

# CDISC+TMF Europe Interchange Trial Master File (TMF) Agenda Geneva | 14-15 May 2025



Day 1

14 May 2025

Opening Plenary International Ballroom, Floor -2		
9:00 - 9:10	CDISC Welcome	Nick De Donder, De Donder Life Sciences; Karen Roy, CDISC
9:10 - 9:50	Keynote Presentation: Standardization and Interoperability in Rare Diseases	Dimitrios Athanasiou, World Duchenne Organization, PCWP Member European Medicines Agency
9:50 - 10:30	CDISC 360i and State of the Standards	Chris Decker, CDISC President and CEO, Peter Van Reusel, CDISC Chief Standards Officer, Paul Carter, Chair, Trial Master File (TMF) Reference Model Steering Committee
11:00 - 12:30	The Future Of TMF Chair: Paul Carter, Montrium, ET3C	Europe Ballroom, Floor -2
11:00 - 11:15	TMF Introduction	Paul Carter, CDISC
11:15 - 12:00	ICH E6 R3 and the TMF	Torsten Stemmler, Head of GCP Inspections, BfArM
12:00 - 12:30	TMF RM V4	TMF RM V4 Project Management Team: Gill Gittens, Transperfect, Lisa Mulcahy, Mulcahy Consulting, Donna Dorozinsky, Just In Time GCP
12:30 - 13:30	Lunch + Poster Session	<ul style="list-style-type: none"> <li>Unlocking Secrets of Seamless eTMF Management: Efficient Quality Control</li> <li>TMF Meetings: Hosting a Proper British Tea Party</li> <li>Advancing Trial Master File Technology: Trends, Challenges, and Practical Applications in a Quality-Driven Era</li> </ul>
13:30 - 15:30	Technology In TMF Management Chair: Anne-Nöelle Charles, GSK	Munich & Paris, Floor -2
13:30 - 15:30	TMF Culture and Engagement Chair: Joanne Malia, Regeneron	Copenhagen & Lisbonne, Floor -2
13:30 - 14:00	How to Leverage Next-Generation Tools Today to Optimize TMF Processing and Enhance Efficiency Aaron Grant and Carol Radwanski, Just in Time GCP	The Danish TMF Network Karla Navera-Andersen, Ascendis Pharma A/S
14:00 - 14:30	TMF Technology Trends: Insights from eTMF Data Jim Horstmann, Veeva Systems	Panel: Building a Unified TMF Culture Strategy: Engaging End Users, Clinical Functional Areas, and Collaborating Clinical Partners Lies Orbie, argenx, Georgiana Brahy, Parexel, Liz Farrell, Agios, Melissa De Swaef, argenx
14:30 - 15:00	Exploring the Role of TMF Metrics and KPIs in Trial Innovation - Is There a Purpose Beyond Inspection Readiness? Rob Jones, Cencora PharmaLex	Elevate Your TMF Inspection Readiness with a Focused Preparation Program Hobson Lopes, Regeneron
15:00 - 15:30	Requirements of the 2023 EMA Guideline on Clinical Systems and CSV Tab of the CDISC TMF RM Lisa Mulcahy, Mulcahy Consulting	Panel: Culture Change Driving Inspection Success Vittoria Sparacio, Novartis, Torsten Stemmler, BfArM, Hobson Lopes, Regeneron
16:00 - 17:30	Risk Based Approaches Chair: James E. Martin, Syneos Health	Munich & Paris, Floor -2
16:00 - 16:30	What Does a Risk Based Approach Really Mean? Summary of the TMF RM Risk Initiative Joanne Malia, CDISC / Regeneron	Fundamentals of TMF Chair: Vittoria Sparacio, Novartis
16:30 - 17:00	TMF Risk Management: Developing A Plan for Mitigating Risk Identified by the CDISC Risk Tool Marion Mays, CDISC / Jerion Consulting Group, Sarah Hitching, Hedian	TMF as a Foundation for Success: Streamlining Operations and Ensuring Data Integrity Laurel-Ann Schrader, TransPerfect
17:00 - 17:30	Panel: Risk Based Approaches in Line with ICH E6 R3 Karen Roy, CDISC / Epista, Torsten Stemmler, BfArM, Joanne Malia, Regeneron, Paul Carter, Montrium	The "5 Identities" of a TMF Reference Model Claudia Panitz, Boehringer Ingelheim
17:00 - 17:30		TMF Completeness - A Major Component of Inspection Ready TMF Sagar Sutar, Emmes Group
19:00 - 22:00	Interchange Evening Networking Event	



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Day 2

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9:00 - 10:30	<b>TMF Interoperability</b> Chair: Lisa Mulcahy, Mulcahy Consulting Munich & Paris, Floor -2	<b>TMF Management</b> Chair: Irina Sargsyan, Enovalife Copenhagen & Lisbonne, Floor -2
9:00 - 9:30	<b>Redefining TMF Excellence: Embedding Quality by Design through QMS Integration</b> Donatella Ballerini, Montrium	<b>TMF Management of Transition ("Rescue") Studies: Navigating Challenges and Strategies</b> Georgiana Brahy, Parexel
9:30 - 10:00	<b>Linking TMF and RIM for Submissions under EU-CTR</b> Martina Duevel, Bayer	<b>TMF Acquisition Preparation: Building Success Brick by Brick</b> Jason Weinstein, Regeneron
10:00 - 10:30	<b>Panel: TMF Interoperability from Concept to Reality?</b> Anne-Noëlle Charles, GSK, Jay Smith, TransPerfect, Jamie Toth, BeiGene, Jaime Chang, Biogen	<b>Key Considerations for Biometrics CROs Not Managing the TMF - The Journey So Far</b> Caroline Terrill, Cytel
10:30 - 11:00	<b>Morning Break</b>	
11:00 - 12:30	<b>AI in TMF Management</b> Chair: Yen Phan, elderbrook solutions Munich & Paris, Floor -2	<b>Partnerships in TMF Management</b> Chair: Martin Hausten, Boehringer Ingelheim Copenhagen & Lisbonne, Floor -2
11:00 - 11:30	<b>The Big TMF Battle: AI Versus the Geek</b> Jacki Petty and Rob Jones, Cencora Pharmalex	<b>Beyond the TMF Plan and TMF Index: Harmonizing Sponsor and CRO Expectations in Outsourced TMF Management</b> Katie Hoover, Vital GxP Consulting
11:30 - 12:00	<b>How to Quiet the TMF Noise Using AI</b> Traci Wendler, Genmab	<b>Next-Gen Security: Customizing Access Profiles for Peak Performance</b> Sofie Webers and Cristina Iannaccone, SGS Pharma Clinical Research
12:00 - 12:30	<b>Exceeding TMF Auto-Classification Accuracy Benchmarks using Generative AI</b> Nataraj Dasgupta, CodLad	<b>argenx eTMF Migration Factory - Enable Clinical Teams to Focus on Core Business Activities</b> John Blunden, NNIT & Francesco Fiorentini, argenx
13:30 - 15:30	<b>The Future of TMF</b> Chair: Jamie Toth, BeiGene Munich & Paris, Floor -2	
13:30 - 14:00	<b>An Update on the ISF RM</b>	Jamie Toth, CDISC / BeiGene Torsten Stemmler, Head of GCP Inspections, BfArM
14:00 - 14:30	<b>Digital Data Flow, ICH M11 Current State and Aligning TMF Standards Development</b>	Nick Hargaden, CDISC / Moderna Dave Iberson-Hurst, data4knowledge
14:30 - 15:00	<b>Presentation of the CDISC TMF Reference Model Roadmap</b>	Paul Carter, CDISC / Montrium
15:00 - 15:30	<b>Panel: TMF Oversight in the Digital Era</b>	Aaron Grant, CDISC / Just in Time GCP Nick Hargaden, Moderna Heather Childs, PPD Jim Horstmann, Veeva
15:30 - 16:00	<b>Afternoon Break</b>	
16:00 - 16:50	<b>Closing Plenary</b> Chair: Sujit Khune, Novo Nordisk, E3C Co-Chair Munich & Paris, Floor -2	
16:00 - 16:40	<b>Closing Keynote Presentation: Improving the Clinical Trial Environment: A New Framework from WHO</b>	Dr. Vaseeharan Sathiyamoorthy, World Health Organization
16:40 - 16:50	<b>Closing Remarks</b>	Sujit Khune, Novo Nordisk A/S, E3C; Paul Carter, Montrium, ET3C

Agenda Details: [Program](#)

Register Here: [CDISC+TMF Europe Interchange](#)