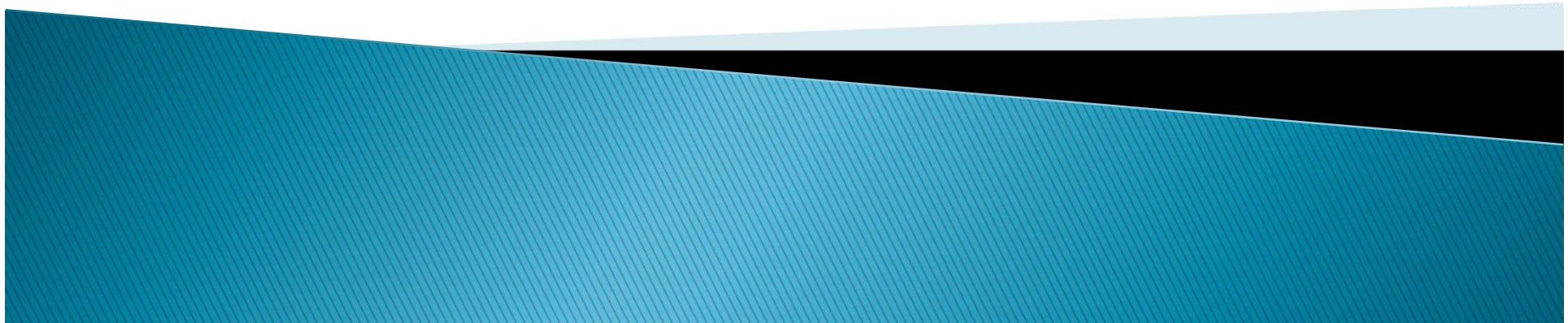




Trial Master File Reference Model

Roadmap

2016



2016 Roadmap

ACTIVITY	Lead	SC Sponsor	Priority
eTMF Interoperability	Paul Fenton / Elvin Thalund	Eldin Rammell	Q1 – Q3
Implementation Toolkit	Mike Czaplicki / Eric Rubinson	Mike Czaplicki / Eric Rubinson	Q1 – Q2
Annual Survey	Jane Twitchen	Fran Ross	Q1 – Q3
User Guide to RM Upgrades	Laurel-Ann Schrader	Mike Czaplicki / Eric Rubinson	Q1 – Q2
Metadata	Todd Tullis	Karin Schneider	Q1 – Q2
Dating Conventions	Melissa Maberry	Kathie Clark	Q2 – Q3
Single-site Template	Karen McCarthy Shau	Fran Ross / Lisa Mulcahy	Q2 – Q3
Artifact Sub-types	Karin Schneider	Karin Schneider	Q2 – Q3
Inspection Preparation	Kathie Clark	Kathie Clark	Q2
Milestones	Kathleen Kirby	Eldin Rammell	Q3 – Q4
Country-specific Artifacts	Eleanor McLaurin	Claire Mooney	Q3 – Q4
TMF Quality Control	Sholeh Ehdaivand	Jamie Toth	Q3 – Q4

eTMF Interoperability

- ▶ To define a standard and simple mechanism for the transfer of eTMF content, using existing standards where appropriate.
- ▶ Lead: Paul Fenton and Elvin Thalund
- ▶ SC Sponsor: Eldin Rammell
- ▶ Timeline: Q1 – Q3

Implementation Toolkit

- ▶ Review and revise the existing Reference Model User Guide. Expand to develop an implementation toolkit.
- ▶ Lead: Mike Czaplicki & Eric Rubinson
- ▶ SC Sponsors: Mike Czaplicki & Eric Rubinson
- ▶ Timeline: Q1 / Q2

Annual Survey

- ▶ Revise annual survey content to accommodate any additional requirements. Conduct survey. Publish results.
- ▶ Lead: Jane Twitchen
- ▶ SC Sponsor: Fran Ross
- ▶ Timeline: Q1 / Q3

User Guide to RM Upgrades

- ▶ Develop a user guide to help adopters of prior versions of the RM to upgrade to v3.0.
- ▶ Lead: Laurel–Ann Schrader
- ▶ SC Sponsors: Mike Czaplicki & Eric Rubinson
- ▶ Timeline: Q1 / Q2

Metadata

- ▶ Review core and recommended metadata for artifacts. Develop revised metadata, ensuring alignment with the Interoperability Group and the EDM Ref Model
- ▶ Lead: Todd Tullis
- ▶ SC Sponsor: Karin Schneider
- ▶ Timeline: Q1 / Q2

Dating Conventions

- ▶ Develop recommended definitions for date property to be used for each artifact, for example meeting date, signature date, effective date.
- ▶ Lead: Melissa Maberry
- ▶ SC Sponsor: Kathie Clark
- ▶ Timeline: Q2 / Q3

Single site RM Template

- ▶ Filter the artifact requirements of the RM for a single-site study. Make available as a stand-alone template.
- ▶ Lead: Karen McCarthy Shau
- ▶ SC Sponsors: Fran Ross and Lisa Mulcahy
- ▶ Timeline: Q2 / Q3

Sub-types

- ▶ Whilst a definition of sub-types is provided in the RM, the concept is not well understood and variously interpreted. Develop clear guidance on the purpose and use of sub-types within the RM.
- ▶ Lead: Karin Schneider
- ▶ SC Sponsor: Karin Schneider
- ▶ Timeline: Q2 / Q3

Inspection Preparation

- ▶ Develop a toolkit of inspection preparation checklists and other resources that are available in the public domain
- ▶ Lead: Kathie Clark
- ▶ SC Sponsor: Kathie Clark
- ▶ Timeline: Q2

Milestones

- ▶ Align each artifact with simple, pre-defined study milestones. Documents must be present in TMF by completion of the milestone
- ▶ Lead: Kathleen Kirby
- ▶ SC Sponsor: Eldin Rammell
- ▶ Timeline: Q3 / Q4

Country-specific Artifacts

- ▶ Define clearly why there might be issues adopting the RM with country-specific requirements. Define deliverables to bring to SC for future activity.
- ▶ Lead: Eleanor McLaurin
- ▶ SC Sponsor: Claire Mooney
- ▶ Timeline: Q3 / Q4

TMF Quality Control

- ▶ Define minimum requirements for quality control of TMF content
- ▶ Lead: Sholeh Ehdaivand
- ▶ SC Sponsor: Jamie Toth
- ▶ Timeline: Q3 / Q4

Wet-ink Signatures

- ▶ Identify which artifacts should be signed, and which should be wet-ink signed
- ▶ Timeline: Deferred to 2017

Translation Guidance

- ▶ Identify the translation requirements for each artifact within the RM
- ▶ Timeline: Deferred to 2017