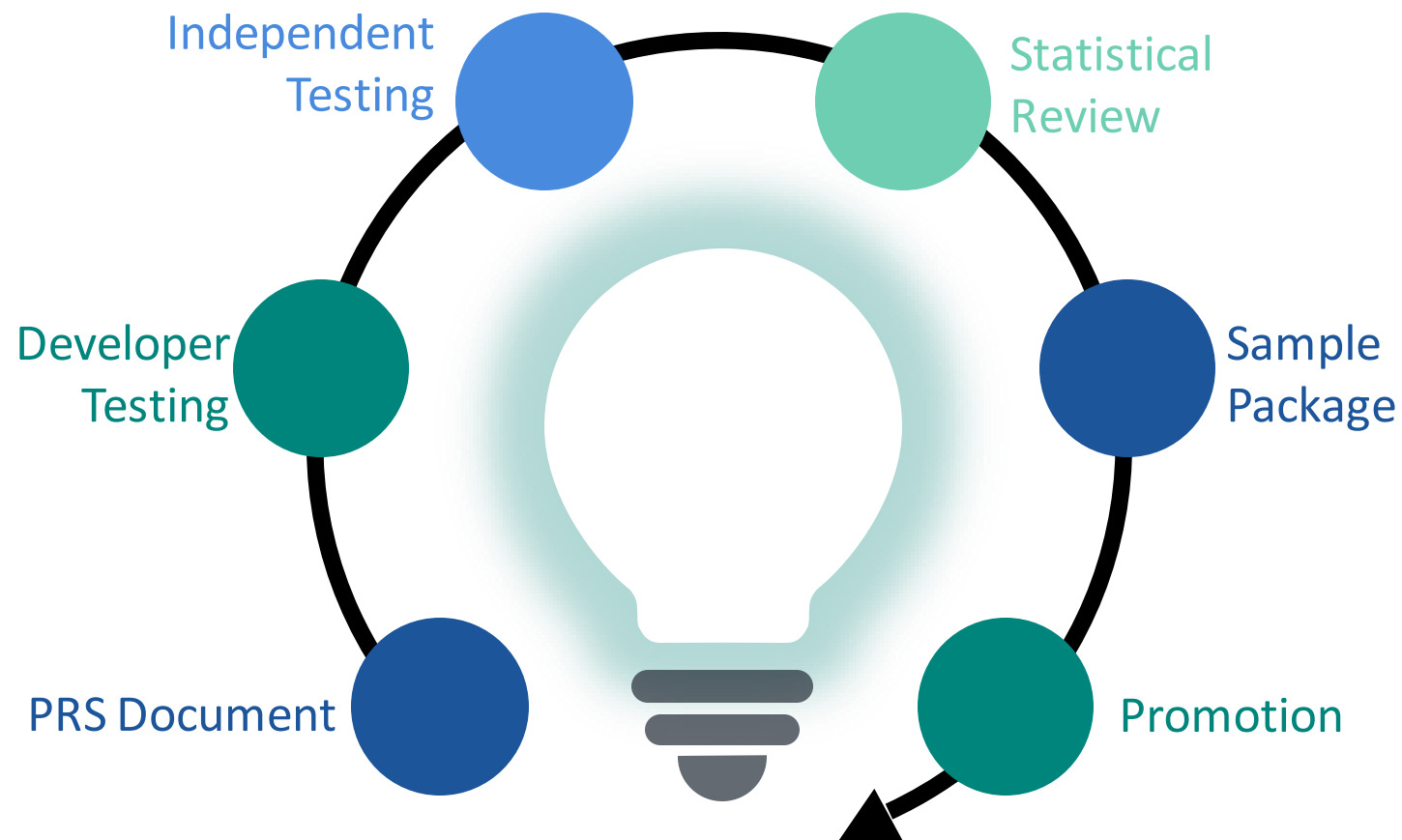
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Macro Development Process



ABC

Validation Process



ABC

Traceability of Macro Development

Macro Project Plan

	A	B
1	Derivable Category	macro library
2	Deliverable	a0hazard0ratio
3	Priority/Tier	1
4	Version	7
5	Programming status	09_ready for promotion
6	Status flag	Bugfix
7	Additional descriptions	Increased precision of p-value.
8	Statistician Assigned to	statistician 1
9	PRS Assigned to	statistician 2
10	PRS Assigned Date	01/Dec/2099
11	PRS Target Date	05/Dec/2099
12	PRS Actual Delivery Date	07/Dec/2099
13	PRS Approved	07/Dec/2099
14	Programmer Assigned to	programmer 1
15	Assigned Date	07/Dec/2099
16	Start Date	07/Dec/2099
17	Target Date	09/Dec/2099
18	Actual Delivery Date	10/Dec/2099
19	Independent Testing Programmer Assigned	programmer 2
20	Independent Testing Assigned Date	10/Dec/2099
21	Independent Testing Start Date	10/Dec/2099
22	Independent Testing Target Date	12/Dec/2099
23	Independent Testing Actual Delivery Date	12/Dec/2099
24	QC Sample Code Programmer Assigned	programmer 3
25	QC Sample Code Assigned Date	13/Dec/2099
26	QC Sample Code Target Date	15/Dec/2099
27	QC Sample Code Actual Delivery Date	15/Dec/2099
28	Initiated	01/Dec/2099
29	Promoted to production	

- Macro Name
- Priority
- Status
- Enhancement/Bugfix

- Development Team Member
- Validation Activity
- Timelines

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Traceability of Macro Development

Macro Library Project Plan

	A	D	R	W	AA	AC
				Independent Testing	QC Sample Code	Promoted to
1	Derivable Category	Version	Actual Delivery Date	Actual Delivery Date	Acutal Delivery Date	production
2	<macroname1>	1				
3	<macroname2>	2	10/Dec/2099			
4	<macroname3>	3	10/Dec/2099	12/Dec/2099		
5	<macroname4>	4	10/Dec/2099	12/Dec/2099	15/Dec/2099	
6	a0hazard0ratio	7	10/Dec/2099	12/Dec/2099	15/Dec/2099	31/Dec/2099

- Program request approved for development
- Program completed development
- Program completed independent review
- Program ready for promotion
- Program promoted to production

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Promotion of Standard Macros

Pre-promotion QC (sample checks)



1. The existence of a Program Requirement Specifications (PRS)
2. The existence of sas/log/lst files with correct filenames
3. The development work and validation activities are completed in the required sequence
4. A complete rerun of the testing programs for each validation stage

ABC

Communication

1. Communication Strategy
2. Feedback, Newsletter, and User Training
3. Performance Metrics

ABC

Communication Strategy

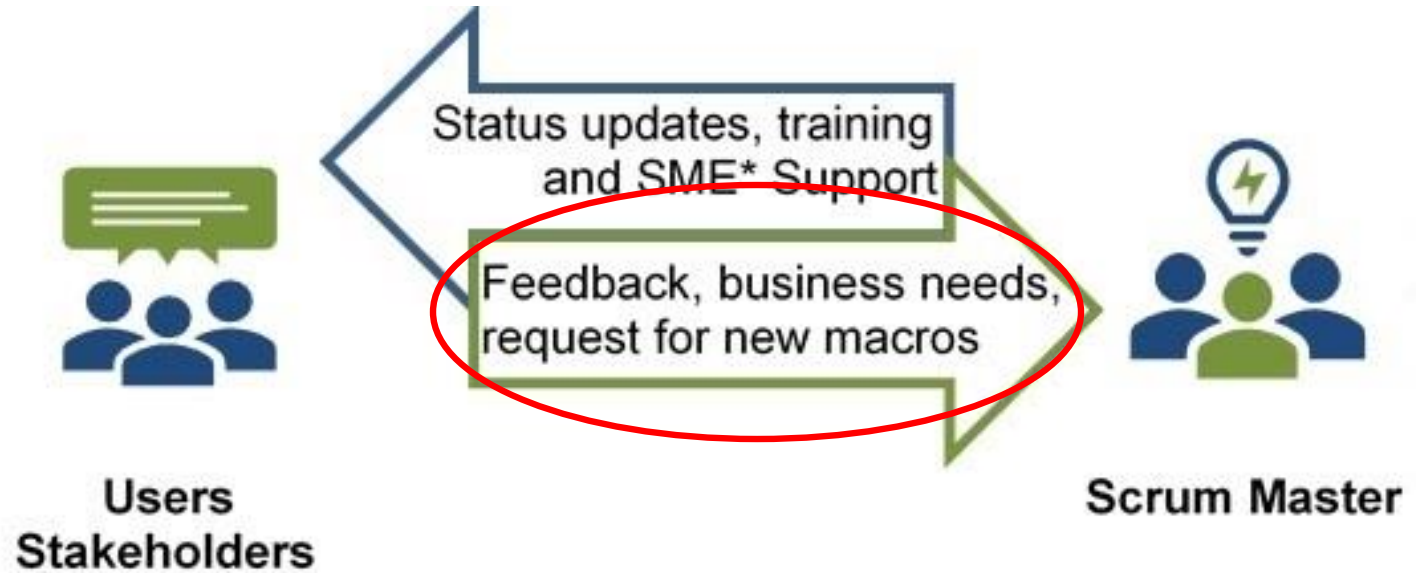




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Feedback,
Newsletter, and
User Training

Feedback Collection



Product owner and scrum master

Requests for new and feedback on existing programs

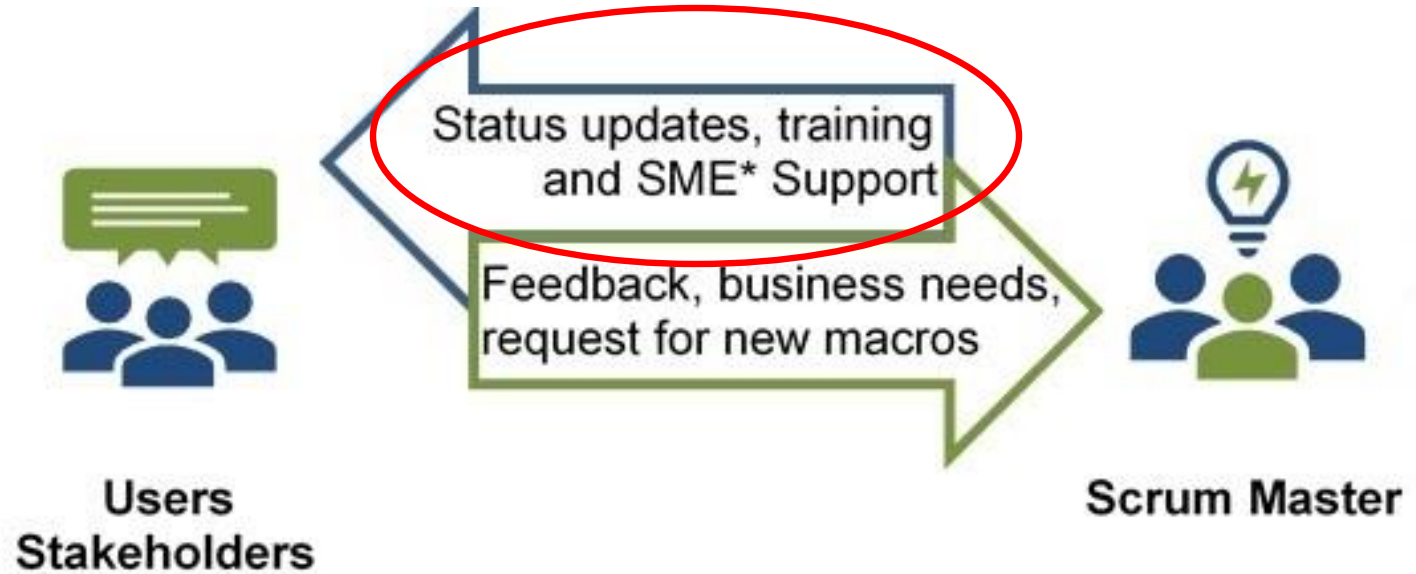
On-going basis



ABC

Feedback,
Newsletter, and
User Training

Macro Promotion Newsletter and User Training



development team(s), stakeholders and sponsors

*new programs and enhancements for existing programs
user training for new and complex macro programs*

Periodically e.g. once a month

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Performance Metrics

Performance Metrics (sample outputs)



Scrum Master

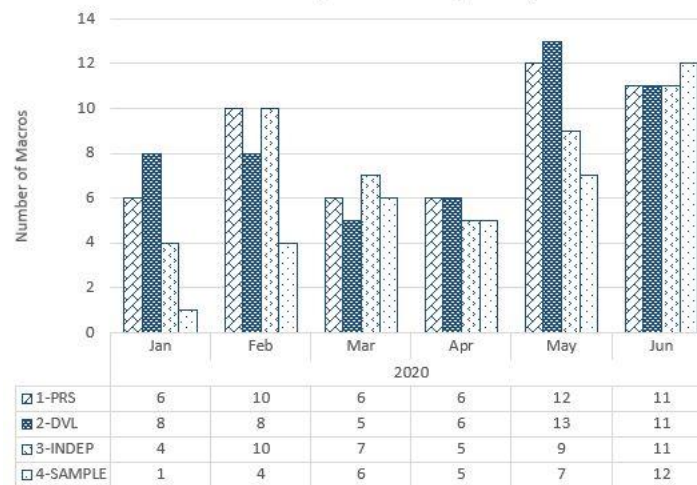
Report accomplishments
and performance metrics

Resources for macro
library development

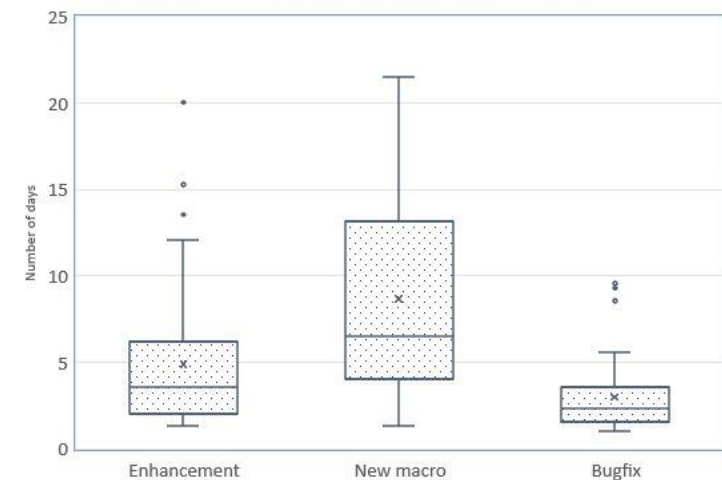


Sponsors

Number of Completed Macros by Activity



Average Development Time/Macro release



D

Discussion

1. The Summary
2. Thoughts for Discussion
3. Q&A – contact us

D

The Summary

A well constructed functional framework with clearly defined key roles and their strategic responsibilities is essential to help all these roles accomplish their designated assignments with high quality and compliance.

Bringing compliance of the validation activities, traceability of the development process, and timely promotion of the macro programs, within a single functional framework is essential for its success.

Communication of the latest macro library updates is as important as developing programs in the library. It relies on successful collaboration amongst the key roles defined in the scrum methodology.

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Thoughts for Discussion

A standards library should be embedded into the business process, which acts as a bridge between the library and its business environment.

Buy-in from the user community is essential, to ensure they consider the standards library as their toolkit, supporting their day to day jobs and not a standard toolkit imposed on them.

Construction of the library framework should be flexible enough to include other standards e.g. standard template programs, ADaM specifications etc.

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Q&A
– contact us

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Thank you