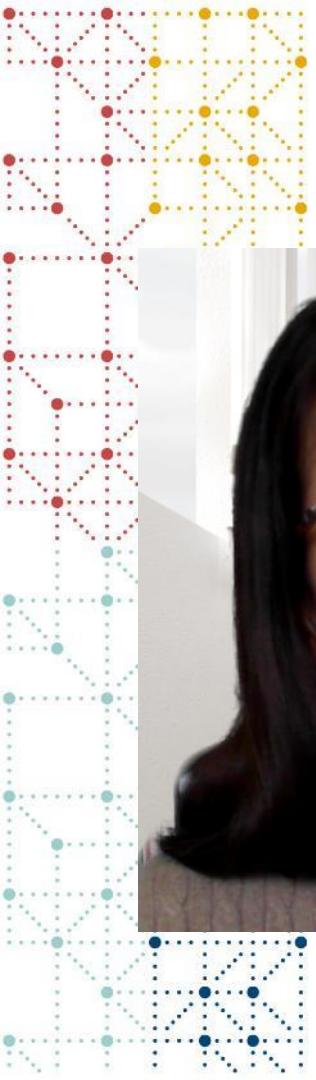




Defining TMF in the Digital Era - Balancing Essential Records Management with Modern Digital Solutions

Martina Duevel, Systems Excellence Project Leader, R&D, Bayer



Meet the Speaker

Dr. Martina Duevel

Title: Systems Excellence Project Leader

Organization: Bayer

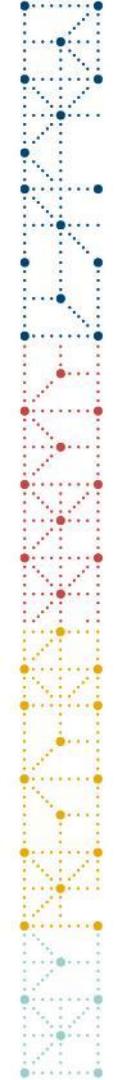
25+ years in the industry with various roles in

- Clinical quality assurance
- Clinical project management
- Process Excellence

I have led implementation of Bayer's first eTMF solution and implementation of EU-CTR at Bayer. Currently I'm co-leading the EU-CTR Focus team ensuring process optimization and smooth adaptation to changes in CTIS and requirements, managing introduction of ICH E6 R3, and leading an initiative for a holistic cross-functional TMF approach.

I'm actively supporting CDISC TMF RM and currently co-leading Workstream 3 of the Risk Initiative and being member of the V4 Triage Committee





Disclaimer and Disclosures

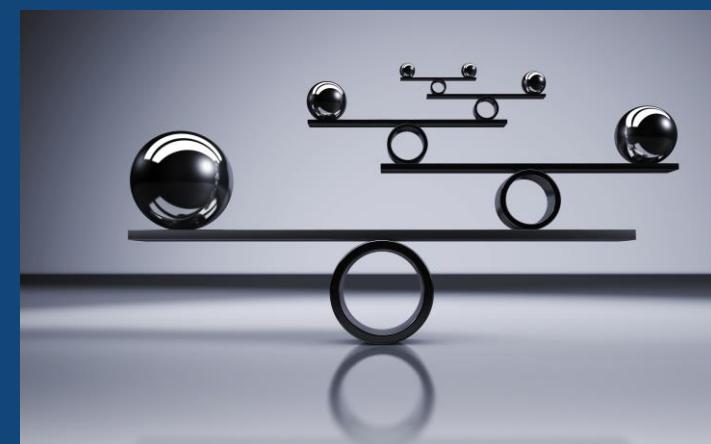
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Agenda

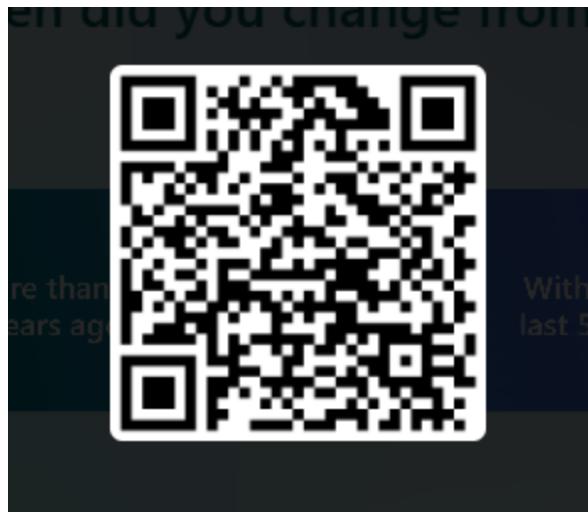
1. Defining TMF in the Digital Era
2. Regulatory Drivers
3. Impact of EU-CTR on TMF filing
4. Managing Records for Applications under EU CTR
5. Interoperability and TMF Considerations

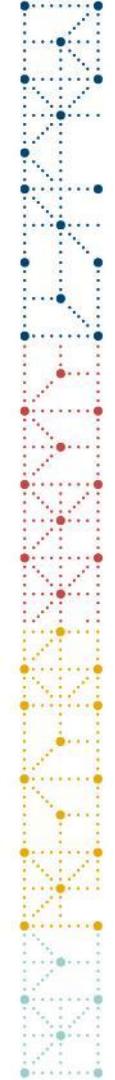
Defining TMF in the Digital Era



The evolution of TMF: from paper to digital

Interactive Quiz – Please scan the QR code





The evolution of TMF: from paper to digital

Interactive Quiz – Please scan the QR code

Why digital transformation matters now

Centralized Trial Management

Digital TMF acts as a central hub for documentation, compliance tracking, and improving trial operations.

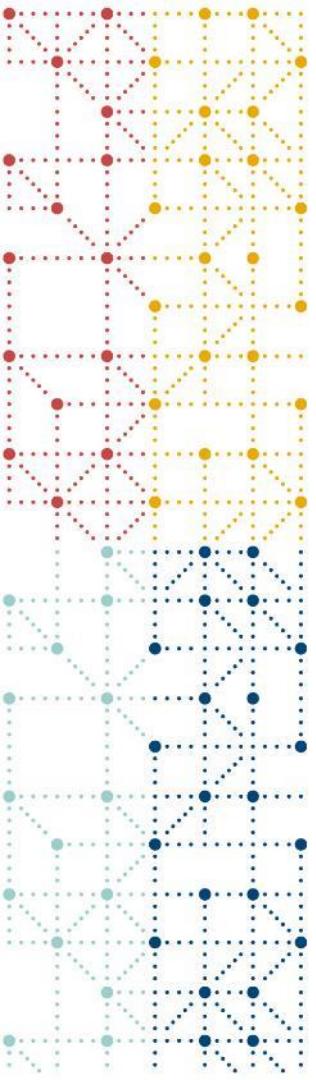
Enhanced Collaboration and Integration

Digital TMF improves collaboration, supports remote audits, and integrates with regulatory and clinical systems.

Ensuring Data Integrity and Compliance

Digitization supports data integrity, transparency, and regulatory readiness essential in clinical research.





Regulatory Drivers

EU-CTR as an Example

Key aspects of EU-CTR

Goals of EU CTR

Harmonization

Single EU submission of clinical trial applications and approval via single Clinical Trial Information System (CTIS)

Transparency

Relevant information submitted via CTIS will be made publicly available

Patient Centricity

Lay language documents required

Forms

Cover letter
Proof of payment
Compliance with Regulation
Supporting docs, e.g., for SM, withdrawal

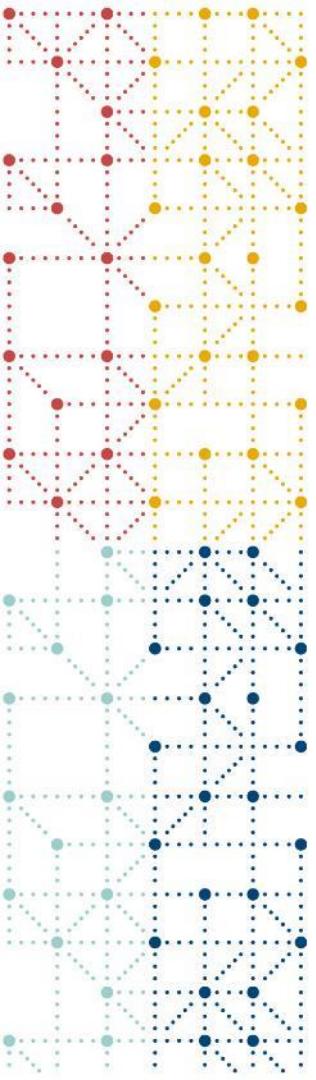
Part I
Justification of low interventional CT
Clinical Study Protocol,
Patient facing docs (end point related)
Synopsis of the Protocol
DSMC Charter
Study Design
Scientific Advice
PIP opinion
Associated CTs:
Agreement from another sponsor
IB
SmPC
GMP certificate, MIA,
IMPD Q, IMPD S&E
Content Labeling

Part II
Recruitment Arrangements
Subject information and informed consent
Suitability of the investigator
Suitability of the facilities
Proof of insurance cover or indemnification
Financial and other arrangements
Compliance with national requirements on Data Protection
Compliance with use of Biological samples

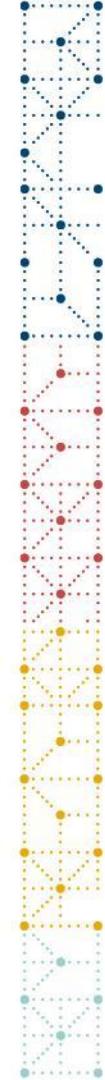
Other documents

RFI, Response to RFI
Part I and II Assessment
Decision letters
GCP inspection reports
Documents provided with corrective measures, ad hoc assessments, Union Control plans + correspond. reports
Intermediate Summary of results
Final Summary of results, Lay person summary of results
Clinical Study Report

- Green documents will never be published for any trial category
- Golden documents might be published at different timepoints depending on the trial category



Impact of EU CTR on TMF filing



Mapping of EU CTR Records for TMF Reference Model Version 4

New Records – requiring classification

- Lay language records
- Results reports
- Compliance statements

Variations of Record Types – requiring classification or guidance for handling

- Redacted versions and translations
- Regulatory submissions and approvals
- Structured data and organization registration information

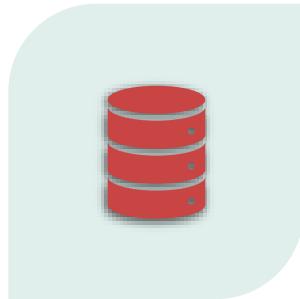
Records not applicable – requiring guidance for managing completeness of TMF

- Acknowledgement of receipt for submitted records
- Information on Ethics committees (members, voting members ...)

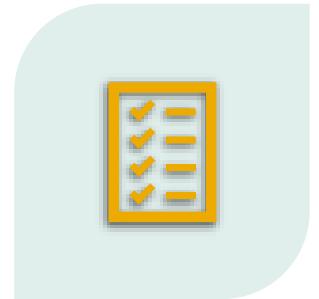
Considerations for TMF RM v4



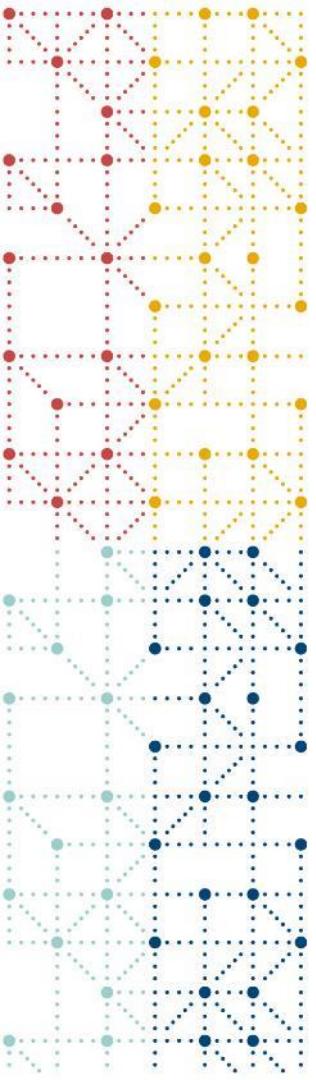
UNIQUE IDENTIFIERS
FOR RECORD TYPES



NEW RECORD TYPES
VS. METADATA



FLEXIBILITY IN
DEFINITION OF CORE
RECORDS



Managing Records for Applications under EU CTR

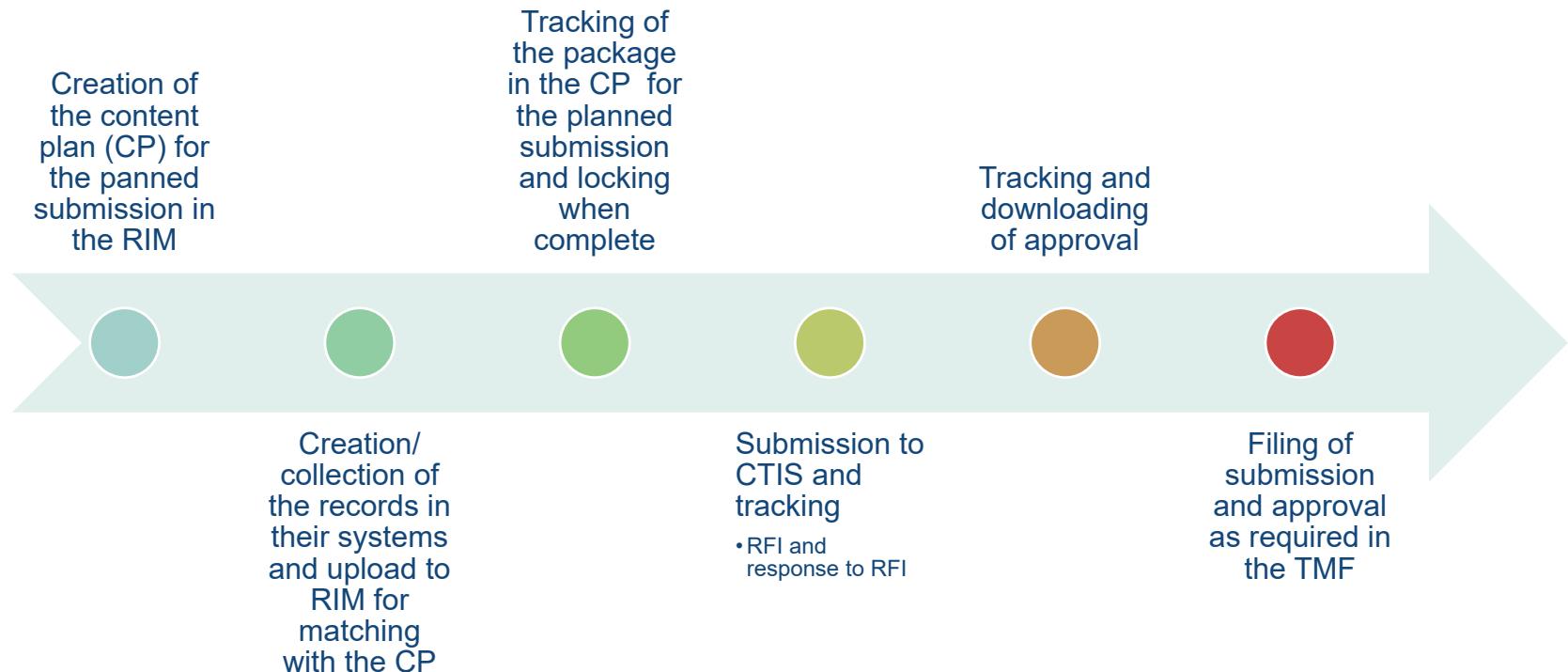
Challenges with EU-CTR submissions

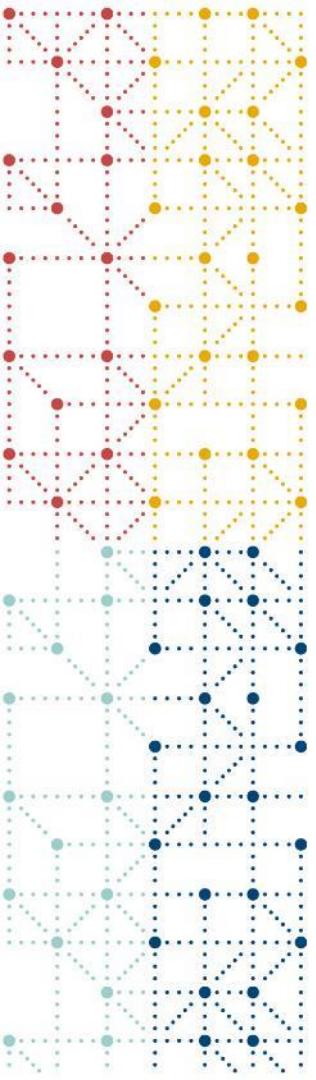
Complexity of the CTA submission packages

Dimensions of the packages	Origin of the records	Structured data
<ul style="list-style-type: none">For an initial Clinical Trial Application (CTA) under the EU Clinical Trials Regulation (EU-CTR) for a study with multiple countries and sites the number of documents required can be substantial	<ul style="list-style-type: none">Records are created/collected by various functions, can be internal or external, and hosted in a number of systems	<ul style="list-style-type: none">Coordination of collection from different functions, alignment with information in the records, must be readily available

Control of the packages is key for successful CTA application

Use of the Regulatory Information Management System (RIM) to control CTIS submissions





Interoperability and TMF Considerations

Evolution of Record Exchange / TMF Interoperability



Manual Record Exchange

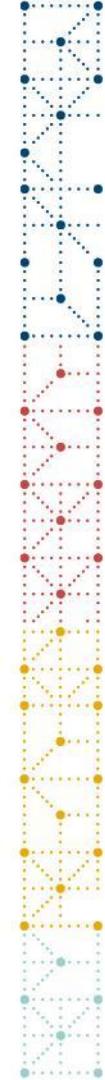
Originally, exchange of records between TMF and other systems (such as RIM) was done through manual downloading and uploading, which is time-consuming and prone to errors.

Triggered Cross-Linking

Implementation of triggered cross-linking improved record exchange by reducing errors and enabling real-time access to records between systems.

Automated Cross-Linking

Automated cross-linking eliminates manual triggers, enhances data accuracy, and increases speed, leading to higher productivity.



How Does Automated Cross-linking Relate to Version 4 of the TMF Reference Model?

Enablers for automation of cross-links and digital workflows



Unique identifiers for record types

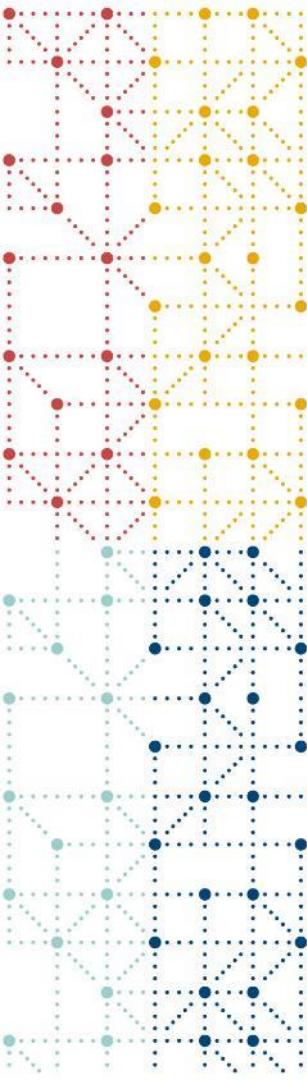


Standardized classification of records



Meta data describing the context and status of a record

Are among the key considerations for TMF RM v4



Thank You!

