Trial Master File Reference Model

STEERING COMMITTEE

NOMINEES FOR FIVE VACANCIES

APRIL 2020

JAMIE TOTH

EMPLOYER: Daiichi Sankyo Inc
JOB TITLE: Head of TMF Operations
GROUP: Pharma/Biotech
LOCATION: USA

RECENT REFERENCE MODEL ACTIVITY:

- TMF Plan Template
- J-GCP
- Email Management

In my role as Head of TMF Operations at Daiichi Sankyo, Inc. I provide strategic guidance to functional groups and CROs who are following our global business process and using our system. I have been involved in the TMF Reference Model since 2013; and a member of many initiatives. In the past 2 years I have led the industry TMF Plan template creation, and industry workshops to promote the template. I helped kick-off the jGCP subgroup. I launched the eMail Handling subgroup November 2019 with aims to publish a whitepaper by June 2020. I am also a Board member for the Health Sciences Records & Archives Association (HSRAA). I am a regular presenter and Chair at many TMF related conferences across the industry. I would love to continue to share my knowledge and experience as a Steering Committee member to further expand the TMF Reference Model usage.

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DONATELLA BALLERINI

EMPLOYER: Chiesi
JOB TITLE: Document and Training Manager
GROUP: Pharma/Biotech
LOCATION: Italy

RECENT REFERENCE MODEL ACTIVITY:

- Non-Interventional Studies

I think that the best sentence that I can write is, as Karen teaches, TMF means Too Much Fun for me!. I really love it and when there are activities related to the management of TMF I'm the first in line.

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LISA MULCAHY

EMPLOYER: Mulcahy Consulting, LLC
JOB TITLE: Consultant
GROUP: Independent Consultant
LOCATION: USA

RECENT REFERENCE MODEL ACTIVITY:

- Steering Committee Member
- Change Control Board
- Zone 6 & 7 SME Teams
- Sub-Artifacts

As a co-founder, with Karen Roy, of the TMF RM team I have the professional objective to ensure that the time and commitment of all of the TMF RM team members are translated into continued applicability and use of the model. My experience as a TMF management process consultant is valuable to the make-up of the SC since I assist different types and sizes of companies incorporate the TMF RM into their processes and eTMF system implementation projects. I bring perspectives gleaned from my consultancy clients into discussions, which in turn impacts decisions made for the TMF RM, including sub-team activit

Besides participating on 2 TMF RM subteams during the last year, during 2018-2019, I project managed the effort that produced the Framework for the Destruction of Paper (v2.0) which impacts the TMF management process.

It would be a huge honor to continue being a SC member of your TMF RM.

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TODD TULLIS

EMPLOYER: Veeva Systems
JOB TITLE: Director of Product Management
GROUP: Vendor (system/services)
LOCATION: USA

RECENT REFERENCE MODEL ACTIVITY:

- Steering Committee Member
- Exchange Mechanism (Metadata Team)

For the past 6 years I have served as a Steering Committee member with dedication, integrity, and effort. I am thankful for opportunity to contribute to the betterment of the clinical research industry, and I'm ready for another term!

We should always seek to improve the Reference Model's value to industry. I believe that version 4 of the model should be optimized for electronic/paperless studies and eTMF systems. Such a model would also be more capable of enabling the electronic exchange of records with investigator sites, IRB/ECs, and regulatory authorities.

My perspective is informed by diverse professional experience and listening to my customers. I began as a consultant to clinical operations & data management across sponsors, CROs, and investigator sites. I then transitioned to designing clinical trial software, initially for study startup (goBalto) & eTMF (Veeva). My current focus at Veeva is on software for investigator sites.

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FRAN ROSS

EMPLOYER: Advanced Clinical
JOB TITLE: TMF Practice Director
GROUP: CRO
LOCATION: USA

RECENT REFERENCE MODEL ACTIVITY:

- Steering Committee Member
- Sub Artifacts
- Annual Survey

As a member of the TMF Reference Model initiative since the development of version 1.0, I'd be honored to continue on the Steering Committee to support the efforts to improve, promote and extend our excellent work. I bring multi-faceted TMF expertise from the sponsor, consultant and CRO perspectives, and am dedicated to the principle that we can robustly meet health authority TMF expectations without undue complexity. Here's to celebrating our TMF Reference Model's 10th anniversary year!

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ELVIN THALUND

EMPLOYER: Oracle
JOB TITLE: Senior Director, Product Strategy
GROUP: Vendor (system/services)
LOCATION: USA

RECENT REFERENCE MODEL ACTIVITY:

- Co-Chair Exchange Mechanism Standard

I have over 20 years as a clinical business analyst consultant, mainly for large pharma.

I have over the last decade worked for goBalto (now Oracle) on defining study startup in the roles as data architect, analytic, product strategy, and is currently in the role of industry strategy.

I have during the last 5 years been pleased to serve as co-chair for the TMF RM Exchange Mechanism Standard and getting the first EMS version published.

I'm also representing Oracle at Association of Clinical Research Organizations (ACRO) supporting the innovative clinical research industry in resolving pain-points.

As a steering committee member, I believe I can help the conveying TMF audit readiness and related quality into operational processes and systems and not just as a standalone TMF process and system.

Specifically, this could include, defining operational TMF events (planned and spontaneous), which needs to be captured and documented with existing TMF artifacts.

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DONNA DOROZINSKY

EMPLOYER: Just In Time GCP
JOB TITLE: President & CEO
GROUP: Vendor (system/services)
LOCATION: USA

RECENT REFERENCE MODEL ACTIVITY:

- Milestones
- Sub Artifacts
- Zone 4 SME Group

I am a business leader with extensive experience in GCP compliance and inspection readiness. I spent the first 15 years of my career in drug development in Pharma. In 2005, I founded Just in Time GCP and have strategically developed it into an organization that is well equipped with both knowledge and experience to support companies in areas of inspection readiness, TMF systems implementations and management and TMF services. This provides me with an industry wide perspective on the many challenges that companies face ensuring that their TMFs are inspection ready.

I have been involved with the Reference Model for the past several years, including leading Zone 4 revisions and participating in several working groups including Milestones and Subtypes.

I am a frequent presenter of workshops on TMF management and inspection readiness and am the TMF chapter author of Good Clinical Practice A Question & Answer Reference Guide, 2016/2018/2020.

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MAMORU FURUICHI

EMPLOYER: Santen Pharmaceuticals Co Ltd
JOB TITLE: Clinical Coordinator
GROUP: Pharma/Biotech
LOCATION: Japan

RECENT REFERENCE MODEL ACTIVITY:

- jGCP Adaption

I was a member to implement eTMF from Japan and have worked as a responsible person of eTMF business/system management in my company for 4 years.