



2025 CDISC + TMF
EUROPE INTERCHANGE

GENEVA

CONFERENCE & EXPO: 14-15 MAY | TRAININGS: 12, 13, 16 MAY

Key Considerations for Biometrics CROs Not Managing the TMF – The journey so far

Presented by Caroline Terrill,
Senior Director of Statistical Programming
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Meet the Speaker

Caroline Terrill

Title: Senior Director of Statistical Programming

Organization: Cytel

Caroline Terrill has 20 years of experience working in the Pharmaceutical industry, in statistical and programming roles. Caroline works with the Cytel commercial team to provide input for the programming and CDISC aspects of new projects, as well as being the author of the statistical programming quality documents. Caroline worked in the internal team that utilized the TMF reference model to form part of the Essential Records process at Cytel.

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.*
- *The views and opinions expressed in this presentation are those of the author and do not necessarily reflect the official policy or position of Cytel.*
- *The author has no real or apparent conflicts of interest to report.*



Agenda

1. Introduction
2. Considerations
 - a) Cross functional team
 - b) TMF Reference model as a tool
 - c) Training
3. Lessons Learned
4. Summary



Introduction

Why is a programmer talking about Essential Records?

Managing TMF – not me!

Biometric CROs do not ‘manage’ the TMF:

- Clinical CRO or Sponsor responsibility
- We provide what is requested
- Our part of TMF is small

BUT

- TMF group now part of CDISC
- CDISC is seen as a Biometric responsibility
- Programmers have responsibility for TMF?



Need to Manage our Part



Essential Records
section of ICH E6
(R3)



Increased visibility
within Biometrics of
TMF Reference
model now part of
CDISC
organization



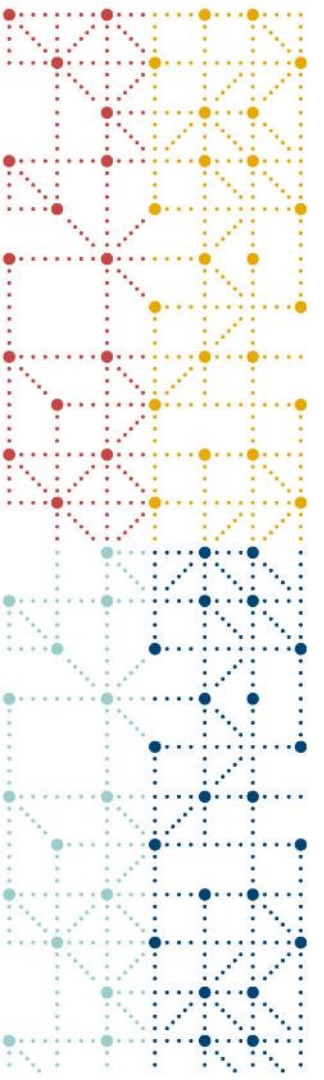
More requests from
sponsors for our
essential records
process



More queries from
team about what is
an essential record



Inspection inquiries
on Essential
Records process



Considerations

Cross Functional Team

Who: QA, Project Management, Data Management, Biostatistics, Statistical Programming, Medical Writing

Goal: Create clarity and accountability

Scope: Focus only on the records we generate or touch



What is needed?

ICH E6 R3: Essential Records Table

- Trial-specific plans (data management, statistical analysis)
- Documentation relating to the statistical considerations and analysis (e.g., sample size calculations, analysis sets decisions, analysis data sets, analysis programs, quality control records and outputs)

Our Process

At the Start

- Project Specific Essential Records Plan
- Essential records folder setup – restricted access



What is included

- Essential Records Filing Plan
- Based on TMF Reference Model



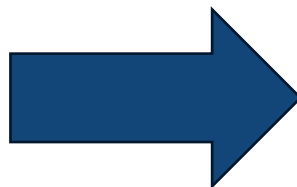
When

- Agreed in plan
- Single documents once finalized
- Analysis documentation after analysis complete

TMF Reference Model as a basis for Filing Plan

Artifact #	Artifact Name	Recommended Subartifacts
11.03.02	Analysis QC Documentation	Analysis QC Documentation Validation Documentation Approval Validation Plan Validation Report

- Programming and Validation Plan
- Validation Report
- QC Checklists
- Issue Logs



One row per
subartifact



Essential Records Filing Plan

Lists all possible Essential Records for Biometrics Projects

Includes names of all subartifacts

Location of subartifact in Standard Folder Structure

Location it will go in Essential Records folder

Essential Records Filing Plan

At study start Filing Plan is updated by leads to only include what is in scope for this project

Finalised for each subartifact depending on type:

- Standalone documents – once finalised
- Documents related to analysis – once each analysis is confirmed finalised

Copied to essential records restricted access folders

Reviewed and confirmed by leads

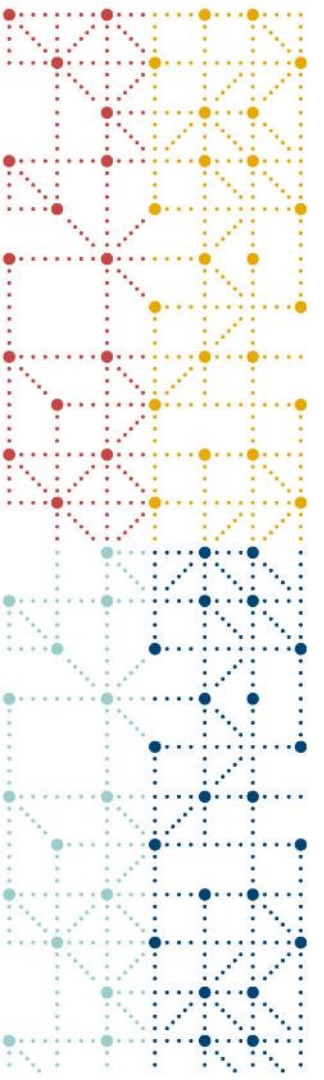
Training



NEW PROCESS
COMMUNICATED



TRAINING CONDUCTED IN
FUNCTIONAL MEETINGS



Lessons Learned



Lessons Learned



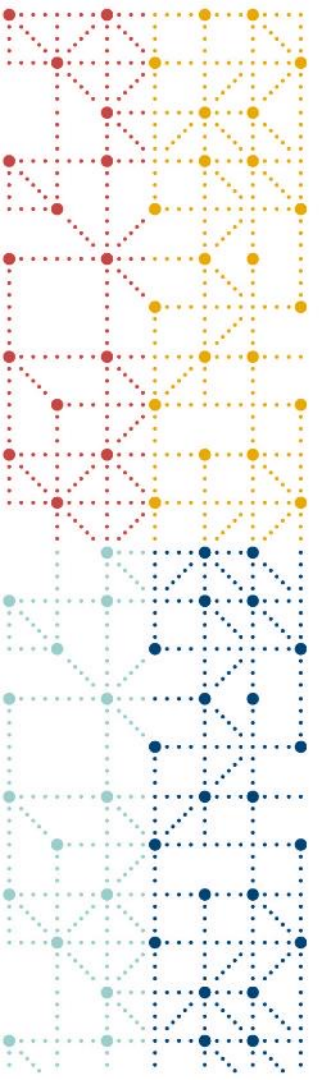
Create plan at the
start



More specific
training



Implementation of
ongoing support



Summary

Summary

Will all need to
take our part

TMF Reference
model
instrumental in
our process

Training and
Support



Thank You!

