SUNDAY 14 JUNE | Hilton Belfast

TIME	SESSION/LOCATION	
12:30	Registration opens at the ICC Belfast	
	Lisburn Suite	Boardroom Suite
13:00	**Pre-conference Course 1** **Quick-thinking, Confident, Communicative, and Collaborative: Fundamentals of Applied Improvisation for (Bio)statisticians and Data Scientists**	**Pre-conference Course 2** **Adjusting for Covariates in RCTs: Translating Guidance into Practice**
	(Bio)statisticians and data scientists are technically proficient. This is unsurprising, since their education focuses on developing quantitative scientists of the highest order. However, this leaves little opportunity for the development of interpersonal skills which are often just as important for success. Ironically, many of the skills leading to technical success can stifle innovation, limit awareness, and inhibit communication. But all is not lost! Applied improvisation is a novel (and fun) way to pursue and practice interpersonal skills that are un- or under-developed. Applied improvisation is the application of the principles of improvisational theatre in non-theatrical settings; it has been used for decades to assist students in developing and expanding quick thinking, confidence, communication, and collaboration. This half-day professional development course introduces individuals to applied improvisation from the perspective of a fellow quantitative scientist. Through several physical and verbal exercises, participants explore interpersonal skills such as creativity, spontaneity, adaptability, courage, and storytelling. Briefings examine how exercises reinforce various competencies and how they relate to the workplace. No experience is required, just an open mind, an eagerness to participate, and a willingness to take risks in a supportive environment. ***Learning objectives*** 1. Recognize how applied improvisation develops and reinforces interpersonal skills appropriate for the workplace.	The FDA's 2023 guidance document on Adjusting for Covariates in Randomized Clinical Trials for Drugs and Biological Products emphasizes key principles while introducing new techniques. This course aims to enhance participants' understanding and implementation of these techniques in study protocols and statistical analysis plans. Focus will be placed on defining the target estimand and its impact on estimation procedures, including the calculation of treatment effect estimator variance. Hands-on exercises and case studies will provide practical experience in executing covariate adjustment analyses across different scenarios. The target audience for this course is statisticians involved in the design and analysis of randomized clinical trials with continuous, binary, and time-to-event endpoints. Throughout the agenda, participants will explore the guidance, examine practical implications, gain hands-on experience, and learn how to apply these techniques effectively to their own trials. ***Learning objectives:*** Participants will be able to identify in which contexts covariate adjustment is useful and be able to engage in discussions with different stakeholders on the pros and cons of covariate adjustment. Participants will also learn how to specify covariate adjusted analyses in study protocols and statistical analysis plans, as well as how to execute covariate adjusted analyses for continuous, binary and time-to-event endpoints. ***Prerequisites:*** Participants are required to have some familiarity with clinical trial

	2. Summarize the skills various physical and verbal exercises emphasize and how exercises can improve communication, collaboration, and spontaneity. 3. Implement feedback and peer evaluation to improve listening, support others, and communicate more effectively. 4. Critique the effectiveness of individual physical and verbal exercises for personal skill development. *Speaker: Richard C. Zink, PhD*	design, including an awareness of the ICH E9 Addendums on Estimands. Some basic knowledge of R software is also assumed. Participants need to bring their own laptop. Practical sessions will be run in Posit cloud. *Speakers: Dominic Magirr (Novartis, Basel, Switzerland), Alexander Przybylski (Novartis, United Kingdom)*
14:45 – 15:15	Refreshment break	
17:00	Workshops end	
19:00 – 22:00	Welcome Reception at the Northern Whig, Belfast	

MONDAY 15 JUNE | ICC Belfast

TIME	SESSION/LOCATION			
	Riverside concourse			
08:00 – 09:00	Registration and Morning refreshments			
	Hall 1a			
09:05 – 09:20	**Conference Opening Remarks** *Vicky Marriott, PSI Conference Chair*			
09:20 – 10:20	**Keynote Plenary - Storytelling with Data to Influence Change** Clinical trials don't succeed on statistical elegance alone; they succeed when stakeholders understand the evidence, trust the data, and make the necessary decisions. In this PSI keynote, master trainer Jonathan McCrea draws on over 15 years of experience in broadcasting and science communication to address a common frustration: being technically correct, yet failing to persuade. Jonathan will demonstrate how to make results clear without making them simplistic, offering practical techniques to influence behaviour based on core communication principles. The session concludes with a critical look at the future of reporting, exploring how to remain ethical, persuasive, and trustworthy as AI fundamentally shifts how data is produced and consumed. *Jonathan McCree, Whipsmart Media*			
10:20 – 11:00	Refreshment Break			
	Stream 1	Stream 2	Stream 3	Stream 4
11:00 – 12:30	**The river keeps moving: How statisticians can survive (and flourish!) in a world that never stands still** *Kimberley Hacquoil, Veramed* *Lucy Rowell, Impactful Authenticity* *Frances Denny, MMS Holdings Europe Ltd* *Sam Ruddell, Chiesi Ltd.*	**Dose response (Career Young Speakers)** The impact of backfilling on early phase dose optimisation trials in oncology - *James Willard, MRC Biostatistics Unit, University of Cambridge* Early Phase Dose-Finding Designs for CAR-T cell Therapies - *Weishi Chen, University of Cambridge*	**Simulation workshop** Don't Get Distracted by Noise: Simulations Done Right *Isabelle Smith, Veramed* *Sam Miller, MMS* *Andy Grieve, Weatherden* *Tim Friede, University Medical Center, Göttingen*	**Patient reported outcomes (SIG)** Tolerability PROs Across the Drug Development Lifecycle *Emily Alger, The Institute of Cancer Research* *Lorenz Uhlmann, Boehringer Ingelheim* *Antoine Regnault, Modus Outcomes*

		BOIN vs. BLRM: a systematic performance comparison in phase 1 dose escalation - *Giulia Brunelli, Cogitars GmbH* *Dose finding in late phase Bayesian trials - Connor Fitchett, MRC Biostatistics Unit, University of Cambridge*		*Konrad Maruszczyk, University of Birmingham*
12:30 – 13:30	Lunch in Exhibition Hall			
	Stream 1	Stream 2	Stream 3	Stream 4
13:30 – 15:00	**Academic-Industry Collaboration and Connection** *Speakers TBC*	**AI & Machine Learning SIG** Practical AI and Developments in Machine Learning *Sam Hadlington, Plus-Project Partnership* *Lesedi Ledwaba-Chapman, MMS* *Paola Berchialla, University of Torino* *Harry Parr, GSK* *Jason Nicholas, GSK*	**HTA workshop** Navigating EU HTA: From pivotal trial to evidence networks based on first experiences *Lena Stein, AMS Advanced Medical Services GmbH* *Stefanie Wüstner, AMS Advanced Medical Services GmbH* *Anton Schönstein, Boehringer Ingelheim* *Amelie Elsäßer, Boehringer Ingelheim*	**Estimands** How about those estimands for my cross-over study? - *Alexandra Jauhiainen, AstraZeneca* All PICOs Great and Small; Dealing with small subpopulations in the EU HTA Landscape - *Dave Gelb, MSD* Not Just Another Estimands Talk: Practical Strategies for Cross-Functional Engagement to Ensure Meaningful, Fit for Purpose Estimands - *Emily Wood, Veramed* Estimands for the Percentage Change from Baseline: Guidance for Clinical Trials - *Tanja Högg, Novartis Pharmaceuticals UK Ltd.* Evaluating Estimand Implementation in Clinical Trials in the UK and Beyond - *Morgaine Stiles, The Institute of Cancer Research*
15:00 – 15:45	Refreshment Break in Exhibition Hall			

	Stream 1	Stream 2	Stream 3	Stream 4
15:45 – 16:55	**Data Monitoring Committees** Advancing Best Practices and Developing Next Generation Experts *Martin Jenkins, AstraZeneca* *Tim Friede, University Medical Center, Göttingen* *Sue Todd, University of Reading* *Chrissie Fletcher, GSK*	**Causal Inference** *Calibrated non-inferiority (NI) margin: A new pragmatic method to account for population shift in head-to-head trials - Nuala Peter, Boehringer Ingelheim* Assessing covariate-adjusted risk differences in small-sample trials: A comparative evaluation of statistical methods - *Martin Schnuerch, Boehringer Ingelheim* A spectrum of causal estimands – differences in dosing adherence patterns - *Anna Menacher, Novo Nordisk* Disentangling Indirect Effects of Vaccine Assignment from Other Causal Pathways in Cluster-Randomized Trials with Noncompliance - *Silvia Noirjean, GSK Vaccines*	**Mixed (Career Young Speakers)** PREDOSE: Pharmacometrically-Refined Early-phase Dose Optimization design for Oncology Study Enhancement - *Damitri Kundu, Eli Lilly* Incorporating prognostic scores in time-to-event analysis - *Harry Parr, GSK* Sensitivity Analysis of Missing Pharmacokinetic Samples in Clinical Trials of Rapid Acting Psychedelics - *Nathan Patrick Burns, GH Research* Evaluation of Z-tests to compare fixed time survival probabilities using stratified Kaplan-Meier estimates with different variance estimators and weights - *Maria P.G Blanco, Staburo GmbH*	**Decision making** Optimising multiplicity adjustment in clinical trials using elicited functions of commercial value and clinical benefit - *Alex Spiers, GSK* Multiple Endpoints in Early Phase Decision Making - *Laura Barker, Aleksandra Buchowics and Chris Gibbs, AstraZeneca* Integrated Decision-Theoretic Optimisation of Phase II/III Oncology Trials - *Haotian Wang, Warwick Clinical Trials Unit* From Data to Decisions: Guide Phase 3 transition with Benchmark-calibrated assurance - a case of Binary outcomes - *Arnab Sarkar, Sanofi*
16:55	Changeover			
	Hall 1a			
17:00 – 17:45	**Gone in 45 seconds**			
	Exhibition Hall			
17:45 – 18:45	**Poster Review**			
19:30 – 22:00	Monday Night Social – Cathedral Quarter Take-Over			

TUESDAY 16 JUNE | ICC Belfast

TIME	SESSION/LOCATION			
08:00 – 08:45	Registration			
	Hall 1a			
08:45 – 10:00	**Keynote Plenary: Reinventing Clinical Development: Why it's time for us to lead the AI-enabled future** Renowned for her visionary leadership and scientific expertise, Justine led the transformation of a global data science organization at a leading pharmaceutical company into an agile, data-driven powerhouse that redefined innovation culture and delivered outstanding results. A recognized catalyst for change, she has contributed to cross-industry collaborations, including a strategic alliance with major pharmaceutical partners and the CCAIM, a premier institute for AI-driven medicine in Cambridge, UK. Co-author of the Charter for Data Science in Pharmaceutical R&D and the Manifesto for AI-Driven Clinical Trials, she champions the transformative though realistic use of AI in drug development. Recently listed in the 2025 Top 10 Trailblazing Women in Pharma by Reuters Events, Justine is widely recognised for her passion, leadership and expertise in AI-driven clinical trials. Following her keynote speech, she will be joined by Danielle Belgrave and Tom Diethe on a panel discussion on the future of AI in our industry. *Justine Rochon, Head of R&D Data and Quantitative Sciences, SVP, Takeda* *Danielle Belgrave, VP of AI and ML, GSK* *Tom Diethe, Executive Director, Head of the Centre for AI, AstraZeneca*			
10:00 – 10:30	Refreshment Break in Exhibition Hall			
	Stream 1	Stream 2	Stream 3	Stream 4
10:30 – 12:00	**Early phase clinical trials (SIG)** Developments in early phase dose-finding trials *Sam Hinsley, Phastar* *Pavel Mozgunov, MRC Biostatistics Unit, University of Cambridge* *Andrew Hall, Leeds Institute of Clinical Trials Research* *Matt George, Phastar*	**AI/Machine Learning** Multi-Study Causal Forest (MCF): Improving the estimation of heterogeneous treatment effects using auxiliary data - *Ashwini Venkatasubramaniam, GSK* From Coders to Drug Developers: The Expanding Role of Statisticians in the Age of AI - *Sofia Tapani, AstraZeneca* Leveraging LLMs to navigate complex language in clinical trial informed consents forms -	**ICH E20 workshop** Implementing ICH E20: Designing and Analysing Adaptive Clinical Trials *Christopher Jennison, University of Bath* *David Robertson, MRC Biostatistics Unit, University of Cambridge* *Michael Grayling, Johnson and Johnson*	**Vaccines SIG** Innovative Statistical Approaches, Designs and Predictive Models in Vaccine Clinical Trials *Giulia Zigon, GSK* *Joshua Havumaki, GSK,* *Xinxue Liu, Oxford University* *Frederico Francone, AstraZeneca* *Seth Seegobin, AstraZeneca*

	Anaïs Andrillon, Department of Statistical Methodology, Saryga *Sandrine Micallef, Debiopharm International SA*	*Mbangula Lameck Amugongo, Boehringer Ingelheim* What if We've Been Looking at the Wrong Data? Reimagining Clinical Trial Success Prediction using AI - *Leo Fournier, Sanofi R&D* Trustworthy AI in Medicine: A Unified Bayesian Approach to Uncertainty, Performance and Fairness - *Bruno Boulanger, Sanaitio*		
	Hall 1a			
12:00 – 13:00	**Annual General Meeting** *(PSI members only)*			
13:00 – 14:00	Lunch in Exhibition Hall			
	Stream 1	Stream 2	Stream 3	Stream 4
14:00 – 15:30	**HTA** JCA Insights Unleashed: What Statisticians Can Learn from the first JCA Procedures *Katrin Kupas, Merck Healthcare KGaA* *Lara Wolfson, MSD*	**Randomisation SIG** Beyond Chance: Randomisation Designs for Innovative Clinical Trials *Diane Uschner, F. Hoffmann-La Roche* *Johannes Krisam, Boehringer Ingelheim* *Peter Jacko, Lancaster University* *Ayon Mukherjee. Eli Lilly*	**Biomarkers ESIG and Treatment Effect Heterogeneity SIG** Biomarker Discovery Across the Dimensionality Ladder *Marie-Karelle Riviere, Saryga* *Hugo Hadjur, Saryga* *Laura Schlieker, Staburo GmbH* *Mathias Cardner, AstraZeneca*	**Adaptive designs** *Including quantitative benefit-risk assessment in seamless phase 2/3 designs with dose selection - Marco Ratta, Saryga* When futility is futile – an economic case for more pragmatism in late phase futility stopping - *James Bell, Elderbrook Solutions GmbH* Assessing the impact of interim decisions in group sequential trials - *Gianmarco Caruso, MRC Biostatistics Unit, University of Cambridge* Framework for timing interim analyses in longitudinal trials with missing data: the role of

				blinding and sample size - *Neža Dvoršak, University of Bath*
15:30 – 16:15	Refreshment Break in Exhibition Hall			
	Stream 1	Stream 2	Stream 3	Stream 4
16:15 – 17:30	**Open source software** Validating Shiny Apps in Regulated Environments with the Litmusverse - *Pedro Silvers, Jumping Rivers* Which CRAN Packages Pharma Can Actually Rely On - *Colin Gillespie, Jumping Rivers* Fast, Fresh & Interactive: R Dashboards for Statisticians in 30 Minutes or Less! - *Martin Brown, PPD* Enhanced reconstruction of pseudo-individual patient data using quadratic programming - *Andrew Titman, Lancaster University*	**Complex trial design** Optimising Logrank Test Power in Group Sequential Trials with Non-Proportional Hazards via Event-Balanced Randomisation - *Anajali Pandey, Eli Lilly* Novel bayesian prediction of event times using mixture model for blinded randomized controlled trials - *Donia Skanji, Servier* Assessing Multiple Endpoints Using a Novel Software Solution in a Late-Stage Oncology Study - *Valeria Mazzanti, Cytel Inc.* Developing a simulation-based decision framework for interpretation of interim survival data in oncology trials - *Alessandra Bisquera, MMS*	**Rare diseases and special populations** Comparing Conditional Mean and Bayesian Imputation under MAR and Reference-Based Strategies in Rare Disease Trials - *Imanol Zubizarreta, Denali Therapeutics* From Nightingale to Now: Why Visualisations Are Still Essential in The Statisticians' Toolkit - *Bethany George, UCB Pharma* A Unified Inference Framework for Risk Difference and Risk Ratio: Enhanced Performance in Small-Sample, Low-Incidence Binary Endpoints - *Linbo Wang, University of Toronto*	**EFPIA Estimand Implementation Working Group** The estimand conundrum - is ICH E9 R1 crystal clear or are there still areas of confusion? *David Wright, AstraZeneca* *Laura Rodwell, Dutch Medicines Agency CBG-MEB*
19:15	Coach departure from Hilton Belfast			
20:00 – 00:30	Gala Dinner at the Titanic Belfast			
22:30	Shuttle coaches begin from Titanic Belfast to Hilton Belfast			
00:40	Final coaches depart			

WEDNESDAY 17 JUNE | ICC Belfast

TIME	SESSION/LOCATION			
08:30 – 09:15	Registration and exhibition viewing Bacon butty breakfast (with veggie option)			
	Hall 1a			
09:15 – 10:30	**Regulatory townhall** What are the key take home messages from the revised CHMP guideline on non-inferiority and equivalence comparison in clinical trials? *Speakers TBC*			
10:30 – 10:45	Closing remarks			
10:45 – 11:15	Refreshment Break in Exhibition Hall with prize announcements			
	Stream 1	Stream 2	Stream 3	Stream 4
11:15 – 12:30	**Bayesian modelling** Accelerating Alzheimer's Research: a modular framework for exploring Bayesian disease progression models - *Oana Petrof, GSK* On the interplay between prior weight and variance of the robustification component in Robust Mixture Prior Bayesian Dynamic Borrowing approach - *Marco Ratta, Saryga* A Comprehensive Self-Adaptive Mixture Prior Approach to Dynamic Borrowing from External Data - *Alfredo Farjat, Bayer B.V.* Information borrowing in Bayesian clinical trials: choice of tuning parameters for the robust mixture	**RWD SIG** Real-world data – do you know all the opportunities? The key questions they can answer and how *Eleanor Ralphs, IQVIA* *Josie Wolfram, Astellas* *Rima Izem, Novartis*	**Benefit-Risk SIG** Advancing the Implementation of Safety Methodologies *Dooti Roy, Boehringer Ingelheim* *Matthias Trampisch, Boehringer Ingelheim* *Florence Le Maulf, Cytel*	**Patient reported outcomes** A comparison of approaches to incorporate patient-selected and patient-ranked outcomes in clinical trials - *David Robertson, MRC Biostatistics Unit, University of Cambridge* Does your PRO sum it all up? Investigating the variability in item specific PRO effects using random item slopes regression - *Tom Booth, Acaster Lloyd* Timepoint selection for long-term PRO data modelling in oncology trials - *Anna Rigazio, IQVIA* Impact of interval-censored data on comparative time-to-event endpoints: a simulation

	prior - *Vivienn Weru, German Cancer Research Center (DKFZ)*			study applied to patient-reported outcomes in oncology - *Joel Sims, Adelphi Values*
	Stream 1	Stream 2	Stream 3	Stream 4
12:35 – 13:35	**Non-technical bitesize** #FakeNews: Statisticians and the Challenge of Misinformation - *Claire Brittain, Novartis* From Behind the Screen to Beside Your Team: Why the Office Still Matters – *Justyna Mlynarczyk, Phastar* From Classroom to Clinical Trials: How PSI Schools is inspiring the next generation of statisticians - *Ciara Lucas-Garner, Amgen* How Statisticians Can Use the Growth Mindset Framework for Stronger FSP Success in Pharma - *Amy Spencer, MMS* Microleadership: The habits of building leadership behaviours - *Emma May, Independent* CRO vs Pharma: from friction to synergy - *Angelina Rozmarytsia, Veramed Ukraine LLC*	**Bayesian adaptive designs** A ballad of a Basket trial and historical information borrowing: application in neurodegenerative diseases - *Libby Daniells, MRC Biostatistics Unit, University of Cambridge* Rigorous Type I error control for randomized BOP2-TE designs under minimal assumptions - *Alexander Ooms, GSK* Integrating Preclinical Insights for Adaptive Dose Escalation in Phase I Oncology Trials: A Methodological Framework for Enhanced Efficiency - *Melanie Guhl, Department of Statistical Methodology, Saryga*	**RSS/PSI prize winner** Forecasting and cost-efficient designing restricted enrolment in clinical trials *Vlad Anisimov, Amgen*	**Novel approaches to binary data** Efficient modelling of complex responder endpoints to improve trial power - *James Wason, Newcastle University* Increasing efficiency of composite endpoint trials: Novel Bayesian latent variable framework with application to late-stage trials - *Paul Newcombe, GSK* Beyond Dichotomization: Efficient Estimation of Response Rates using Continuous Outcomes - *Michael Sweeting, GSK*
13:35	Departure with grab and go lunches in registration area			