CDISC+TMF Europe Interchange Agenda

Geneva | 14-15 May 2025

Day 1

	7:00-17:00 Registration Open, Lobby | 8:00-9:00 Welcome Coffee, International Foyer, Floor -2 | 8:00-17:30 Exhibition, International Foyer, Floor -2							
9:00 - 10:30	**Session 1: Opening Plenary (All Attendees), Location: International Ballroom, Floor -2**							
9:00 - 9:10	**CDISC Welcome**							
9:10 - 9:50	**Keynote Presentation: Standardization and Interoperability in Rare Diseases, the Journey from Efficiency to Equity, the Duchenne Experience**							
9:50 - 10:30	**CDISC 360i and State of the Standards**							
10:30 - 11:00	**Morning Break, International and Geneva Foyers, Floors -1 & -2**							
11:00 - 12:30	**Session 2, Tracks A,B, & C: The European Landscape of Clinical Research and Health Care** Location: International Ballroom, Floor -2				11:00 - 12:30	**Session 2, Tracks D & E The Future of TMF (TMF Track)** Location: Europe Ballroom, Floor -2		
11:00 - 11:20	**ICH M11**				11:00 - 11:15	**TMF Introduction**		
11:20 - 11:40	**EU Initiatives**				11:15 - 12:00	**ICH E6 R3 and the TMF**		
11:40 - 12:00	**EMA Update**				12:00 - 12:30	**TMF RM V4**		
12:00 - 12:30	**Panel Discussion**							
12:30 - 13:30	**Lunch + Poster Session | International & Geneva Foyers, Floors -1 & -2 (Poster Session in Geneva Rooms, Floor -1)**							
13:30 - 15:30	**Session 3A: Digital Data Flow** Location: Zurich, Floor -2		**Session 3B: Artificial Intelligence** Location: Londres, Floor -2		**Session 3C: Innovation Showcase** Location: New York, Floor -2 **SESSION SPONSOR** TCS TATA CONSULTANCY SERVICES	13:30 - 15:30	**Session 3D: Technology In TMF Management** Location: Munich & Paris, Floor -2 **SESSION SPONSOR** Agatha	**Session 3E: TMF Culture and Engagement** Copenhague & Lisbonne, Floor -2
13:30 - 14:00	**ICH M11, TransCelerate, CDISC & HL7 Vulcan: Making the Electronic Protocol a Reality**		**Leveraging AI to Simplify SDTM Standards and Streamline Clinical Data Management**		**Demonstration by Tata Consultancy Services**	13:30 - 14:00	**How to Leverage Next-Generation Tools Today to Optimize TMF Processing and Enhance Efficiency**	**The Danish TMF Network**
14:00 - 14:30	**Protocol to Study Live in 15 Mins. AI, USDM and BCs in Action**		**Let Robots Sort It Out: Smarter CDISC Open Rules with AI**		**CDISC Standards Implementation: Best Practices and Case Studies in Success**	14:00 - 14:30	**TMF Technology Trends: Insights from eTMF Data**	**Panel: Building a Unified TMF Culture Strategy: Engaging End Users, Clinical Functional Areas, and Collaborating Clinical Partners**
14:30 - 15:00	**Bringing the USDM Model to the Catwalk**		**The Role of Data Standardization in AI-Driven Clinical Research**		**Demonstration TBD**	14:30 - 15:00	**Exploring the Role of TMF Metrics and KPIs in Trial Innovation - Is There a Purpose Beyond Inspection Readiness?**	**Elevate Your TMF Inspection Readiness with a Focused Preparation Program**
15:00 - 15:30	**Navigating Post-Go-Live Changes in Automated Clinical Study Builds: Optimizing USDM / M11 for EDC and Beyond**		**AI for Standards Library Search**		**Demonstration TBD**	15:00 - 15:30	**Requirements of the 2023 EMA Guideline on Clinical Systems and CSV Tab of the CDISC TMF RM**	**Panel: Culture Change Driving Inspection Success**
15:30 - 16:00	**Afternoon Break, International and Geneva Foyers, Floors -1 & -2**							
16:00 - 17:30	**Session 4A: CDISC 360i** Location: Zurich, Floor -2		**Session 4B: CDISC Foundational** Location: Londres, Floor -2		**Session 4C: Academia** Location: New York, Floor -2	16:00 - 17:30	**Session 4D: Risk Based Approaches** Location: Munich & Paris, Floor -2	**Session 4E: Fundamentals of TMF** Copenhague & Lisbonne, Floor -2
16:00 - 16:30	**Breaking Down Silos with CDISC 360i: A Technical Roadmap**		**Unraveling the Complex Web of Data Relationships**		**Pioneering Efforts to Expand CDISC Standards in Japanese Academic Research**	16:00 - 16:30	**What Does a Risk Based Approach Really Mean? Summary of the TMF RM Risk Initiative**	**TMF as a Foundation for Success: Streamlining Operations and Ensuring Data Integrity**
16:30 - 17:00	**Enhanced Biomedical Concepts: A Design Perspective in OpenStudyBuilder Supporting CDISC 360i**		**Enhancing Clinical Data Quality and Consistency with Value Level Metadata for Non-CRF Data Collection**		**The Importance of CDISC Standards when Retaining, Archiving, and Preserving Clinical Trial Records and Data**	16:30 - 17:00	**TMF Risk Management: Developing A Plan for Mitigating Risk Identified by the CDISC Risk Tool**	**The "5 Identities" of a TMF Reference Model**
17:00 - 17:30	**CDISC 360i, and the Worm that Turned**		**CDISC Protocol Deviation Sub-Team SDTMIG 4.0 Updates and Open Topics**		**Mapping REDCap Data into SDTM: A Case Study of Healthy Volunteer Research Data**	17:00 - 17:30	**Panel: Risk Based Approaches in Line with ICH E6 R3**	**TMF Completeness - A Major Component of Inspection Ready TMF**
19:00 - 22:00	**Interchange Evening Networking Event, Uptown Geneva (Must Preregister to Attend)**							

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Day 2

7:00-17:00 Registration Open, Lobby | 8:00-9:00 Welcome Coffee, International Foyer, Floor -2 | 8:00-16:00 Exhibition, International Foyer, Floor -2

	Session 5A: CDISC Open Rules Location: Zurich, Floor -2	Session 5B: Analysis Results Standard (ARS) Location: Londres, Floor -2	Session 5C: Real World Data (RWD) Location: New York, Floor -2	Session 5D: TMF Interoperability Location: Munich & Paris, Floor -2	Session 5E: TMF Management Location: Copenhague & Lisbonne, Floor -2
9:00 - 9:30	Utilizing CDISC CORE Validation Tools: Validating Clinical Submission Domains from SAS	ARS/eTFL Portal Presentation	Bridging the Standards: Standardized Mapping and Lineage	Redefining TMF Excellence: Embedding Quality by Design through QMS Integration	TMF Management of Transition ("Rescue") Studies: Navigating Challenges and Strategies
9:30 - 10:00	From Silos to Synergy: Uniting Forces for a Successful CDISC Open Rules Implementation	Analysis Results Standard for Test-Driven Development	The Curious Case of External Controlled Arms (ECA): Practical Solutions for External and RWD Integration	Linking TMF and RIM for Submissions under EU-CTR	TMF Acquisition Preparation: Building Success Brick by Brick
10:00 - 10:30	FDA Business Rules and CDISC Open Rules, the Road to Adoption	ARS Implementation Journey & Benefits	International Patient Summary for Research (IPS+R): New Priority Data Category in the EHDS	Panel Discussion: TMF Interoperability from Concept to Reality?	Key Considerations for Biometrics CROs Not Managing the TMF - The Journey So Far
10:30 - 11:00	**Morning Break, International and Geneva Foyers, Floors -1 & -2**				
	Session 6A: Regulatory Submissions Location: Zurich, Floor -2	**Session 6B: Standards in Action** Location: Londres, Floor -2	**Session 6C: ADaM** Location: New York, Floor -2	**Session 6D: AI in TMF Management** SESSION SPONSOR cencora PharmaLex Location: Munich & Paris, Floor -2	**Session 6E: Partnerships in TMF Management** Location: Copenhague & Lisbonne, Floor -2
11:00 - 11:30	Collaborating on Standards: An Approach to Harmonizing Vaccine Regulatory submissions	AstraZeneca Standard Output Library (AZSOL): Driving Excellence in Standardization and Automation for Tables, Figures, and Listings (TFLs)	Estimands in ADaM: Overcoming Challenges of Multiple Estimands and Intercurrent Events	The Big TMF Battle: AI Versus the Geek	Beyond the TMF Plan and TMF Index: Harmonizing Sponsor and CRO Expectations in Outsourced TMF Management
11:30 - 12:00	CDISC-Compliant ISS Submission: A Use Case	Best Practices for Efficient CDISC-Compliant PK NCA	Rethinking ADaM Specs: Efficient Creation of High-Quality ADaM Datasets and Metadata Without Predefined Specifications	How to Quiet the TMF Noise Using AI	Next-Gen Security: Customizing Access Profiles for Peak Performance
12:00 - 12:30	Implementation of RTOR Standards at AstraZeneca	Fitting Multi-Omics Data into SDTM	Enhancing PK Data standardization: Insights from ADaM IG for Non-Compartmental Analysis	Panel on AI in TMF	argenx eTMF Migration Factory - Enable Clinical Teams to Focus on Core Business Activities
12:30 - 13:30	**Lunch, International and Geneva Foyers, Floors -1 & -2**				
	Session 7, Track A & B: AC/BC - Highway to Automation Zurich & Londres, Floor -2		**Session 7C: Applied Standards Governance** New York, Floor -2	**Session 7D+E: The Future of TMF (TMF Track)** Chair: Jamie Toth, BeiGene Europe Ballroom, Floor -2	
13:30 - 13:50	Enhancing Clinical Research Efficiency: Leveraging CDISC Biomedical Concepts for Automation		13:30 - 14:00 Library Navigator: A Novel Approach to Standard Library Presentation in Clinical Trials Using Define.xml	13:30 - 14:00 An Update on the ISF RM	
13:50 - 14:10	AI-Powered Discovery of Biomedical Concepts		14:00 - 14:30 User-Centric Data Standards Browser - From Concept to Reality	14:00 - 14:30 Presentation of the CDISC TMF Reference Model Roadmap	
14:10 - 14:30	Analysis Concepts definition – Initial perspectives from the CDISC Working Group		14:30 - 15:00 Turbocharging Operational Efficiency with 100% Standardization	14:30 - 15:00 Digital Data Flow, ICH M11 Current State and Aligning TMF Standards Development	
14:30 - 14:50	Data Concepts from Protocol to CSR, Use Cases and Progress		15:00 - 15:30 Governing the Ungovernable: Can A CRO Effectively Govern Its Standards?	15:00 - 15:30 Panel Discussion: TMF Oversight in the Digital Era	
14:50 - 15:30	Panel Discussion				
15:30 - 16:00	**Afternoon Break, International and Geneva Foyers, Floors -1 & -2**				
16:00 - 16:50	**Session 8: Closing Plenary (All Attendees) Location: International Ballroom, Floor -2**				
16:00 - 16:40	Closing Keynote Presentation: Improving the Clinical Trial Environment: A New Framework from WHO				
16:40 - 16:50	Closing Remarks				

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