TransCelerate BIOPHARMA INC.

Process Management Framework: Guidance to Successful Implementation of Processes in Clinical Development

October 8, 2019 10am -11.30am EDT

8pm - 9.30pm EDT

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Mike Husovich

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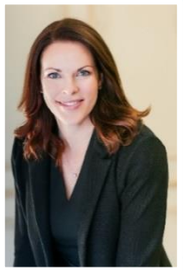

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Logistics for this Webinar

All participants will be muted for this call.

For audio: *Connect to audio to listen to presentations via your computer or phone*

You can reduce control panel for a better view of presentation

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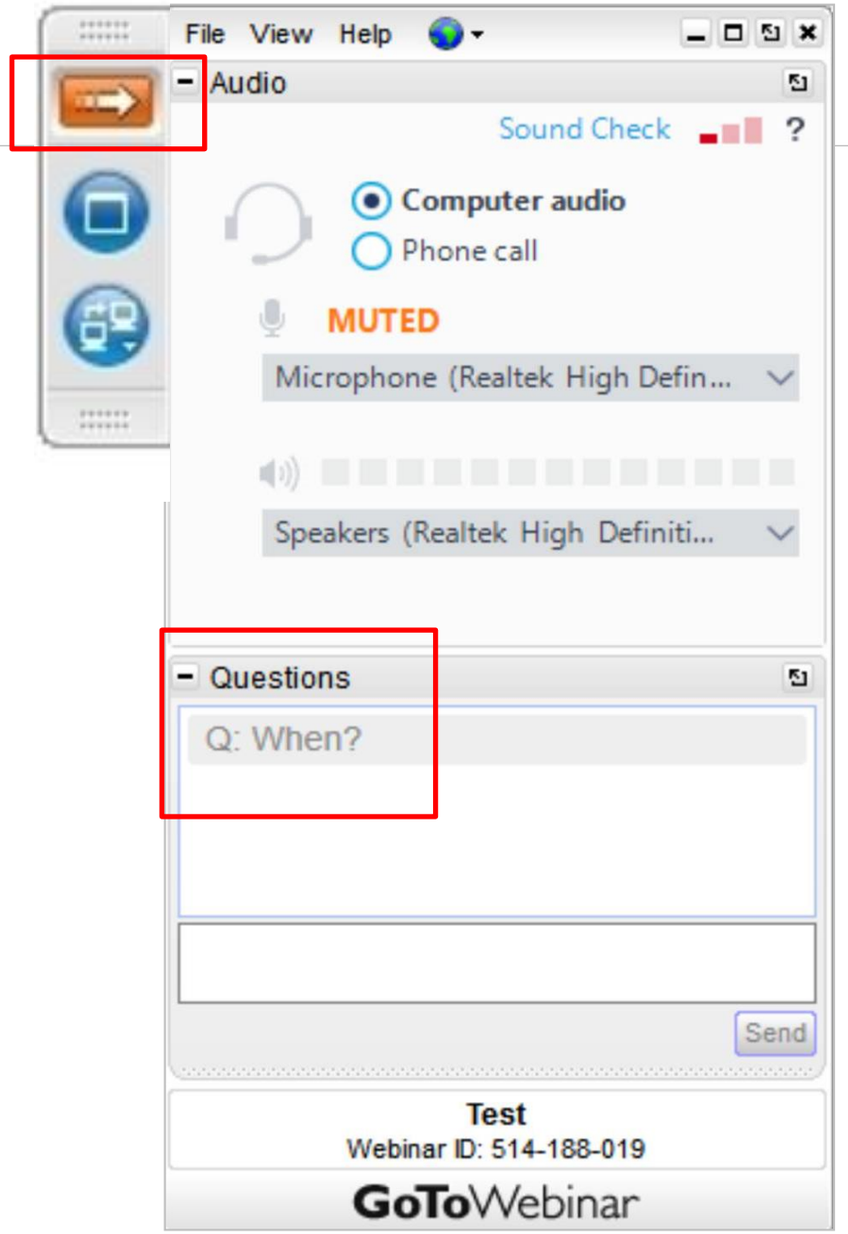

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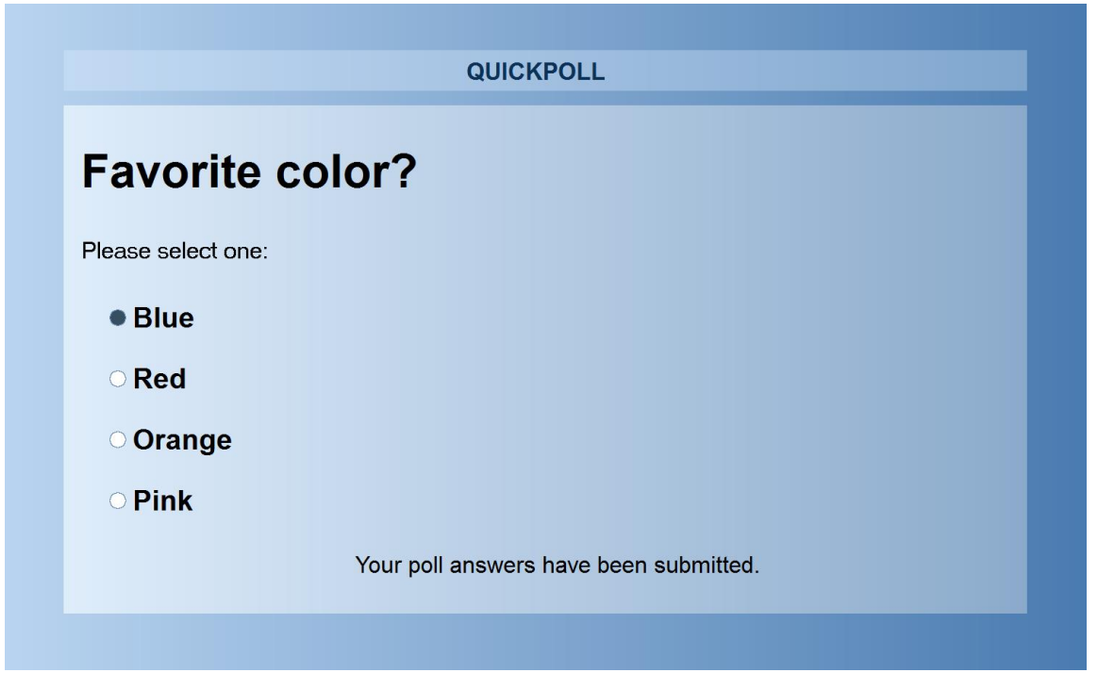
Logistics for this Live Polling

To help make this session interactive and facilitate sharing of useful information, we will conduct live polls throughout the session. Your participation is completely **voluntary** and all responses will be **anonymous**. Answers will be shared only as a percentage of respondents.

Instructions: When the blue poll question appears, enter your response and submit.



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Ground Rules

We want to make this discussion helpful and answer as many of your questions as we can, so some quick ground rules:

- Participation is voluntary, as is using TransCelerate assets / tools
- You don't have to identify what company you work for
- **Things we would ask you not to discuss:**
  - What vendors / sites / CROs you are using or not using
  - Any issues you have with any vendors / sites / CROs
  - Your long term development plans
  - Anything related to costs
- **We can't answer questions about:**
  - Vendors
  - Costs of using / implementing TransCelerate assets / tools
  - Which member companies are using the assets / tools

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AGENDA

TransCelerate Overview & QMS Framework (10 Mins)

Process Management Framework (30 Mins)

Q&A (5 Mins)

Process Toolkit & Scenarios (30 Mins)

Q&A/Audience Poll (15 Mins)

All slides will be made available after the webinar

Assessing a Clinical QMS

Risk Management

Processes

Name	Description	Value
Processes Manuscript	DIA TIRS publication which describes a framework for effective processes management within clinical development. *(published January 2019)*	Assists clinical development organizations in understanding the benefits and basic components of process management for clinical development.
Toolkit for Implementing Processes	A document that describes detailed examples for a clinical development organization implementing a processes framework, identifying how the processes should be documented based on their assessed risks, and how a learning management plan can support the clinical development organization implement the processes and documentation requirements.	Facilitates the implementation of a processes framework for clinical organizations. The toolkit identifies select steps from the processes development framework that would benefit from further instruction, examples, and templates to ensure consistent and robust application of the concepts described in the paper.
QMS Processes Scenarios	This scenario tool uses examples to illustrate how an effective Process Management Framework can ensure the efficient and effective delivery of clinical development programs.	Each scenario is presented in four parts: the Scenario description, its business impact, possible Process Management Solutions, potential Process Management Benefits to help readers understand the real and potential benefits to a robust process management program.

Materials to be Covered Today:

1. **Processes Manuscript**
2. **Toolkit for Implementing Processes**
3. **Process Scenarios**

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Gloria McHugh

- Webinar Operations Lead
- Project Manager TransCelerate

Overview of TransCelerate & QMS Framework

TransCelerate:

A Not-for-Profit Entity Created to Foster Collaboration

Our Shared Vision:

To improve the health of people around the world by accelerating and simplifying the research and development of innovative new therapies.

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Current state of organization

2012

TransCelerate Founded

10 MEMBER COMPANIES

5 INITIAL INITIATIVES

2016

BioCelerate Founded

BioCelerate

focus on preclinical research

Today

20 MEMBER COMPANIES

Regeneron most recent member

25+ INITIATIVES

including 4 pharmacovigilance initiatives

BREADTH & DEPTH

Over 30 solutions being delivered across 25+ initiatives, across 3 strategic priorities

ENHANCING INDUSTRY COLLABORATION

With an effective and proven governance structure have increased the ease and desire to collaborate

FACILITATING FUTURE PLATFORM TRIALS

12+ initiatives deliver solutions that facilitate future platform trials

DataCelerate

platform to enable data sharing

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The Reach of our Global Membership is Expanding

Membership is available to biopharmaceutical research and development organizations that engage in innovative discovery, development and manufacturing of new medicines*.

abbvie
Allergan
AMGEN
astellas
AstraZeneca
Boehringer Ingelheim
Bristol-Myers Squibb
Merck KGaA
Darmstadt, Germany
gsk GlaxoSmithKline
Johnson & Johnson
Lilly
MERCK & CO., INC.
Kenilworth, N.J., U.S.A.
novo nordisk
NOVARTIS
Pfizer
REGENERON
SCIENCE TO MEDICINE
Roche
SANOFI
SHIONOGI
ucb

There are
over
1,000
people
from Member Companies that design and develop TransCelerate solutions.

* to be eligible for membership, companies must meet specified eligibility criteria.

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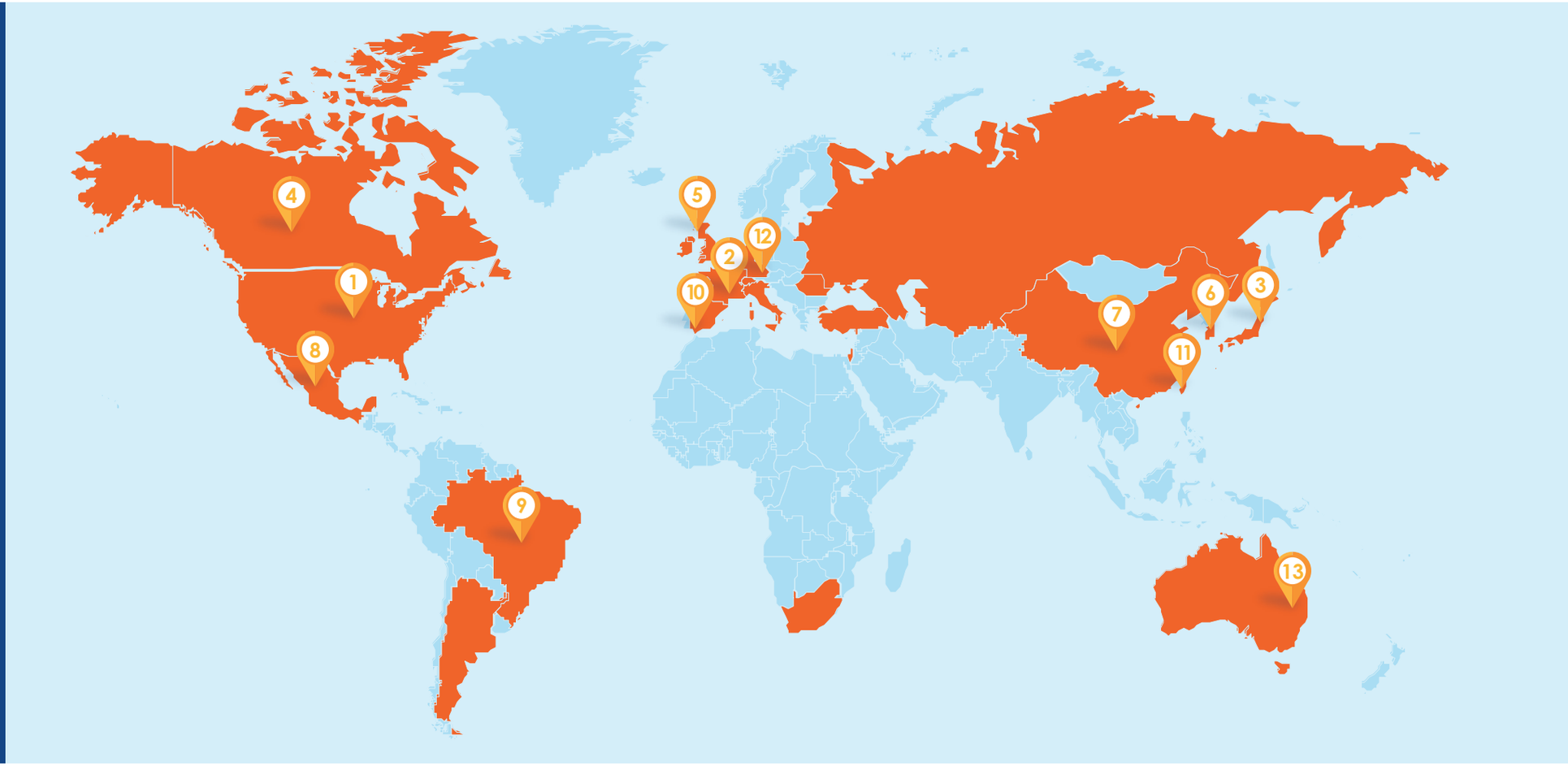
Our Presence, Impact and Engagement is Worldwide

Our Country Network spans

30
COUNTRIES,
and

13 **GLOBAL REGULATORY AUTHORITIES**

have engaged with TransCelerate.



1 FDA
2 EMA
3 PMDA
4 Health Canada
5 MHRA
6 MFDS
7 CFDA
8 COFEPRIS
9 ANVISA
10 AEMPS
11 TFDA
12 BfArM
13 TGA

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TransCelerate's Clinical Quality Management System Framework Purpose

A Clinical QMS is an integrated framework through which organizations systematically define quality objectives linked to their broader strategic goals

Purpose of the Clinical QMS

+ Efficiently achieve an organization's quality and organizational objectives.
+ Reduce recurring quality-related issues that undermine patient safety and data integrity, and consume resources.
+ Increase confidence in clinical research and its results.
+ Integrate individual trial-level quality and risk management activities to provide a holistic view of whether clinical quality objectives are being met, and risks to subjects and data quality are appropriately addressed across the enterprise.

Special Section

Enhancing Quality and Efficiency in Clinical Development Through a Clinical QMS Conceptual Framework: Concept Paper Vision and Outline

Ann Meeker-O'Connell, MS[1], Maria Magdalena Borda, MD[2], Janis A. Little, MS[3], and Leslie M. Sam, BA[4]

Abstract

A quality management system (QMS) is an integrated framework through which organizations can systematically plan and achieve their quality objectives. While the International Conference on Harmonisation (ICH) Q10 provides clear guidance for QMS in the pharmaceutical manufacturing sector, there is no harmonized regulatory guidance describing a framework that provides an enterprise-wide view of achievement of clinical quality objectives, that is capable of being customized to fit an organization's unique circumstances, and that accommodates the variability inherent in clinical development. In the absence of such guidance, clinical QMS varies dramatically across industry, sometimes resulting in over-engineered, cumbersome systems that are not adaptable or fit-for-purpose. This paper will describe the ongoing activities of a TransCelerate initiative developing a conceptual framework for a Clinical QMS designed to provide a consistent, streamlined, and proactive quality approach across all stages of clinical research.

Keywords

quality management system, clinical development, risk management, proactive quality

Ann Meeker-O'Connell, Maria Magdalena Borda, Janis A. Little, Leslie M. Sam, "Enhancing Quality and Efficiency in Clinical Development Through a Clinical Development through a Clinical QMS Conceptual Framework: Concept Paper Vision and Outline," Therapeutic Innovation & Regulatory Science, p. 8. June 2015. http://dij.sagepub.com/content/49/5/615.abstract

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TransCelerate's Clinical QMS Conceptual Framework

The framework includes elements that through our research and interviews, were reported to contribute to success in the clinical arena

7 elements integrate quality into clinical development activities

4 elements provide foundational aspects

2 elements provide ongoing monitoring of the achievement of quality objectives and the performance of a QMS

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Examples of TransCelerate cQMS Conceptual Framework Alignment with ICH E6 R2

ICH E6 R2 Language	cQMS Element	Tools
5.0 Quality Management. "The Sponsor should implement **a system to manage quality** throughout all stages of the trial process."	**Clinical QMS Framework**	1. **Assessing the CQMS Tool** 2. **Assessing Clinical Knowledge Management Tool** 3. **Toolkit for Implementing Processes** 4. **Etc….**
5.0.1 Critical Process and Data Identification. "the sponsor should **identify those processes and data that are critical** to ensure human subject protection and the reliability of trial results."	**Processes**	
5.0 "The quality management system should use a **risk-based approach** …" 5.0.1-5.0.7 Risk Identification, Evaluation, Control, Communication, Review and Reporting. "the sponsor should **identify risks** to critical trial processes and data."	**Risk Management**	
5.0.7 Risk Reporting. "The sponsor should describe the quality management approach implemented in the trial and **summarize important deviations** from the predefined quality tolerance limits and remedial actions taken in the clinical study report."	**Issue Management**	
5.0.6 "The sponsor should **periodically review risk control measures to ascertain** whether the implemented quality management activities remain effective and relevant, taking into account emerging **knowledge and experience**."	**Processes, Risk Management, Knowledge Management, Management Review**	
5.2 **Contract Research Organization**. "The sponsor should ensure oversight of any trial-related duties and functions carried out on its behalf, including trial-related duties and functions that are **subcontracted** to another party by the sponsor's contracted CRO(s)."	**Partnering**	

Deeper Dives into the Elements

Conceptual Paper (All Elements, FAs)*
- Manuscript July 2016
- Supportive Tools Aug 2017

Issue Management*
- Manuscript July 2016
- Supportive Tools Aug 2017

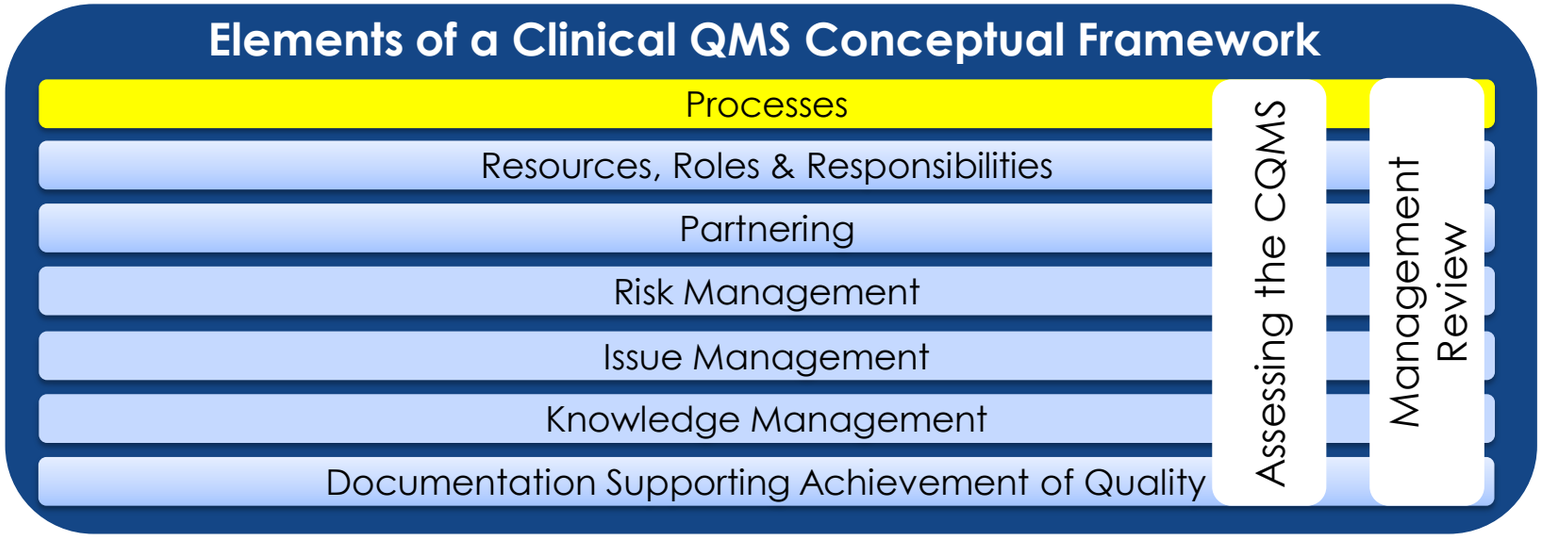
Knowledge Management
- Manuscript September 2016
- Supportive Tools Aug 2017

Assessing the CQMS
- Supportive Tool September 2017

Risk Management
- Manuscript January 2019
- Supportive Tools March 2019

Processes:
- Manuscript January 2019
- Supportive Tools March 2019

>28,000 Downloads



*Chinese Translation

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- Lead author of the Process Management Framework paper

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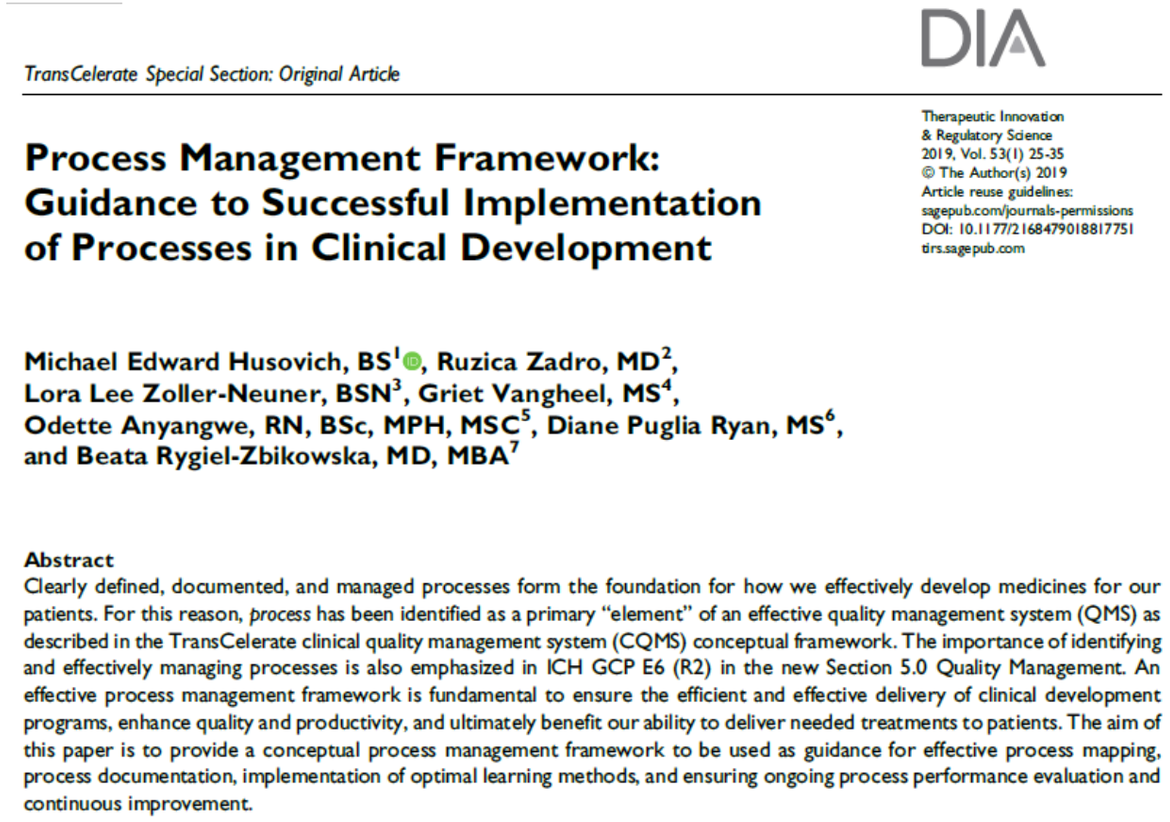
Process Management Framework

PUBLICATION

TransCelerate published article Quality Process Management Framework

Therapeutic Innovation & Regulatory Science 2019, Vol. 53(1) 25-35



TransCelerate Special Section: Original Article

DIA

Therapeutic Innovation
& Regulatory Science
2019, Vol. 53(1) 25-35
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Process Management Framework: Guidance to Successful Implementation of Processes in Clinical Development

Michael Edward Husovich, BS[1], Ruzica Zadro, MD[2], Lora Lee Zoller-Neuner, BSN[3], Griet Vangheel, MS[4], Odette Anyangwe, RN, BSc, MPH, MSC[5], Diane Puglia Ryan, MS[6], and Beata Rygiel-Zbikowska, MD, MBA[7]

Abstract

Clearly defined, documented, and managed processes form the foundation for how we effectively develop medicines for our patients. For this reason, *process* has been identified as a primary "element" of an effective quality management system (QMS) as described in the TransCelerate clinical quality management system (CQMS) conceptual framework. The importance of identifying and effectively managing processes is also emphasized in ICH GCP E6 (R2) in the new Section 5.0 Quality Management. An effective process management framework is fundamental to ensure the efficient and effective delivery of clinical development programs, enhance quality and productivity, and ultimately benefit our ability to deliver needed treatments to patients. The aim of this paper is to provide a conceptual process management framework to be used as guidance for effective process mapping, process documentation, implementation of optimal learning methods, and ensuring ongoing process performance evaluation and continuous improvement.

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Polling Question #1

Question: How aware of the TransCelerate Process Management manuscript and tool are you?

- ❑ Not aware at all
- ❑ Somewhat aware
- ❑ Very aware

Polling Question #2

Question: How mature do you consider Process Management in your organization?

- ❑ Not mature
- ❑ Somewhat mature
- ❑ Very mature

Processes

What is "Processes"

- Understanding the steps an organization carries out to complete a Clinical Development activity, determining whether and to what degree these steps should be documented, and importantly, determining the most effective training to ensure consistent and compliant process outcomes

Value Proposition

- Focus on end-to-end clinical development process approach provides greater assurance of meeting customer requirements
- Documentation strategy is commensurate to level of inherent risk
- A modern learning approach should be leveraged to best enable staff to perform their tasks

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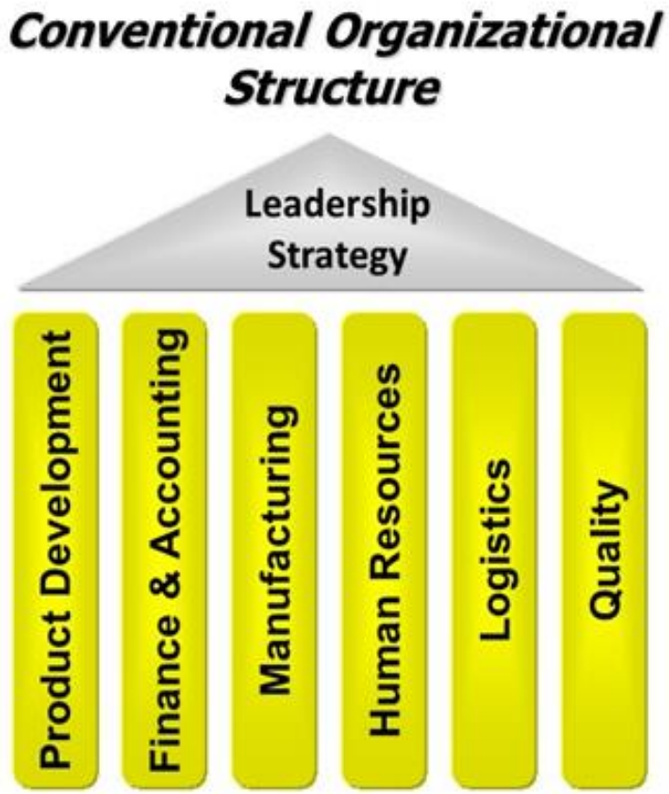
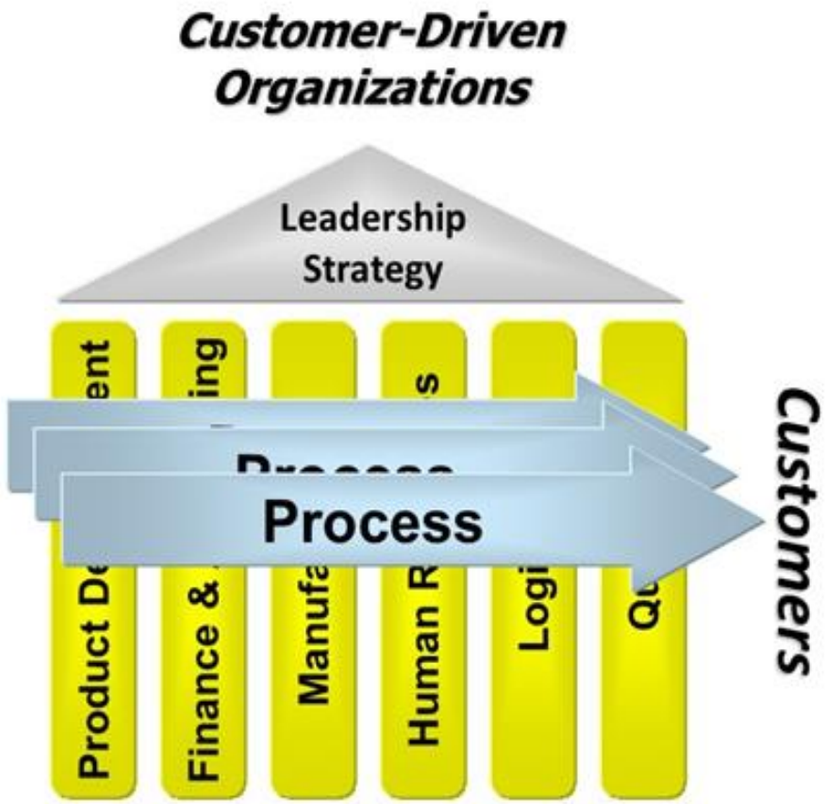
Moving from a Conventional Approach to a Process Approach



- Hierarchical Control, Vertical Role Clarification, Functional , Large



- Speed, Functional Integration and Line-of-Sight to Customer

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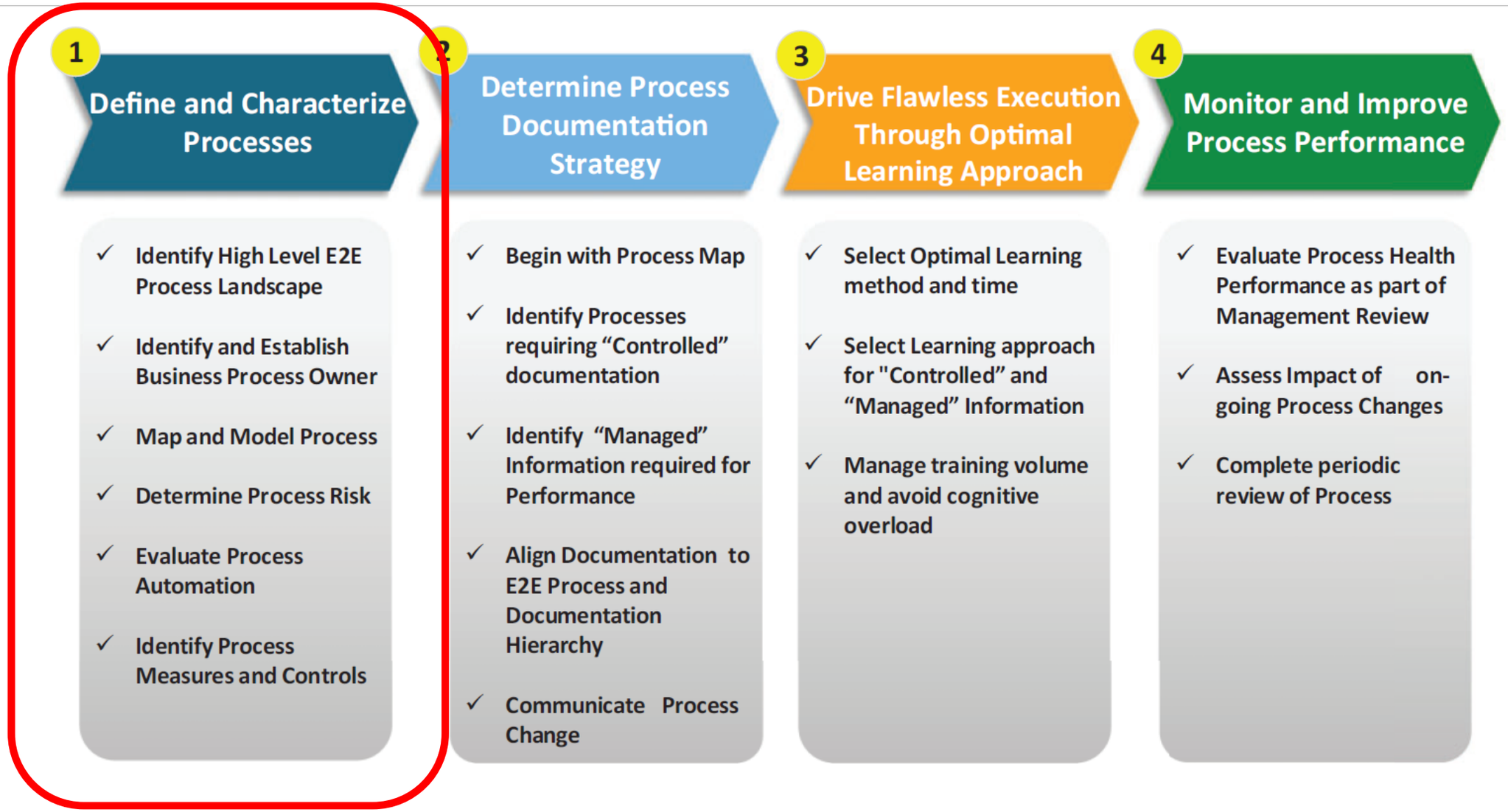
Processes Management Framework



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1 Define and Characterize Processes

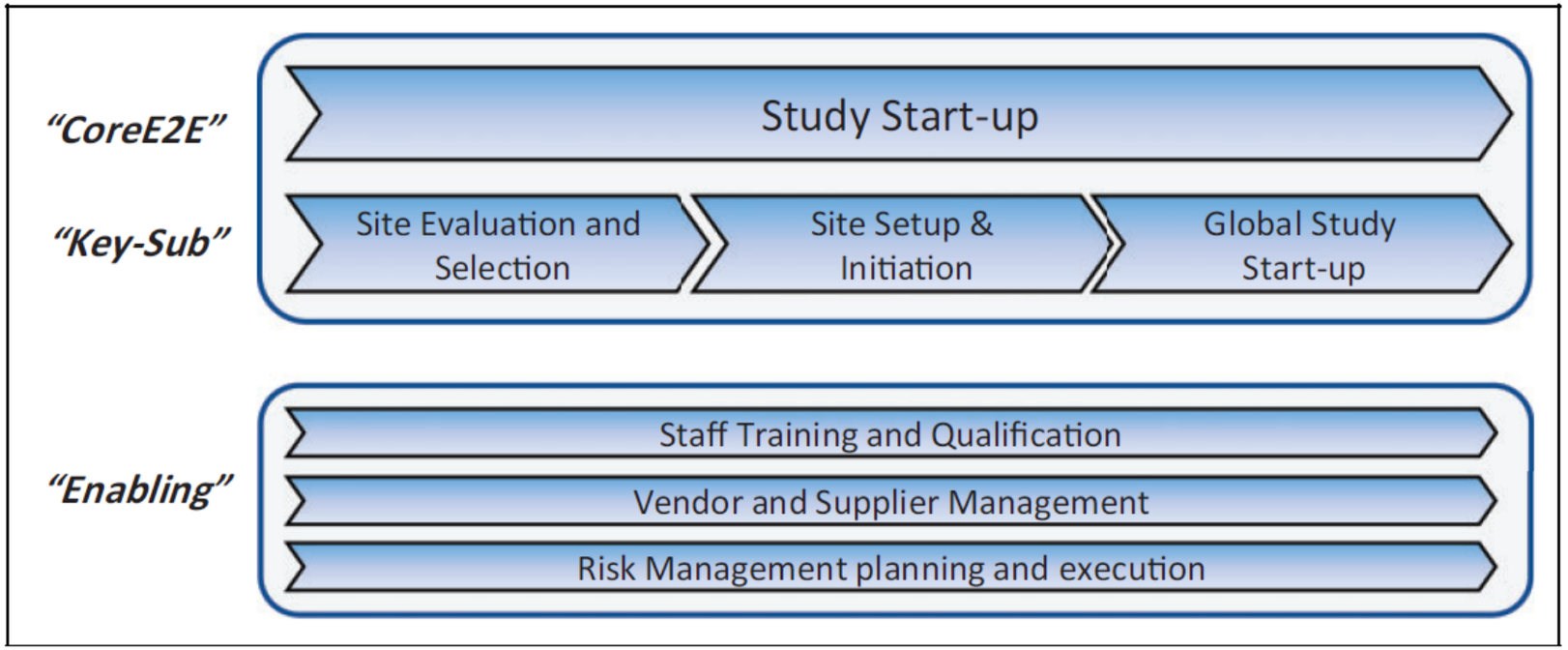
✓ Identify High Level E2E Process Landscape

✓ Identify and Establish Business Process Owner

Core Process - a set of cross-functional activities or steps that deliver a specific output that impacts strategic business objectives

Key Sub-Process – constitutes the sum of the core processes

Enabling Process – doesn't necessarily belong to any one core or key sub-process, but is essential to conduct work



Identify **Business Process Owners** for processes to be a single point of ownership that drives process health and continuous improvement.

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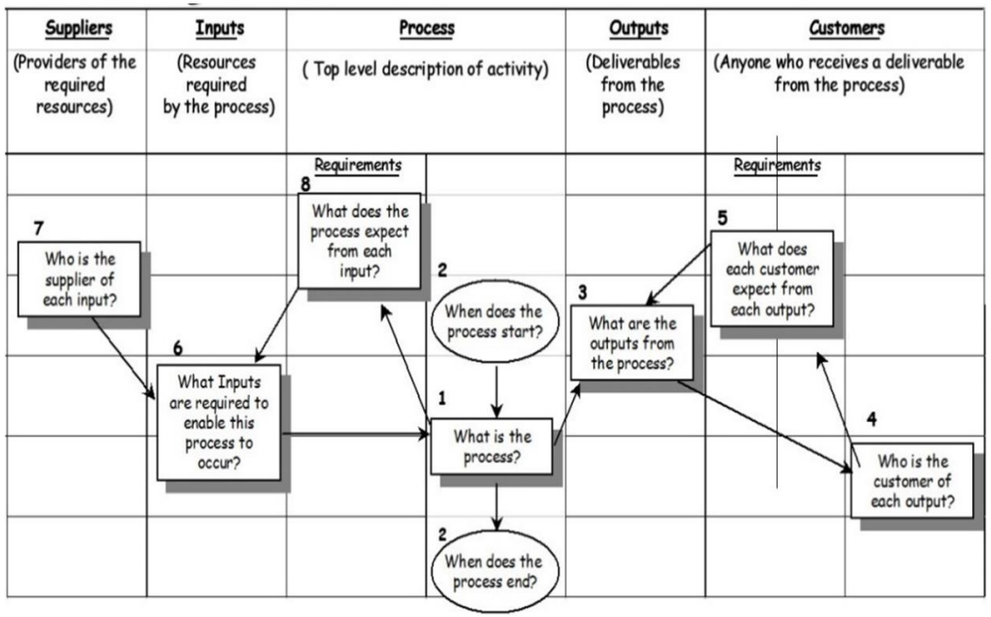
1 Define and Characterize Processes

Map and Model Process

SIPOC

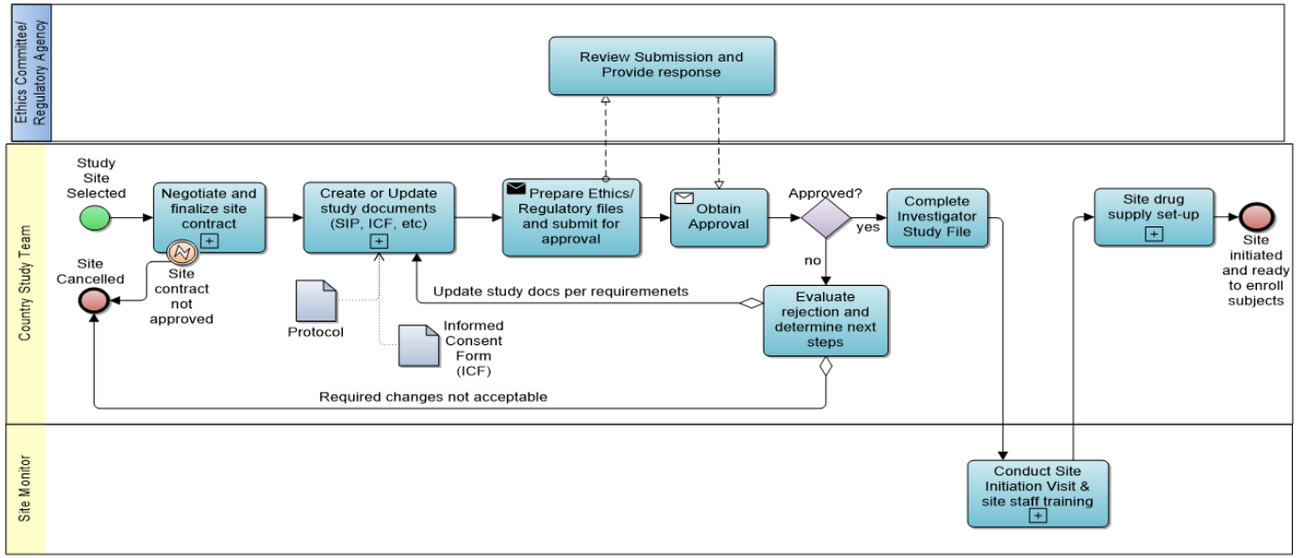


GOAL

To provide a high-level understanding of the process as it relates to:

- the customer (anyone who received a deliverable or output from the process)
- inputs (resources required by the process)

Swim Lane / Process Map



GOAL

To show the details of the process and identify the following:

- Key milestones or activities
- Roles / responsibilities
- Handoffs
- Inputs / outputs
- Interdependencies
- Associated information
- inputs (resources required by the process)

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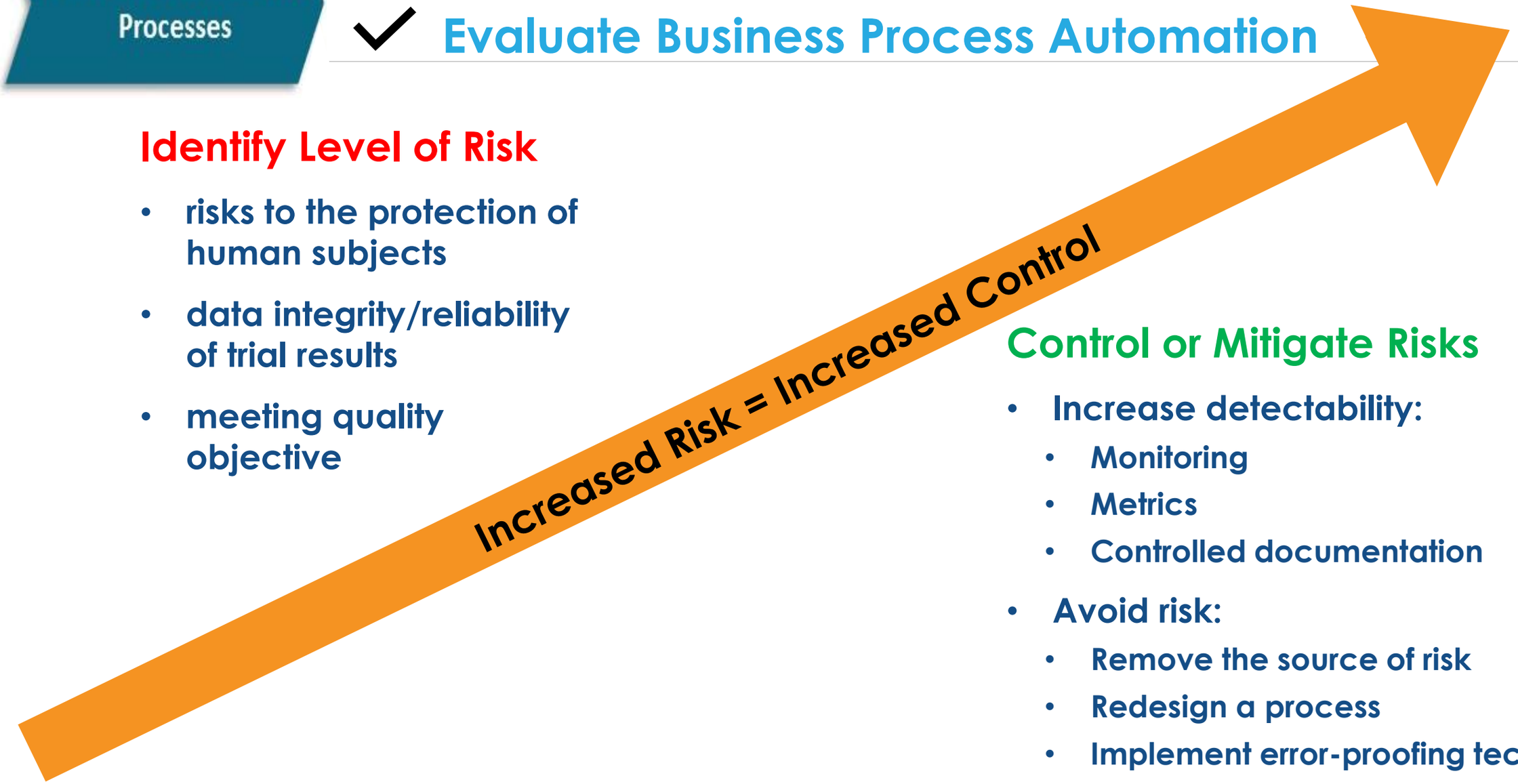
1

Define and Characterize Processes

- ✓ Determine Process Risk
- ✓ Evaluate Business Process Automation

Identify Level of Risk

- risks to the protection of human subjects
- data integrity/reliability of trial results
- meeting quality objective



Control or Mitigate Risks

- Increase detectability:
  - Monitoring
  - Metrics
  - Controlled documentation
- Avoid risk:
  - Remove the source of risk
  - Redesign a process
  - Implement error-proofing techniques

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1 Define and Characterize Processes

Identify Process Measures and Controls

Identify Effective Process Measures

- Define what critical to quality (CTQ) and how to measure it
- Determine performance targets
- Identify ownership for each metric

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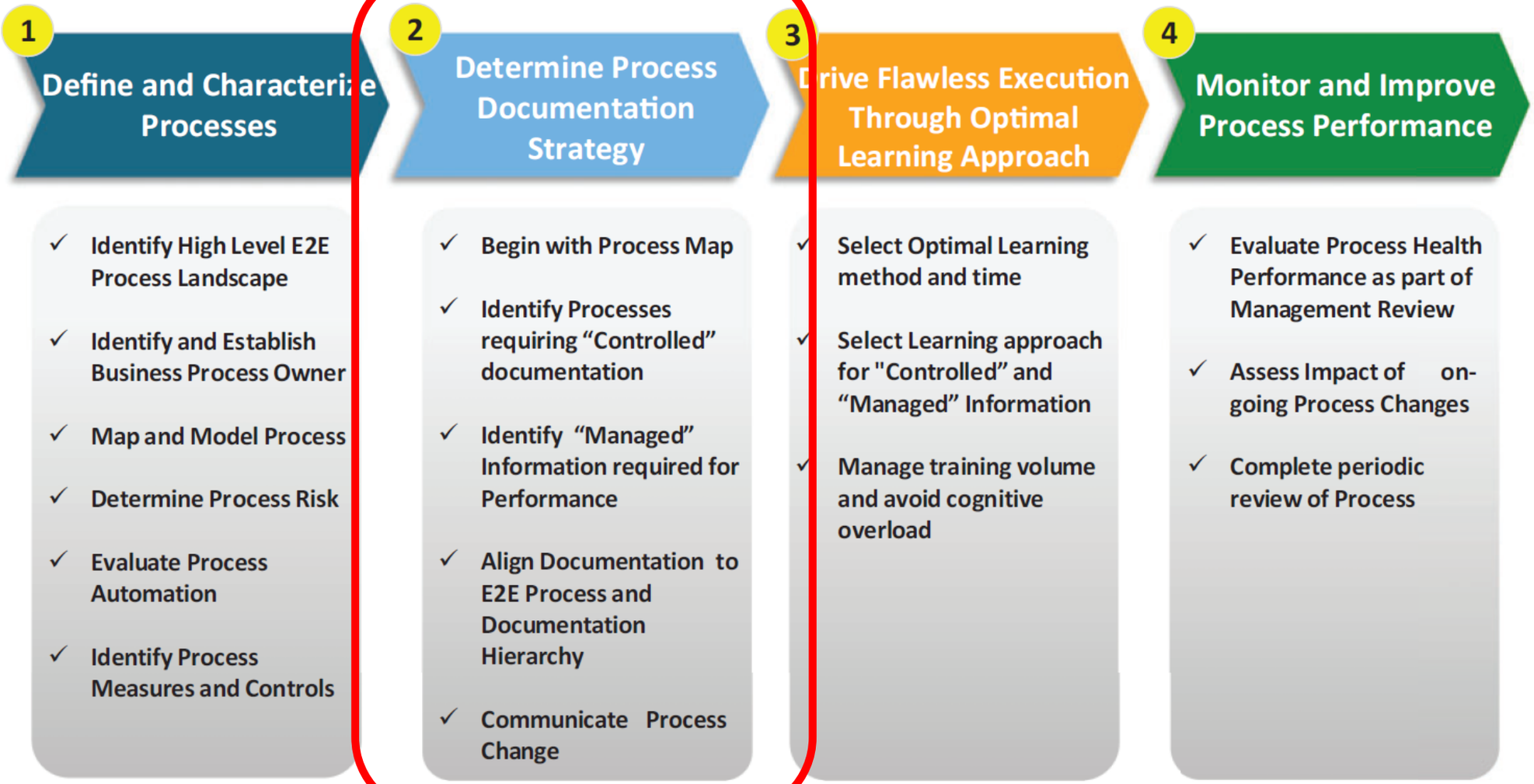
Processes Management Framework



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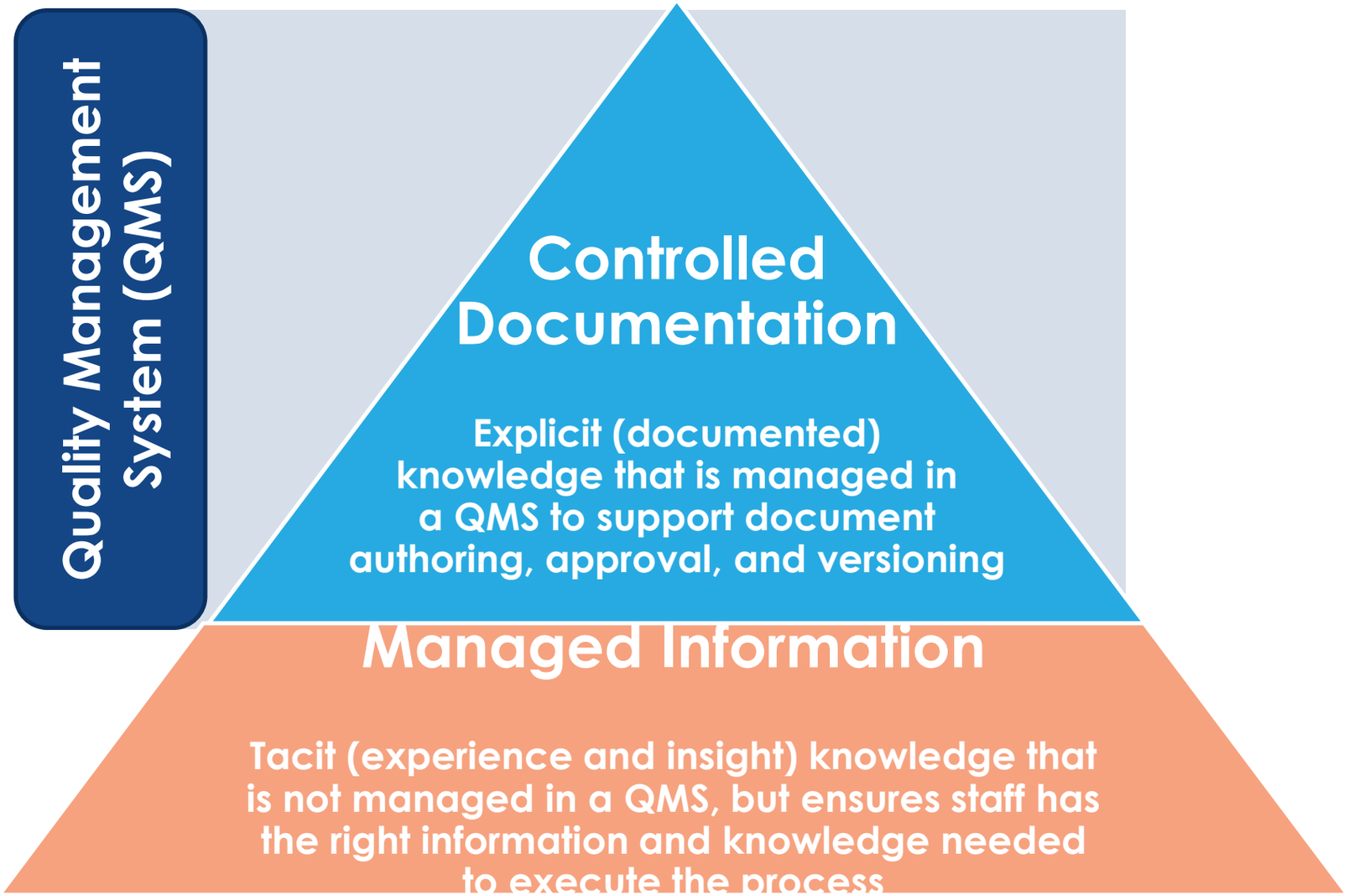
2

Determine Process Documentation Strategy

- ✓ Identify Processes Requiring Controlled Documentation
- ✓ Identify Managed Information Required for Performance

DOCUMENTATION STRATEGY

- Ensures that documentation represents the actual end-to-end process
- Should be easy to understand and follow
- Identifies the right level of controls and quality oversight



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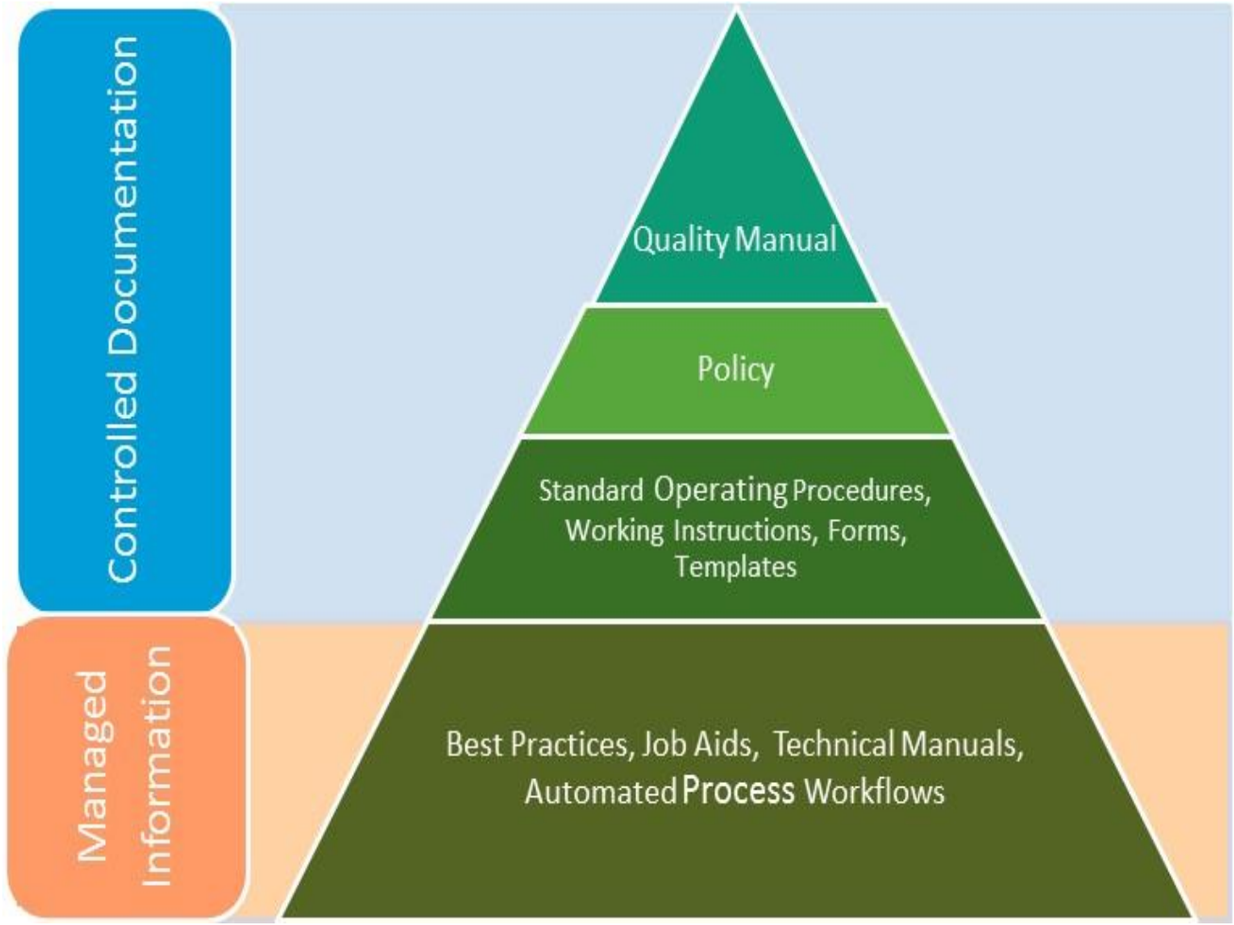
2

Determine Process Documentation Strategy

✓ Align Documentation to E2E Process and Documentation Hierarchy



NOTE: This figure is for guidance only. The specific documentation types are for illustrative purposes only. Individual company naming conventions may differ.

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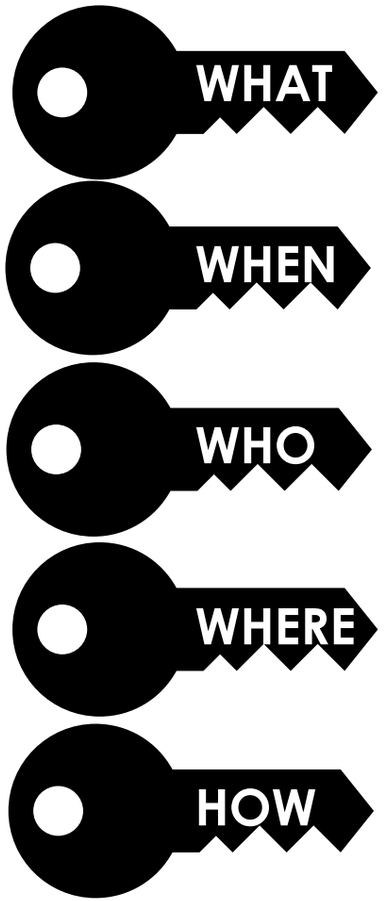
2

Determine Process Documentation Strategy

✓ Communicate Process Change

Communication Prior to Implementation



documents have been issued / updated / retired

the documents become effective / retired

is impacted

documents are located

training will be provided

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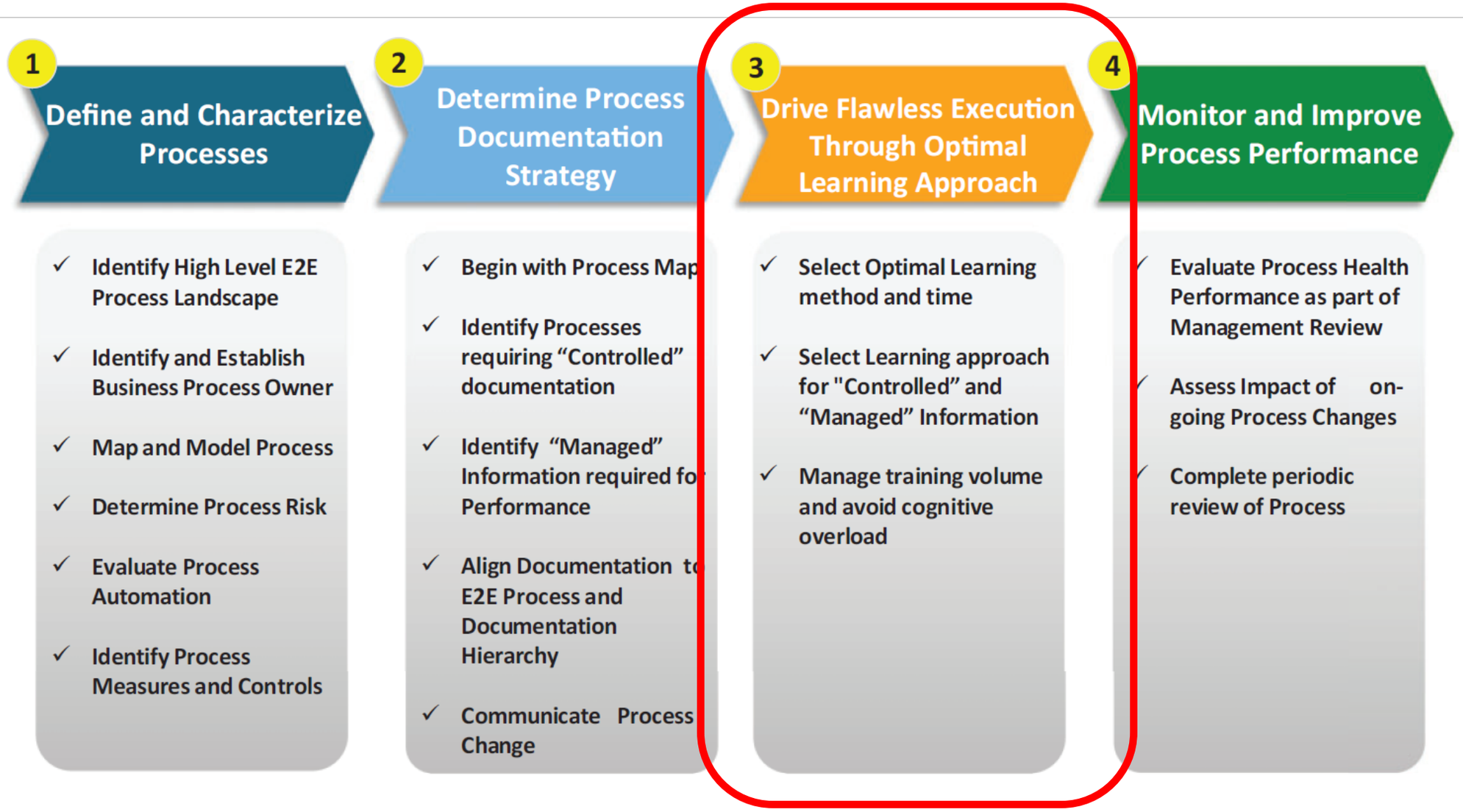
Processes Management Framework



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3

Drive Flawless Execution Through Optimal Learning Approach

Select Learning Method and Time

Select learning delivery based on:

- Organizational Culture
- Documentation
- Knowledge required
- Experience and Target Size of Audience
- Complexity of the Process

Determine timing of training delivery

- Consider providing training as close to execution as possible to maximize effectiveness
- Consider resource limitations (LMS and people)

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3 Drive Flawless Execution Through Optimal Learning Approach

Select Learning Approach for Controlled and Managed Information

Mandatory training based on controlled information:

- Training is delivered automatically to affected users
- Includes learning modules critical for an individual to execute his/her job
- Employee needs to demonstrate effective training was completed prior to executing related tasks

Voluntary training based on managed information:

- Training can be requested by users when there is need or interest
- Knowledge centers can be set up to make content easy to access

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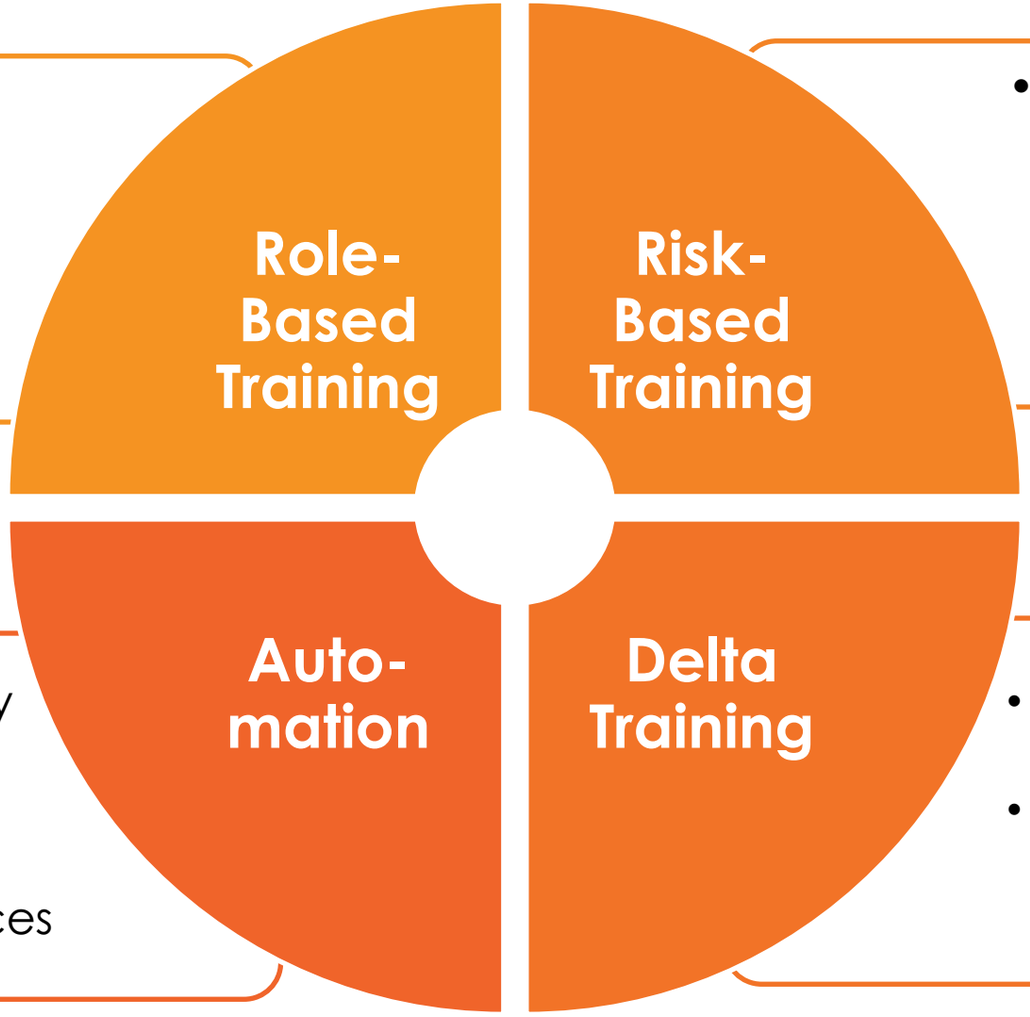
3

Drive Flawless Execution Through Optimal Learning Approach

Manage Training Volume to Avoid Cognitive Overload



- Focuses on responsibilities in a process
- Understand role in E2E process

- Focuses on high risk elements to ensure full understanding

- Provides consistency to process
- Reduces need for users to remember steps or dependences

- Targeted training for experienced users
- Focuses only on changes

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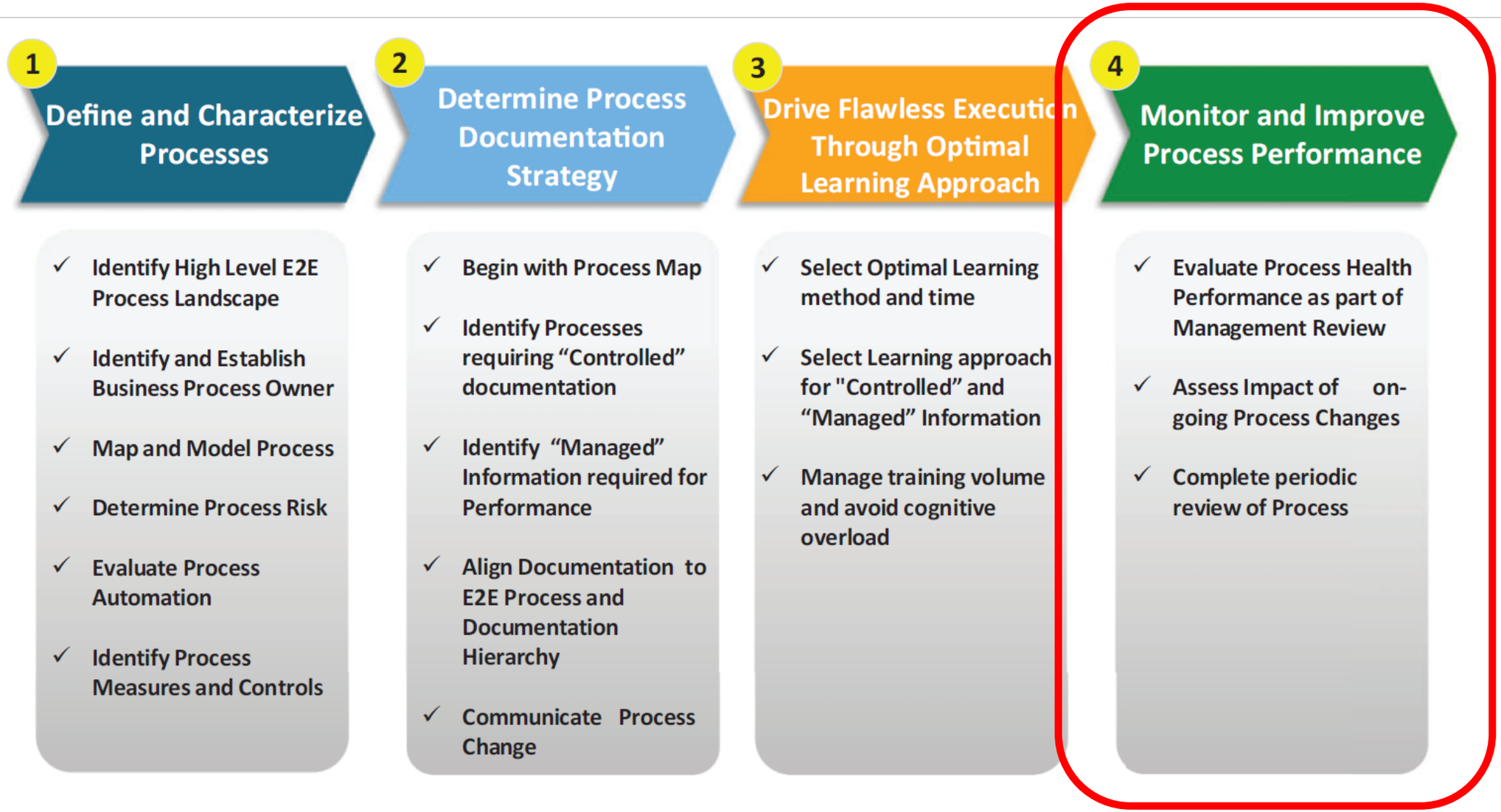
Processes Management Framework



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Evaluate Process Health Performance as Part of Management Review

Management Review

PURPOSE

- To assess whether a QMS as a whole is performing as intended
- To provide opportunity for ongoing due diligence by senior management

OBJECTIVES

- Engage senior management in the evaluation of processes
- Take action / allocate resources to improve processes when needed
- Review key performance indicators (KPIs) to measure quality and compliance

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4

Monitor and Improve Process Performance

✓ Assess Impact of On-Going Process Changes

Create or modify processes for the following reasons:

- Address changes in the underlying process
- Address evolving customer requirements
- Address changes identified by audit findings
- Mitigate risks to quality objectives

Assess the impact of the changes:

- Understand the overall impact that the process change may have on other "upstream" or "downstream" process
- Identify conflicting or overlapping priorities associated with the change

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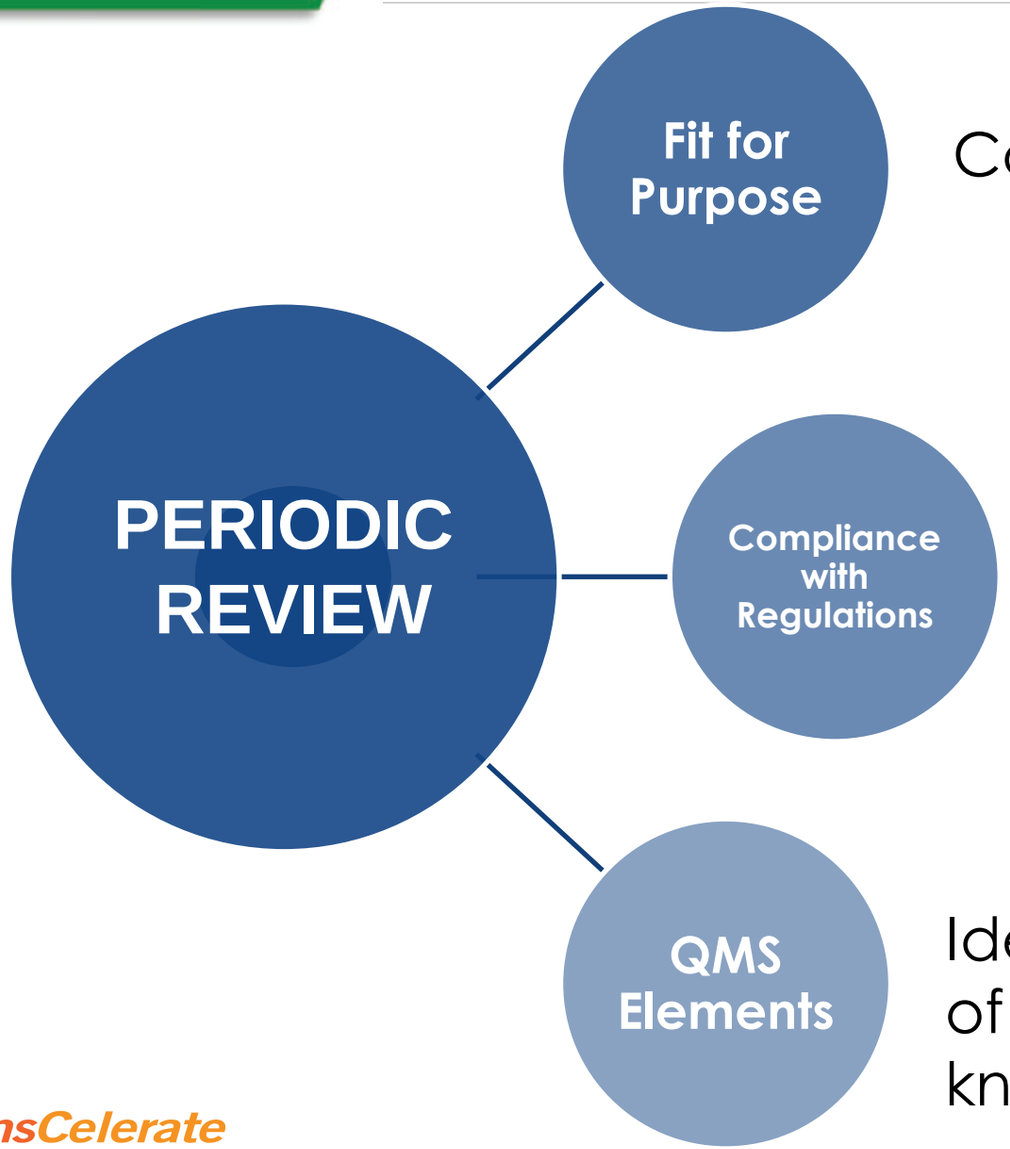
4

Monitor and Improve Process Performance

Monitor and Improve Process Performance



Consult BPO / SMEs

Review process against new or revised regulations / guidance

Identify issues or trends noted in other aspects of a QMS, such as risk, issue or knowledge management

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- Lead author of the Process Management Framework paper

Carol Southwood

- Senior Project Manager, Amgen
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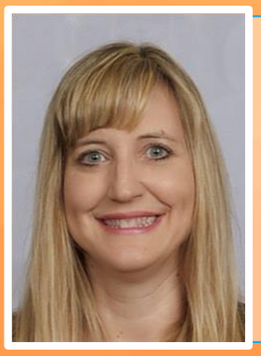
Q & A

Type your questions for the presenters into the Questions panel on your GoToWebinar screen, click “Submit”



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Process Tool Kit & Scenarios

Process Toolkit

Purpose

- Supports the practical application of concepts described in the Process Management Framework paper
- Provides tangible examples of the process management framework in action beyond what's described in the paper
- Provides a way to both "think through" and develop an organization's processes and associated documentation strategy

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Introduction

Define and Characterize Processes	Determine Process Documentation Strategy	Drive Flawless Execution Through Optimal Learning Approach	Monitor and Improve Process Performance
» **Identify High Level End to End (E2E) Process**	» Begin with Process Map	» **Select Optimal Learning method and time**	» **Evaluate Process Health Performance as part of Management Review**
» Identify and Establish Process Owner (BPO)	» **Identify Processes requiring "Controlled" documentation**	» **Select Learning approach for "Controlled" and "Managed" Information**	» Assess Impact of ongoing Process Changes
» **Map and Model Process**	» **Identify "Managed" Information required for Performance**	» **Manage training volume and avoid cognitive overload**	» Complete periodic review of Process
» **Determine Process Risk**	» **Align Documentation to E2E Process and Documentation Hierarchy**		
» Evaluate Process Automation	» Communicate Process Change		
» Identify Process Measures and Controls			

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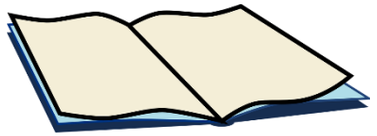
How To Use The Toolkit

Read the Manuscript



Find the corresponding tool and examples

- Each of the steps in the framework are sequenced and built upon one another.
- Each of the highlighted steps corresponds to a section of the toolkit and are color-coded to match the high-level phase of the Process Management Framework.
- Each section is numbered and contains the following information:

➢ **Even pages:** Instructions for completing the tool with an example(s)
➢ **Odd pages:** Interactive tool template that moves through each of the tool steps on the subsequent pages

1 Identify High Level Process

Identify all steps of an end to end (E2E) process by mapping core processes, sub-processes, and enabling processes.

2 Map & Model Process

Capture the SIPOC metadata (key process roles, inputs, outputs, interdependencies, and related documentation).

3 Determine Process Risk

Assess risks for processes by completing the assessment concerning Business Risk, Process Complexity Risk, and Process Operational Risk.

4 Documentation Strategy

Determine which processes require controlled documentation vs. managed information based on the process risk score.

5 Optimal Learning Approach

Assess the Critical to Quality (CTQ) process and documentation to develop the Learning Plan for controlled documentation vs. managed information.

6 Management Review

Evaluate process health performance as part of Management Review by defining line of sight goals, metrics, roles, frequency and forum.

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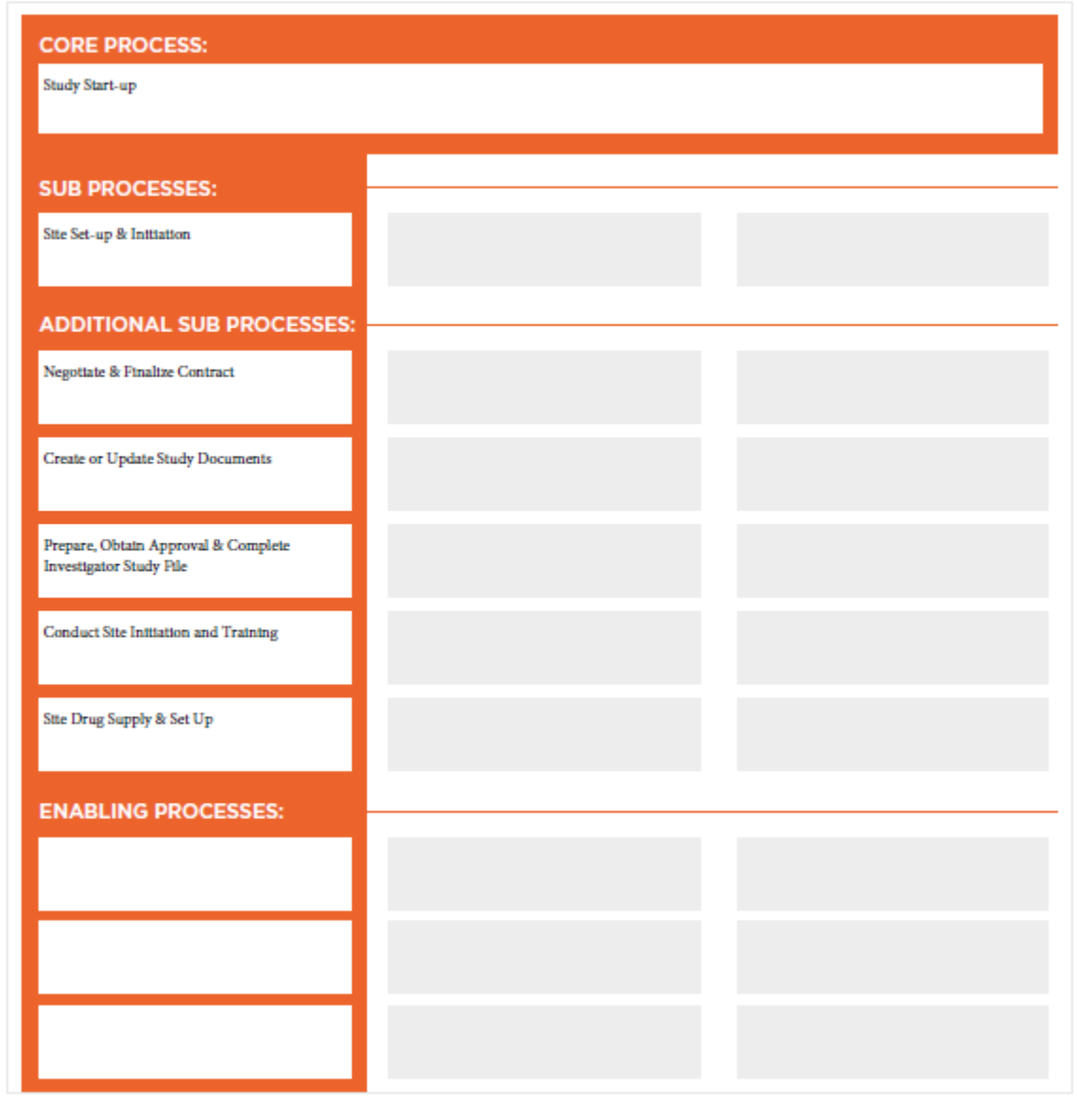
Define and Characterize Processes

Identify High Level Process

EXAMPLE

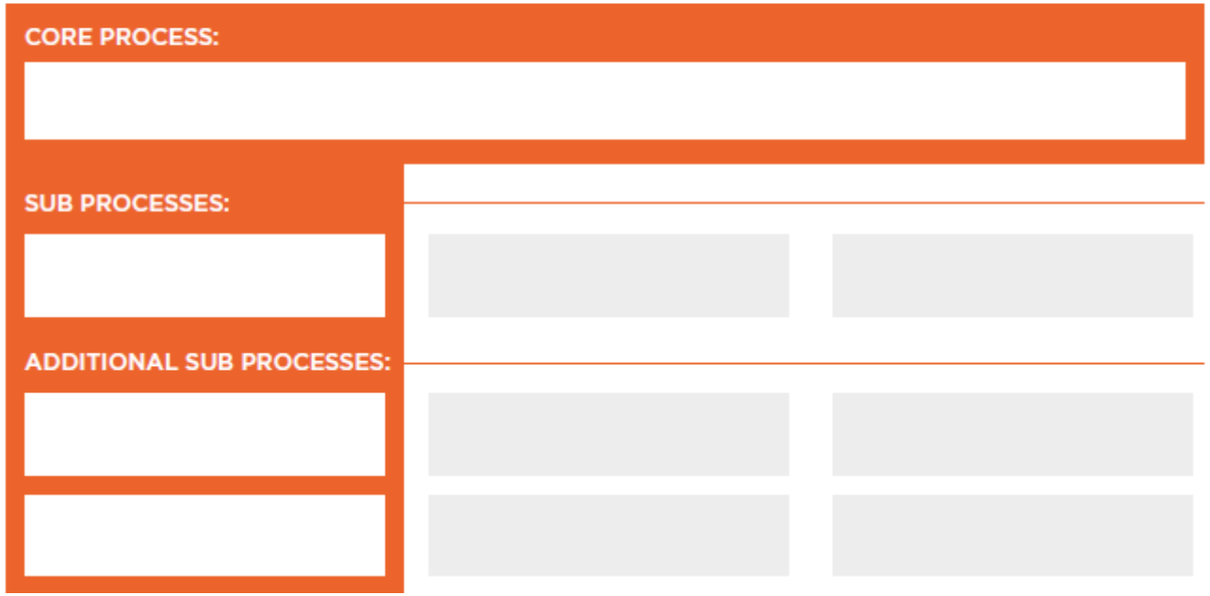


Instructions

- Identify all steps of an end to end process

TOOL

1 Identify Process Areas



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Define and Characterize Processes

Map & Model Process

Supplier	Input	Process	Output	Customer
Identify the providers of the critical to quality inputs	Identify critical to quality inputs to the process	Use the additional sub-processes and enabling processes listed in section 1: Identify Process Areas	Identify the deliverables from the process	Identify the Internal Functions/External organisations who receive the outputs

EXAMPLE: SIPOC for Site Set-Up and Initiation

Supplier	Input	Process	Output	Customer
	• Study Outline • Study Protocol • Draft Study Level Site Budget	Negotiate & Finalize Contract	• Vendor Contract • Statement/Scope of Work • Study Site Contract & Budget	
	• Study Outline • Study Protocol	Create or Update Study Documents	• Study Documents	
	• Study Protocol • Key Study Documents	Prepare, Obtain Approval & Complete Investigator Study File	• Final & Approved Study Site Documents	
	• Study Protocol • Training Materials • Key Study Documents	Conduct Site Initiation and Training	• Site Activation Notification • Approval to Ship Drugs to Site	
	• Study Protocol • Investigational Product • Selected Vendor List	Site Drug Supply & Set Up	• Packaged Investigational Product • Drug Delivery System(s)/ Vendors	

Instructions

- Using a SIPOC, capture the metadata (key process roles, inputs, outputs, interdependencies, and related documentation).

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Define and Characterize Processes

Determine Process Risk

Process Risk Matrix

RISK CATEGORIES / RISK LEVELS	Risk 1 Compliance	Risk 2 Process Complexity	Risk 3 Process Operational	Overall Risk Scores
High (5)	Direct impact to Company or Product Quality, Patient Safety or Data Integrity/Reliability of Trial Results	Involves Global and local cross-functional area affiliates	Involves Service Providers with no Quality Agreement and/or Governance oversight in place	
Medium (3)	Indirect impact to Company or other health-related activities with no direct impact on Product Quality, Patient Safety or Data Integrity	Involves multiple functional areas	Involves Service Providers with Quality Agreement and/or Governance oversight in place	
Low (1)	No impact to Company or Product Quality, Patient Safety or Data Reliability	Involves one functional area only (e.g. Clinical, Safety, Regulatory affairs etc.)	Does not involve Service Provider	
RISK SCORE	High (5) Medium (3) Low (1) +	High (5) Medium (3) Low (1) +	High (5) Medium (3) Low (1) =	High (10-15) Medium (6-9) Low (3-5)

EXAMPLE: Process Risk Template

Process	Risk 1 Compliance		Risk 2 Process Complexity		Risk 3 Process Operational		Overall Risk Scores
Negotiate & Finalize Contract	3	+	1	+	1	=	5
Create or Update Study Documents	3	+	3	+	1	=	7
Prepare, Obtain Approval & Complete Investigator Study File	5	+	5	+	3	=	13

Click here to view complete example

Instructions

- For each process, select the appropriate risk level for each of the three Risk Categories in the Process Risk Matrix.
- Overall Process Risk Score is determined by adding the corresponding numeric value for each of the Risk

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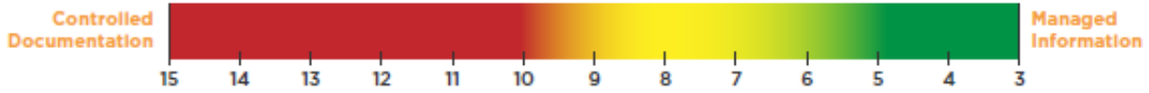
Documentation Strategy

Identify Processes Requiring Controlled Documentation
Identify "Managed" Information Required for Performance

Controlled Documentation	Managed Information
Describes process and business requirements	Describes process at the level of execution

Figure 1: Processes requiring controlled documentation vs. managed information.



Note: *Additionally managed information may be used when key roles, systems, and activities need to be described to support controlled documentation.*

EXAMPLE

Process	Overall Risk Scores	Controlled Documentation		Managed Information	
Negotiate & Finalize Contract	5	☐		✓	Job Aid
Create or Update Study Documents	7	✓	Standard Operating Procedure	✓	Job Aid
Prepare, Obtain Approval & Complete Investigator Study File	13	✓	Standard Operating Procedure	✓	Job Aid
Conduct Site Initiation and Training	11	✓	Standard Operating Procedure	☐	
Site Drug Supply & Set Up	13	✓	Standard Operating Procedure	✓	Decision Tree

Instructions

- Apply the score from the "Determine Process Risk" tab to determine which processes documentation hierarchy.

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Learning Approach

Select Learning Method and Time
Select Learning Approach for "Controlled" and "Managed" Information
Manage Training Volume and Avoid Cognitive Overload

Figure 1: Learning Plan for Process and Documentation

Learning Plan		Location	Key Roles
Select the Focus of training: Role-based, End-to-end, Risk, Delta *(see Learning Plan and Performance Considerations table for additional context)*	Select the Learning Method *(see Learning Method and Definition table)*	List repositories for Controlled Documentation *(e.g. LMS with mandatory assignment)* List repositories for Managed Information *(e.g. Knowledge Hub accessed through search as needed)*	Identify and list roles accountable for the execution of the process activities.

Learning Plan and Performance Considerations

Training should be fit-for-purpose, value added and effective for the modern learner (i.e., allows for mobility, searchable content, varying methods of delivery, modularized and engages through social collaboration).

- Controlled Documents/Managed Information out of alignment or redundant is made obsolete or appropriately archived.
- Learning activities should consider level of expertise. Knowledge checks can be used to advance a user through the training.
- Training should be developed to consider learning preferences (i.e., classroom, virtual, instructor-led, self-directed).
- Training development to consider resources (i.e., audience, location(s), timeline, budget and availability of technology).
- Assessments or knowledge checks should be used to successfully demonstrate an understanding of a concept or skill.

Learning Method and Definition

Instructor-Led Classrooms should be used when interaction with trainer and participants is important, guided discussions will lead to more learning, questions require immediate answers, individualization is not critical. Technology-based solutions such as a virtual classroom is an option.

On-the-Job Does not require a classroom but does require a knowledgeable trainer/mentor and well-designed structure. Method should be used when the number of trainees is small, and the tasks are core to their role, change frequently or may involve non-movable equipment.

Self-Instruction/Self-Directed This method requires a well-designed structure and should be used when turnover is high, the content is stable, simulations or case studies are value added, feedback is not required, scheduling is difficult, the use of multiple media formats will enhance learning and can be developed properly. Interactive methods can incorporate virtual instruction. Note: Managed Information and Self-Instruction/Self-Directed learning are often used interchangeably.

EXAMPLE: Learning Plan for Process and Documentation

Process	Overall Risk Score	Controlled Documentation	Managed Informaton	Learning Plan		Location	Key Roles
				Focus	Method		
Negotiate & Finalize Contract	5		Job Aid	Role-based	Self-Instruction/Self	Sharepoint - Job Aid	• Contract Facilitator • Pricing and Payment Lead
Create or Update Study Documents	7	Standard Operating Procedure	Job Aid	Role-based	Self-Instruction/Self	• LMS - SOP - (required) • Sharepoint - Job Aid	• Clinical Manager • Functional Representative
Prepare, Obtain Approval & Complete Investigator Study File	13	Standard Operating Procedure	Job Aid	Role-based	Self-Instruction/Self	LMS - SOP (required)	• Clinical Manager • Clinical Monitor • Study Planner

Instructions

- Assess the documentation strategy based on overall risk to develop a commensurate learning plan for identified key roles.

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Management Review

Evaluate Process Health Performance as part of Management Review

Goal	Metrics	Role(s)	Frequency	Forum	Focus
E.g. Target or improvement you are trying to achieve, i.e. SMART format	E.g. Cost, Time, Quality	Person responsible for oversight and accountability of the process	Annually, Quarterly, Monthly	Decision making body made up of functional leadership responsible for Quality oversight.	Review metrics based on the forum frequency, i.e. escalation, mitigation or decision making

Strategic Goals Flow Down

Executive leadership sets high level process expectations, which will create goals for each sub-process with line of sight to meet overarching high level process expectations.

Process Capabilities Flow Up

As each lower level process continues to advance and mature, the effects flow upward to improve the process above it.

EXAMPLE

	Goal	Metrics	Role(s)	Frequency	Forum	Focus
EXECUTIVE OVERSIGHT						
	Study Start-up	Improved Start Up Efficiency	9% Savings per Study	Sponsor & Executive Leadership	Annually	Steering Committee	Goal Setting & Collaboration
OPERATION OVERSIGHT						
	Site Set-up & Initiation	Improve Target Enrollment Plan	9% Studies within target enrollment plan	BPO & Sponsor	Quarterly	Operations Review	Metrics & Performance
FUNCTIONAL OVERSIGHT						
	Site Drug Supply & Set Up	Improve Plan to Actual Target Date	# of days for approval of Supply Plan before Site initiation	BPO & Team	Monthly	Dashboard	Continuous Improvement Activities

Instructions

Evaluate process health performance as part of Management Review by defining line of sight goals, metrics, roles, frequency and forum.

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Process Scenarios

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Process Management Framework

SCENARIOS

TransCelerate Quality Management System
Initiative Process Management Sub-Team

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Examples of Scenarios

Selecting an Organizational Structure

Unifying a fragmented process for protocol development by applying a process-centric approach

1

Identifying E2E Processes

Identifying core, sub-processes, and enabling processes for site start up activities

2

Mapping and Modelling a Process

An organization is seeing lengthy delays in the site start up process, specifically the part following ethics approval and prior to site activation

3

Determining Process Risk

Following successful identification and mapping of site start up processes, an organization wishes to identify areas of risk so that mitigation steps can be built into the process

4

Controlled versus Managed Documents

Following the identification of core processes for site start up activities (scenario 2), an organization has no documented methodology for determining if process content should be in a controlled or managed document

5

Determining Training Needs

An organization is updating numerous procedures around study start up and is unsure what delivery type, detail level, and assessment of training is required

6

Identifying Process Measures and Controls

Following successful mapping of trial start up activities, the organization wants to develop metrics to monitor and improve each part of the process

7

Management of Process Changes

Following unification of fragmented processes for protocol development (scenario 1), an organization needs to secure stakeholder "buy-in" and ownership to ensure ongoing support

8

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Selecting an Organizational Structure

SCENARIO	An organization is structured in such a way that is organized and measured by **departmental goals and objectives**. Executive leaders operate as a team but are focused individually on their functions.
BUSINESS IMPACT	This **conventional approach** serves the basic needs of the organization as it maintains hierarchical control, especially in the context of large organizations, but this does not serve the needs of the customer…the patient.
PROCESS MANAGEMENT POTENTIAL SOLUTION	A **process or customer-driven** approach – where an organization's focus remains on cross-functional process capabilities and serving the needs of the customers of the processes.
PROCESS MANAGEMENT BENEFITS	• **Accountability**: Focuses on overcoming functional area silos through single points of process accountability. • **Quality**: Clearly defined processes, documentation, and training enable "right the first time" operations, improving quality and reducing risk. • **Compliance**: Clearly defined processes give confidence to health authorities on sponsors' intentions of meeting regulatory requirements. • **Speed**: Provides end-to-end performance management and "sightline" to customer.

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Controlled versus Managed Documents

Using the QMS Initiative — Toolkit for Implementing Processes - Real World Scenario

Scenario:

Following the identification of core processes for site start up activities (scenario 2), an organization has no documented methodology for determining if process content should be in a controlled or managed document.

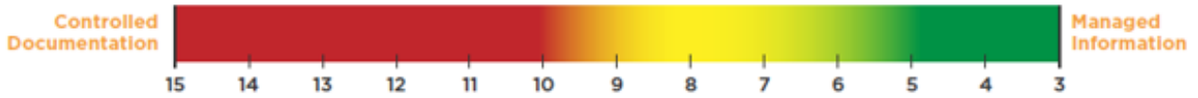
Problem:

Managed documents are key in that they enable individual functions to retain ownership of documentation around best practices, internal workflows etc. However, any high risk or key compliance aspects of a process require more robust control to ensure quality & compliance – if this balance cannot be determined, the organization risks consistency/quality issues and fragmentation of core compliance tasks across the document landscape.

Potential Solution:

Using the risk based approach, the organization will have much more confidence in the criticality of document content, and can use this to make the separation on where they are willing to "draw the line" in terms of what becomes managed information versus controlled information. Utilize the risk scorecard to make an assessment of the content of the document itself.

Figure 1: Processes requiring controlled documentation vs. managed information.



Note: *Additionally managed information may be used when key roles, systems, and activities need to be described to support controlled documentation.*

Process	Overall Risk Scores	Controlled Documentation		Managed Information
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Create or Update Study Documents	7	✓	Standard Operating Procedure	✓ Job Aid
Prepare, Obtain Approval & Complete Investigator Study File	13	✓	Standard Operating Procedure	✓ Job Aid
Conduct Site Initiation and Training	11	✓	Standard Operating Procedure	☐
Site Drug Supply & Set Up	13	✓	Standard Operating Procedure	✓ Decision Tree

Note: Figures are for guidance regarding controlled documentation and managed information. The specific documentation types are for illustrative purposes only. Company naming conventions may differ.

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Conclusion

- The Process Management Framework represents an integral part of an effective QMS.
- Common understanding of the steps required for implementation can provide greater organizational success in implementing process management in a robust way.
- Successful process management implementation will help to:
    - Identify and define key and critical processes associated with clinical development,
    - Provide clear and concise procedural documentation that are consistent and fit for purpose to support effective staff training,
    - Allow staff to excel at executing the executing the process “Right the First Time”
- This is “must have” for today’s competitive landscape.

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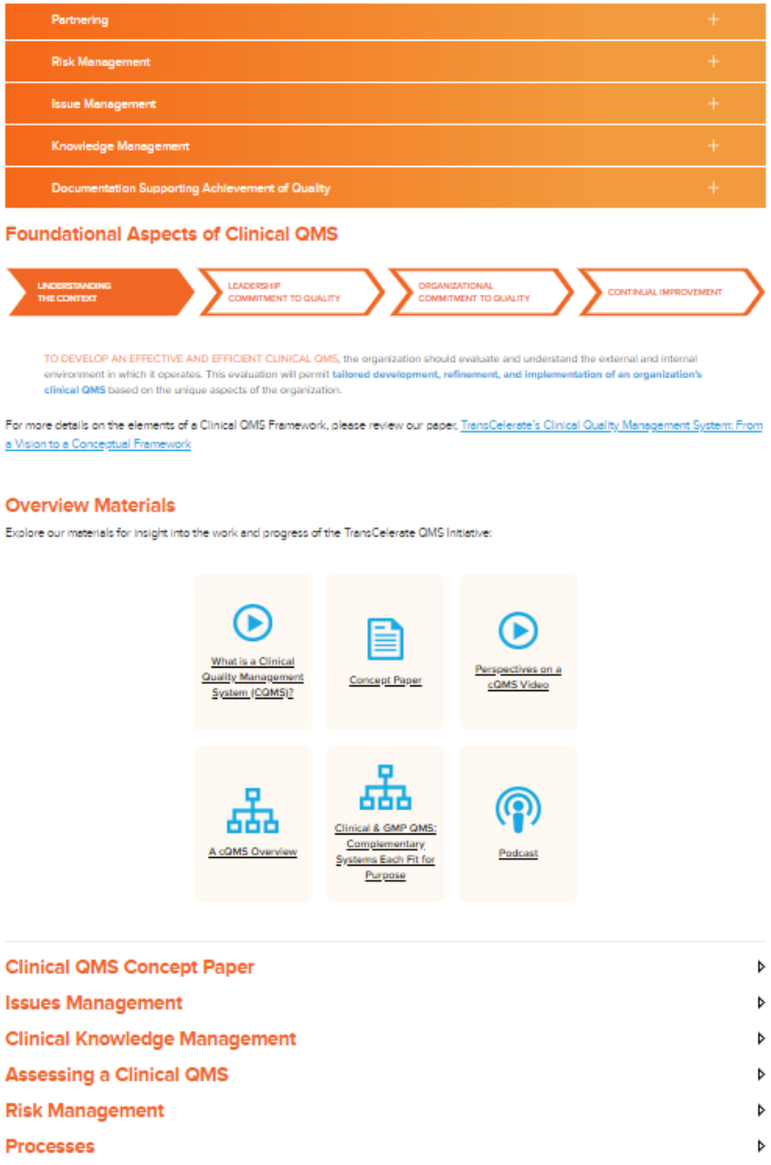
Resources Available

https://transceleratebiopharmainc.com/assets/quality-management-system-assets/



Processes Manuscript

Toolkit for Implementing Processes

QMS Processes Scenarios

Processes

Name	Description	Value
Processes Manuscript	DIA TIRS publication which describes a framework for effective processes management within clinical development. *(published January 2019)*	Assists clinical development organizations in understanding the benefits and basic components of process management for clinical development.
Toolkit for Implementing Processes	A document that describes detailed examples for a clinical development organization implementing a processes framework, identifying how the processes should be documented based on their assessed risks, and how a learning management plan can support the clinical development organization implement the processes and documentation requirements.	Facilitates the implementation of a processes framework for clinical organizations. The toolkit identifies select steps from the processes development framework that would benefit from further instruction, examples, and templates to ensure consistent and robust application of the concepts described in the paper.
QMS Processes Scenarios	This scenario tool uses examples to illustrate how an effective Process Management Framework can ensure the efficient and effective delivery of clinical development programs.	Each scenario is presented in four parts: the Scenario description, its business impact, possible Process Management Solutions, potential Process Management Benefits to help readers understand the real and potential benefits to a robust process management program.

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Q & A

Type your questions for the presenters into the Questions panel on your GoToWebinar screen, click "Submit"

Polling Question #3

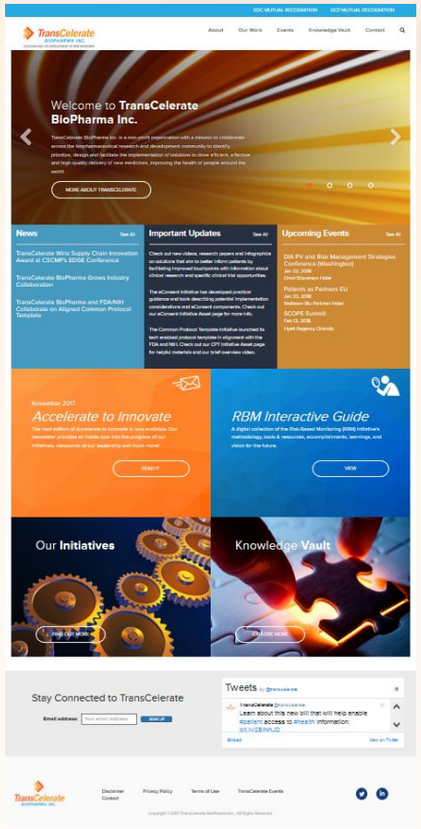
Question: Will the materials presented here today be helpful to you in your organization's Process Management activities?

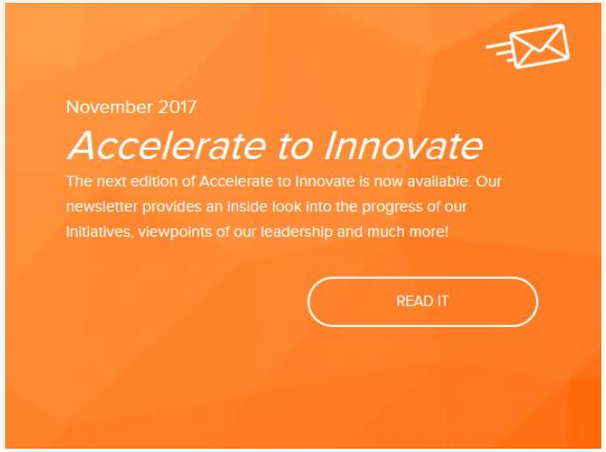
- ❑ Definitely Yes
- ❑ Likely Yes
- ❑ I'm not sure
- ❑ Not likely
- ❑ Definitely Not

Polling Question #4

Question: How much value did this webinar provide?

- ❑ No value
- ❑ A little value
- ❑ Moderate value
- ❑ A lot of value





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