Trial Master File
Reference Model

TMF Exchange Mechanism

Presentation to the TMF Reference Model Steering Committee
May 24, 2017
Content Exchange – Current Challenges
Standards are Key

- Existing data exchange standards
  - eCTD
  - CDISC

- TMF Reference Model Exchange Mechanism
  - Standardizes exchange of TMF documents
  - Based on TMF Reference Model
The Exchange Mechanism Initiative

- Objective
  - Define simple standard for eTMF content transfer.
- Technical sub-committee
  - Sponsors
  - CROs
  - Vendors
## How could it be used?

<table>
<thead>
<tr>
<th>Use Case</th>
<th>Exchange Parties</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Final eTMF transfer for archiving</strong></td>
<td>Sponsor or CRO, Archival service</td>
</tr>
<tr>
<td><strong>Interim transfer of eTMF content to central eTMF or other trial management system</strong></td>
<td>Site, CRO, Sponsor, Partner</td>
</tr>
<tr>
<td><strong>Migration of eTMF for merger or acquisition</strong></td>
<td>Sponsor or CRO, Internal systems</td>
</tr>
<tr>
<td><strong>Migration of eTMF for system upgrade or change</strong></td>
<td>Sponsor or CRO, Internal systems</td>
</tr>
<tr>
<td><strong>Long term archiving of eTMF content and metadata</strong></td>
<td>Sponsor or CRO, Archival service</td>
</tr>
</tbody>
</table>
How it works – In simple terms…

Content Export

Exchange File

XML

Study #

Process Zone

Section

Section

Artifact

Artifact

TRIAL MASTER FILE
REFERENCE MODEL
Deliverables

- Exchange XML Specifications
- Exchange XML Schema (for validation)
- User Guides
- Technical Implementation Guide
- Viewing Tool (optional)
Scope

- **Version 1**
  - Final records
  - Standard metadata

- **Versions 2+**
  - Non-standard metadata
  - Draft content or multiple files
  - Better support for translations
  - Metadata improvements
Success Factors

- Flexibility and Simplicity
- Stakeholder commitment
  - Sponsors
  - CROs
  - Vendors
  - Others
- Alignment with TMF Reference Model
- Easy to implement and maintain
Progress To-Date

- Core Team meets weekly
- Draft Specification sent to Steering Committee
- Review cycle initiated:
  - by vendors
  - by business e.g. sponsors and CROs