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 Fenton Carter**, Chair, Trial Master File (TMF) Reference Model Steering Committee
11:00 - 12:30	The Future Of TMF Chair: **Paul Fenton Carter,** Montrium, ET3C — Europe Ballroom, Floor -2	
11:00 - 11:15	TMF Introduction	**Paul Fenton 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	• Unlocking Secrets of Seamless eTMF Management: Efficient Quality Control • TMF Meetings: Hosting a Proper British Tea Party • Advancing Trial Master File Technology: Trends, Challenges, and Practical Applications in a Quality-Driven Era

13:30 - 15:30	Technology In TMF Management Chair: **Anne-Nöelle Charles**, GSK — Munich & Paris, Floor -2	TMF Culture and Engagement Chair: **Joanne Malia**, Regeneron — Copenhague & 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	Fundamentals of TMF Chair: Vittoria Sparacio, Novartis — Copenhague & Lisbonne, 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	TMF as a Foundation for Success: Streamlining Operations and Ensuring Data Integrity **Laurel-Ann Schrader**, TransPerfect
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	The "5 Identities" of a TMF Reference Model **Claudia Panitz**, Boehringer Ingelheim
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 Fenton Carter**, Montrium	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	**TMF Interoperability** Chair: **Lisa Mulcahy**, Mulcahy Consulting Munich & Paris, Floor -2	**TMF Management** Chair: **Irina Sargsyan**, Enovalife Copenhague & Lisbonne, Floor -2
9:00 - 9:30	Redefining TMF Excellence: Embedding Quality by Design through QMS Integration **Donatella Ballerini**, Montrium	TMF Management of Transition ("Rescue") Studies: Navigating Challenges and Strategies **Georgiana Brahy**, Parexel
9:30 - 10:00	Linking TMF and RIM for Submissions under EU-CTR **Martina Duevel**, Bayer	TMF Acquisition Preparation: Building Success Brick by Brick **Jason Weinstein**, Regeneron
10:00 - 10:30	Panel: TMF Interoperability from Concept to Reality? **Anne-Nöelle Charles**, GSK, **Jay Smith**, TransPerfect, **Jamie Toth**, BeiGene, **Jaime Chang**, Biogen	Key Considerations for Biometrics CROs Not Managing the TMF - The Journey So Far **Caroline Terrill**, Cytel
10:30 - 11:00	Morning Break	
11:00 - 12:30	**AI in TMF Management** Chair: **Yen Phan**, elderbrook solutions Munich & Paris, Floor -2	**Partnerships in TMF Management** Chair: **Martin Hausten**, Boehringer Ingelheim Copenhague & Lisbonne, Floor -2
11:00 - 11:30	The Big TMF Battle: AI Versus the Geek **Jacki Petty** and **Rob Jones**, Cencora Pharmalex	Beyond the TMF Plan and TMF Index: Harmonizing Sponsor and CRO Expectations in Outsourced TMF Management **Katie Hoover**, Vital GxP Consulting
11:30 - 12:00	How to Quiet the TMF Noise Using AI **Traci Wendler**, Genmab	Next-Gen Security: Customizing Access Profiles for Peak Performance **Sofie Webers** and **Cristina Iannaccone**, SGS Pharma Clinical Research
12:00 - 12:30	Exceeding TMF Auto-Classification Accuracy Benchmarks using Generative AI **Nataraj Dasgupta, CodLad**	argenx eTMF Migration Factory - Enable Clinical Teams to Focus on Core Business Activities **John Blunden**, NNIT & Francesco Fiorentini, argenx
13:30 - 15:30	**The Future of TMF** Chair: **Jamie Toth**, BeiGene Munich & Paris, Floor -2	
13:30 - 14:00	An Update on the ISF RM	**Jamie Toth**, CDISC / BeiGene **Torsten Stemmler**, Head of GCP Inspections, BfArM
14:00 - 14:30	Digital Data Flow, ICH M11 Current State and Aligning TMF Standards Development	**Nick Hargaden**, CDISC / Moderna **Dave Iberson-Hurst**, data4knowledge
14:30 - 15:00	Presentation of the CDISC TMF Reference Model Roadmap	**Paul Fenton Carter**, CDISC / Montrium
15:00 - 15:30	Panel: TMF Oversight in the Digital Era	**Aaron Grant**, CDISC / Just in Time GCP **Nick Hargaden**, Moderna **Heather Childs**, PPD **Jim Horstmann**, Veeva
15:30 - 16:00	Afternoon Break	
16:00 - 16:50	**Closing Plenary** Chair: **Sujit Khune**, Novo Nordisk, E3C Co-Chair Munich & Paris, Floor -2	
16:00 - 16:40	Closing Keynote Presentation: Improving the Clinical Trial Environment: A New Framework from WHO	**Dr. Vaseeharan Sathiyamoorthy**, World Health Organization
16:40 - 16:50	Closing Remarks	**Sujit Khune**, Novo Nordisk A/S, E3C; Paul Fenton Carter, Montrium, ET3C

Agenda Details: Program

Register Here: CDISC+TMF Europe Interchange