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

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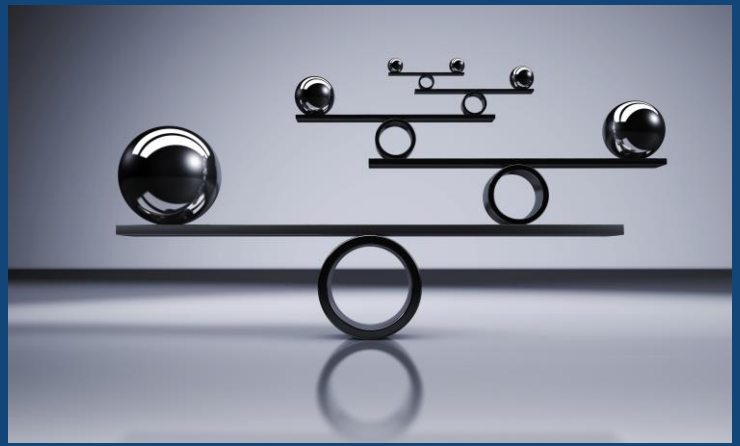
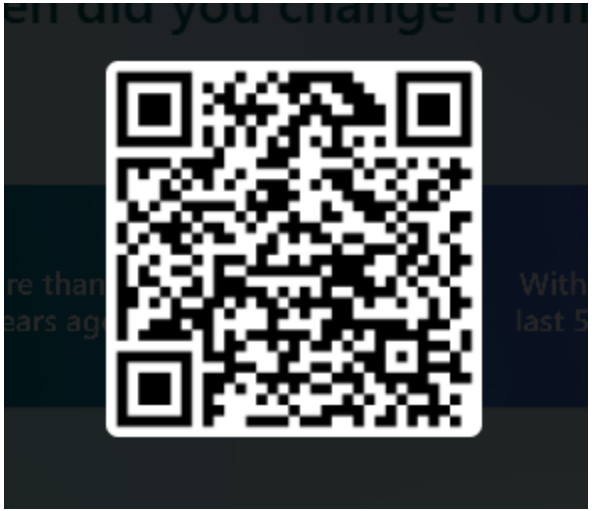
Agenda

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.

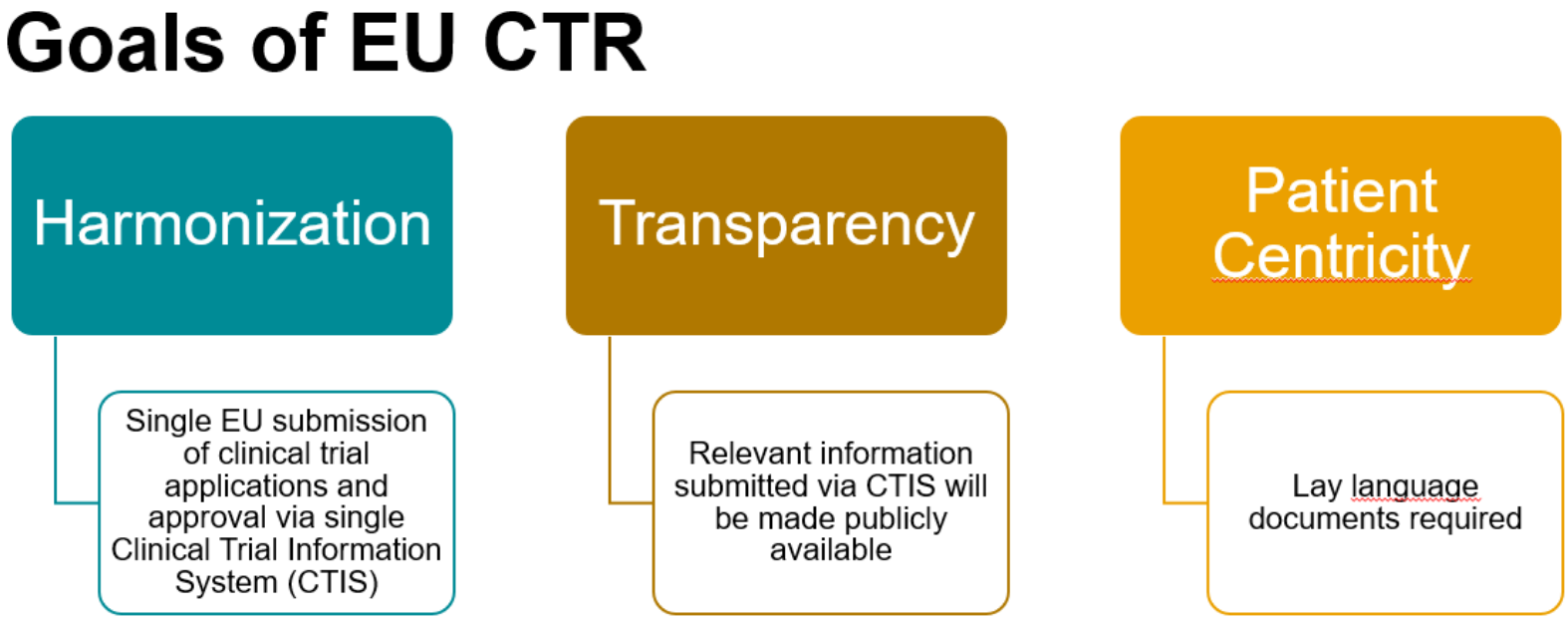
Ensuring Data Integrity and Compliance

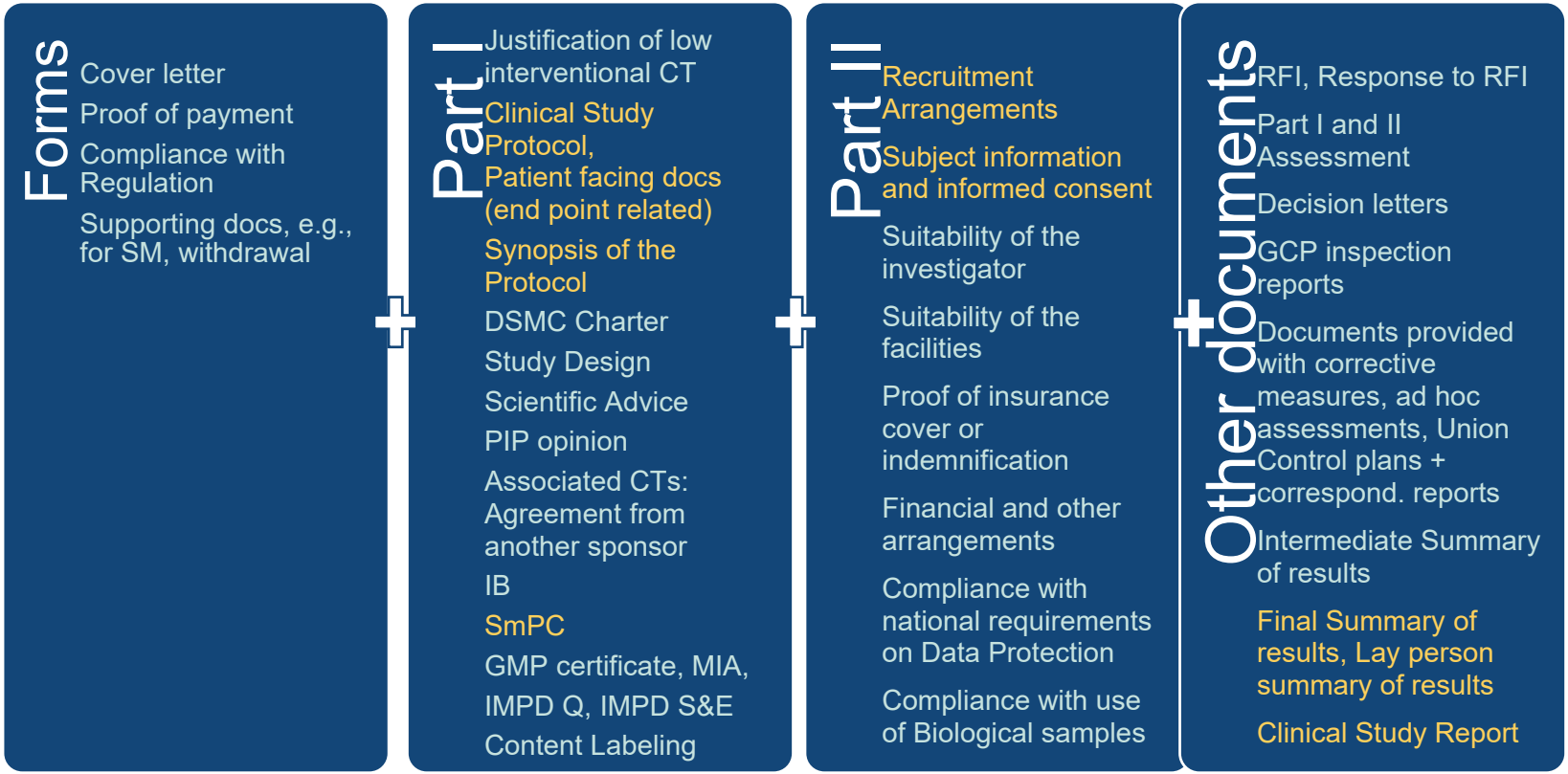
Digitazation supports data integrity, transparency, and regulatory readiness essential in clinical research.

Regulatory Drivers

EU-CTR as an Example

Key aspects of EU-CTR





- 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

- 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

Origin of the records

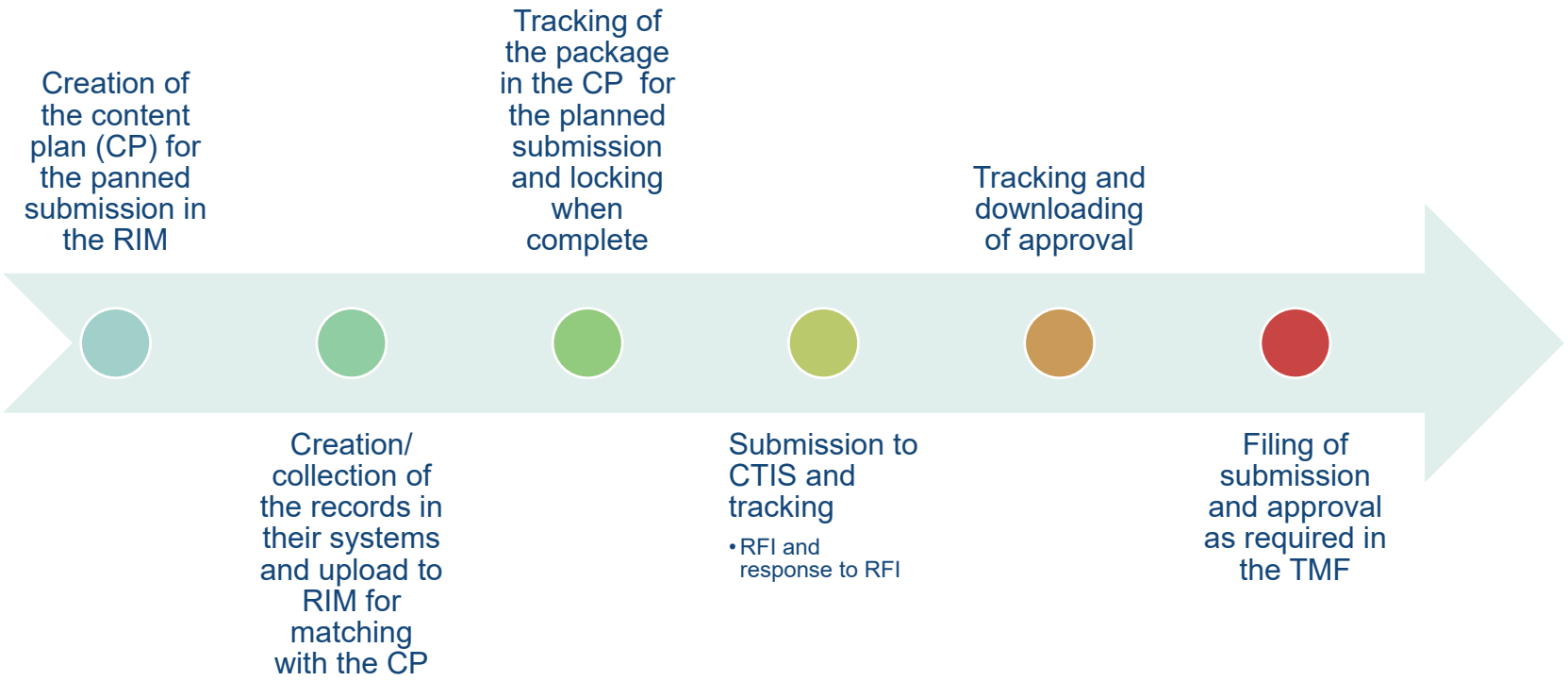
- **Records are created/ collected by various functions, can be internal or external, and hosted in a number of systems**

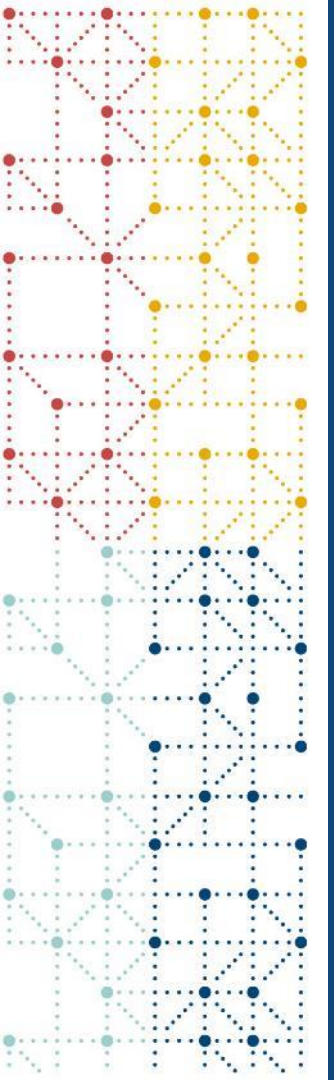
Structured data

- 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!