



# CDISC+TMF US Interchange Trial Master File (TMF) Agenda Nashville | 13-14 October 2025



Day 1

13 October 2025

Opening Plenary Symphony Ballroom		
9:00 - 9:15	25th Anniversary and Welcome!	Jennifer Duff, NA3C Chair, Merative and Karen Roy, T3C Chair, CDISC
9:15 - 9:45	CDISC 360i and State of the Standards	Chris Decker, CDISC President and CEO, Peter Van Reusel, CDISC Chief Technology Officer, Paul Carter, Chair, Trial Master File (TMF) Reference Model Steering Committee
9:45 - 10:30	Keynote Presentation: Advancing Clinical Research Through Data and Technology	Regulatory Representative Invited
11:00 - 12:30	Session 2: TMF Plenary - The Future of TMF Chair: Jamie Toth, BeiGene	Symphony Ballroom III
11:00 - 11:15	TMF Introduction	Paul Carter, Montrium
11:15 - 11:45	Setting the Scene for Version 4	Donna Dorozinsky, Just In Time GCP
11:45 - 12:30	Digging into the Details of the TMF RM V4	TMF RM V4 Project Management Team: Gill Gittens, Transperfect; Lisa Mulcahy, Mulcahy Consulting; Kathleen Mellet, CDISC; Paul Fenton, Montrium
12:30 - 13:30	Lunch + Poster Session	Symphony Foyer & Starstruck
13:30 - 15:00	Session 3: Track D The Impact of Version 4 Chair: Dawn Niccum, InSeption	Starstruck
13:30 - 15:00	Session 3: Track E TMF Culture and Engagement Chair: Steph Viscomi, Apellis	Blackbird Studio A&B
13:30 - 14:00	The ISF Reference Model: What You Need to Know About It! Jamie Toth, BeOne; Matt Lowery, MGH	Saddling Up on the TMF Culture Trail Jared Brooslin, Intellia Therapeutics; Seth Pearl, Cencora
14:00 - 14:30	Navigating eTMF Complexity in Real-World Data Research Chris Huang and Tom Stonehouse, Oracle	The Japanese TMF Community Yuto Kanda, Chugai Pharmaceutical Co., Ltd.; Miyuki Taguchi, Inseption
14:30 - 15:00	Defining TMF in the Digital Era - Balancing Essential Records Management with Modern Digital Solutions Martina Duevel, Bayer	Panel Discussion: Why A Strong TMF First Culture Leads to a Successful Inspection Teryn Maihiot, Ultragenx • Matt Lowery, MGH • Colleen Butler, Syneos • Steph Viscomi, Apellis
15:30 - 17:00	Session 4: Track D - The Impact of Version 4 Chair: Lisa Mulcahy, Mulcahy Consulting	Starstruck
15:30 - 17:00	Session 4: Track E - Partnerships in TMF Management Chair: Colleen Butler	Syneos Health Blackbird Studio A&B
15:30 - 16:00	Computerised System Records and the TMF Nick Hargaden, CDISC	Performing TMF QC Oversight: A Sponsor's Perspective Princess Barcelona Martin, Beacon Therapeutics
16:00 - 16:30	Metadata Matters: Standardising Metadata in the TMF RM V4 Aaron Grant, CDISC	Enhancing Sponsor & External Service Provider TMF Management through Budget and Scope Alignment Niamh Smith, CSL Behring
16:30 - 17:00	Getting Ahead of the Curve: Strategic Planning for the TMF RM V4 Implementation V4 Project Management Team, CDISC	Building Smarter TMF Completeness Processes: A Framework for Better CRO and Sponsor Oversight Katherine Novak, Epista; Andrew Waite, Gilead
18:30 - 20:30	Interchange Evening Networking Event	

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## Day 2

14 October 2025

9:00 - 10:30	<b>Session 5: Track D - Risk Based Approaches</b> Chair: Sarah Hitching, Hedian Starstruck	<b>Session 5: Track E - TMF Interoperability</b> Chair: Bryan Souder, Merck Blackbird Studio A&B
9:00 - 9:30	<b>What Does a Risk Based Approach Really Mean? Summary of the TMF RM Risk Initiative</b> Joanne Malia, Regeneron	<b>Don't Fear the Audit Trail: It's Your TMF's Insightful BFF</b> Lori Braun, Mulcahy Consulting
9:30 - 10:00	<b>TMF Risk Management: Developing A Plan for Mitigating Risk Identified by the CDISC Risk Tool</b> Marion Mays, Jerion Consulting Group; Sarah Hitching, Hedian	<b>Breaking the Silos: TMF Integration Across the Trial Ecosystem</b> Ricky Lakhani, PHARMASEAL
10:00 - 10:30	<b>Redefining Risk: Leveraging Clinical Data and Critical to Quality Factors (CTQs) to Drive Compliance in the R3 Era</b> Donna Dorozinsky, Just in Time GCP	<b>Panel Discussion: The Invisible Compliance Threat - How Ancillary Systems Could Undermine Your eTMF</b> Olga Radyushkina, Epista • Jamie Toth, BeOne • Bryan Souder, Merck • Deb Wells, Novartis
10:30 - 11:00	<b>Morning Break</b>	
11:00 - 12:30	<b>Session 6: Track D - Migrations / EOS</b> Chair: Sarah Dean, Precision for Medicine Starstruck	<b>Session 6: Track E - TMF Management</b> Chair: Joanne Malia, Regeneron Blackbird Studio A&B
11:00 - 11:30	<b>The Remix: Reworking Data for Modern TMF Migrations</b> Nisi Nazim, BeOne Medicines USA, Inc.	<b>How Pfizer is Modernizing Its TMF Strategy for Efficiency and Collaboration</b> Neha Ramani, Veeva Systems, Inc.; Leila Canlas, Pfizer
11:30 - 12:00	<b>Acquisition Migrations: Weathering the Storm - The Voyage to TMF Ownership</b> Nita Whyte, Gilead Sciences, Inc; Marion Mays, Jerion Consulting	<b>From Insight to Impact: Driving Resilient and Compliant TMFs through Smarter Decision Making</b> Janice Cassamajor and Angie Gill, Cencora
12:00 - 12:30	<b>Good Practice Approaches to Retaining Essential TMF Records and Data</b> Chris Sigley, Arkivim	<b>Blueprint for A Successful TMF Rescue</b> Katie Hoover, Vital GxP Consulting LLC
12:30 - 13:30	<b>Lunch + Poster Session</b>	
12:30 - 13:30	Symphony Ballroom III	
13:30 - 15:00	<b>Session 7: TMF Plenary - The Future of TMF</b> Chair: David Ives, Novartis	
13:30 - 14:00	<b>Presentation of the CDISC TMF Reference Model Roadmap</b>	Paul Carter, Montrium
14:00 - 14:30	<b>Ted Talks: ICH E6 R3 Impact on TMF</b>	Speaker Invited
14:30 - 15:00	<b>Panel Discussion: Is AI Real in the TMF World</b>	David Ives, Novartis • Rob Jones, Cencora • Guillaume Gerard, Agatha • Eleanor Hewes, Syneos
15:00 - 15:30	<b>Afternoon Break</b>	
15:30 - 17:00	<b>Session 8: TMF Plenary - The Future of TMF</b> Chair: Paul Carter, Montrium Symphony Ballroom III	
15:30 - 16:00	<b>TMF Version 4: Who's Afraid of Becoming a Digital TMF? The Challenges and Opportunities in Moving to the Next TMF Digital Standard</b>	Jay Smith, TransPerfect
16:00 - 16:30	<b>ICH M11 - What Does this Really Mean to TMF</b>	Speaker Invited
16:30 - 17:00	<b>Panel Discussion: The Plan for Implementing Version 4</b>	Vendor Representatives Invited
17:00 - 17:10	<b>Short Break</b>	
17:10 - 17:30	<b>Session 9: CDISC &amp; TMF Closing Remarks</b> Donna Sattler, NA3C Vice-Chair & Jamie Toth, BeOne, TMF Vice-Chair Symphony Ballroom	