DAY 1 (23 OCTOBER) 2024 US CDISC+TMF INTERCHANGE CONFERENCE AGENDA

7:00-4:30 REGISTRATION DESK (GRAND FOYER – MAIN FLOOR) | **7:30-8:30 BREAKFAST (FORUM – FLOOR -1)** | **7:30-6:15 EXHIBITION (FORUM – FLOOR -1)**

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SESSION	TIME	GENERAL SESSION (Grand Ballroom)
1›	8:30-10:00	OPENING PLENARY
	8:30-9:00	CDISC Vision: Rebuilding Our Foundation and Transforming the Standards Paradigm
	9:00-9:30	CDISC Roadmap: Focus on Realizing the Long-Term Vision
	9:30-10:00	Keynote Presentation: Unlocking the Power of Data to Modernize R&D and Improve Patient Outcomes

MORNING BREAK 10:00-10:30 (FORUM – FLOOR -1)

SESSION	TIME	CDISC GENERAL SESSION (Grand Ballroom)
2›	10:30-12:00	SESSION 2: SECOND OPENING PLENARY - REGULATORY PRESENTATIONS & ROUNDTABLE
	10:30-10:45	Project PRISM Update: Use Cases and Pilots
	10:45-11:00	Envisioning How Reviewers Could Leverage the M11 Digital Protocol in the Future
	11:00-11:15	The Role of Standardized Study Data in Efficient and Effective Drug Application Reviews
	11:15-11:30	FDA Presentation
	11:30-12:00	Panel Discussion: The Future of Regulatory Review: What Would a Dynamic and Collaborative Review from Protocol Through Submission Look Like?

SESSION	TIME	TRACK D – TMF GENERAL SESSION (Rattlers+Bouchon)
2D›	10:30-12:00	TMF VISION FOR THE FUTURE
	10:30-10:45	TMF Welcome
	10:45-12:00	Panel Discussion: A Vision for the Journey to TMF RM Version 4

LUNCH BREAK & POSTERS 12:00-1:00 (FORUM – FLOOR -1)

SESSION	TIME	TRACK A (North Ballroom)
3A›	1:00-2:30	DIGITAL PROTOCOL (PART I)
	1:00-1:30	ICH M11, TransCelerate, CDISC & HL7: Driving the Adoption of Digital Protocol
	1:30-2:00	Digital Data Flow: Achieving Protocol Digitalization and Clinical Research Interoperability through Multi-stakeholder Collaboration
	2:00-2:30	USDM in Action – From Protocol to SDTM

SESSION	TIME	TRACK B (Center Ballroom)
3B›	1:00-2:30	REAL WORLD DATA SOURCES TO CDISC
	1:00-1:30	Using the CDISC SDTM Implementation in Observational Studies and Real World Data, Document in a Postmarketing Observational RWE Study: A Case Study
	1:30-2:00	Avoiding Problems with Analysis – Best Practices when Developing an eCOA Data Transfer
	2:00-2:30	From Source to Submission: Getting the Best of Multiple Standards

SESSION	TIME	TRACK C (South Ballroom)
3C›	1:00-2:30	CDISC OPEN RULES WORKSHOP
	1:00-1:30	CDISC Open Rules Update
	1:30-2:30	CDISC Open Rules Workshop

SESSION	TIME	TRACK D – TMF (Rattlers)
3D› Session Sponsor cencora PharmaLex	1:00-2:30	TMF ESSENTIALS
	1:00-1:30	Introduction to the TMF Reference Model and TMF Plan
	1:30-2:00	Press Start: Initiating Your TMF Set-Up Adventure
	2:00-2:30	Navigating Change Resistance: Understanding Resistor Profiles and Strategies for Effective Change Management

SESSION	TIME	TRACK E – TMF (Bouchon)
3D› Session Sponsor Just in Time GCP	1:00-2:30	THE IMPACT OF REGULATIONS (TMF)
	1:00-1:30	The Requirements of the 2023 EMA Guideline on Clinical Systems and the CSV Tab of the CDISC TMF RM
	1:30-2:00	The EU CTR and its Impact on the TMF
	2:00-2:30	Unveiling the Secrets of eTMF Audit Trail Review

AFTERNOON BREAK 2:30-3:00 (FORUM – FLOOR -1)

SESSION	TIME	TRACK A (North Ballroom)
4A›	3:00-4:30	DIGITAL PROTOCOL (PART II)
	3:00-3:30	DDF and Breaking Down the Document Barrier
	3:30-4:00	Transforming Vision into Reality: BMS Journey to Embrace the Digital Protocol
	4:00-4:30	Digital Protocol Panel Discussion

SESSION	TIME	TRACK B (Center Ballroom)
4B›	3:00-4:30	STANDARDS GOVERNANCE & MDRs
	3:00-3:30	Using a Standards Library to Support End-to-End CDISC Automation
	3:30-4:00	Advancing Clinical Data Integrity: Moderna's Integrative Approach to Metadata Compliance and Governance
	4:00-4:30	Adjudication of Events and Findings

SESSION	TIME	TRACK C (South Ballroom)
4C› Session Sponsor SGS	3:00-4:30	CDISC OPEN RULES UPDATE
	3:00-3:30	FDA Business Rules and CDISC Open Rules, the Road to Adoption
	3:30-4:00	CDISC CORE Adoption and Certification
	4:00-4:30	Bending the Rules: A Deep Dive into Custom Rule Creation with the Open Rules Project

SESSION	TIME	TRACK D - TMF (Rattlers)
4D›	3:00-4:30	RISK BASED APPROACHES
	3:00-3:30	Considerations for Risk-Based Approaches
	3:30-4:00	How to Use Current Regulations to Take TMF Risk-Based Approaches?
	4:00-4:30	Applying Quality by Design to TMF Risk Management

SESSION	TIME	TRACK E - TMF (Bouchon)
4E›	3:00-4:30	TMF MANAGEMENT THROUGH METRICS
	3:00-3:30	A Live Case Study in Using Reports to Address TMF Completion
	3:30-4:00	TMF Training Through Performance Metrics
	4:00-4:30	TMF Management through Metrics – 2024 TMF RM Survey

EVENING EVENT 4:45-6:15 (FORUM – FLOOR -1): ATTENDEES MUST REGISTER TO ATTEND

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DAY 2 (24 OCTOBER) 2024 US CDISC+TMF INTERCHANGE CONFERENCE AGENDA

7:00-5:00 REGISTRATION DESK (GRAND FOYER – MAIN FLOOR)

7:30-8:30 BREAKFAST (FORUM – FLOOR -1)

7:30-4:30 EXHIBITION (FORUM – FLOOR -1)

SESSION	TIME	TRACK A (North Ballroom)
	8:30-10:00	CONCEPTS IN PRACTICE
5A›	8:30-8:45	Concepts in Practice Presentation
	8:45-9:00	Activity Concepts in OpenStudyBuilder
	9:00-9:15	Biomedical Concept/Analysis Concept Use Case - Protocol, Collection, Analysis, Mapping
	9:15-9:30	Analysis Concepts at Roche
	9:30-10:00	Panel Discussion

SESSION	TIME	TRACK B (Center Ballroom)
	8:30-10:00	REGULATORY
5B›	8:30-8:52	ICH Initiatives: M4Q(r2)/Q12/M11 and Global Harmonization; Impacts to Regulatory Submissions
	8:52-9:14	Navigating Regulatory Compliance: Complexities Around the EU Clinical Trials Regulation
	9:14-9:36	Conventional Wisdom for Conventional Units
	9:36-9:58	Food Allergy Research with CDISC Standards

SESSION	TIME	TRACK C (South Ballroom)
	8:30-10:00	SPECIAL TOPICS/IMPLEMENTING CDISC
5C›	8:30-9:00	Advancing Clinical Trial Diversity: Beyond the Traditional Race Categories
	9:00-9:30	Status of CDISC Implementation and Outreach Activities in Japanese Academia
	9:30-10:00	ADaM Adventures in Oncology

SESSION	TIME	TRACK D - TMF (Rattlers)
	8:30-10:00	END OF STUDY CHALLENGES
5D›	8:30-9:00	Navigating GCP Record Retention: A Practical Approach
	9:00-9:30	TMF Migrations and Transfers for Mergers and Acquisitions
	9:30-10:00	Panel Discussion: Managing Study TMFs Between Sponsors and CROs: Before, During, and After TMF Delivery

SESSION	TIME	TRACK E - TMF (Bouchon)
	8:30-10:00	PARTNERSHIPS IN TMF MANAGEMENT
5E›	8:30-9:00	Managing Effective Oversight of Outsourced Studies
	9:00-9:30	A Journey to TMF Excellence Using A Risk-Based Approach
	9:30-10:00	Streamline the TMF Reference Model for Optimal Clinical Trial Document Management

MORNING BREAK 10:00-10:30 (FORUM – FLOOR -1)

SESSION	TIME	TRACK A (North Ballroom)
	10:30-12:00	*360i* - MOVING FROM PROOF OF CONCEPT TO IMPLEMENTATION
6A›	10:30-10:50	Transforming from Silos to End to End Realizing the Value of Standards
	10:50-11:10	The Past, Present, and Future of 360
	11:10-11:30	Practical Benefits of the "Enable and Automate" Strategy to Support End-to-End Automation
	11:30-12:00	Expert Panel: Industry Perspective on Delivering a 360 Vision

SESSION	TIME	TRACK B (Center Ballroom)
	10:30-12:00	CDISC FOR BEGINNERS
6B›	10:30-11:00	Practical Guidance for Successful Global Regulatory Submissions: FDA & PMDA Data Standard Reqs
	11:00-11:30	Name that ADaM Dataset Class
	11:30-12:00	SDTM as the Single Source of Clinical Data

SESSION	TIME	TRACK C (South Ballroom)
	10:30-12:00	ANALYSIS RESULTS STANDARDS - eTFL
6C›	10:30-11:00	Launching the eTFL Portal
	11:00-11:30	Driving Efficiency and Automation in TFL Generation: A Case Study of Establishing & Oncology TFL Library & Analysis Results Metadata Repository
	11:30-12:00	Lilly's Metadata-Driven Innovation Journey

SESSION	TIME	TRACK D - TMF (Rattlers)
	10:30-12:00	AUDITS AND INSPECTIONS
6D›	10:30-11:00	How to Use the TMF Index as an Auditing Tool
	11:00-11:30	TMF Sub-Repositories
	11:30-12:00	Panel Discussion: Inspections for Different Functions

SESSION	TIME	TRACK E - TMF (Bouchon)
	10:30-12:00	TMF REFERENCE MODEL BECOMING A STANDARD
6E› Session Sponsor IQVIA TECHNOLOGIES	10:30-11:00	Understanding Data Driven TMF
	11:00-11:30	TMF Interopability: The Critical Importance of Standard Integrations of Clinical Trial Management Data to Promote eTMF Health and Completeness
	11:30-12:00	Panel Discussion: TMF Standards from the Vendors Perspective

LUNCH BREAK & PRIZE DRAWING 12:00-1:00 (FORUM – FLOOR -1)

SESSION	TIME	TRACK A (North Ballroom)
	1:00-2:30	DATA SCIENCE
	1:00-1:30	Dataset-JSON Update
7A› Session Sponsor Domino	1:30-2:00	Running the CDISC Open Rules Engine (CORE) in BASE SAS
	2:00-2:30	RWD Lineage Initiative

SESSION	TIME	TRACK B (Center Ballroom)
	1:00-2:30	ENABLE & AUTOMATE
	1:00-1:30	Automatic Data Classification in Action
7B›	1:30-2:00	Applying Guidance from "Submitting Patient-Reported Outcome Data in Cancer Clinical Trials" as a Best Practice for COA Data and Analysis in Non-Cancer Studies
	2:00-2:30	Pharmaverse – Disrupting the Status Quo with Collaborative Solutions for Common Clinical Data Flow Processes

SESSION	TIME	TRACK C (South Ballroom)
	1:00-2:30	ANALYSIS RESULTS STANDARDS & eTFL HANDS-ON WORKSHOP
7C›		

SESSION	TIME	TRACK D - TMF (Rattlers & Bouchon)
	1:00-2:30	TECHNOLOGY AND INNOVATION IN TMF MANAGEMENT
	1:00-1:30	AI-Onic TMFs: A Case Study
7D›	1:30-2:00	The Interoperability Advantage: Streamline Your Clinical Trials with TMF Automation
	2:00-2:30	Brainstorming V4 Updates… Be a Part of the Future of the TMF RM

AFTERNOON BREAK 14:30-15:00 (FORUM – FLOOR -1)

SESSION	TIME	TRACK A (North Ballroom)
	3:00-4:30	AI & ML
	3:00-3:30	SDTM Transformation through Artificial Intelligence (AI) and Human in the Loop (HITL): Lessons Learnt from Abbvie Case Study
8A›	3:30-4:00	Embracing Metadata Management with Artificial Intelligence (AI)
	4:00-4:30	Harmony and Melody - The Role of Metadata Standards in Improving Machine Learning Efficiency

SESSION	TIME	TRACK B (Center Ballroom)
	3:00-4:30	Foundational Standards
	3:00-3:30	Which ADaM Data Structure Is Most Appropriate? Gray Areas in BDS and OCCDS
8B›	3:30-4:00	Advanced Approaches to Missing Data in Rare Disease Studies: Using SAS and ADaM Datasets to facilitate LOCF, MMRM, and MI Analysis
	4:00-4:30	Analyzing the Shift: From CDISC Define-XML 2.0 to 2.1

SESSION	TIME	TRACK C (South Ballroom)
	3:00-4:30	COSA
8C›	3:30-4:00	Schedule of Activities in OpenStudyBuilder
	4:00-4:30	OAK
		Admiral: An Open-Source R Package for Creating ADaM Datasets with Modularized Functions in a Readable and Easily-Constructable Manner

SESSION	TIME	TRACK D -TMF (Rattlers & Bouchon)
	3:00-4:30	INVESTIGATORS AND INSPECTORS
8D›	3:00-3:30	FDA Update on Inspections Across Sites, Sponsors and CROs
	3:30-4:00	CDISC ISF Initiative
	4:00-4:30	Panel Discussion: The Intersection between Sponsors, CROs, Vendors, and Sites

SMALL BREAK 4:30-4:45 (FORUM – FLOOR -1)

3:00-4:30 CLOSING PLENARY (North & Center Ballrooms)

4:45-5:00 Closing Remarks

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