



cdisc® 2026 Europe Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



MILAN, ITALY | MAIN CONFERENCE: 20-21 MAY | TRAININGS & WORKSHOPS: 18, 19, & 22 MAY

Impact of EU CTR on Trial Master File (TMF) Record Management

Curran Murphy

Senior Director, Clinical Operations / Blueprint Medicines, a Sanofi Company

Speaker



Curran Murphy
Senior Director,
Clinical Operations
Blueprint Medicines,
a Sanofi Company

Curran Murphy is a Senior Director in Clinical Operations with 20+ years leading global oncology and rare disease programs. She leads Clinical Business Operations at Blueprint Medicines overseeing TMF, Clinical Systems and Process Excellence.

Agenda

1. EU CTR Sub Team Objective and Process
2. Sub Team Recommendations
3. Next Steps

Let's Paint By Number!



Learning Objectives

- Relief
 - Help Is On The Way
- Alignment
 - Solutions Today Are Probably OK
- Ah Ha Moments
 - EU CTR Record Placement Solutions
- What We Still Need To Solve
 - Business Process Issues



Our Team



Sub Team

- **Jo Oliver**
 - TMF Study Owner & IVDR TMF SME, Parexel FSP
- **Dr. Martina Duevel**
 - Systems Excellence Project Leader, Bayer
- **Curran Murphy** (Speaker)



Consulted Experts

Thank You!

- **Karla Navera-Anderson**
 - Senior eTMF Manager, Zealand Pharma
- **Preeya Beczek**
 - Regulatory Affairs & Compliance Expert, BECZEK.COM-Consulting
- **Multiple CTIS Administrators**



EU CTR Sub Team Art Project

- Perform Review Of the TMF RM against EU CTR Requirements.
 - Determine:
 - New Records?
 - Missing Records?
 - Remaining Hardships?



Log All Findings and Send to the Zone Team Experts



Resources

- EU CTR Regulation
- TMF Reference Model
- Learnings of TMF Model Direction
- ICH E6 (R3)



*“Creativity takes
Courage”*

- Henri Matisse



Our Findings

What's Missing / New / Has a Place.....

Color Missing From The Kit

TMF Artist

Help!

The canvas shows a number to fill, but the color was not supplied in the kit.....



Am I missing a required record?



= Record Type (Sub/Artifact)

Color [Record] Missing From The Kit [TMF]?



Zone	Current TMF Location	Current Record Type [Former Artifact]	EU CTR Sub Team Recommendation
3	03.01.01 Reg Submission	Receipt of Acknowledgement	Accommodate for a process issue CTIS is a system – no RESPONSE RECORD. Acknowledge evidence [example: screen shots / downloads] are acceptable
4	04.01.03 IRB or IEC Composition	IRB or EC Composition	No longer provided Acknowledge “Not Applicable for EU” is acceptable
4	04.01.04 IRB or IEC Documentation of Non-Voting Status	IRB or IEC Documentation of Non-Voting Status	

Acknowledgement In Instructions (“Definitions”) Could Solve

New Colors



*TMF Artist: I have color #112 provided in my kit but there is no corresponding number of my canvas.
Will my picture be wrong?*



I think I have a new record, but I don't know where to file them.

Recommendations For New Colors [Records]



Zone	Current TMF Reference Section	Current Record Type [Former Artifact]	NEW Record Type	EU CTR Sub Team Recommendation
2	02.01 Protocol & Trial Documentation	---	- Protocol Redacted - Protocol Amendment Redacted	NEW or Metadata Solution
2	02.01 Protocol & Trial Documentation	---	In public domain Protocol Synopsis – Layperson Version	NEW or Metadata Solution
2	02.03 Clinical Study Report	---	In public domain Summary of Results – Layperson Version	NEW or Part of the CSR
3	03.01.01 Reg Submission	---	- Recruitment Arrangements - Suitability of the Investigator - Suitability of the Facilities - Financial and/or Other Arrangements - Proof of Payment Fee - Compliance Statements (proof data processed w Data Protection) - Non-/Substantial Modification Description	NEW for Zone 3? – OR.... Part of Submission Package? – OR..... Business Record (Zone 3 or other?)
3	03.01 Reg Authority Decision	---	Submission Content Listing (used to be in Cover Letter)	NEW business record
3	03.01 Reg Authority Decision	List of Content Approved	List of Content Approved	Need Instructions in TMF Definitions (Standardize Quality of Screen Shot)

Recommendations For New Colors [Records], cont'd

*The SUBMISSION COVER LETTER issue:
Submission listing is no longer required*



*Used to list an
inventory*

Zone	Current TMF Reference Section	Current Record Type [Former Artifact]	NEW Record Type	EU CTR Sub Team Recommendation
3	03.01 Reg Authority Decision	---	Submission Content Listing	NEW business record
3	03.01 Reg Authority Decision	List of Content Approved	List of Content Approved	Need Instructions in TMF Definitions (Standardize Quality of Screen Shot)

We Have The Color To Complete The Masterpiece!



TMF Artist: I used to always use #47 Fairy Blue but now I have #47 Fata Turchina.

Are they the same color?



Do I have a new record? The names are different but a similar record.....

We May Have The Color To Finish The Masterpiece!

Zone	Reference Section	Current Record Type [Artifact and /or Sub Artifact]	New Record Type	EU CTR Sub Team Recommendation
3	03.01.01Trial Approval	[A] Regulatory Submission → [Sub-A] List of Content Submitted	---	It's Here! USE 'List of Content' for EU
		[A] Regulatory Submission	• Recruitment Arrangements • Suitability of the Investigator • Suitability of the Facilities • Financial and/or Other Arrangements • Proof of Payment Fee • Compliance Statements (proof data processed w Data Protection) • Non-/Substantial Modification Description	It's Here? Should these be distinct new record types filed individually? OR Simply List All records in the Submission Package

EU CTR Process Challenges

Zone	Topic	EU CTR Sub Team Recommendation
3 (REG) and 4 (IEC)	Part II [EC Records] now with Health Authority Records	MOVE RECORDS: EU EC to Zone 3? Need a Final Destination Decision
Any Involved	Screen Shot Evidence	Screen shot standards May be out of scope for TMF Model Update and future guidance could be considered.
3	Draft Documents Outside of CTIS System • Example: RFI Responses	Final RFI response only - adequate?
--	Archiving – CTIS is not a LT repository!	Confirming all information has been extracted from CTIS system
--	Translations	How to manage? Suggested: Meta data solution



Next Steps



- **Coming Soon**

- Contribute To TMF Model 1 Review

- **Future Considerations**

- Additional EU CTR Guidance (if needed) to supplement the TMF Model





Questions?

