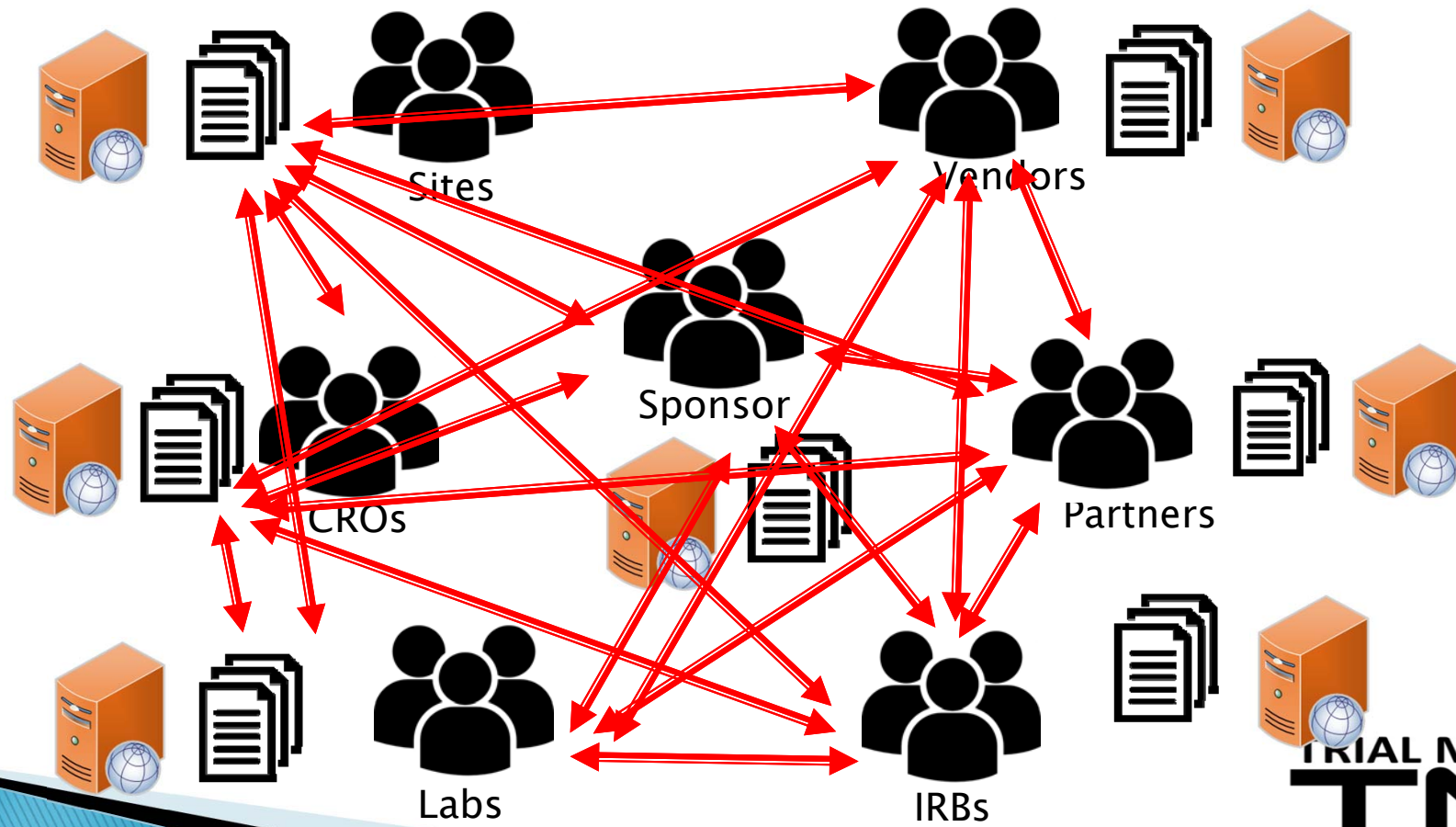# Trial Master File Reference Model

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
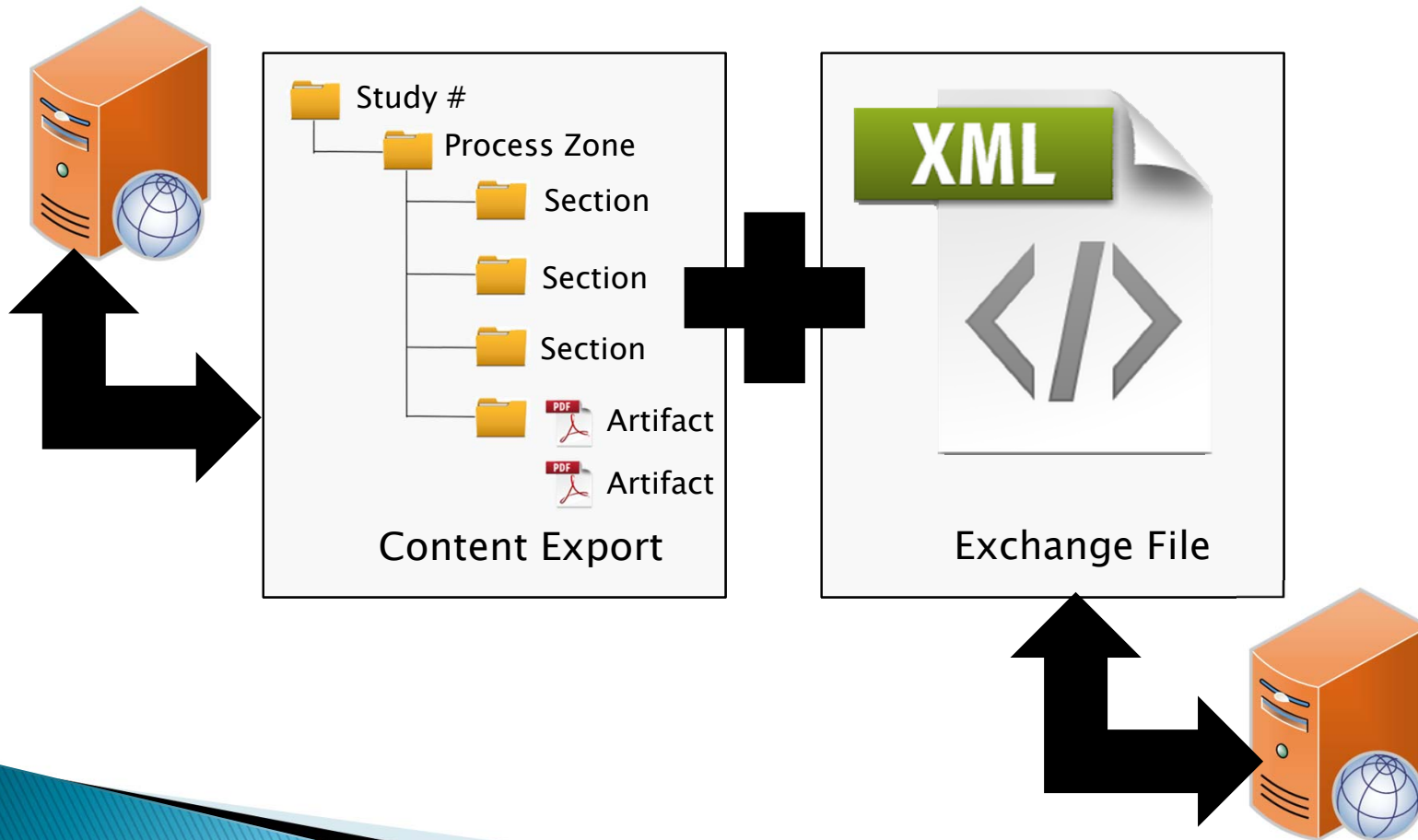 - Standardizes exchange of TMF documents
  - Based on TMF Reference Model

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TMF
REFERENCE MODEL

The Exchange Mechanism Initiative

- ## Objective
  - Define simple standard for eTMF content transfer.
- ## Technical sub-committee
  - Sponsors
  - CROs
  - Vendors

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How could it be used?

Use Case	Exchange Parties
Final eTMF transfer for archiving	Sponsor or CRO, Archival service
Interim transfer of eTMF content to central eTMF or other trial management system	Site, CRO, Sponsor, Partner
Migration of eTMF for merger or acquisition	Sponsor or CRO, Internal systems
Migration of eTMF for system upgrade or change	Sponsor or CRO, Internal systems
Long term archiving of eTMF content and metadata	Sponsor or CRO, Archival service

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How it works – In simple terms...

Study #
Process Zone
Section
Section
Section
Artifact
Artifact

Content Export

XML

Exchange File

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Deliverables

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

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Scope

- Version 1
  - Final records
  - Standard metadata
- Versions 2+
  - Non-standard metadata
  - Draft content or multiple files
  - Better support for translations
  - Metadata improvements

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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

TRIAL MASTER FILE TMF REFERENCE MODEL