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A Deep Dive Into the TMF RM Change Control Process

Kate Santoro - Intellia Therapeutics, CCB Co-Chair
Leila Ponce - Seagen, CCB Co-Chair (Lead)

Meet the Speakers

Kate Santoro

Title: Director, Operational Excellence

Organization: Intellia Therapeutics

- 20+ years in industry
- Initiated several eTMF systems & processes
- Overseeing process creation and inspection readiness pertaining to TMF
- Co-chair of CCB and Zone Team Lead



Leila Ponce

Title: Sr Manager, Clinical Systems & Records Management

Organization: Seagen

- 20+ years progressive experience spanning oncology clinical research, trial management, clinical SOP writing, electronic Trial Master File (TMF) management, vendor oversight, inspection readiness, and management of validated clinical systems
- Expertise in people management and development, and creating processes governing TMF health and inspection readiness.
- Co-chair of CCB (Lead)





Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC or the companies they represent.*



Agenda

1. An Introduction to the CCB
2. Managing/Maintaining the Reference Model
3. The Importance of Zone Teams
4. A Day in the Life of a Change Request



What is the TMF RM CCB?

- Change Control Board (CCB)
 - Established in 2017
 - Formal Board
 - Reports to Reference Model Steering Committee
 - Meets monthly
 - Formal governance/process documents
- Change Control Board Charter
 - States CCB Purpose
 - Defines CCB structure
 - Defines CCB role
 - Defines SC role in CCB process
 - Lists CCB members
- Other Formal CCB Documents
 - Change Control Procedure
 - Version Control Policy

Purpose of CCB

Triage change requests

Make recommendations

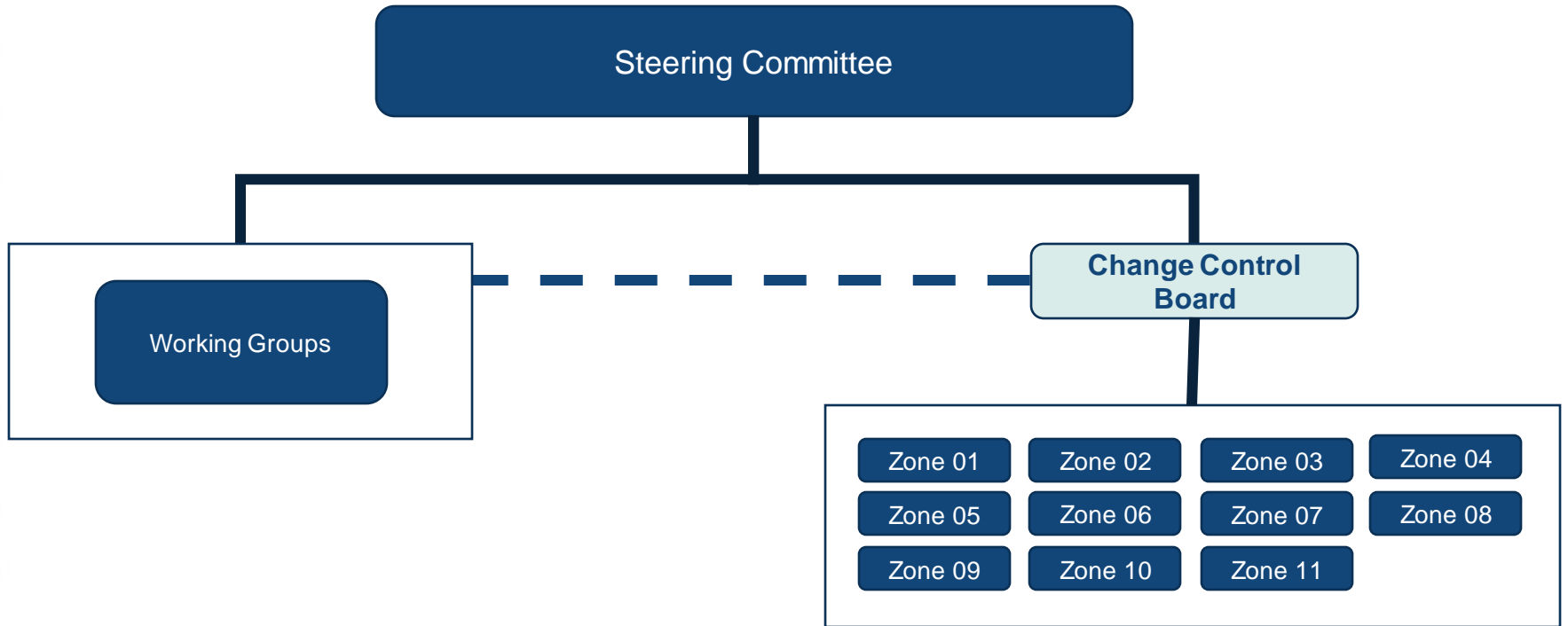
Forward changes to SC

Maintain version control

Release new updates

Oversee Zone Teams

TMF Reference Model - Project Structure





How has CDISC helped the CCB

- Structure
 - CDISC-TMF website
 - Formal registration process
 - JIRA issue tracker
 - Formally tracks change requests
 - WIKI
 - Share information
 - Eventually house TMF Reference Model
- Administrative Support
 - Dedicated staff
 - Technology support
- Migration from old website to CDISC site
 - Organizing information
- What's to Come . . .
 - CCB reviewing changes to the Exchange Mechanism
 - Working with Controlled Terminology for standards



Maintaining Version Control

- Major Release (1.0.0, 2.0.0)
 - Indicates substantial change in content
 - Could cause incompatibility with previous version or technical changes to eTMF
 - Examples:
 - Addition of artifacts
 - Removal of artifacts
 - Attribute deletions that are likely to cause incompatibility issues with prior versions
 - No more than 1 major release/year
- Minor Release (1.1.0, 1.2.0)
 - Indicates substantial change unlikely to cause incompatibility issues
 - Examples:
 - Inclusion of additional option elements (e.g, milestones)
 - Changes to the alignment of artifacts with filing level (study, country, and site)
 - Attribute updates or attribute additions
 - Attribute deletions that are unlikely to cause incompatibility issues
 - No more than 2 Minor releases/year



Version Control (cont'd)

- Maintenance Release (1.0.1, 1.0.2)
 - Indicates no significant impact on adoption or implementation of the Model
 - Examples:
 - Changes to the definition/purpose text
 - Inclusion or deletion of example sub-artifacts
 - Addition or modification of regulatory guidance references
 - Correction of typographical errors
 - No more than 4 Maintenance releases per year
- Additional Information
 - Current version: **3.3.1**
 - Complete review of Reference Model every other year
 - Trying to align with working groups (terminology group/standard development committee)
 - Annually vs biannually
 - Releases are currently demand driven
 - Based on change requests
 - No formal cadence



TMF Reference Model Zone Teams

Zone Teams - A Vital Component of the RM

- 12 Zone Teams
 - Match 11 Zones of the Reference Model + Device
 - Zone Lead
 - Zone Members
- Purpose of Zone Teams
 - Experts in their RM Zone
 - Review new CRs in their zone
 - Discuss - make recommendations to CCB
 - Initiate new CRs when necessary
- Formal Structure
 - Each Zone Lead manages their team differently
 - Introduce more formal structure:
 - Zone Leads check JIRA at least 1x/month
 - Schedule meeting to discuss any CRs
 - If no CRs, Zone check-in at least quarterly



Zone Team Members

- Requirements:
 - Must be registered as CDISC volunteers
 - Should have experience with documents/sub-artifacts for that Zone
 - Have manager's support for participation & time commitment
 - Ad hoc meetings to review changes
 - At **least** quarterly
 - Scheduled by Zone Lead
 - Commitment to the Team



Zone Leads

Zone	Zone Name	Zone Lead
1	Trial Management	Jessica Vicari
2	Central Trial Documents	Joanne Bilmazes*
3	Regulatory	Abida Zameer
4	IRB-IEC	Ramya Iyer
5	Site Management	Kristen Bretzius*
6	IP & Trial Supplies	Lisa Mulcahy*
7	Safety	Katie Kelly
8	Central & Local Testing	Karen Hue
9	Third Parties	Stephanie Viscomi
10	Data Management	Belinda Mabe
11	Statistics	Lisa Mulcahy*
	Device	Joanne Bilmazes*

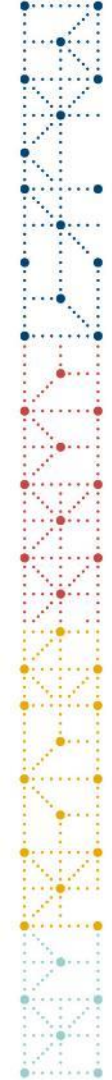


Lifecycle of a Change Request



Idea for improvement

- Potential new artifact
- Update to definition
- Additional sub-artifact



Step 1 - Initiating a New Change Request



Need a CDISC account

- Log onto [CDISC.org](https://www.cdisc.org) and create a password

Submit a Change Request

- [CDISC.org/tmf/change-request-form](https://www.cdisc.org/tmf/change-request-form)

Enter type of feedback

- General comment
- Change existing artifact
- Propose new artifact

Submitting a Change Request



[Home](#) / [TMF - Submit a Change Request to the Change Control Board](#)

TMF - Submit a Change Request to the Change Control Board

If you have any suggestions for changes to the TMF Reference Model, please use the form below to submit your feedback. You may use this form for requests to change artifacts, add artifacts, remove artifacts or general suggestions for improvements to the Model.

Please do NOT use this form to:

- ask general questions about the TMF Reference Model (please post a question on our online forum)
- send comments or questions to the TMF Reference Model Project
- ask where specific documents should be filed (please post a question on our online forum)
- ask questions about implementation of the Reference Model (head to the online forum)

Your comment/question will be automatically deleted without any acknowledgment.

Data submitted here is only reviewed by the Change Control Board if considered a genuine request or suggestion for a change to the Reference Model.

When selecting the type of change request in the form below, please do **NOT** select "General" if you are commenting on a specific artifact or specific artifacts or are suggesting a change to a specific part of the Reference Model. In these cases, select "Change existing artifacts" and submit as many forms as you have comments for. Use a separate form for each comment submitted. Our volunteer Change Control Board do not have the time to reclassify or edit your comments. Thanks!

Type of feedback to submit

- None -

Type of feedback to submit

Change existing artifact

Change existing artifact

Artifact Number

Column(s) affected by proposed change

Proposed change

describe the change that you are proposing

Rationale

briefly explain why you think this change is necessary

Your contact information

Name

Email address

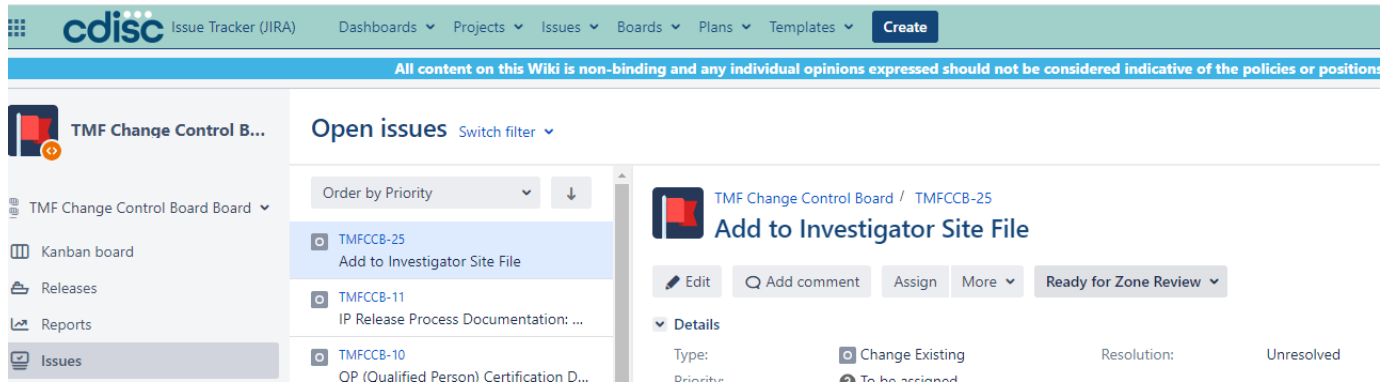
Company

Title



JIRA - Change Request Issue Tracker

- CCB Leads Notified
 - Create CR in JIRA (automation in process)
 - CCB Triage
 - Assign to Zone Teams
 - Assessed
 - Recommendations
 - All tracked



The screenshot shows the JIRA Issue Tracker interface for the 'TMF Change Control Board'. The top navigation bar includes the 'cdisc' logo, 'Issue Tracker (JIRA)', and various menu items like 'Dashboards', 'Projects', 'Issues', 'Boards', 'Plans', and 'Templates', along with a 'Create' button. A blue banner below the navigation bar states: 'All content on this Wiki is non-binding and any individual opinions expressed should not be considered indicative of the policies or positions'. The main content area is divided into three sections:

- Left Sidebar:** Contains the 'TMF Change Control Board' icon and a list of board views: 'TMF Change Control Board Board', 'Kanban board', 'Releases', 'Reports', and 'Issues'.
- Open issues:** A list of issues is displayed, ordered by priority. The top issue is 'TMFCCB-25 Add to Investigator Site File'. Other visible issues include 'TMFCCB-11 IP Release Process Documentation: ...' and 'TMFCCB-10 OP (Qualified Person) Certification D...'. A 'Switch filter' dropdown is located to the right of the list.
- Issue Details:** The details for 'TMFCCB-25 Add to Investigator Site File' are shown. It includes action buttons for 'Edit', 'Add comment', 'Assign', and 'More'. A 'Ready for Zone Review' dropdown is also present. The 'Details' section shows 'Type: Change Existing' and 'Resolution: Unresolved'. Other details like 'Priority' and 'To be assigned' are partially visible.

Step 2 - CCB Triage



Decline

- Notification sent to submitter (email)

Forward

- Zone Team for review & recommendation

Step 3 - Zone Team Review



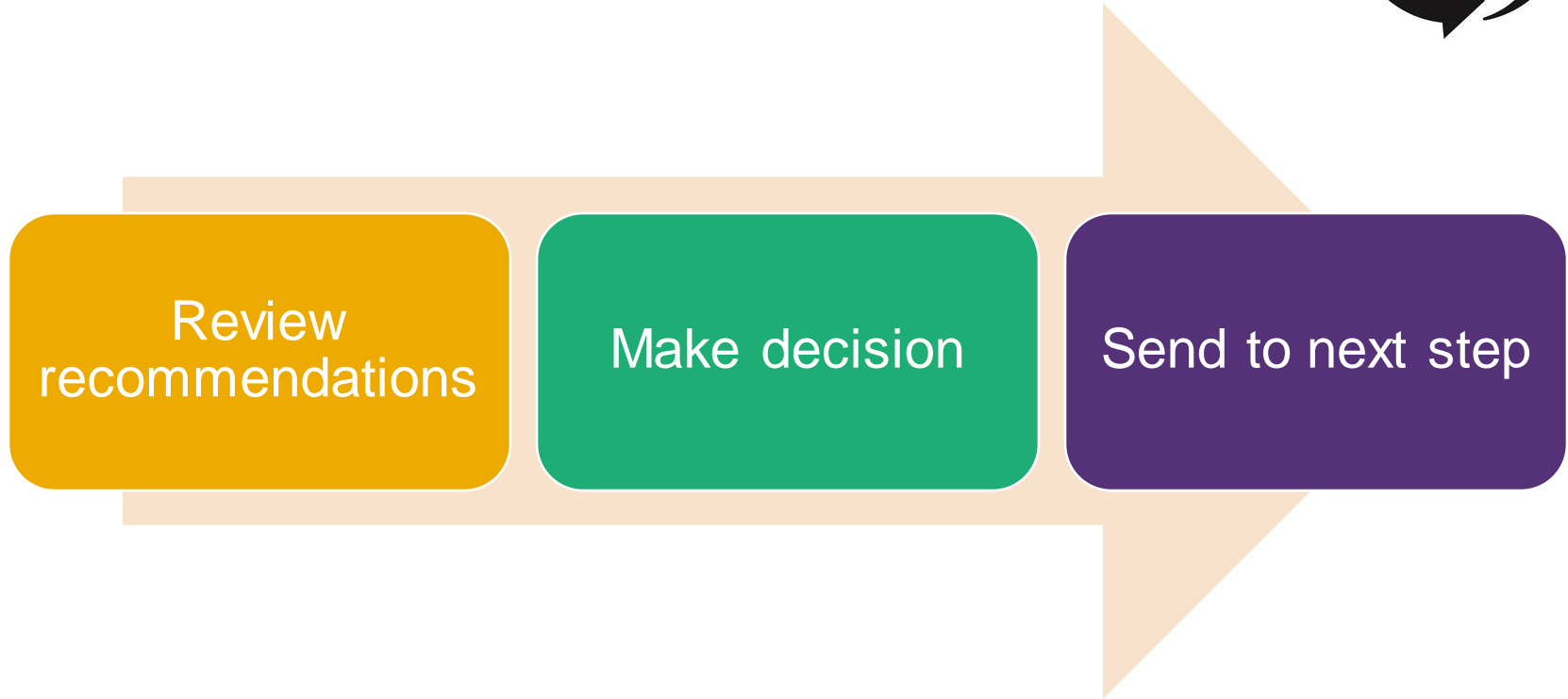
Assigned to Zone Team

- Zone Team reviews
- Makes recommendations
- Notes in JIRA comments

Recommendations

- Approve change
- Approve with edits
- Decline

Step 4 - CCB Review



Step 5 - Steering Committee Review



The Final Step

Move Forward

- Added to the Reference Model

Decline

- Notification sent to submitter

Updated Reference Model





Thank You!

Kate.Santoro@intelliatx.com

Lponce@seagen.com

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