Trial Master File Reference Model

General Meeting

6 November 2017
Agenda

- Welcome
- Steering Committee Update – Call for new members – Karen
- Change Control Board – Eldin
- Revised DIA DRM Community – Lisa
- Draft FDA Q&A on 21 CFR Part 11 for clinical investigations – Kathy
- TMF Plan – Jamie
- User and Implementation guide – Mike
- Update on Exchange mechanism – Fran
- Other Subgroup activity update – Karen and Leads
- Med device call to action – Karen
- TMF Summit in London Summary – Jane
- TMF Summit in Tokyo Summary – Karen
- Upcoming conferences – Karen
Steering Committee Update

- Resigned Committee Members
  - Eric Rubinson, Allergan

- Call for 2 new Committee Members
  - One can be from anywhere
  - One has to be from CRO or Vendor or Consultant
  - Nominees must meet requirements in Charter e.g. participated as team member for at least 12 months
  - Provide max. 150 bio (feedback@tmfrefmodel.com)
  - Extended deadline 15th November for self nomination
Change Control Board

- 15 members – no additional members needed
- Inaugural meeting held!
- Kelly Robinson, Pfizer: Chair
- Joanne Malia, Regeneron: Deputy Chair
- Gift Chareka, UCSF: Exchange Team Liaison
- Eldin Rammell: Steering Committee Liaison

- Hoping to triage change requests (61 received so far!) to Zone Teams shortly
- Submit requests here: https://tmfrefmodel.com/feedback/
Zone Teams

- Thanks to volunteers!
- Still need members for:
  - Zone 3, Zone 4, Zone 6, Zone 7, Zone 8, Zone 9, Zone 10, Zone 11
  - .... but especially zones 6 and 11 !!
Document & Records Management Community

**Scope**

- Assess and respond to document management & records management developments that impact management of our content, including:
  - technological development
  - regulatory development
  - operational development
- Covers all the GxPs (and none) and not specific to any Reference Model
- Includes support for the ongoing Reference Model teams
Build on the success of the Reference Models
Encourage wide participation on workstreams
Suggested workstreams:
- Data protection
- Electronic signatures best practice
- Good documentation practice
- Periodic literature reviews
Modus operandi
Other suggestions?
Framework for the Destruction of Paper

- Renewed interest in the framework from:
  - Impact of revised guidance on ‘certified copies’ (ICH E6(R2)
  - MHRA TMF Focus Workshop
  - Industry interest in scan/destroy process

► **Workstream: Review & revise framework**
► **Call for volunteers!**
  • We need members to be DIA DRM Community members.
  • Through DIA, provide a comment to a discussion initiated in the a DRM Community website
  • If you have trouble with this method, contact me at MulcahyConsulting@comcast.net

► **Teams being formed now for immediate kick-off**
  • Project Management
  • Technology
  • Quality
  • Regulatory – including ‘certified copies’
  • Records Management
  • Legal

► **Link to current framework paper:**
Draft FDA Q&A on 21 CFR Part 11 for clinical investigations

[Image]

[Link](https://www.fda.gov/downloads/drugs/guidanceregulatoryinformation/guidances/ucm563785.pdf)

- Issued June 2017
- Comment period closed 60 days after publication in Federal Register
- Provides guidance to sponsors, clinical investigators, institutional review boards (IRBs), contract research organizations (CROs), and other interested parties on the use of electronic records and electronic signatures in clinical investigations
- Clarifies, updates, and expands upon recommendations in the guidance for industry Part 11, Electronic Records; Electronic Signatures – Scope and Application
Key and Interesting Points (1 of 2)

- Much of this guidance is devoted to re-examining requirements in an **outsourced cloud environment** and to addressing **mobile technology**
- **Risk based approach** based on nature of system and whether they integrate with other systems
  - Including heavy reliance on vendor documents
  - Change control and re-validation
- No discussion of requiring digital signature in the guidance, even though it is acknowledged that cloud is an “open” system
- FDA still states that they requiring a **signed, dated signature** for certifying paper copies. This is not new.
“Under certain circumstances, FDA may choose to inspect the electronic service vendors”

FDA says they could require access to systems during audit

Vendor audit is not required, but should be a risk-based decision

- “Sponsors … should consider periodic, but shared audits conducted by trusted third parties.”
- Vendor audit criteria are provided.

Vendor SLAs are highly recommended and some detail given.
## Project Overview – TMF Plan Template

**Working Group Lead:** Jamie Toth  
**Co-Lead:** Lorna Patrick  
**Team Members:** See next slide

<table>
<thead>
<tr>
<th>Brief description of project &amp; objectives</th>
<th>Objective: Develop a cross-industry usable, simplistic TMF Management Plan template. Guidance provided on how to deal with variations depending on study size, phase, type.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Scope - In:</strong></td>
<td>Template to be used for studies that are Early Phase I - Phase IV, Investigational Drug and Medical Device, Biologics.</td>
</tr>
<tr>
<td><strong>Scope - Out:</strong></td>
<td>Development of an SOP: Processes already created within a given company around the TMF.</td>
</tr>
</tbody>
</table>
| **Desired deliverables**                 | • A simplistic Plan template that can be used within any company, where company specifics can be added.  
  • Guidance on Plan usage and any variations in how to adapt the Plan.                                                                                                                                   |
| **Target end date**                      | Early January 2018 – Final Draft presented at 7th TMF Summit in Orlando, FL                                                                                                                           |
| **Status**                               | • First meeting held on 31-Mar-2017; Biweekly meetings scheduled through January 2018  
  • Draft consolidated TMF Plan 15-Nov; Subgroup review 15-Nov to 15-Dec                                                                                                                                  |
## Team

<table>
<thead>
<tr>
<th>Name</th>
<th>Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deborah Castellana</td>
<td>Celgene</td>
</tr>
<tr>
<td>Elaine Berry</td>
<td>The Emmes Corporation</td>
</tr>
<tr>
<td>Etienne Hinton</td>
<td>Duke Clinical Research Institute</td>
</tr>
<tr>
<td>Jamie Toth</td>
<td>Daiichi Sankyo, Inc.</td>
</tr>
<tr>
<td>Jennifer Eberhardt</td>
<td>Shire</td>
</tr>
<tr>
<td>Brenda Brown</td>
<td>Pfizer</td>
</tr>
<tr>
<td>Lisa Mulcahy</td>
<td>Mulcahy Consulting</td>
</tr>
<tr>
<td>Marion Mays</td>
<td>PhlexGlobal</td>
</tr>
<tr>
<td>Menzi Reed</td>
<td>Pharma Consulting Group</td>
</tr>
<tr>
<td>Mike Czaplicki</td>
<td>GSK</td>
</tr>
<tr>
<td>Dina Antonacci</td>
<td>Mallinckrodt Pharmaceuticals</td>
</tr>
<tr>
<td>Marie Christine Poisson-carvajal</td>
<td>Pfizer</td>
</tr>
<tr>
<td>Anne-Mette Varney</td>
<td>Novo Nordisk</td>
</tr>
<tr>
<td>Sarah Curno</td>
<td>Hedian Records Management</td>
</tr>
<tr>
<td>Linda Hoppe</td>
<td>Veeva</td>
</tr>
<tr>
<td>Lorna Patrick</td>
<td>Quotient Clinical</td>
</tr>
<tr>
<td>Meghan Page</td>
<td>Shire</td>
</tr>
<tr>
<td>Luisa Monica</td>
<td>LMK Clinical Research Consulting</td>
</tr>
<tr>
<td>Wendy Trimboli</td>
<td>Esai</td>
</tr>
</tbody>
</table>
Draft sections created for (list below is not in order of what template will look like) - Following the MHRA GCP Guide, chapter 10 recommendations for what should be in a TMF Plan:

1. Introduction & Scope
2. Relevant Correspondence
3. TMF Index/Structure, Essential Document List
4. Paper/Wet Ink Handling
5. Approvals
6. Revisions
7. TMF Review
8. Authoritative Source for TMF and Other Sources
9. Ownership, Roles & Responsibilities
10. Training
11. Transfer
12. Retention/Destruction
13. Legal Hold
14. Archival
15. Regulatory Authority Audits/Inspections Handling
16. TMF Applicable SOPs

Consolidated template of all sections to be available in Draft for Subgroup to begin deeper review on 15–Nov–2017
Existing User Guide was created in 2015
SC approved workstream to review and create new deliverable 2016
Expected Deliverables:
◦ User Guide
◦ Implementation Guide
Current Target Timelines Status:
◦ Workstream has created drafts and reviewed in team meetings
◦ Final Drafts to SC for Input/Approval (November 2017)
◦ Final Version posted and Presentation to TMF RM Group
  • December 2017 / January 2018
# Table of Contents

1. Introduction to the TMF reference model .................................................. 4
   1.1 Goal of TMF Reference Model .......................................................... 4
   1.2 History of TMF Reference Model ....................................................... 4
   1.3 How to contribute to the TMF Reference Model ................................. 4

2. Introduction to the User Guide ..................................................................... 5
   2.1 Goal of the User Guide ....................................................................... 5

3. Structure of the TMF reference model ...................................................... 6
   3.1 Overview of the content in the model .................................................. 6
   3.2 TMF reference model zones and artifacts ......................................... 6
      3.2.1 Zones and sections .................................................................... 7
      3.2.2 Artifacts .................................................................................. 7
   3.3 How to work with the artifacts ............................................................ 8

4. How to use the TMF reference model ...................................................... 10
   4.1 Filtering ......................................................................................... 10
   4.2 Sorting ......................................................................................... 11

### 3.1 Overview of the content in the model

The content in the TMF reference model is split into five different sections. The TMF reference model itself is found on the left side. The other four tabs contain supporting information and some of this information is also included in this user guide.

The document base in the model is organized in zones, each zone is divided into sections and each section lists a number of chapters or documents.
Implementation Guide
Focused on how to implement Reference Model

4 TMF RM Implementation Process Overview

<table>
<thead>
<tr>
<th>Initiation Phase</th>
<th>TMF RM Mapping</th>
<th>TMF RM Implementation</th>
<th>Monitoring &amp; Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Business Case</td>
<td>Stakeholders</td>
<td>Pilot Study TMF RM</td>
<td>TMF QC</td>
</tr>
<tr>
<td>Preparation/Implementation Plan</td>
<td>Requirements/Collections</td>
<td>Implementation</td>
<td>TMF Audits</td>
</tr>
<tr>
<td>Change Management</td>
<td>Scope/Timeframe/Budget</td>
<td>Study Team Training</td>
<td>Change Control</td>
</tr>
<tr>
<td>Procedures</td>
<td>TMF RM Specification</td>
<td>Meetings</td>
<td>Procedures</td>
</tr>
<tr>
<td>TMF Maintenance Model Proposal</td>
<td>Mapping</td>
<td>Mapping Documentation</td>
<td>Maintenance Procedures</td>
</tr>
<tr>
<td>Stakeholders Overview</td>
<td>Specification</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

OUTCOMES

Implementation Checklist/Best Practices:

Initiation
- Review all of the material sent out in the Background Package
- Prepare the project implementation plan/chapter and the resources required for the expected project
- Answer any questions and address any resistance
- Plan future mapping meetings/Plan mapping communication
- Identify Stakeholders

Mapping Actions
- Review the TMF RM Zones and their descriptions as captured in the TMF RM and determine if they are appropriate for the Organization
- The team should consider each Artifact or groups of Artifacts and how they have been organized in the Zones and Levels of the TMF RM
- With exception of the repeating Artifacts in the TMF RM, Artifacts should appear only once in the TMF to ensure clarity in filing procedures and accountability for placement of the content into the TMF

TRIAL MASTER FILE
REFERENCE MODEL
Exchange mechanism

• Exchange Mechanism
  • XML standard to support data transfer between eTMF systems

• Preparing for draft Specification review
  • Technology review – eTMF Vendors
  • Business review – Sponsors / CROs

• Seeking volunteers for business review
  • One hour orientation session
  • Estimated effort 4–6 hours for orientation, review, feedback
  • Join us! Exchange-Business+subscribe@tmfrefmodel.groups.io

• New to TMF RM Working Groups? Start here: https://tmfrefmodel.com/join/join-here/
## Activity Other Subgroups

<table>
<thead>
<tr>
<th>Group</th>
<th>Lead</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metadata</td>
<td>Todd Tullis</td>
</tr>
<tr>
<td>Implementation toolkit / Upgrade User Guide</td>
<td>Mike Czaplicki / Lisa Mulcahy</td>
</tr>
<tr>
<td>Sub-artifacts</td>
<td>Karin Schneider</td>
</tr>
<tr>
<td>Country specific artifacts</td>
<td>Eleanor Hewes</td>
</tr>
<tr>
<td>Single Site Structure</td>
<td>Karen McCarthy Shau</td>
</tr>
<tr>
<td>TMF Plan Template</td>
<td>Jamie Toth</td>
</tr>
<tr>
<td>Exchange Mechanism</td>
<td>Paul Fenton / Elvin Thalund</td>
</tr>
<tr>
<td>Change Control Board</td>
<td>Kelley Robinson / Joanne Malia</td>
</tr>
</tbody>
</table>
Medical Devices?

• Is there a need to update the TMF Reference Model with Device Artifacts?
Conference Summary

Co-Chairpersons:
Vittoria Sparacio & Karen Roy

- 110 Attendees
- >20 Countries represented
  - 68 Sponsor Attendees
  - 41 Companies
- 12 CRO Attendees
  - 4 Companies
- 30 Vendor / Consultant Attendees
  - 16 Companies
- 1 Site Attendee
  - 1 Company
Pre Conference Workshops:

<table>
<thead>
<tr>
<th>TITLE</th>
<th>PRESENTER</th>
</tr>
</thead>
<tbody>
<tr>
<td>WORKSHOP A</td>
<td>Review eTMF System Capabilities and needs to create a clear process and efficient system</td>
</tr>
<tr>
<td>WORKSHOP B</td>
<td>Select and implement an out-of-the box eTMF System</td>
</tr>
</tbody>
</table>

Day 1: morning sessions:

<table>
<thead>
<tr>
<th>TITLE</th>
<th>PRESENTER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Common challenges and suggested best practices from MHRA Forum</td>
<td>Chairs</td>
</tr>
<tr>
<td>Case Study: Develop &amp; roll–out a TMF Management Plan with CRO</td>
<td>Claudia Panitz, Novartis</td>
</tr>
</tbody>
</table>

Still a HOT TOPIC with lots of discussion around audit trails and certified copies...
### Day 1: morning sessions cont.:

<table>
<thead>
<tr>
<th>TITLE</th>
<th>PRESENTER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transition from TMF to eTMF: tips and tools for minimising the Pain</td>
<td>Patricia Santos-Serrao, MASTERCONTROL</td>
</tr>
</tbody>
</table>

### Day 1: afternoon sessions:

<table>
<thead>
<tr>
<th>TITLE</th>
<th>PRESENTER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ensure TMF Process Completeness</td>
<td>Wendy Koc, Gilead</td>
</tr>
<tr>
<td>PANEL: Utilise an eTMF system to monitor all aspects of TMF, Vendors, Quality, Process</td>
<td>Moderator: Jamie Toth, Daiichi-Sankyo</td>
</tr>
<tr>
<td>Managing TMFs practically with Lessons Learnt</td>
<td>Franciska Darmer, VEEVA</td>
</tr>
<tr>
<td>Address TMF Strategy Considerations for Essential Safety Documents to be Compliant with Article 57</td>
<td>Lucy Hampshire, Eli-Lilly Jennifer Maier, Alexion</td>
</tr>
</tbody>
</table>

Took us back to basics: understanding the WHY and the WHAT
## Day 2: morning sessions

<table>
<thead>
<tr>
<th>TITLE</th>
<th>PRESENTER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Case Study: Bolster eTMF System Compliance &amp; Data Quality through Metrics, Dashboards &amp; Automations</td>
<td>Timothy Rafferty, Roche</td>
</tr>
<tr>
<td>Discussion Session: Oversee an eTMF Process for a CRO run study</td>
<td>Kathie Clark, Wingspan                                          Martin Hausten, Boehringer Ingelheim</td>
</tr>
<tr>
<td>Ensure TMF System Quality through the engagement of people &amp; establishment of process &amp; Systems</td>
<td>Matthias Wittig, NNIT Switzerland</td>
</tr>
<tr>
<td>Case Study: Apply a risk-based approach to your TMF process</td>
<td>Ruth Coll, TRIZELL</td>
</tr>
</tbody>
</table>

## Day 2: afternoon sessions:

<table>
<thead>
<tr>
<th>TITLE</th>
<th>PRESENTER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Case Study: Document &amp; Content Management as part of a robust QMS.</td>
<td>Scott McCulloch, BioMarin</td>
</tr>
<tr>
<td>Understand the impact and showcase the process of documentation through TMF</td>
<td>Nancy Meyerson, Hess</td>
</tr>
<tr>
<td>PANEL: Any more burning questions?</td>
<td>Moderator:                                                      Karen Roy</td>
</tr>
</tbody>
</table>

Topical presentations; aligned with hot topics of risk assessment & Oversight of critical process
Conference Summary  コンフェランスのまとめ
Attendees from all over the World!
世界の各地からようこそ！

KyowaKirinHakko
Wingspan
Covance
DainipponSumitomo
CMIC
A2
QC
Hitachi
Bayer
ONO
INC
Mitsubishi
Pfizer
Sankyo
Daiichi
Astex
Phlexglobal
ISID
Eisai
JapanTobacco
Day 1 Morning Sessions 第1日目・午前中の発表から

- **Key Success Factors to Implement Your eTMF Strategy**
  「eTMFの実施の成功を握る要素」
  Asakawa-san and Someya-san, Chugai

- **Case Study: Refine Your Approach to Implementing a TMF Process**
  「TMFプロセスを実施するアプローチを洗練する」
  Okutani-san, Japan Tobacco
  - TMF management based on the business needs (ビジネスニーズに基づいたTMF管理)
  - Stakeholder management (関係者の巻き込み)
  - Change management (新プロセス導入) “The Phantom Menace”
  - Apply DIA TMF reference model (DIA TMF reference modelの適用)
  - Inspection readiness (e-TMF is not archive.) – 査察準備対策（e-TMFはアーカイブではない）

- **Implement Quality to Prevent Critical Findings**
  「品質の実践で監査結果を防ぐ」
  Karen, Phlexglobal
  - Inspector's View (査察官の見方)
    - Timeliness, Completeness, Sponsor's oversight evidence (適時性、完全性、スポンサーの管理監督記録)
    - Certified copies (保証された複写)
Day 1 – Afternoon Sessions 第1日目・午後の発表から

- Panel – eTMF Implementation Panel
  パネル ー eTMF実装 パネル
  - Get buy in from management and users is critical （マネジメント、ユーザーの支援を得ることが欠かせない）
  - TMF structure implementation and governance （TMF構造の実施とガバナンス）
  - Communicate effectively throughout （プロセス中、効果的なコミュニケーションを務めること）
  - It will take many more resources than planned （あらかじめ計画していたよりも資源を要すること）
  - Don’t underestimate migrations （移行を甘く見ないこと）
  - Get your processes agreed e.g. paper management （プロセスへの同意を得ること。例：紙媒体管理）
  - Use specialist support （スペシャリストの支援を得ること）
Day 1 – Afternoon Sessions  第1日目・午後の発表から

- **Develop a Plan for Migrating Your TMF Process**
  「TMFプロセス移行プランの発展」
  Kathie, Wingspan
  ◦ Migrations are not simple （移行は簡単ではない）
  ◦ CRO eTMF / paper to e / etmf to etmf / other systems （CRO eTMF/紙からeTMF/eTMF、他のシステムへ）
  ◦ Validated process required （認証済みのプロセスが必須）
  ◦ Exchange mechanism will help! （交換メカニズムが助けてくれる）

- **Manage Your TMF Effectively by Developing a TMF Structure and Execution Plan that Accounts for All Challenges and Solutions**
  「起こりゆる課題と解決法を踏まえたTMF構造と実装プランの発展によりTMFを効果的に管理する」
  Akihara–san and Inamura–san, Bayer
  ◦ TMF Reference Model （TMF参照モデル）
  ◦ Planning for an eTMF （eTMFの計画）
  ◦ Working to obtain a quality TMF （品質の高いTMFを構える姿勢）
Day 2 – Morning Sessions 第2日目・午前中の発表から

- *An Update on the Implementation of an eTMF Process in Japan*
  「日本でのTMFプロセスアップデート」
  Watanabe-san, DSP
  - Challenge of Japanese vs global implementations – have regular teleconferences（日本VSグローバル実践にあたっての課題 - 定期的に電話でのミーティング）
  - TMF structure – Add a column for JGCP documents (TMF構造 - JGCPドキュメント用にコラムを追加する)
  - Increased workload – understand how this will impact （仕事が増える - どのような影響を及ぼすのかを理解すること）

- *Case Study: Simulate Using an eTMF Plan as a CRO to Improve the Quality of the TMF Process*
  「事例: CROとしてeTMFの使用をシミュレートしTMFの品質を向上させる」
  Akimoto-san, A2 Healthcare
  - Case Study: Sponsor’s e-TMF / Own e-TMF / Global CRO’s e-TMF
    （事例: スポンサー e-TMF / 自社 e-TMF / Global CRO のe-TMF）
  - Agreement with Sponsor before study start-up （試験開始前のスポンサーとの取り決め）
  - Establish eTMF support organization（e-TMF事務局の設置）
Panel: Improve eTMF Process Quality Through Sponsor and CRO Partnerships

パネル: CRO・スポンサーとのパートナーシップを基盤にeTMFの品質向上を図る

— Sponsor’s e-TMF utilization vs CRO e-TMF utilization (Consider your development strategy and business model)
（スポンサー e-TMFの利用 vs CRO e-TMFの利用 （開発戦略とビジネスモデルを考 慮））
— Several QC steps to ensure TMF quality are designed in the process, however we still have challenges… “Communication, Collaboration, Connection”
（TMFの品質を確保するためのQCステップがプロセスの中に組み込まれているが、いまだ改善すべき点がある… ）

- Paper management – certified scanning processes （紙媒体の管理– 保証されたスキャンプロセス）
- End of study transfers – define how, and what to do with audit trails（治験終了時の移転– どのように、そして監査記録の対処法）

Day 2 – Morning Sessions 第2日目・午前中の発表から

TRIAL MASTER FILE
TMF REFERENCE MODEL
Day 2 – Afternoon Sessions 第2日目・午後の発表から

**TMF Process Quality Oversight – Metrics/Report Utilization and CRO Collaboration**

「TMFプロセス品質監督–メトリクス・帳票の利用とCROとのコラボレーション」

Matsushima-san and Yamamoto-san, Pfizer

- TMF health reflects a condition of Study health. Inspection readiness means to keep health of TMF process.
  （TMFの健全性は試験の健康状態を反映している。Inspection readinessとはTMFプロセスの健全性を保つことを意味する。）
- Utilize metrics/report to oversee TMF quality
  （TMFの品質を管理するためにメトリクス/帳票を利用）
- Review metrics at project status meeting and quality review meeting
  （プロジェクト会議、品質レビュー会議でメトリクスをレビュー）
- Use several communication pathway for collaboration (TMF newsletter, Support site, TMF governance meeting with CRO, TMF point of contact with CRO)
  （複数のコミュニケーション方法を使う(TMFニュースレター、支援サイト、CROとのガバナンス会議、CROとの専任窓口)）
Day 2 – Afternoon Sessions  第2日目・午後の発表から

- **Case Study: Globalizing eTMF Management, with the Collaborative Efforts of EU/US & JP Regions**
  「事例: 欧・米・日共同でのeTMF管理のグローバル化への取り組み」
  Wendy, Eisai
  - Case Study of Japan implementation – paper management, JGCP alignment, gaining buy-in to advantages （日本での実践事例–紙溶媒管理、JGCP体制、支援を得る事でのメリット）
  - Developed working group – 2 models – scanning vendor and CRO model （作業グループ(スキャンニングベンダーとCROモデルの2モデル)の発展）
  - Training in Japanese （日本語でのトレーニング）

- **Case Study: Establish an eTMF System Management Process to Ensure TMF Process Quality**
  「事例: eTMFシステム管理プロセスを設け、TMFプロセスの品質を保証」
  Hirai-san, Daiichi Sankyo
  - TMF management plan introduction (TMFマネジメントプランの紹介)
  - QC steps to ensure TMF completeness, timeliness and quality (partner QC, Sponsor QC, periodically TMF review by document owner)
  TMF の完全性、即時性、品質を確保するためのQCステップ（パートナーQC、スポンサーQC、ドキュメントオーナーによる定期的なTMFレビュー）
I was delighted to see so many TMF specialists together. eTMF Implementation in Japan was a significant theme, with Japan-specific mapping of J-GCP to the TMF Reference Model. Working effectively with CROs was also an important topic – great to see a few CROs attending, more next year!

Thank you for joining at 2nd TMF summit. I believe that you would take home with helpful information and hints to improve your TMF business. I look forward to meeting you at next TMF Summit in Tokyo.

Karen Roy, Phlexglobal Ltd.

Yasuko Meguro, Daiichi Sankyo Co., Ltd.
eTMF Conferences coming up

- ExL–Pharma Data Integrity & Protection for Clinical Research Summit, London, UK, December 2017
- ExL–Pharma TMF Summit, Florida, USA, January 2018
- Health Sciences Records & Archives Association Conference, Brighton, UK, April 2018 (formerly Scientific Archivists Group)
TMF RM General Meetings

- 22–Jan
- Add to your calendar NOW or download the calendar file (.ics file) when you receive the meeting notification from MailChimp
- Outlook Meeting Request no longer distributed
QUESTIONS?

Join the TMF Reference Model Yahoo! Discussion Group
https://groups.yahoo.com/neo/groups/tmfrefmodel/info

• Knowledge sharing
• Networking
• Too Much Fun!

Join the TMF Reference Model Project Team
(but be prepared to work!)
http://tmfrefmodel.com/join