Five Identities of a TMF Reference Model

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Meet the Speaker

Claudia Panitz

Title: Head of Clinical Documentation Management Capability Area

Organization: Boehringer Ingelheim

After graduating as a veterinarian, I started my career in the biopharmaceutical industry 22 years ago as a Medical Writer. My passion for projects driving digitalization efforts & re-engineering business processes in Clinical Development and Regulatory Affairs lead to varying roles from Business Analyst, Project Manager and Team Lead for Amersham Biosciences, GE Healthcare, Sandoz / Novartis, Dr Falk Pharma and Boehringer Ingelheim. In my current role as Capability Area Head for Clinical Documentation Management at Boehringer Ingelheim, my team is supporting clinical trial teams and all other TMF contributing functions to ensure inspection readiness and process efficiency for eTMF and Site Record Exchange processes.
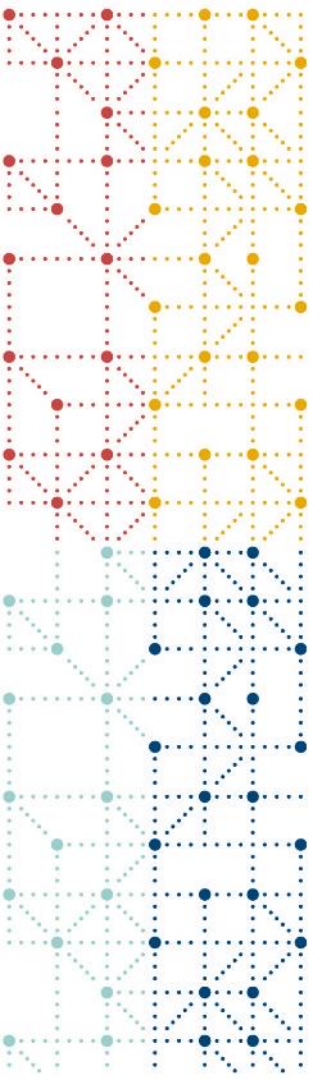
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Agenda

1. Introduction – What Does the TMF Reference Model Stand For?

2. Five "Identities" of a TMF Reference Model

3. So What - Take Away Messages

Introduction

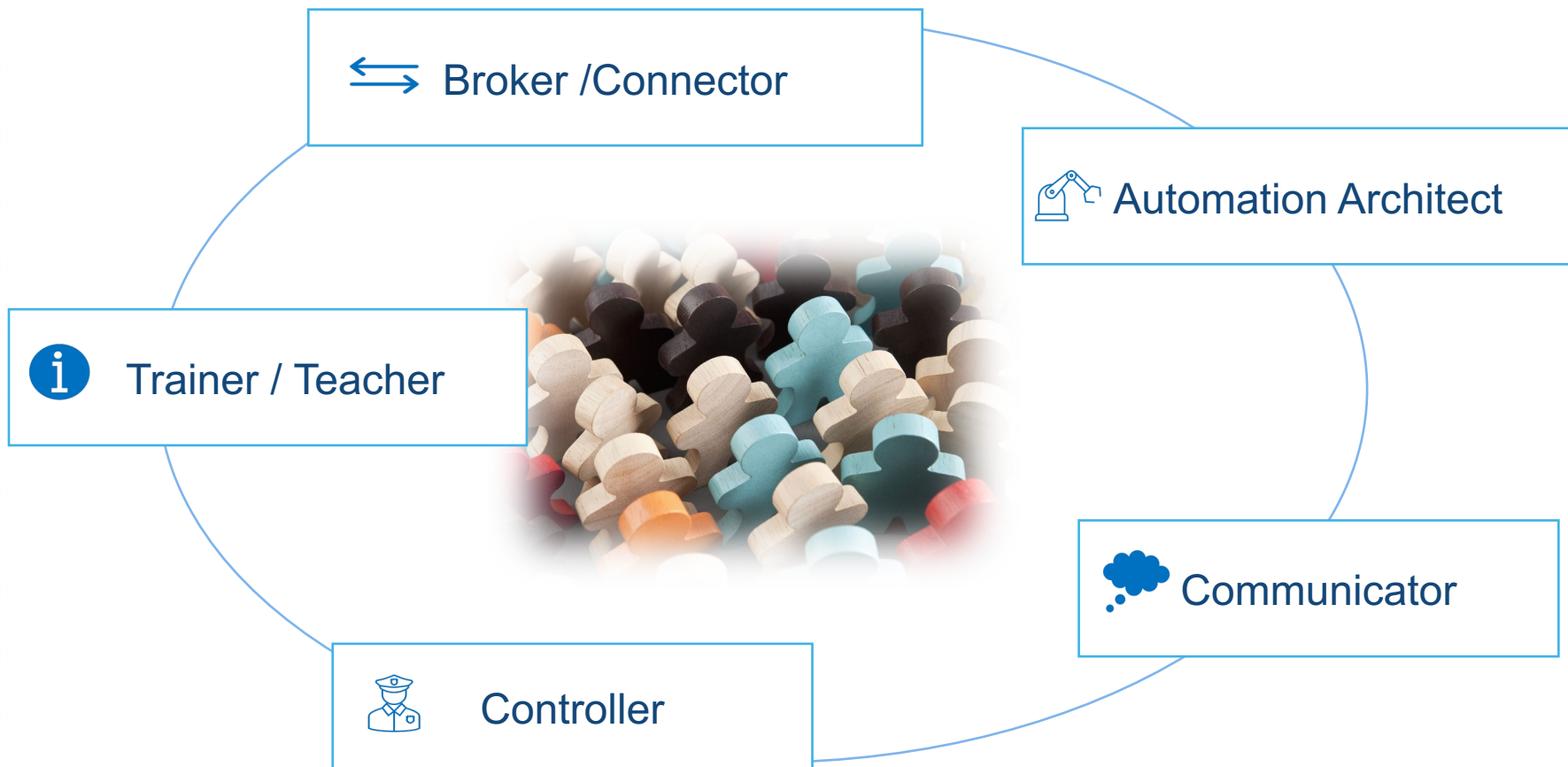What Does the TMF Reference Model Stand For?

The TMF Reference Model

o The TMF Reference Model is known for providing standardized nomenclature and structure for our TMFs, building the bridge to align with ICH requirements

o It is well adopted in the industry and is used and appreciated by Sponsors, CROs, Health Authorities and Technology Providers

o Although not defined as an enforceable standard, most users of the Reference Model would probably describe it as their foundation for standardisation, both from a business as well as a technical perspective

What else is it, or what else can it be?

If somebody asks you how you would describe the role that the TMF Reference Model plays in your organisation, what would you answer?

Five „Identities" of a TMF Reference Model

Broker /Connector

Automation Architect

Trainer / Teacher

Communicator

Controller

The 5 "Identities" of a TMF Reference Model

1. The Trainer / Teacher

2. The Controller

3. The Communicator

4. The Automation Architect

5. The Broker / Connector

The Trainer / Teacher

Structured Guidance ➤ Source of information for TMF Users

- Guidance on filing location / TMF navigation
- Guidance on artifact naming / identification of records
- Possibility to extend by additional information:
  - Pointer towards sponsor-specific artifact granularity (e.g. subartifacts, metadata points)
  - Guidance on sponsor-specific workflows (QC or Self-approval allowed, esignature requirements, etc.)
  - Additional information on filing requirements / related SOPs (e.g. in case of paper source or for generic TMF filing locations outside of core TMF system)
  - Artifact Risk Scores
  - References to Templates
  - etc.

The Trainer / Teacher

Points to Consider

❖ **Decide on General Strategy**
  - Do you allow organisational standards, e.g. terminology, granularity, or do you stick to industry standard 100%?

❖ **Consider Different Points of View**
  - Users experienced with TMF Ref Model vs „TMF beginners" have different interests
  - External vs internal users (e.g., recognize sponsor-specific additions)

❖ **Balance Amount of Information in Ref Model vs Other Procedural Documents**

The Controller

Source of Truth ➤ Governance of Many TMF Related Processes

- Ability to easily identify deviations from process
  - Location / granularity / naming of records
  - Workflows used
  - Record ownership

- Source of truth for Risk Classification of artifacts

- Milestone relationships of artifacts & completeness Tracking

- Foundation for eTMF System configuration

The Controller

Points to Consider

❖ Decide on type / nature of your TMF Reference Model document (SOP vs supportive/supplementary document)

❖ In any case – apply version-control!

❖ Manage change requests

➢ Safeguard match of eTMF system configuration & Ref Model (Config Changes vs Content Updates)

➢ Safeguard match of referenced procedural documents

The Communicator/Connector

Mandatory Element of a Trial ➡ **Exchange Inevitable**

- Dialogue with all contributing functions mandatory required to keep Reference Model up-to-date (Business Partners required)

- The more additional information is added and/or the more use cases are implemented for the Reference Model, the more dialogue is required (e.g. IT from interfacing systems, external TMF Service Groups)

The Communicator/Connector

Points to Consider

❖ „Infrastructure" to collect and process requests from contributors on an ongoing basis

❖ Regular User Forums / Business and IT Partnering

❖ Ability to distribute information on changes / updates

❖ Intuitiveness of information

– (Color-coding, function/role -specific filtering?)

– Format (Excel, eTMF system, other options)
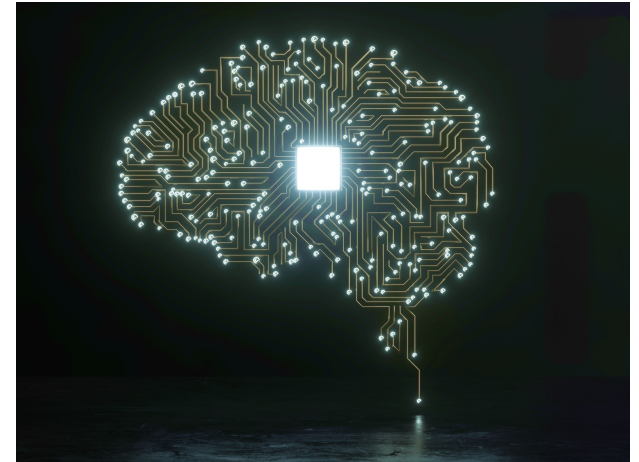
❖ Not to forget - dialogue with external parties!

The Automation Architect

Foundation for automation ➡️ **Technical Specification**

- Auto-Naming

- Milestones & event relationships

- Auto-Linking across „TMF Universe"

- Requiredness of artifacts for different levels / standards

- Reference for auto-classification
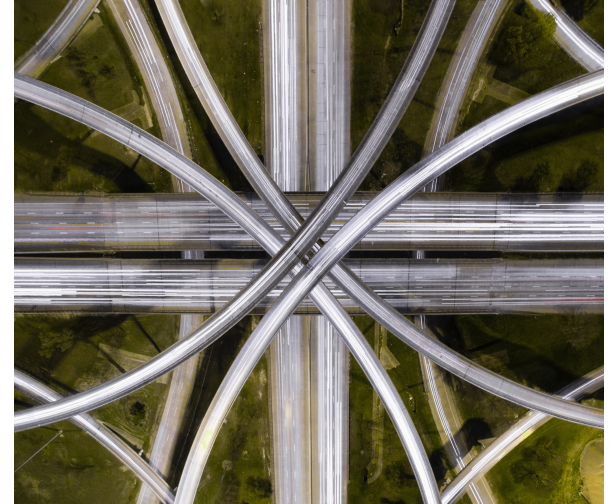
The Automation Architect

Points to consider

❖ Automation can hit limits - how „digital" is your TMF community?

❖ Data quality determines downstream automation, for example
- Milestone data
- Site staff entries
- Autonaming / correct classification

The Broker / Connector

Foundation for Exchange ➡ **We Are All in this Together**

- Foundation for TMF mapping activities
    - Sponsor System migration
    - CRO TMF to Sponsor Mapping as part of initial TMF Process Review and/ or TMF handovers
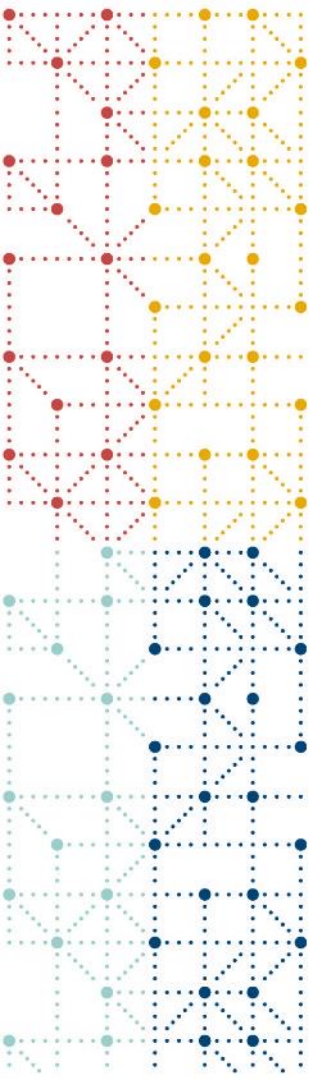- TMF Exchange Model paving the way to a seamless future

The Broker / Connector

Points to Consider

❖ Mapping activites eased due to wide adoption
  ➤ Planning of resources still to be considered

❖ Joint evolution of standard is key!
  ➤ Sponsors, Software Providers, CROs – adoption across all players is key!

So What ?

Take Away Messages

Key Take Aways

- TMF Ref Model as a "must have" has many facets in its daily use

- Overcoming complexities, raising user acceptance and ensuring adequate maintenance requires investments

- Reward will be a TMF Ref Model that is of use for many functions/processes

➢ **How many of these purposes are already fulfilled in your organization?**

➢ **Are there more?**

Thank You!