

EU Connect 2023 Event Agenda

5–8 November ICC Birmingham



Navigate the Agenda

Application Development (AD)

Analytical Risk-based Monitoring (AR)

Analytics & Statistics (AS)

Coding Tips & Tricks (CT)

Connected Health & Machine Learning (CM)

Data Handling & Data Engineering (DH)

Data Standards & Governance (DS)

Data Visualisation (DV)

Leadership Through Innovation (LI)

Professional Development (PD)

People Leadership & Management (PM)

Poster Presentations (PP)

Real-world Evidence (RE)

Submissions & Agencies (SA)

Software Demonstrations (SD)

Standards Implementation (SI)

Scripts, Macros & Automation (SM)

Trends & Technology (TT)

View all Stream descriptions here.

Hands-on Workshops (HoW)

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

Interactive Sessions

The Professional Development and the People Leadership & Management Streams will both be holding Interactive Sessions. These will cover the topics of neurodiversity and building a strengths-based team.

Connect Theme Presentations

Connect Themes are carefully selected groups of presentations that relate to a particular topic, with a combined Q&A session at the end of the block. View the titles and abstracts here.

View the colour-blocked sessions within the agenda that indicate the Interactive Sessions and Connect Theme Presentations.

- **INTERACTIVE SESSIONS**
- **CONNECT THEME PRESENTATIONS**

Don't miss the open source panel discussion taking place on Tuesday. Read the abstract here.

Social & Networking Events

1. Speed Networking Event

Work the room each time the bell rings. This is an exciting evening consisting of quick informal networking, whilst enjoying refreshments.

2. PHUSE Connect Dinner

Truly 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 an hour of engaging conversation and networking.

Sunday 5 November

Time (GMT)	Hall 7	Hall 9	Media Suite	Time (GMT)		
From 14:00	Registration			From 14:00		
14:30–16:00	Hands-on Workshop Dazzled and Delighted by Define-XML: Creating Define-XML with Pinnacle 21 PINNACLE 21 BY CERTARA	Hands-on Workshop Mastering USDM Standards with an Interactive Demo and Hands-on Workshop TransCelerate BIOPHARMA INC.	Hands-on Workshop Setting Sail for Synergy: Navigating the Biostatistician-Statistical Programmer Partnership Alira Health	14:30–16:00		
16:00–17:00		Chair & Speakers Meeting		16:00–17:00		
17:00–18:30	Speed Networking Exhibition Hall (Hall 3)					
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Due to the overwhelming number of submissions PHUSE have received this year, the conference will kick off mid afternoon on Sunday with a variety of Hands-on Workshop sessions! Please bear this in mind when booking your travel.

Monday 6 November

Time (GMT)	Hall 6a	Hall 7	Hall 9	Hall 10a	Hall 10b	Hall 11	Media Suite	Time (GN
9:00-10:30	Keynote Speaker - Naomi Sesay Plenary Ro	om – Hall 1						09:00-10:3
:30–11:00	Morning Break – Sponsored by PointCross L	fe Sciences						10:30–11:0
1:00-11:30	TTO1: Experiences of Training Teams in R GSK	PD01: Statistical Programming 101 for the Fourth Industrial Revolution Novartis	CTO1: SAS Arrays in R Way Princeps Technologies CTO2: Streamlining Clinical Data Analysis and Reporting with R: Best Practices, Tips and Techniques for Efficient Workflow Management and Code Optimisation Genpro, now part of Catalyst CTO3: Multiple Myeloma: Challenges in Identifying Regimen Modification for a Given Line of Chemotherapy	ASO1: Implementation of Estimands Using Data Standards Roche	SIO1: Harmonising Clinical Reporting Through the {falcon} Initiative: A Collaborative Leap Forward Roche	SA01: Drafting Your Plain Language Summaries: Hurdles to Overcome and How to Overcome Them ICON	Hands-on Workshop Do You Get the Full Picture of Your Data? Build Your Interactive Clinical Data	11:00-11:
			Ephicacy Consulting Group & IQVIA				Visualisation in a Secure and Scalable	
1:30–12:00	TTO2: R Validation: Getting Started Lundbeck	PD02: A Beginner's Journey with SAS: One Small SAS for Man Sekharico Informatics	CTO4: SAS Packages for Clinical Programming Genpro, now part of Catalyst CTO5: Dynamic Testing for Empty Datasets AstraZeneca	ASO2: Size Matters – Sample Size Calculation with SAS and R mainanalytics	SIO2: Oak Garden – Metadata-Driven SDTM Automation in R Roche	SA02: Regulating the Future: Navigating the Complexities of 3D Printing in the Pharmaceutical Industry MMS	S sas	11:30-12:(
2:00-12:30	TTO3: Eyes On the Prize - The Development of {admiralophtha}, an R Package for Ophthalmology ADaMs	PD03: Stay Ahead of the Curve: Learn About Leapfrogging as a Statistical Programmer IQVIA	CTO6: Concomitant Medication Duration Calculation Using the SAS DS2 Procedure Bristol Myers Squibb	ASO5: Eat, Sleep, R, Repeat Veramed	SIO3: Open-Source MDR and SDR - Managing Your Standards with the OpenStudyBuilder Novo Nordisk	SAO3: Detroit, Michigan: A Case Study for DEI Via Decentralised Clinical Trials (DCTs) Johnson & Johnson		12:00-12
2:30-13:30	Lunch Break - Sponsored by PointCross Life	Sciences						12:30–13:
3:30-14:00	TT15: Generative AI: A Case Study Highlighting the Potential and the Risks Domino Data Lab	PDO4: Heart: The Must-Have for a Good Project Hearthought Enterprises	LI01: Connecting the Dots to Shape Our Future. The Exciting Journey of an Evolving Statistical Programming Team UCB Biosciences	REO1: Real-World Observational Studies and the Challenges in Data Collection Novo Nordisk	SD01: Xploratum: A System for Pharmacovigilance Incorporating Medical Monitoring Review and Reporting Wood Street Consultants	SA04: The Journey of Preparing an ISS OCS Life Sciences	Hands-on Workshop Dataset-JSON Submission Pilot Workshop	13:30–14:
4:00-14:30	TTO4: Navigating R Package Management in a Validated Environment: Maintaining and Implementing the Latest R Packages with Different Versions of R Instem	PD05: Mastering the Art of Adaptation: Innovative Strategies for Effective Change Management Johnson & Johnson	LIO8: Innovating the Leadership Toolkit Through Design Thinking Achieve Intelligence	REO2: Avoid Major Pitfalls When Using Real-World Evidence (RWE) in Regulatory Submissions BC Platforms & SAS	SD02: Driving Better Health for More People – SAS Life Science Analytics SAS	SA05: Practical Operations of Electronic Study Data Submissions PAREXEL International		14:00–14:
4:30-15:00	TT05: Getting Ready for R Roche	PD06: When the Post(er)man Rings Twice – Make Your Science Sexy Chrestos Concept		REO3: Submission Standards for Real- World Data: Gaps, Limitations and Recommendations Pinnacie 21 & IBM	SDO3: Automation of Patient Profiles and Adverse Event Narratives Using JMP Clinical	SA12: Unleashing the Role of a Statistical Programmer in Expediting a Submission Novartis		14:30–15:
5:00-15:30	TTO7: Open-Source Protocol Automation with the OpenStudyBuilder Novo Nordisk	PD07: Stoic OS: Installing Ancient Wisdom for Holistic Leadership in the Digital World Bayer	LIO3: Road to Rome or Roaming – A Reprise AstraZeneca & Roche	REO4: A Beginner's Guide to Overcoming the Attrition Bias in Clinical Research: The Method of Inverse Probability of Attrition Weighting (IPAW) Cytel	SD04: Digitalisation of Specifications – Enabling the Next Generation of Clinical Trials Saama Technologies	SA07: Development Safety Update Report (DSUR)/Periodic Safety Update Report (PSUR) Fortrea		15:00–15:
5:30–16:00	Afternoon Break – Sponsored by PointCross	Life Sciences	•		•		·	15:30–16:
6:00-16:30	TT08: End-to-End Open-source Collaboration Guidance Roche & Atorus Research	PMO8: Management Impact on Employee Engagement – Statistical Programmers in Focus ICON	CTO7: Customisable Smart Search Tool for Project Leads PAREXEL International CTO8: No Adobe Pro, No Worries Exploristics	ASO7: Machine-Learning Approaches to Survival Analysis of Clinical Data HMS Analytical Software	Connect Theme Presentations (SI) CORE: Everything You Always Wanted to Know but Never Dared to Ask SI04: CDISC Conformance Rules and the	SAO8: Interaction with the FDA During and After a Type C Meeting, From the Perspective of a Statistical Programmer Boehringer Ingelheim		16:00–16:
6:30–17:00	TTO9: Heading to Base Camp On Our Way Up the Open-Source Mountain GSK	PMO9: Office-based or Home-based: Are We Remotely Close to the New Steady State? A Working Session	CTO9: Implementation of a MedDRA Upgrade in SDTM: A SAS-based Approach Business & Decision Life Sciences	ASO9: Efficacy Endpoints in Adjuvant and Neo-Adjuvant Oncology Trials Intego Clinical	CORE Engine: Continuing the Road to Adoption CDISC	SA09: Experiencing the FDA CBER Cytel	Hands-on Workshop Ditch the Macro Madness: Crafting R from Macros via Al	16:30-17:
		GSK	CT10: Mr (R)ight - Why R Should Be Used for Validating TFLs in Clinical Trials Intego Clinical		SIO5: Developing and Implementing CDISC CORE Rules: From Zero to Hero SGS Health Science		DOMINO	
:00-17:30	TT10: TFL Automation the CDISC 360 Way PHASTAR	ay	CT11: Optimising a (Supposedly) Reusable Program to Reduce the Need for Manual Changes AstraZeneca	Different Recurrent Events Analysis	Biomedical Concents the C	SA10: It's Easy Peasy Submitting Data to the China NMPA – Really? Roche	-//	17:00-17:
			CT12: Know Your Environment Plus-Project					
7:30	Close							17:30
9:00-00:00	PHUSE Connect Dinner Hall 4							19:00-00

Tuesday 7 November

Please note, this agenda is subject to change and is correct as of 3 November.

					Hall 10b		Media Suite	Time (GMT)	
06:30	PHUSE 5k Run Around Birmingham - Meet O	utside the ICC All abilities welcome						06:30	
09:00 - 10:30	Keynote Speaker - Gareth Thomas Plenary	Room – Hall 1						09:00 - 10:30	
10:30–11:00	Morning Break							10:30–11:00	
11:00-11:30	TTO6: Red Pill or Blue Pill? Assessing the Impact of Artificial Intelligence on Pharmaceutical Programming Katalyze Data	PMO4: Navigating Unprecedented Challenges: Journey Through a Pandemic and International Conflict Veramed	Panel Discussion Let's Discuss Open Source Openly: A New Path in Pharma	Connect Theme Presentations (DS) Digital Data Flow – From Vision to Reality DS01: ICH M11 Clinical Electronic Structured Harmonized Protocol (CeSHarP) and	SIO7: Gear Up SDTM with Digital Health Devices Novo Nordisk	Connect Theme Presentations (AD) Innovative Applications of R Shiny in Clinical Research: Enhancing Efficiency, Collaboration and Data-Driven Decision-Making	AR01: Analytical Risk-Based Monitoring (ARBM) – How Central Monitors Detect the Ripple in the Dataflow that Hides Danger On Site (CON	11:00–11:30	
11:30–12:00	TT14: Automation and Orchestration of Data Science Applications Using OpenAPI Entimo	PM05: An Agile Approach to Onboarding GSK		CDISC: Making the Electronic Protocol a Reality CDISC		AD01: H2H Portal – A Shiny Automation of Reproducible and Traceable Analysis and Reporting Using a Metadata Framework MSD	ARO2: Advanced Analytics for Data Quality Assessment in Countries and Regions Affected by Crisis Johnson & Johnson	11:30–12:00	
12:00–12:30	TT16: Taking Down the Fence Between Biostatistics and Medical Writing GSK	PM06: Statistical Programming – Hiring Mission Made Possible Johnson & Johnson		DSO2: The TransCelerate/CDISC Digital Data Flow Project: Practical Electronic Study Designs data4knowledge & CDISC DSO3: The Digital Protocol Is Just the Beginning. Or Is It? Instem	SIO9: "It's ARM, Jim, But Not As We Know It" – Our Journey to Automating Output Delivery Through Metadata GSK	ADO2: Developing a Shiny Web Application to Address Suboptimal Treatment of Urology Patients Through Predictive Modelling and Improved Communication of Science GSK AD21: Improving Clinical Operational	ARO3: Quality Tolerance Limits – More Critical Aspects of Clinical Trials with Much Less Visibility Fortrea	12:00-12:30	
						Insights Delivery to different Levels of Leadership Seniority Using Shiny-Based Automation Johnson & Johnson			
12:30-13:30	Lunch Break							12:30-13:30	
13:30–14:00	SM01: Let's Compare Them All – TFL Comparisons Bayer	SD05: ADaM Designer – Tool for Writing Better ADaM Specifications and Simplifying the Define-XML IQVIA	Interactive Session (PD) Exploring Neurodiversity: Impacts, Experiences and Best Practices Within Our Industry	LIO5: Drive Results with Emotional Intelligence Plus-Project	DH05: A Data Lake is Not a CDR and a CDR is Not a Data Lake: Understanding the Differences and the Value of Each Instem	Connect Theme Presentations (AD) Transforming Statistical Computing Environments for Enhanced Efficiency in Clinical Trial Data Analysis: Innovations,	ARO4: Applying Central Statistical Monitoring to Find Anomalies and Address Quality Issues in Clinical Trial Data GSK	13:30–14:00	
14:00–14:30	SM02: Same But Different: Leveraging R for Comparing Clinical Study TFL Versions Novartis & Bristol Myers Squibb	SD06: Leveraging the Cloud to Transform Your SCE Instem		LIO6: A Green CRO – Why We Should All Be on a Journey of Continuous Improvement Chrestos Concept	DH02: How Can Python Be Used in Clinical Trials? UCB Biosciences & Veramed	Collaborations and Open Source Solutions AD04: Be Future-Minded While Designing	AR05: R You Ready to Join the RBQM Revolution? Introducing rbqmR Roche	14:00-14:30	
14:30–15:00	SM03: Validating Outsourced Programming Tasks by Comparing SAS Datasets Without PROC COMPARE Danone Nutricia Research	SD07: Increasing Business Impact of Connected Standards with a Metadata- Driven Platform TrialTwin		Wo You	LI10: How to Work When You're Not Working: Coaching Effectively to Develop Your Programming Team AstraZeneca	DH03: Increasing Trend of Biomarker Analysis in Clinical Trials Novartis	Your Next Generation SCE SAS AD05: Further Adventures in SCE Alchemy	ARO7: Risk-Based Monitoring in Clinical Trials with Machine-Learning-Powered Anomaly Detection Lindus Health	14:30–15:00
15:00–15:30	SM04: Automated Compliance in Projects Is Possible! MSD	SD08: TFL Designer: Automating Tables, Figures and Listings Design and Generation for Clinical Trial Analysis Clymb Clinical		LIO9: Becoming an Integrated Part of the Open-Source Pharma Community Posit	DH04: Look to the Sky: Introducing COMET - The COncomitant MEdication Review Tool AstraZeneca			15:00–15:30	
15:30–16:00	Afternoon Break							15:30–16:00	
16:00–16:30	TT11: Building a Scalable Utility Service to Make Multi lingual Applications Available to the Masses! Ferring Pharmaceuticals	DV01: Will R/Shiny Provide a Novel Way for Study Teams to Review Clinical Data? AstraZeneca	Interactive Session (PM) Building a Diverse and Successful Strengths- Based Team in Today's New World	DS04: Standardisation in a Fast-Growing Environment: MDR, EDC and Other Abbreviation OCS Life Sciences & Innovion	DH01: Slicing Codes: A Modular Approach to ADaM Programming Novo Nordisk	AD16: Leveraging the Analysis Results Standard (ARS): The Cytel PRISM Experience Cytel	CM01: Knowledge Graphs for Clinical Trials Capish	16:00–16:30	
16:30–17:00	TT12: From Legacy to the Cloud: Novo Nordisk's Journey Towards a Modern Statistical Computing Environment Novo Nordisk	DV02: Revolutionising Data Exploration: An Interactive Journey Through R Shiny Roche		DS05: Empowering Paediatric Drug Development: CDISC Standards and ICH Guidelines for Clinical Trials with Little Participants Gilead Sciences	DH06: Transparent is the New Black – Improving Data Findability Through Better Clinical Metadata Biogen	AD10: Integrating Isolated Clinical Trial Systems with RESTful APIs: Enhancing Data Accessibility and Collaboration Johnson & Johnson	CMO2: A Dive into the World of Biomedical Concepts ClinLine	16:30–17:00	
17:00–17:30	TT13: InnerSource: A Stepping Stone Towards Open Source in Statistical Programming Novo Nordisk	DV03: Optimising Clinical Trial Design with Real-Time Sample Size Calculation and Enrolment Projection: A Shiny Dashboard Solution Genpro, now part of Catalyst		DS06: Changing the Mindset - Can We Think of the Analysis First? AstraZeneca	DH07: A Robust Framework to Provide and Validate Real-Time SDTM Data Bioforum	AD11: Creating Applications with Mash-Ups: User Written Functions, Stored sql Queries and Interfaces elderbrook solutions	CMO8: The Human in the Loop: Accelerating AI/ML Efficiencies for Clinical Data eClinical Solutions	17:00-17:30	
17:30–18:30	Poster Session & Reception Exhibition Hall (· · · · · · · · · · · · · · · · · · ·			•	•	•	17:30–18:30	
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Wednesday 8 November

Time (GMT)	Hall 6a	Hall 7	Hall 9	Hall 10a	Hall 10b	Hall 11	Media Suite	Time (GMT)
09:00–10:30	Keynote Speaker - Cathy O'Dowd Plenary Ro	oom – Hall 1						09:00-10:30
10:30–11:00	Morning Break							10:30-11:00
11:00–11:30	REO5: Handling Missing Data in Exploratory Analyses Using RWD: 'Collect the Data You Love or Love the Data You Get' – A Case Study Quallance	SM12: Traceability Confirmation at Your Fingertips Shafi Consultancy	Connect Theme Presentations (CM) Unlocking the Potential of ChatGPT CM04: Boosting SAS Programming Efficiency with ChatGPT: A Clinical Trial Perspective	DV04: Get the Full Picture of Your Data with SAS SAS	DH08: Data Managers and R Programming: The Unlikely Pair klorsia Pharmaceuticals	DSO7: Automated Pipellines for Non-CRF Value-Level Metadata: A Meta-Programming Approach Roche	AD12: Design Considerations for Building a System for Automated Statistical Analysis Novo Nordisk	11:00-11:30
11:30–12:00	REO6: The Curious Case of Observational Studies – A Programmer's Dilemma Novartis	SM06: An Experience of Creating Questionnaire ADaMs Using the Admiral ADQS Package Roche	Intego Clinical CM05: GPT (Generative Pretrained Transformers) and LLM (Large Language Models) have generated a lot of attention	DV05: Expanding Visual Clarity: Multi-Page Figure Partitioning and Adaptive Zero-Value Depiction Using PROC SGPLOT STATECS	DH09: Human BioGeography: Predicting Clinical Trial Outcomes Using 3D Human Body Simulation with a GIS Framework TrialTwin	DS08: A New Standard of Excellence: Introducing the Annotated Screen Report YPrime	AD13: MINT+ Automation and Digitisation of SDTM Specifications Roche	11:30–12:00
12:00–12:30	REO7: Building an Integrated Preclinical and Clinical Data Platform to Enable Rapid Translational Data Review Instern	SM07: Metadata-Driven ADaM R-Code Generation by Leveraging Automation Potential Merck KGaA	since their inception in early 2023 with the advent of OpenAl GPT3.5, then GPT4.0 SAS & Microsoft CM06: Unleashing the Power of Large Language Models for Clinical Data Approaches: Will Al Chatbots such as ChatGPT/Bard Replace Statistical Programmers and Statisticians Over Time?	DV06: Patient Profiles v2.0: Easy and Quick Clinical Trial Insights in Tableau SGS Health Science	DH12: Automating ADaM Dataset Generation via Definitive Specification Writing with A Domain-Specific Language AstraZeneca	DSO9: Handling Multiple Screenings Using the New Domain DC (Demographics for Multiple Participations) at Merck – Implementation of a New Mapping Process Merck KGaA	AD14: Building a Large-Scale Clinical Trials IT System with In-House Software and OpenClinica University of Oxford	12:00-12:30
12:30–13:30	Lunch Break				<u>:</u>	:	<u>:</u>	12:30–13:30
13:30-14:00	REO8: The Role of FHIR Resources in Ensuring Semantic Equivalence in EHR2EDC Direct Data Capture Zenetar	SM08: The Hassle of Validating Global SAS Programs: Made Easy(ier) Novo Nordisk	CMO7: SAS Macro Development Using ChatGPT Bristol Myers Squibb	DVO7: Visualising Your Protocol Objectives Novartis	DH10: Integrating Privacy By Design to Enable Innovative Clinical Trials and Post- Trial Data Sharing Privacy Analytics	ASO8: Efficacy Analyses with Imputations: Methods, Limitations and Lessons Learned Business & Decision Life Sciences	AD15: Janssen DATA4YOU Platform Approach for Clinical Data Review Johnson & Johnson	13:30-14:00
14:00-14:30	REO9: Real-World Outcomes and Biomarker Testing in Cancer Patients: Exploration of a Novel Genetic Database from Routine Clinical Practice in England	SM09: Using Python to Automate Reviewer's Guides PHASTAR	CMO9: Unlock Privacy-Sensitive Data with Al-Generated Synthetic Data Syntho	DV08: Real-Time Safety and Medical Review by Integrating Data Visualisations with an SCE Entimo & Zifo RnD Solutions	DH11: Challenges in Oncology Modular Studies: The Fortrea Approach Fortrea	AS11: Comparing Analysis Method Implementations in Software (CAMIS): An Open Source Repository to Document Differences in Statistical Methodology Across Software GSK & PAREXEL International	ADO9: 'Beep Beep': A Metadata Code Writer to Generate SAS Programs UCB Biosciences	r 14:00–14:30
14:30-15:00	RE10: Leveraging Real-World Data to Provide Deeper Insight into Treatment Effects in Clinical Trials SAS	SM10: The Forgotten Outputs – Data for ClinicalTrials.gov and EudraCT Lundbeck	CM10: Using Machine Learning for Building a Demonstrative Model to Counter the Underdiagnosis of Dementia University of Birmingham	DV09: Oversight and Insight within a Fast- Moving Biotech Company argenx	DH13: Exploring Antidepressant Side Effects in the UK Through Topic Modelling and Social Media Analysis University of Birmingham	ASO6: Structural Equation Modelling of Quality of Life in Adults with Down's Syndrome in Nigeria Bournemouth University	AD17: CodeGeneration: Turning Metadata into SAS, R or Python ^{Veramed}	14:30-15:00
15:00–15:30	Closing Remarks & Awards Plenary Room – H	all 1	:	:	:	:	:	15:00–15:30
15:30	Close							15:30



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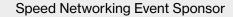


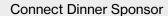






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