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US Connect 2026 Event Agenda

March 22–26
Austin, Texas

phuse.global

Agenda subject to change. Correct as of December 17.

US Connect 2026

ADVANCE SESSIONS
PAVILION SESSIONS

Navigate the Agenda

Stream Codes

Analytics & Statistics **(AS)**
Artificial Intelligence, Machine Learning and Large Language Models **(ML)**
Data Handling & Engineering **(DH)**
Data Standards, Governance & Implementation **(DS)**
Data Visualisations **(DV)**
Emerging Trends & Innovation **(ET)**
Leadership **(LE)**
Open Source Technologies **(OS)**
Professional Development **(PD)**
Real-world Evidence **(RE)**
Risk-based Quality Monitoring **(RM)**
Scripts, Macros & Automation **(SM)**
Software Demonstrations **(SD)**
Submissions & Agencies **(SA)**

View the Stream descriptions *here.*

NEW Advance Sessions

With the conclusion of the PHUSE/FDA CSS, PHUSE is introducing a dedicated Working Group component at the US Connect. This enhanced format gives Working Groups a broader platform to showcase their initiatives, while offering attendees deeper insights, opportunities for active involvement, and a chance to help shape solutions.

NEW PHUSE Pavilion™

Four themed, self-curated Pavilions provide 'conferences within the conference,' each hosted by a leading organisation and designed for interactive, deeply engaging sessions. Find out more *here.*

Hands-on Workshops

Hands-on Workshops are interactive sessions which allow topics to be explored in greater detail.

Panel Discussions

A series of three engaging panel discussions will bring together leaders from across the field to share insights.

Social & Networking Events

1. **Welcome Event**
   Begin the Connect with an evening of relaxed networking – the perfect opportunity to meet new people, share ideas, and build connections from the start.

2. **Connect Monday Dinner**
   Always a night to remember, this renowned PHUSE social event gathers all attendees for an evening of celebration where they can enjoy a delicious dinner and dance the night away!

3. **Poster Session**
   Poster Presentations cover Stream topics in a visual manner and allow for a dedicated hour and a half of engaging conversation and networking directly with the presenters.

Sunday March 22

Afternoon

SUNDAY | MONDAY | TUESDAY MORNING | TUESDAY AFTERNOON | WEDNESDAY MORNING | WEDNESDAY AFTERNOON | THURSDAY

Time (EDT)		Time (EDT)
From 2:00pm	**Registration**	From 2:00pm
4:15pm–5:00pm	**Chair & Speakers Meeting** – Glass Oaks Ballroom	4:15pm–5:00pm
5:00pm–6:30pm	**Welcome Event** – Rio Grande	5:00pm–6:30pm

Monday March 23

SUNDAY | MONDAY | TUESDAY MORNING | TUESDAY AFTERNOON | WEDNESDAY MORNING | WEDNESDAY AFTERNOON | THURSDAY

Time (EDT)	Frio	San Antonio	San Macros	Sabine	Pecos	Trinity A	Trinity B	Concho	Glass Oaks Ballroom	Bluebonnet Ballroom	Time (EDT)
From 8:00am	**Exhibitor Hall Open** – Welcome Refreshments										From 8:00am
9:00am–10:30am	**Keynote Speaker** – Lynne Peeples | Grand Ballroom										9:00am–10:30am
10:30am–11:00am	**Morning Break**										10:30am–11:00am
11:00am–11:30am	**ET01: AI as Copilot: Empowering, Not Replacing, Statistical Programmers** *Spaulding Clinical*	**ML01: AI-Driven Automation of Statistical Analysis Plans: Leveraging LLMs to Transform Protocol Interpretation** *EDETEK*	**AS01: Estimand-Aligned Multiple Imputation Strategies in CNS Trials with Complex Intercurrent Events** *MMS Holdings*	**SA01: From Data to Dossier: Lessons from Cross-Company Regulatory Submissions** *Daiichi Sankyo*	**PD01: Beyond the Code: Building a Purpose-Driven Career in Clinical Research and Data Science** *Genentech*	**Panel Discussion: AI Pulse: Integration of Gen-AI in Statistical Programming Workflows**	**Hands-on Workshop: Next Generation Clinical Workflows in R & GenAI with Posit Team** posit	**SD01: CLIQ: An AI-Native Framework for Unified Clinical Trial Data Quality Assurance** *Care2Data*	**Data Transparency Pavilion** **Global Data Sharing Platforms: Aligning Frameworks, Pressures & Opportunities**	**Open Source Pavilion** **GxP Panel Discussion**	11:00am–11:30am
11:30am–12:00pm	**ET02: AI + Metadata: An Agentic Approach to Standards-Based Automation** *Veramed*	**ML02: Interactive and Instant: GenAI-Driven Creation of Clinical Trial Applications** *Appsilon*	**AS02: Framework for Incorporating Estimands within the Statistical Analysis Plan** *GENINVO*	**SA02: Breaking Free from the xpt: Exploration of Dataset-JSON as an Alternative Transport File to Regulatory Agencies** *GSK*	**PD02: Breaking into Statistical Programming: How SAS, R, Python, AI and ML Are Shaping Career Paths** *Vita Global Sciences*			**SD02: Building the Information Infrastructure Required for AI with Human in the Loop** *Verisian*			11:30am–12:00pm
12:00pm–12:30pm	**ET20: Challenges and Solutions for Generating Synthetic CDISC Data** *SAS*	**ML03: AutoProgramming: Agents Are All You Need** *AutoCheng Clinical Data Services*	**AS03: Demystifying TMLE: A Practical Approach for Clinical Data Scientists** *Phastar*	**SA03: Acquiring a Compound with Multiple Clinical Trials? Let's Get Ready for a Type C Meeting! Key Considerations for Preparing Its Regulatory Submission** *GSK*	**PD03: Becoming a Lead Programmer: Skills, Responsibilities, and Career Pathways** *UCB Biosciences*			**SD03: SDTM Navigator: An Agent-Based LLM Framework for Automated Specification and Programming** *Saama*			12:00pm–12:30pm
12:30pm–1:30pm	**Lunch Break**										12:30pm–1:30pm
1:30pm–2:00pm	**ET04: Transforming Clinical Trials: Present Innovations and Future Paths with AI and Agentic Tools** *Summit Therapeutics*	**ML32: Voice–Driven Agent–Assisted Open–Source Data Science** *Posit*	**AS04: AI-Augmented Bayesian Methods for Late-Onset Toxicity in Early-Phase Trials** *Syneos Health*	**SA04: Trends in eSub Evaluation Findings: A Twenty-Year Perspective** *Iris Statistical Computing*	**PD04: In the Room Where it Happens: A Behind-the-Scenes Peek into the Performance Evaluation Process** *Arcsine Analytics*	**AV01: Safety Analytics Advance Session:** Analysis and Displays Associated with Hepatotoxicity – Stage 1 and Stage 2 White Papers and Hepatotox Tool	**AV13: Emerging Trends & Innovation Advance Session:** Emerging Trends & Innovation	**AV03: Optimizing the Use of Data Standards Advance Session:** Building a Better MDR	**Theme: Frameworks and Readiness for Transparency** **Plain Language Meets AI: Lessons Learned at BMS and What's Next** *BMS* **Building Disclosure-Ready Submissions** *Privacy Analytics* **Complex Trials, Simple Disclosures: Streamlined Transparency of Innovative Study Designs** *MSD*	**Hands-on Workshop: Metadata-driven Automation**	1:30pm–2:00pm
2:00pm–2:30pm	**ET05: Automation vs AI: A Debate on Strategic Priorities in the Era of Data Science** *AstraZeneca*	**ML04: Validation Strategies for Agentic AI Platforms in GxP-Regulated Clinical Data Environments** *Maxis AI*	**AS05: Enhancing ISS Analyses with the Continuity-Corrected CMH Method: An SAS-Based Solution for Zero-Event Strata** *BioPier*	**SA05: Electronic Submission of Population PK Analysis Files... What's Your Modus Operandi?** *Pfizer*	**PD05: Leadership Strategies and Practical Frameworks for Statistical Programming in a Multilingual Era** *Merck*						2:00pm–2:30pm
2:30pm–3:00pm	**ET06: The AI Reckoning: Why Statistical Programmers Must Evolve Now** *Clymb Clinical*	**ML05: Performance-Driven Risk Oversight for AI Agents in Clinical Research** *Maxis AI*	**AS06: A Practical Approach to Causal Inference** *SAS*	**SA06: Submitting eCRT SDTM Data for ISS** *Takeda*	**PD06: Prompt Engineering in Gen AI: A Game Changer for the Professional Development of Statistical Programmers and Data Scientists** *ClinVia*						2:30pm–3:00pm
3:00pm–3:30pm	**ET07: DevOps for Clinical Data Science: A Leap into the Future of Clinical Analysis** *Bioforum The Data Masters*	**ML06: Teaching Small Models To Think Big: Enterprise-Ready AI Through Knowledge Distillation** *Saama*	**AS07: Is There Really Any Benefit to Stratified Randomisation in Practice?** *Boehringer Ingelheim*	**SA07: Common Issues in BIMO Clinical Site Dataset Packages** *Certara*	**PD07: Scaling Biometric Teams in Emerging Regions: Lessons from Armenia** *STATECS*						3:00pm–3:30pm
3:30pm–4:00pm	**Afternoon Break**										3:30pm–4:00pm
4:00pm–4:30pm	**ET08: SCE White Paper 2.0 – A Modernised Framework for the Next Generation of Data Analysis** *Johnson & Johnson*	**ML07: Integrating LLMs Using R Shiny for Clinical Data Review by Ensuring Data Privacy and Validity** *CIMS Global*	**AS08: Defining Time Zero: Evaluating Index Line Selection Methods in External Control Arms (ECAs)** *Bristol Myers Squibb*	**SA08: Key Guidelines, Tricks and Experiences for the PMDA and a Comparison with FDA and NMPA CDE Submissions** *Servier Pharmaceuticals*	**PD08: What Can Data Scientists Learn from Sales Professionals? Rejection, Resilience, and the Soft Skills Needed in Everyday Life on the Job** *Instem*	**Panel Discussion: From Knowledge to Harnessing Insight: Rethinking Learning, Systems, and Growth through Personal Knowledge Management**	**Hand-on Workshop: Weave a Multilingual Program Tapestry** ALTAIR	**SD04: AI Code Generator: Automating TFL Programming with ARS Metadata** *Clymb Clinical*	**Theme: Data Integrity and Public Trust** **Strategic Approaches to Patient Centricity in Data Science** *MRCT Centre* **Data Sharing Practices: Do Companies Meet their Public Obligations?** *Yale* **Panel Discussion Including AI Ethics** *Johnson & Johnson, Ben's Friends, PAIR & Yale University*	**Open Source in Pharma Connect (Block Party)**	4:00pm–4:30pm
4:30pm–5:00pm	**ET09: Next Generation QC Workflow Optimisation: Current Practices and Future Directions from the Emerging Trends & Innovation Working Group** *Vertex*	**ML08: Next-Gen Statistical Programming: AI as Your Coding Co-Pilot in R** *Johnson & Johnson*	**AS09: Across the Multiverse...Statistically Speaking** *Cytel*	**SA09: Multi-Standard Submission – Process, Learnings and Recommendations for Best Practice** *Sumptuous Data Sciences*	**PD09: Data Can't Do It Alone: The Untold Power of Soft Skills in IDMCs** *SGS Pharma Clinical Research*			**SD05: Verify: Accelerating TFL Validation and Review with AI-Enabled Workflows** *Beaconcure*			4:30pm–5:00pm
5:00pm–5:30pm	**ET26: Perspective on Enterprise AI and Posit Tooling** *Posit*	**ML09: AI-Powered Multiple-Agent Pipeline for Automating ADaM Dataset Generation** *Yesod*	**AS10: Ensuring Reliability of Medical Devices Through Statistical Oversight in the Age of AI** *Symbio*	**SA10: From Legacy to ISS/ISE: Real-World Lessons in Module 5 Submissions** *Vita Global Sciences*	**PD10: Optimising Global Team Dynamics in Statistical Programming** *Pfizer*			**SD06: Data Designer: Empowering Data Preparation, Transformation, ARD Creation and Summarisation for Insights and Decision-Making** *Sanofi*			5:00pm–5:30pm
5:30pm	**Close**										5:30pm
7:00pm–11:00pm	**Connect Dinner** – *Sponsored by Instem* | Grand Ballroom instem										7:00pm–11:00pm

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Tuesday March 24

SUNDAY | MONDAY | TUESDAY MORNING | TUESDAY AFTERNOON | WEDNESDAY MORNING | WEDNESDAY AFTERNOON | THURSDAY

Time (EDT)	Frio	San Antonio	San Macros	Sabine	Pecos	Trinity A	Trinity B	Concho	Glass Oaks Ballroom	Nueces	Bluebonnet Ballroom	Time (EDT)
8:00am–9:00am	**Exhibitor Hall Open** – Welcome Refreshments										Open Source Pavilion **Breakfast**	8:00am–9:00am
9:00am–9:30am	**RE09: You Can't Just Cut the Gordian Knot: Approaches to Real-World Data Quality** *SAS*	**ML36: Risk-Driven AI Oversight in Clinical Research: A Tiered Framework Using ISO, ICH Q9 and FMEA** *MAXIS AI*	**AS11: Applying Artificial Intelligence (AI) for Optimal Dose Selection in Oncology** *Bioforum The Data Masters*	**SA12: Development Process of the Bioresearch Monitoring (BIMO) Package and the Obstacles Successfully Addressed** *Merck*	**PD13: Stronger Together: Tech Pathways to Workforce Resilience in Pharma** *AstraZeneca*	**DH01: Ready for Next-Level SDTM and ADaM Compliance with End-to-End Processing?** *Gupta Programming*	**SM02: A Proc Compare Enhancement Macro** *Bristol Myers Squibb*	**DV01: Reduce, Reuse, R Shiny: A Framework for Building Generalised and Extensible R Shiny Applications** *Cytel*	Data Transparency Pavilion **Keynote: Data Access, Data Ownership, and Who Gets Sued When It All Goes Wrong** *Kulkarni Law Firm*		**Open Source Demonstrations**	9:00am–9:30am
9:30am–10:00am	**RE02: Supporting Clinical Trial Recruitment Using Real-World Data** *Pfizer*	**ML11: Beyond the Hype: Practical Guidance for LLM Adoption in Statistical Programming** *Bioforum The Data Masters*	**AS12: Orchestrating Multi-Agent Workflows for Complex Trial Data Integration** *Maxis AI*	**SA17: From Policy to Practice: A Compliance Checklist for EMA Policy 0070** *Certara*	**PD12: A Skeptics Guide to Using AI for Programming** *Atorus Research*	**DH02: Analysis Concepts Definition: Initial Perspectives from the CDISC Working Group** *Veramed*	**SM01: Optimising Output Review: A Targeted and Scalable RTF Validation Framework** *Navitas Life Sciences*	**DV07: Combining Trigonometry, Functions and the Polygon Plot to Create Complex Figures Not Available in SAS, Including Sankey, Sunburst and CIRCOS Charts** *Regeneron*				9:30am–10:00am
10:00am–10:30am	**RE03: Privacy Considerations of Using RWD from a Statistical Programming Perspective** *Bristol Myers Squibb*	**ML12: Utilising AI for Automated Conversion of ADaM Specifications to R Code** *GSK*	**AS13: Modernising Statistical Computing Environments: Scalable, AI-Ready and GxP-Compliant by Design** *Appsilon*	**SA13: Digital Twins for Clinical Submissions: Simulating Regulatory Review Before Submission** *Sycamore Informatics*	**PD11: The EQ Matrix: Unlocking the Human Edge in an AI World** *Cytel*	**DH03: Evolve Clinical Data Management: A Python-Based Framework for Clinical Data Transformation with Generative AI Integration** *Johnson & Johnson*	**SM03: Group, Collapse, Repeat: A Dynamic SAS Macro for Stratification Pooling in Oncology Efficacy Analysis** *Merck*	**DV05: Scaling Interactive Apps for Clinical and RWE Impact** *Domino Data Lab*				10:00am–10:30am
10:30am–11:00am	**Morning Break**											10:30am–11:00am
11:00am–11:30am	**RE04: Outcome Blinding in External Control Arm Construction Using RWD: Challenges and Best Practices** *Bristol Myers Squibb*	**ML14: From Automation to Audit Readiness – AI's Growing Role in Statistical Programming** *Cytel*	**AS14: Consistency, Speed and Satisfaction: The Impact of TFL Mock Shell Centralisation** *SGS Pharma Clinical Research*	**SA11: Building Cross-Functional Regulatory and Programming Alignment for Successful Submissions** *MMS Holdings*	**PD14: Unseen, Unstoppable: The Art of Invisible Leadership** *Alcon Vision*	**AV04: Safety Analytics Advance Session:** Double Dutch: Integrating JMP with R, Python, and AI-Driven RAG Workflows for Clinical Safety Analysis	**SM04: Automated Programming Consistency Checks: Enhancing Clinical Programming Quality, Efficiency and Scalability** *Merck*	**AV07: Optimizing the Use of Data Standards Advance Session:** BIMO FAQ Forum	**Theme: Global Transparency Trends and Regional Insights** **Industry Trends in EU CTIS Transparency Documentation: A Comprehensive Analysis** *MSD & Xogene* **RegulASIAN Uncovered: Navigating Asia's Clinical Trial Disclosure Landscape** *CiteLine* **Good Pharma Scorecard** *Yale*	Data Transparency Pavilion **Theme: Data Protection and Anonymization at Scale** **Anonymisation of Imaging Data for External Research Platforms** *Biogen* **Scalable Anonymisation for Complex Clinical Trial Data: A Sponsor–Vendor Perspective** *Privacy Analytics & Johnson & Johnson*	**Open Source Change Management Panel Discussion**	11:00am–11:30am
11:30am–12:00pm	**RE10: Where are my Agents? Automating Cohort Building with a Dynamic Cohort Builder** *SAS*	**ML18: Real-Time AI-Driven TLF Generation with GAutoTLF** *AstraZeneca*	**AS16: Statistical Programming Methods for Evaluating the Impact of Immunogenicity on Safety and Efficacy Outcomes** *Takeda*	**SA15: Harnessing AI to Streamline ClinicalTrials.gov PRS Submissions** *Certara*	**PD15: Redefining Quality: Transforming Internal Reviews into Team Development Tools** *STATECS*		**SM06: AUTOCODE: Metadata-Driven Automation for Faster, Traceable SDTM and ADaM Programming** *Vertex*					11:30am–12:00pm
12:00pm–12:30pm	**RE06: The Curious Case of External Controlled Arms (ECAs): Practical Solutions for External and RWD Integration** *Cytel*	**ML19: SpectoSAS: AI-Powered Instant SAS Code Generation from Study Specs** *AstraZeneca*	**AS15: Integrated Summary of Safety (ISS) Demystified: Practical Considerations for a Successful ISS** *BioPier*	**SA16: LLM-Powered Clinical Data Flow with Traceability – From Siloed Pipelines to a Semantic Fabric** *SAS*	**PD16: Level Up: Change Management Skills as Your Career Accelerator** *Atorus Research*		**SM05: AI-Optimised AESI Flagging: Streamlined SAS Hash Table Logic with Dynamic CALL EXECUTE and Metadata-Driven Specifications** *Bristol Myers Squibb*					12:00pm–12:30pm
12:30pm–1:30pm	**Lunch Break**											12:30pm–1:30pm

Thank You to the Data Transparency and Open Source Pavilion Sponsors

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Tuesday March 24

Time (EDT)	Frio	San Antonio	San Macros	Sabine	Pecos	Trinity A	Trinity B	Concho	Glass Oaks Ballroom	Nueces	Bluebonnet Ballroom	Time (EDT)
									Data Transparency Pavilion		Open Source Pavilion	
1:30pm–2:00pm	**RE07: From Chaos to Clarity: Can AI/ML Truly Decode Unstructured Clinical Data?** *Zifo RnD Solutions*	**ML16: AI-Driven Metadata Integration in Modern TLF Development** *Beaconcure*	**AS17: Beyond Box-Checking: Five Best Practices for Embedding QC in Modern SCEs** *Domino Data Lab*	**SA14: Data Harmonisation for ISS and ISE: A Practical Checklist for Integration Success** *BioPier*	**PD17: Beyond Administration: Leveraging AI for Strategic Clinical Project Management** *Vita Global Sciences*	**DH04: Enhancing Clinical Trial Dataset Mapping with AI/ML Techniques: An Approach for CDISC Variable Prediction** *GENINVO*	**SM07: Streamlining Report Reusability in SAS Viya: A REST API Approach** *SAS*	**DV04: Safety at a Glance: Enhancing Participant Monitoring in Oncology Trials with Data Visualisation** *SGS Pharma Clinical Research*	**Theme: Participant Empowerment and Responsible Data Sharing** **Is Your Registration Data Hurting Recruitment?** *CiteLine* **Participant Data Return – Forging a Path Forward** *Biogen* **Leading the Way in PLS: Insights & Innovations from Industry Experts** *Johnson & Johnson*	**Theme: AI and Automation** **Implementing AI in Authoring Plain Language Summaries: Insights from a Live Project Experience** *Krystelis* **Leveraging AI for Clinical Data Transparency: Automating Complex Disclosure Workflows** *Xogene* **Safeguarding CCI in the Age of AI** *TrialAssure* **Honey, I Shrunk the Workload: An Introduction to AI and Automation** *Regeneron*	**Hands-on Workshop: AI in Clinical Data Analysis**	1:30pm–2:00pm
2:00pm–2:30pm	**RE05: Submitting RWD: Where We Are and Where We Are Going** *Certara*	**ML17: Prompting for Precision: Leveraging LLMs To Accelerate Clinical Trial Document Understanding** *Saama*	**AS18: From Data Cutoffs to Decision-Making: Programming Futility Analysis in Oncology Clinical Trials** *Merck*	**SA18: Electronic Clinical Data Submissions Across Global Regulatory Authorities** *AstraZeneca*	**PD18: Developing the Workforce of the Future** *AstraZeneca*	**DH05: Real-Time Integration of EDC and Third-Party Data and Query Actions within an R Shiny Data Review and Patient Profile Tool** *Veeva Systems*	**SM08: AI-Assisted Metadata Programming: A Transparent Framework for PCS in Lab Data Analysis** *Bristol Myers Squibb*	**DV03: Accelerating Study Insights: Agile Data Visualisation Using R-Shiny** *Astellas Pharma*				2:00pm–2:30pm
2:30pm–3:00pm	**RE01: Robust Causal Inference in Real-World Evidence Studies with Double Machine Learning** *Jazz Pharmaceuticals*	**ML13: Your Brain on AI: What We Gain, What We Risk, and How to Harness AI Without Losing Trial Integrity** *Saama*	**AS19: Data Diaries Don't Lie: Stats That Spot ePRO Risks** *Pfizer*			**DH06: Reimagining SDTM Mapping with Agentic AI and Automation** *eClinical Solutions*	**SM13: AI–Supported Validation of Open–Source Software** *Entimo*	**DV06: Straight to the Source: Interactive Visual Dashboards for Data Cleaning** *Fortrea*				2:30pm–3:00pm
3:00pm–3:30pm		**ML15: Coding Clinical R with Confidence: Digital AI Assistant Based on Self-Hosted LLMs** *Intego Clinical*	**AS20: Practical Survival Analysis Techniques for Clinical Trials Using SAS** *Bristol Myers Squibb*	**OS22: Building for the Long Haul: Managing Scope, Refactoring, and CI/CD in Internal R Packages** *Fred Hutch Cancer Center*	**PD20: Data Storytelling: A Crucial Leadership Skill in Today's Clinical Research Landscape** *Spaulding Clinical*	**DH07: Blind/Unblind Workflows: Secure Separation and Governance in the CDR SCE** *Sycamore Informatics*	**SM10: CDISC ARS Template Code: Gearing Up with Automation in TFL Programming** *Clymb Clinical*	**DV02: Visualising Essential Metrics for Assessing Disease Dynamics in Haematologic Oncology Trials: An SAS Graphic Approach** *Merck*				3:00pm–3:30pm
3:30pm–4:00pm	**Afternoon Break**											3:30pm–4:00pm
4:00pm–4:30pm	**DS01: Deriving Phantom Records in BDS Datasets To Support the FDA's Standard Safety Figures for Missing Data Analysis** *Merck*	**ML22: Is the AI Coding Assistant Catching Your Vibe? A Practical Assessment of Generative AI Tools in Clinical Data Analytics** *Recursion*	**AS21: Advancing Precision Medicine and Regulatory Readiness: Data Harmonisation and Statistical Methods for Companion Diagnostics Bridging Studies** *Bayer*	**OS04: Introduction of PharmaForest – Forest of SAS Packages** *Takeda*	**PD19: Navigating Diversity in Global Pharmaceutical Programming Departments** *Biogen*	**DH08: One Eye Open, One Eye Closed: How To Approach Masking in Open-Label Oncology Studies** *GSK*	**Hands-on Workshop: The Role of Standards in a World of Agentic AI** AliraHealth · MEDIDATA	**DV08: Design of Everyday Shiny Apps** *Atorus Research*	**Theme: Industry Perspectives on Anonymization and Data Disclosure** **What Drives Anonymisation Choices? Industry Perspectives from a Global Survey** *Krystelis* **Balancing Privacy and Utility with Smart Anonymisation** *TrialAssure* **Conflict and Convergence: A Triple Perspective on Clinical Trial Transparency** *Certara*	**Theme: Best Practices in Handling CCI** **One Workflow to Rule Them All: Uniting Anonymization and CI** *RLS Sciences & CSL Behring* **Enhancing Protection of Confidential Commercial Information through Unified Cross-Functional Strategic Alignment** *Johnson & Johnson* **Managing Commercially Confidential Information Redaction in Contemporary Regulatory Submissions** *Otsuka*	**Interactive Session: Sustainability of OS Solutions in Pharma**	4:00pm–4:30pm
4:30pm–5:00pm	**DS02: CDISC 360i Demo: Automating from Study Design to Submission** *CDISC*	**ML21: GenAI Multi-Agent Pipeline for Scalable SAS-to-R/Python Code Translation in Pharma** *HMS Analytical Software*	**AS22: Multi-Dimension Comparison Using SAS in the Context of Counting Haemophilia Bleeding Episodes** *Sanofi*	**OS02: Machine Learning Model for Risk Qualification of R Libraries** *Fortrea*		**DH09: Closing the Gap: Identifying Missing Tumour Assessments in Oncology Studies** *Boehringer Ingelheim*						4:30pm–5:00pm
5:00pm–5:30pm	**DS07: The Revolution of Digitised Study Designs: Standards, Use Cases and Tools** *ClinLine*	**ML20: Deterministic Foundations, AI Acceleration: Lessons from Developing Hybrid Clinical Review Tools** *Bayer*	**AS23: Problem-First Agentic AI-Transforming Statistical Computing with Purposeful Automation** *MAXIS AI*	**OS03: Pharmula 1 – Driving Innovation in Reporting** *GSK*	**PD22: Influence Without Authority: Leadership Lessons for Statistical Programmers** *Wu Consulting Group*	**DH10: The Journey Beyond Anonymisation: Exploring the Secondary Use of Clinical Trial Data** *Intego Clinical*		**DV09: Empowering Clinical Data Review with Interactive Patient-Level Visualisations in {teal}** *Genentech*				5:00pm–5:30pm
5:30pm–6:30pm									**Data Transparency Pavilion Networking Event**			5:30pm–6:30pm
6:00pm	**Close**											6:00pm
7:00pm–11:00pm	**Poker Night** – Hosted by *Vita Global Sciences* VITA Global Sciences | *Stay tuned for more social events being announced shortly!*											5:30pm–6:30pm

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Wednesday March 25

Time (EDT)	Frio	San Antonio	San Macros	Sabine	Pecos	Trinity A	Trinity B	Concho	Glass Oaks Ballroom	Bluebonnet Ballroom	Time (EDT)
8:00am–9:00am	**Exhibitor Hall Open** – Welcome Refreshments										8:00am–9:00am
9:00am–9:30am	**DS04: Around the Data DOSE-y Doe: Using DOSExx Variables within ADaM Datasets** *InkaStat Solutions*	**ML23: Harnessing LLM-Augmented Automation for ADaM Dataset Generation** *K3-Innovations*	**ET10: Thriving in Change: Building People, Process and Technology Capabilities in Statistical Programming** *Pfizer*	**OS01: How R We Now? Tracking Industry Progress in Adopting R and Open-Source for Clinical Reporting** *Atorus Research*	**PD21: Bridging Analysis and Strategy: The Transformative Role of Statistical Analysts in Drug Development** *Bayer*	**DH11: Pre-Conf as a Data Review Layer: An AbbVie Case Study for Optimised Clinical Data Flow** *AbbVie*	**Hand-on Workshop: Implementing Novel Clinical Trial Designs: Effectively Leveraging Artificial Intelligence and Machine Learning** BioForum · PHASE V	**DV10: Detecting Trends Before They Appear: AI-Driven Visualisations in Clinical Trials** *Wu Consulting Group*	Vulcan Pavilion **Vulcan Unveiled: Bridging Care and Research Through Interoperability**	Real-World Evidence Pavilion **Introduction & Keynote Presentation** *TransCelerate*	9:00am–9:30am
9:30am–10:00am	**DS05: From ATC to ACG: Implementing the Concomitant Medication Grouping (ACG) Dataset in Clinical Trial Analysis** *Roche*	**ML24: QC Without Code: ChatGPT Enterprise for Sponsor Oversight of Outsourced TFLs** *UroGen Pharma*	**ET11: An R Shiny App for Real-Time Continuous Safety Monitoring in Post-POC Trials: A Bayesian Approach to Decision-Making** *Pfizer*	**OS05: The Year of Yes! How saying "Yes" Ignited GSK's R Adoption** *GSK*		**DH12: Semi-automating Case Report Form Annotations Using Python and a Metadata Repository** *Alnylam Pharmaceuticals*		**DV11: QInsight – The Complete Data Visualisation Solution for Summary Reporting** *ACL Digital*		**Panel Session: Transforming Real-world Evidence: Integrating AI, Digital Health and Patient Centric RWE** *TransCelerate & SAS*	9:30am–10:00am
10:00am–10:30am	**DS06: Building High-Quality SDTM from Real-World Data: Lessons and Solutions** *Bristol Myers Squibb*	**ML25: Accelerating Study Build Using AI Enabled CRF Design** *Otsuka Pharmaceutical*	**ET12: From SAS to Cursor: Vibe-Coding into SAS, R & Python** *ClinVia*	**OS06: Objects in Mirror Are Closer Than They Appear – How an Organisation Came Together to Accelerate Open Source Adoption** *GSK*	**PD23: The Biopharmaceutical Industry Leadership's Guide to Post-Acquisition: Dos and Don'ts** *Summit Analytical*	**DH13: Leveraging Python for Synthetic External Vendor Data Generation for eCOA and ePRO** *GENINVO*		**DV12: From Black Box to Glass Box: A Context-Aware Approach to SDTM Mapping Automation with Interactive Visual Validation** *Merck*			10:00am–10:30am
10:30am–11:00am	**Morning Break**										10:30am–11:00am
11:00am–11:30am	**DS03: Mapping Minimal Residual Disease (MRD) Biomarker Data in Haematologic Malignancies: Clinical Significance and Data Standards in SDTM and ADaM** *Takeda*	**ML26: Validating AI in GxP: Test Harnesses, Guardrails and Compliance Controls** *Sycamore Informatics*	**ET13: Rule-Based Auto-SDTM Mapping Software in Python, Which Automatically Generates Executable SAS or R Programs** *ClinChoice*	**OS07: {tflmetaR}: An R Package to Manage Metadata of Statistical Outputs** *UCB Biosciences*	**Leadership Presentations: From Vision to Value: Leadership in AI-Powered Clinical Development**	**AV06: Safety Analytics Advance Session:** SA Education – Updated PHUSE Library	**Panel Discussion: Data at the Forefront: Unlocking Meaningful Insights & Navigating Data-Driven Decisions for Innovative Therapeutics**	**AV05: Optimizing the Use of Data Standards Advance Session:** BIMO FAQ Forum	**Inside the Vulcan Pipeline: Turning Standards into Practice**	**Interactive Workshop: Mapping OMOP for Regulatory Purposes** *Pfizer & ClinLine*	11:00am–11:30am
11:30am–12:00pm	**DS08: Case Study: Leveraging CDISC CORE for Proactive SDTM Compliance and Submission Readiness** *Clymb Clinical*	**ML27: Enhancing Clinical Study Report Authoring with Generative AI: Lessons Learned on TFL Formatting and Metadata Integration in Merck's iRAP Tool** *Merck*	**ET14: AI Reading and Understanding the SAP to Generate the TFL TOC** *Arcsine Analytics*	**OS08: Deceptive Twins: An Interactive Python Tool for Automated RTF Document Comparison in Clinical Submissions** *Bristol Myers Squibb*							11:30am–12:00pm
12:00pm–12:30pm	**DS09: Agentic AI-Powered SDTM Automation: A CDISC 360i Metadata-Driven Approach** *AILENS*	**ML28: From Demo to Deployment: Bridging the AI Implementation Gap** *Formation Bio*	**ET15: AI-Powered Approach for Faster, More Efficient Authoring of Clinical and Regulatory Documents** *GENINVO*	**OS09: Your Next Teammate? Proving the Power of an AI Assistant for R Programmers in Clinical Reporting** *Roche*							12:00pm–12:30pm
12:30pm–1:30pm	**Lunch Break**										12:30pm–1:30pm

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Wednesday March 25

Time (EDT)	Frio	San Antonio	San Macros	Sabine	Pecos	Trinity A	Trinity B	Concho	Glass Oaks Ballroom	Bluebonnet Ballroom	Nueces Room	Time (EDT)
1:30pm–2:00pm	**DS10: Not Another Other: Bridging Data Collection with SDTM Mapping Without Open Text Fields** *ICON*	**ML29: Revolutionising Clinical Data Transformation: Harnessing GenAI and Open Source for Automated SDTM Conversion** *BeiGene*	**ET16: The Future of Statistical Programmers in the Age of AI** *Biogen*	**OS10: The Use of Git in Statistical Programming** *Takeda*	**Leadership Roundtable: Human + AI Collaboration: Driving Efficiency Across the E2E Clinical Lifecycle**	**AV08: Safety Analytics Advance Session:** Updates from the PrOACTS Working Group	**AV09: Data Visualisation & Open Source Technology Advance Session:** {teal} as a Catalyst for Cross-Industry Collaboration and Innovation in Clinical Insight Generation	**AV10: Optimizing the Use of Data Standards Advance Session:** SDTM/ADaM FAQs	Vulcan Pavilion **Vulcan Projects: From Design to Deployment – Implementation Guides in Action** **Deep Dive: The VIB Integration Sandbox – Connecting EHRs, CDISC, and Real-World Data, Test beds BETA building concpets, Tech Trials, Wire Frame, Sand Box, Pilot**	Real-World Evidence Pavilion **Sponsor Demonstrations**	**Real-World Evidence Pavilion: Real-World Evidence WG Projects & Updates** *ClinLine*	1:30pm–2:00pm
2:00pm–2:30pm	**DS11: Enabling Innovation: Lessons from the CDISC AI Innovation Challenge** *CDISC*	**ML30: From Tables to Text: Revolutionizing CSR Development with Generative AI** *Sycamore Informatics*	**ET17: Orchestrating Efficiency: Symphony and Composer in Clinical Reporting** *Bristol Myers Squibb*	**OS11: Time To Roclet! Admiral's Use of Custom Roclets To Enhance and Extend Examples in Function Documentation** *GSK*						**Interactive Workshop: RWD and the Data Reviewers Guide** *Pfizer*	**Interactive Workshop: Bridging Estimands & Target Trial Emulation** *Amgen*	2:00pm–2:30pm
2:30pm–3:00pm	**DS12: Standardising Exposure-Response Data for Modelling and Simulation Using CDISC Principles and {admiral}** *Navitas Life Sciences*	**ML31: Batch Cleaning of SAS Programs for Submission Readiness: An AI and Python Hybrid Approach** *BioPier*	**ET18: Rethinking Data Quality - From Fragmented Checks to Connected Insights** *Capish*	**OS12: Handle with Care: A Study-Specific Assessment of R Package Risk** *Fred Hutch Cancer Center*								2:30pm–3:00pm
3:00pm–3:30pm	**DS13: SDTMIG v4.0: Are You Ready For It?** *Certara*	**ML33: Enhancing Clinical Study Processes Through AI-Driven Documentation Automation** *GENINVO*	**ET19: Code Switching: Parallels Between Human Languages and Multilingual Programming** *Atorus Research*	**OS13: Open Source as a Strategic Enabler for EMA Submissions: An R Shiny Approach** *Bristol Myers Squibb*								3:00pm–3:30pm
3:30pm–4:00pm	**Afternoon Break**											3:30pm–4:00pm
4:00pm–4:30pm	**DS16: SDTM Automation: Implementation, Rollout and Lessons Learnt** *Alcon Vision*	**ML34: Transparent Models or Black Box? Using Generative AI to Generate Real-World Intelligence** *SAS*	**ET27: Scaling for the Future: Transitioning from In-House to Commercial Statistical Computing Environments** *Merck*	**OS14: From SAS to R for TLGs: A Case Study on Implementing an 'R-First, SAS-QC' Workflow for Time-to-Event Analysis** *Intego Clinical*	**Leadership Panel: Lead the AI Era – Act Now, Transform Pharma: From Data to Breakthroughs**	**SM11: Methods of a Fully Automated CONSORT Diagram Macro %CONSORT** *Regeneron*	**AV11: Data Visualisation & Open Source Technology Advance Session:** From Pilot to Policy: Developing the Open-Source ADRG Standard to Support R-Based Regulatory Submissions		**Vulcan Connect: Meet, Match, and Collaborate**	**Catalyst Challenge – Winner Presentations**		4:00pm–4:30pm
4:30pm–5:00pm	**DS15: CDISC 360i: From Vision to Implementation – Lessons Learned and the Road Ahead** *CDISC*	**ML35: Democratising SDTM Transformations: AI-Assisted Function Development with Business-Driven Governance** *Merck*	**ET21: Business Event Triggers – The Next Level of Automation** *Entimo*	**OS15: Adopting gtsummary at Scale: How Roche Built a Companion to gtsummary to Standardise and Simplify ARD-Based Reporting** *Genentech*		**SM12: Automating Analysis Report Programming in SAS with VGSART: A Metadata-Driven Approach** *Vita Global Sciences*						4:30pm–5:00pm
5:00pm–5:30pm	**DS14: Multiple Sclerosis Trials Unpacked: Standards, Endpoints and Programming Experience** *Intego Clinical*	**ML37: Predictive Healthcare: Using Machine Learning Models to Recommend Personalised Treatment** *IQVIA*	**ET22: What Pharma Can Learn from Data Science Outside the Industry** *MMS Holdings*	**OS20: Hybrid SAS–R–Python Pipelines: Coordinating Multi-Language Workflows** *Sycamore Informatics*		**SM09: Automated File Comparison and Validation Across Programming Platforms** *Pfizer*						5:00pm–5:30pm
5:30pm–7:00pm	**Poster Session** – *Sponsored by Entimo* | Rio Grande entimo											5:30pm–7:00pm
7:00pm	**Close**											7:00pm
From 7:00pm	*Stay tuned for more social events being announced shortly!*											From 7:00pm

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Thursday March 26

SUNDAY | MONDAY | TUESDAY MORNING | TUESDAY AFTERNOON | WEDNESDAY MORNING | WEDNESDAY AFTERNOON | THURSDAY

Time (EDT)	Frio	San Antonio	San Macros	Sabine	Pecos	Trinity A	Trinity B	Concho	Glass Oaks Ballroom	Bluebonnet Ballroom	Time (EDT)
8:00am–9:00am	**Exhibitor Hall Open** – Welcome Refreshments									Real-World Evidence Pavilion Breakfast Networking Session	8:00am–9:00am
9:00am–10:30am	**Keynote Speaker** – Grand Ballroom										9:00am–10:30am
10:30am–11:00am	**Morning Break**										10:30am–11:00am
11:00am–11:30am	**DS17: CDISC Biomedical Concepts for Breast Cancer: A CDISC 360i Perspective** *AstraZeneca*	**RM01: From Oversight to Insight – Rethinking Risk-Based Quality Management** *Capish*	**ET23: The Clinical Data Lake: Empowering the Data Caterer Vision with Veeva, SAS and Open Source** *Bayer*	**OS17: Harmonising gsm and the pharmaverse: Orchestrating SDTM, ADaM, TFLs and ARS in a Unified R Workflow** *Atorus Research*	**SD09: Demonstrations of AutoTable** *AutoCheng Clinical Data Services*	**AV12: Safety Analytics Advance Session:** Estimands in Safety Analytics – Bringing Safety Evaluation in Clinical Developments to the Future	**AV02: Data Visualisation and Open Source Technology Advance Session:** CVARS - Transforming Drug Safety Analytics and Deliverables for Enhanced and Comprehensive E2E Review, Analysis, Signal Detection, Reporting, and Regulatory Submissions with the Aid of AI and LLMs	**AV14: Emerging Trends & Innovation Advance Session:** Workshop to Review Use Cases and Applications of AI/ML to Clinical Trial Biometrics	Vulcan Pavilion **The Standards Debate: Collaboration, Not Competition**	**Hackathon: Missing Data**	11:00am–11:30am
11:30am–12:00pm	**DS18: Metadata-Driven TFL Generation: End-to-End Automation from Protocol to Output** *Sycamore Informatics*	**RM02: Operationalising ICH E6 R3: A Risk-Based Blueprint for Data Management** *eClinical Solutions*	**ET24: R We There Yet? A Readiness-Assessment Framework for Adoption of R and Open-Source Solutions** *Syneos Health*		**SD08: Reproducible RWE at Scale: From Fragmented Data to Regulatory-Ready Insights** *Domino Data Lab*						11:30am–12:00pm
12:00pm–12:30pm	**DS19: From System Exports to Standards: Will Standardisation of External Vendor Data Redefine Clinical Data Management/ Analysis?** *Zifo RnD Solutions*	**RM03: Equity as a Dimension of Quality: Embedding Inclusion into RBQM Oversight Frameworks** *L&B BioPharma Solutions*	**ET25: Incubating Innovation with R: Building the Team Behind Denali's First BLA Submission** *Denali Therapeutics*	**OS18: Check Yourself: Edit Checks and Queries Made Easy with Shiny** *Atorus Research*	**SD07: Turning Trial Data into Patient-Centric Insights** *Capish*						12:00pm–12:30pm
12:30pm–1:30pm	**Lunch Break**										12:30pm–1:30pm
1:30pm–2:00pm	**DS20: Transforming Legacy Data into CDISC Standards: Practical Approaches and Regulatory Insights** *Cytel*	**RM04: {gsm} Operations – Implementing an Open Central Monitoring Framework** *Gilead Sciences*	**ET03: Automated Code Generation: Evaluating Deterministic and Probabilistic Approaches** *Clymb Clinical*	**OS16: mkheader: An R Package for Automated Generation and Management of Program Headers in Clinical Trial Programming** *Merck*	**SD10: Comparing Medical Queries with Interactive Graphics using JMP Clinical** *JMP*	**SM14: Reimagining the Clinical Data Continuum – Automating the aCRF to TFL Journey** *ACL Digital*	**Hands-on Workshop**		**Vulcan in the Future Workshop: What's Next for Interoperability?**	**Hackathon: Missing Data**	1:30pm–2:00pm
2:00pm–2:30pm	**DS21: Revolutionising Regulatory Review: How AI and Interoperability Standards Unlock Unstructured Data** *IBM*	**RM05: Scalable R Packages Qualification Using a CI/CD Approach** *Atorus Research*		**OS19: Reproducible Validation Framework for R & Python in GxP** *Sycamore Informatics*	**SD11: Maximising Longevity and Saving Costs Through Refactoring of Statistical Computing Environments** *Bayer*	**SM15: The Dating Game: Fuzzy Matching Analysis Date to the Correct DOSEON Date Interval Across SAS (DATA Step, PROC SQL, SAS Macro and PROC FCMP)** *InkaStat Solutions & Data Llama Analytics*					2:00pm–2:30pm
2:30pm–3:00pm	**DS22: Optimising Trial Design Dataset Creation To Minimise P21 Compliance Issues** *Merck*	**RM06: AI-Driven Quality Risk Management for Contract Manufacturing Oversight: An ML Approach** *Apozeal Pharmaceuticals*	**ET29: Title to be confirmed**	**OS21: Manual vs AI-Assisted Workflows: Practical Strategies for Complex R Package Development** *Appsilon*	**SD12: Clinical Programming in the Fast Lane: Accelerating with SAS** *SAS*	**SM16: Geocoding with the Google Maps API: Using PROC FCMP To Call User-Defined SAS and Python Functions that Geocode Coordinates, Calculate Routes, and More** *Data Llama Analytics*					2:30pm–3:00pm
3:00pm–3:30pm	**Closing Remarks & Awards** – Grand Ballroom										3:00pm–3:30pm
3:30pm	**Close**										3:30pm

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