# SUNDAY 14 JUNE | Hilton Belfast

| TIME | SESSION/LOCATION | |
|---|---|---|
| 12:30 | Registration opens at the Hilton Belfast | |
| | Boardroom Suite | Lisburn 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.<br><br>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.<br><br>***Learning objectives***<br>1. Recognize how applied improvisation develops and reinforces interpersonal skills appropriate for the workplace.<br>2. Summarize the skills various physical and verbal exercises | 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.<br><br>***Learning objectives:***<br>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.<br><br>***Prerequisites:***<br>Participants are required to have some familiarity with clinical trial design, including an awareness of the ICH E9 Addendums on |

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| | emphasize and how exercises can improve communication, collaboration, and spontaneity.<br>3. Implement feedback and peer evaluation to improve listening, support others, and communicate more effectively.<br>4. Critique the effectiveness of individual physical and verbal exercises for personal skill development.<br>**Speaker:** *Richard C. Zink, PhD* | 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.<br>**Speakers:** *Dominic Magirr (Novartis, Basel, Switzerland), Alexander Przybylski (Novartis, United Kingdom)* |
| 14:45 – 15:15 | Refreshment break | |
| 17:00 | Pre-conference courses end | |
| 19:00 – 22:00 | Welcome Reception at the Northern Whig, Belfast<br>***Sponsored by MMS*** | |

# MONDAY 15 JUNE | ICC Belfast

| TIME | SESSION/LOCATION | | | |
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| | Riverside concourse | | | |
| 08:00 – 09:00 | Registration and morning refreshments<br>**Introduction for students and new starters** – *Oswald Dallimore, Charlotte Chrispin and Lucia Poyatos Baena (PSI Careers Committee)* | | | |
| | Hall 1a | | | |
| 09:05 – 09:20 | **Conference opening remarks**<br>*Vicky Marriott, PSI Conference Chair* | | | |
| 09:20 – 10:20 | **Keynote Plenary - Storytelling with data to influence change**<br>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.<br>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.<br>**Speaker:** *Jonathan McCrea, Whipsmart Media* | | | |
| 10:20 – 11:00 | Refreshment Break | | | |
| 10:20 – 10:45 | **Apprentice Networking Session**<br>For all apprentices (current or graduates) – The Apprentice Network are having an informal networking session in Hall 2b, join to meet other apprentices, ask them questions and discuss your experiences of the apprenticeship. | | | |
| | Hall 1a | Hall 2a | Hall 2b | Meeting Room 1 |
| 11:00 – 12:30 | **The river keeps moving: How statisticians can survive (and flourish!) in a world that never stands still**<br>**Chair:** *Lucy Rowell, Impactful Authenticity* | **Dose response (Career Young Speakers)**<br>**Chairs:** *Lucia Poyatos Baena & Charlotte Crispin*<br>BOIN vs. BLRM: A systematic performance comparison in phase | **Simulation workshop**<br>**Don't get distracted by noise: Simulations done right**<br>*Isabelle Smith, Veramed*<br>*Sam Miller, MMS* | **Patient-Focused Drug Development SIG**<br>**Tolerability PROs across the drug development lifecycle**<br>**Chair:** *Alexandra Lauer, Boehringer Ingleheim* |

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| | *Kimberley Hacquoil, Veramed*<br>*Frances Denny, MMS Holdings Europe Ltd*<br>*Sam Ruddell, Chiesi Ltd*<br>***Sponsored by Amgen***<br>AMGEN<br>Technical rating = 0 | 1 dose escalation - *Giulia Brunelli, Cogitars GmbH*<br>The impact of backfilling on early phase dose optimisation trials in oncology - *James Willard, MRC Biostatistics Unit, University of Cambridge*<br>Early phase dose-finding designs for CAR-T cell therapies – *Weishi Chen, University of Cambridge*<br>Dose finding in late phase Bayesian trials – *David Robertson, MRC Biostatistics Unit, University of Cambridge*<br>Technical rating = 2.5 | *Andy Grieve, Weatherden*<br>*Tim Friede, University Medical Center, Göttingen*<br>Technical rating = 1 | *Emily Alger, The Institute of Cancer Research*<br>*Lorenz Uhlmann, Boehringer Ingelheim*<br>*Antoine Regnault, Modus Outcomes*<br>*Konrad Maruszczyk, University of Birmingham*<br>Technical rating = 2 |
| 12:30 – 13:30 | Lunch in Exhibition Hall<br>**Career Young Networking Session** – *Oswald Dallimore, Charlotte Chrispin and Lucia Poyatos Baena (PSI Careers Committee)* | | | |
| | Hall 1a | Hall 2a | Hall 2b | Meeting Room 1 |
| 13:30 – 15:00 | **Academic-Industry Collaboration and Connection**<br>**Chair:** *Sue Todd, University of Reading*<br>Direct research collaborations - *David Wright, AstraZeneca & Dea Hazewinkel, London School of Hygiene & Tropical Medicine*<br>PhD industry supervision - *Tom Burnett, University of Bath, Ian Wadsworth, Phastar & Samuel Williams, University of Bath*<br>Collaborating on grant applications - *Michael Grayling, Johnson & Johnson & James Wason, Newcastle University* | **AI & Machine Learning SIG**<br>**Practical AI and developments in machine learning**<br>**Chair:** *Sam Hadlington, Plus-Project Partnership*<br>*Lesedi Ledwaba-Chapman, MMS*<br>*Paola Berchialla, University of Torino*<br>*Harry Parr, GSK*<br>*Jason Nicholas, GSK*<br>Technical rating = 2 | **HTA workshop**<br>**Navigating EU HTA: From pivotal trial to evidence networks based on first experiences**<br>*Stefanie Wüstner, AMS Advanced Medical Services GmbH*<br>*Anton Schönstein, Boehringer Ingelheim*<br>*Lena Stein, AMS Advanced Medical Services GmbH*<br>Technical rating = 1 | **Estimands: Uptake, application and communication**<br>**Chair:** *Maria Efstathiou, IQVIA*<br>Estimands for the percentage change from baseline: Guidance for clinical trials - *Tanja Högg, Novartis Pharmaceuticals UK Ltd*<br>How about those estimands for my cross-over study? - *Alexandra Jauhiainen, AstraZeneca*<br>All PICOs great and small; Dealing with small subpopulations in the EU HTA Landscape - *Dave Gelb, MSD and Joel Baldwin, UCB* |

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| | **Panel:** *with above speakers -Kate Taylor, Amgen & Claire Brittain, Novartis*<br><br>Technical rating = 0 | | | Evaluating Estimand implementation in clinical trials in the UK and beyond - *Morgaine Stiles, The Institute of Cancer Research*<br><br>Not just another Estimands talk: Practical strategies for cross-functional engagement to ensure meaningful, fit for purpose Estimands - *Emily Wood, Veramed*<br><br>Technical rating = 2 |
| 15:00 – 15:45 | Refreshment Break in Exhibition Hall | | | |
| | Hall 1a | Hall 2a | Hall 2b | Meeting Room 1 |
| 15:45 – 16:55 | **Data monitoring committees - Best practices and future development**<br><br>**Chair:** *Martin Jenkins, AstraZeneca*<br><br>*Tim Friede, University Medical Center, Göttingen*<br><br>*Sue Todd, University of Reading*<br><br>*Chrissie Fletcher, GSK*<br><br>*Elina Asikanius, FIMEA*<br><br>Technical rating = 1 | **Causal inference**<br><br>**Chair:** *Maria Efstathiou, IQVIA*<br><br>A spectrum of causal estimands – differences in dosing adherence patterns - *Anna Menacher, Novo Nordisk*<br><br>Disentangling indirect effects of vaccine assignment from other causal pathways in cluster-randomized trials with noncompliance - *Silvia Noirjean, GSK Vaccines*<br><br>Can NI margin calibration safeguard against invalid results in an evolving population? - *Nuala Peter, Boehringer Ingelheim*<br><br>Assessing covariate-adjusted risk differences in small-sample trials: A comparative evaluation of statistical methods - *Martin Schnuerch, Boehringer Ingelheim* | **Mixed (Career Young speakers)**<br><br>**Chairs:** *Lucia Poyatos Beaena & Charlotte Crispin*<br><br>PREDOSE: Pharmacometrically-refined early-phase dose optimization design for oncology study enhancement - *Damitri Kundu, Eli Lilly*<br><br>Sensitivity Analysis of missing pharmacokinetic samples in a simulated study of rapid acting psychedelics - *Nathan Patrick Burns, GH Research*<br><br>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**<br><br>**Chair:** *Nicola Scott, GSK*<br><br>Multiple Endpoints in early phase decision making - *Aleksandra Buchowicz & Chris Gibbs, AstraZeneca*<br><br>Integrated decision-theoretic optimisation of Phase II/III oncology trials - *Haotian Wang, Warwick Clinical Trials Unit*<br><br>Optimising multiplicity adjustment in clinical trials using elicited functions of commercial value and clinical benefit - *Alex Spiers, GSK*<br><br>Technical rating = 2 |

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| | | Technical rating = 2.5 | Incorporating prognostic scores in time-to-event analysis - *Harry Parr, GSK*<br>Technical rating = 2.5 | |
| 16:55 | Changeover | | | |
| 17:00 – 17:45 | **Gone in 45 seconds – *Hall 1a***<br>**Chair:** *Thomas Burnett, University of Bath* | | | |
| 17:45 – 18:45 | **Poster review – *Exhibition Hall***<br>***Sponsored by RSS*** | | | |
| 19:30 – 22:00 | Monday Night Social – Cathedral Quarter Take-Over<br>***Sponsored by Phastar*** | | | |

# 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**<br><br>AI's potential to transform medicine, from drug discovery through clinical development and health technology assessment to patient access, is unprecedented. Realizing that potential will not be driven by hype. It will be driven by scientific discipline and thoughtful leadership. At its core, AI is statistics.<br><br>This keynote will offer a practical perspective on how AI is being applied in clinical trials today, where it is creating measurable value, where it is not yet delivering, and what the next wave of advances may look like. A central theme is that data and AI do not change anything unless they lead to action. Building on John Tukey's reminder that the right question matters most, the session will focus on keeping AI grounded in real development decisions, supported by fit for purpose evidence, and implemented in day-to-day workflows with appropriate governance. The role of statisticians will be highlighted as pivotal to the AI-enabled future, not only in methods and validation, but in turning evidence into decisions by framing the right questions, characterizing uncertainty, being explicit about limitations and opportunities, and offering clear recommendations that enable responsible action.<br><br>The keynote will also address workforce implications that are often avoided. Efficiency gains are reshaping roles, especially at entry levels where routine tasks once built capability. Combined with hybrid and remote work, this shift demands more intentional mentoring and new pathways for talent development. The session will close with the multi-stakeholder collaboration required to scale AI-enabled innovation with integrity, and with a forward-looking call to action.<br><br>**Chair:** *Chrissie Fletcher, VP Head Respiratory, Immunology and Inflammation (RII) Statistics, GSK*<br><br>**Speaker:** *Justine Rochon, Head of R&D Data and Quantitative Sciences, SVP, Takeda*<br><br>**Panel:** *Danielle Belgrave, VP of AI and ML, GSK & Tom Diethe, Executive Director, Head of the Centre for AI, AstraZeneca*<br><br>***Sponsored by GSK***<br><br>GSK |
| 10:00 – 10:30 | Refreshment Break in Exhibition Hall |

| | Hall 1a | Hall 2a | Hall 2b | Meeting Room 1 |
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| 10:30 – 12:00 | **Early phase SIG**<br>**Developments in early phase dose-finding trials**<br>**Chair:** *Samantha Hinsley, Phastar*<br>*Pavel Mozgunov, MRC Biostatistics Unit, University of Cambridge*<br>*Andrew Hall, Leeds Institute of Clinical Trials Research*<br>*Matthew George, Phastar*<br>*Anaïs Andrillon, Department of Statistical Methodology, Saryga*<br>*Sandrine Micallef, Debiopharm International SA*<br>***Sponsored by Pierre Fabre***<br>LABORATOIRES Pierre Fabre<br>Technical rating = 2 | **AI/Machine learning**<br>**Chair:** *Nicola Scott, GSK*<br>From coders to drug developers: The expanding role of statisticians in the age of AI - *Sofia Tapani, AstraZeneca*<br>Leveraging LLMs to navigate complex language in clinical trial informed consents forms - *Mbangula Lameck Amugongo, Boehringer Ingelheim*<br>What if we've been looking at the wrong data? Reimagining clinical trial success prediction using AI - *Leo Fournier, Sanofi R&D*<br>Multi-Study Causal Forest (MCF): Improving the estimation of heterogeneous treatment effects using auxiliary data - *Ashwini Venkatasubramaniam, GSK*<br>Trustworthy AI in medicine: A unified Bayesian approach to uncertainty, performance and fairness - *Bruno Boulanger, Sanaitio*<br>***Sponsored by Pfizer***<br>Pfizer<br>Technical rating = 2 | **ICH E20 workshop**<br>**Implementing ICH E20: Designing and analysing adaptive clinical trials**<br>*Christopher Jennison, University of Bath*<br>*David Robertson, MRC Biostatistics Unit, University of Cambridge*<br>*Michael Grayling, Johnson and Johnson*<br>Technical rating = 2 | **Vaccines SIG**<br>**Innovative statistical approaches, designs and predictive models in vaccine clinical trials**<br>**Chair:** *Fabian Tibaldi, GSK*<br>*Giulia Zigon, GSK*<br>*Joshua Havumaki, GSK,*<br>*Xinxue Liu, Oxford University*<br>*Federico Francone, AstraZeneca*<br>*Seth Seegobin, AstraZeneca*<br>Technical rating = 2 |
| | Hall 1a | | | |
| 12:00 – 13:00 | **Annual General Meeting** *(PSI members only)* | | | |

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| 13:00 – 14:00 | Lunch in Exhibition Hall | | | |
| 13:10 – 13:45 | **Apprenticeship Scheme discussion**<br>Join Valerie Millar and Claire Brittain, in **Hall 2a**, to hear about where the campaign currently stands, the next steps, and discuss options for Level 6 (BSc) apprenticeships to help bring new programmers and future statisticians into the industry. | | | |
| 13:10 – 13:45 | **DEIB within PSI – Exchange of Ideas**<br>Join the DEIB AG team, in **Hall 2b**, to give feedback on planned DEIB deliverables for the upcoming year. | | | |
| | Hall 1a | Hall 2a | Hall 2b | Meeting Room 1 |
| 14:00 – 15:30 | **HTA**<br>**JCA Insights unleashed: What statisticians can learn from the first JCA procedures**<br>**Chair:** *Katrin Kupas, Merck Healthcare KGaA*<br>*David McConnell PhD, National Centre for Pharmacoeconomics (NCPE)*<br>*Sarah Böhme, Pfizer*<br>*Thomas Ecker, Ecker + Ecker and Accessus Health*<br>*Arthur Allignol, Daiichi Sankyo*<br>Technical rating = 1 | **Randomisation SIG**<br>**Beyond chance: Randomisation designs for innovative clinical trials**<br>**Chair***: Annika Scheffold, Boehringer Ingelheim*<br>*Diane Uschner, F. Hoffmann-La Roche*<br>*Johannes Krisam, Boehringer Ingelheim*<br>*Peter Jacko, Lancaster University*<br>*Ayon Mukherjee, Eli Lilly*<br>Technical rating = 2 | **Biomarkers SIG and Treatment Effect Heterogeneity SIG**<br>**Biomarker discovery across the dimensionality ladder**<br>**Chair:** *Ashwini Venkatasubramaniam, GSK*<br>*Marie-Karelle Riviere, Saryga*<br>*Hugo Hadjur, Saryga*<br>*Laura Schlieker, Staburo GmbH*<br>*Mathias Cardner, AstraZeneca*<br>***Sponsored by AstraZeneca***<br>AstraZeneca<br>What science can do<br>Technical rating = 2 | **Adaptive designs**<br>**Chair***: Sue Todd, University of Reading*<br>Including quantitative benefit-risk assessment in seamless phase 2/3 designs with dose selection - *Marco Ratta, Saryga*<br>When futility is futile – an economic case for more pragmatism in late phase futility stopping - *James Bell, Elderbrook Solutions GmbH*<br>Assessing the impact of interim decisions in group sequential trials - *Gianmarco Caruso, MRC Biostatistics Unit, University of Cambridge*<br>Framework for timing interim analyses in longitudinal trials with missing data: the role of blinding and sample size - *Neža Dvoršak, University of Bath*<br>Technical rating = 2 |
| 15:30 – 16:15 | Refreshment Break in Exhibition Hall | | | |

| | Hall 1a | Hall 2a | Hall 2b | Meeting Room 1 |
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| 16:15 – 17:30 | **Use of Open-source software**<br>**Chair**: *Ian Wadsworth, Phastar*<br>Which CRAN packages pharma can actually rely on - *Colin Gillespie, Jumping Rivers*<br>Validating shiny apps in regulated environments with the Litmusverse - *Pedro Silva, Jumping Rivers*<br>Fast, fresh & interactive: R dashboards for statisticians in 30 minutes or less! - *Martin Brown, PPD*<br>Enhanced reconstruction of pseudo-individual patient data using quadratic programming - *Andrew Titman, Lancaster University*<br>Technical rating = 1 | **EFPIA Estimand Implementation Working Group**<br>**The estimand conundrum - is ICH E9 R1 crystal clear or are there still areas of confusion?**<br>**Chair:** *Chrissie Fletcher, GSK*<br>*David Wright, AstraZeneca*<br>*Laura Rodwell, Dutch Medicines Agency CBG-MEB*<br>*Gerhild Angyalosi, Novartis*<br>*Steffan Ballerstedt, Novartis*<br>Technical rating = 1 | **Addressing the challenges of small sample size in rare diseases**<br>**Chair**: *Clelia Cahuzac, F. Hoffmann-La Roche Ltd*<br>From Nightingale to now: Why visualisations are still essential in the statisticians' toolkit - *Bethany George, UCB Pharma*<br>Comparing conditional mean (with resampling) and Bayesian imputation under MAR and reference-based strategies in rare disease trials - *Imanol Zubizarreta, Denali Therapeutics*<br>A unified inference framework for risk difference and risk ratio: Enhanced performance in small-sample, low-incidence binary endpoints - *Linbo Wang, University of Toronto*<br>Technical rating = 2 | **Complex trial design**<br>**Chair**: *Simon Newsome, Novartis*<br>Novel bayesian prediction of event times using mixture model for blinded randomized controlled trials - *Donia Skanji, Servier*<br>Assessing multiple endpoints using a novel software solution in a late-stage oncology study - *Valeria Mazzanti, Cytel Inc.*<br>Developing a simulation-based decision framework for interpretation of interim survival data in oncology trials – *Andrew Mills, MMS*<br>***Sponsored by Johnson & Johnson***<br>Johnson&Johnson<br>Technical rating = 2 |
| 19:00 | Coach departure from Hilton Belfast | | | |
| 19:15 – 00:30 | Gala Dinner at the Titanic Belfast | | | |
| 22:30 | Shuttle coaches begin from Titanic Belfast to Hilton Belfast | | | |
| 00:30 | Final coaches depart | | | |

# WEDNESDAY 17 JUNE | ICC Belfast

| TIME | SESSION/LOCATION |
|---|---|
| 08:30 – 09:15 | Registration and exhibition viewing<br>Bacon butty breakfast (with veggie option) |
| 08:30 – 09:15 | **Breakfast with the Book Club**<br>Grab a bacon butty and join the PSI Book Club, in the Exhibition Hall, to have a relaxing start to the day discussing books, podcasts and professional development |
| | Hall 1a |
| 09:15 – 10:30 | **Regulatory townhall: Regulatory Hot Topics**<br>Non-inferiority and equivalence comparisons in clinical trials<br>**Chair***: David Wright, AstraZeneca*<br>*Helle Lynggaard, Novo Nordisk*<br>*Florian Lasch, EMA*<br><br>Use of external controls and real-world evidence to support regulatory decision making<br>**Chair:** *Rima Izem, Novartis*<br>*Elina Asikanius, FIMEA*<br>*Khadija Rantell, MHRA*<br><br>Technical rating = 1 |
| 10:30 – 10:45 | Closing remarks<br>*Naomi Givens, PSI Chair, Board of Directors* |
| 10:45 – 11:15 | Refreshment Break in Exhibition Hall with prize announcements |

| | Hall 1a | Hall 2a | Hall 2b | Meeting Room 1 |
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| 11:15 – 12:30 | **Bayesian modelling**<br>**Chair:** *Ian Wadsworth, Phastar*<br>Accelerating Alzheimer's research: a modular framework for exploring Bayesian disease progression models - *Oana Petrof, GSK*<br>A comprehensive self-adaptive mixture prior approach to dynamic borrowing from external data - *Alfredo Farjat, Bayer B.V.*<br>Information borrowing in Bayesian clinical trials: choice of tuning parameters for the robust mixture prior - *Vivienn Weru, German Cancer Research Center (DKFZ)*<br>On the interplay between prior weight and variance of the robustification component in robust mixture prior Bayesian dynamic borrowing approach - *Marco Ratta, Saryga*<br>Technical rating = 2 | **RWD SIG**<br>**Real-world data – do you know all the opportunities? The key questions they can answer and how**<br>**Chair**: *Simon Newsome, Novartis*<br>*Eleanor Ralphs, IQVIA*<br>*Josie Wolfram, Astellas*<br>*Rima Izem, Novartis*<br>Technical rating = 1 | **Benefit-Risk SIG**<br>**Advancing the implementation of safety methodologies**<br>**Chair**: *Naomi Givens, GSK*<br>*Dooti Roy, Boehringer Ingelheim*<br>*Matthias Trampisch, Boehringer Ingelheim*<br>*Florence Le Maulf, Cytel*<br>Technical rating = 1 | **Patient reported outcomes**<br>**Chair:** *Sue Todd, University of Reading*<br>A comparison of approaches to incorporate patient-selected and patient-ranked outcomes in clinical trials - *David Robertson, MRC Biostatistics Unit, University of Cambridge*<br>Does your PRO sum it all up? Investigating the variability in item specific PRO effects using random item slopes regression - *Tom Booth, Acaster Lloyd*<br>Timepoint selection for long term PRO data modelling in oncology trials - *Anna Rigazio, IQVIA*<br>Impact of interval-censored data on comparative time-to-event endpoints: a simulation study applied to patient-reported outcomes in oncology - *Joel Sims, Adelphi Values*<br>Technical rating = 2 |
| | Hall 1a | Hall 2a | Hall 2b | Meeting Room 1 |
| 12:35 – 13:35 | **Non-technical bitesize**<br>**Chair:** *Kate Taylor, Amgen*<br>How statisticians can use the Growth Mindset Framework for stronger FSP success in pharma - *Amy Spencer, MMS* | **Bayesian adaptive trial designs**<br>**Chair***: Ayon Mukherjee, Eli Lilly*<br>Integrating preclinical insights for adaptive dose escalation in Phase I oncology trials: A methodological framework for enhanced efficiency - | **RSS/PSI prize winner**<br>**Chair***: Clelia Cahuzac, F. Hoffmann-La Roche Ltd*<br>Forecasting and cost-efficient designing restricted enrolment in clinical trials<br>*Vlad Anisimov, Amgen* | **Statistical innovations for efficient endpoint analysis: Beyond dichotomization**<br>**Chair***: Ian Wadsworth, Phastar*<br>Efficient modelling of complex responder endpoints to improve |

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| | From Priors to Partnership: A Bayesian View of CRO-Sponsor Collaboration – *Kimberley Hacquoil, Veramed*<br><br>From classroom to clinical trials: How PSI Schools is inspiring the next generation of statisticians - *Ciara Lucas-Garner, Amgen*<br><br>From behind the screen to beside your team: Why the office still matters – *Justyna Mlynarczyk, Phastar*<br><br>#FakeNews: Statisticians and the challenge of misinformation - *Claire Brittain, Novartis*<br><br>The Career Habits of Building Leadership Behaviours - *Emma May, The Career Habit*<br><br>Technical rating = 0 | *Melanie Guhl, Department of Statistical Methodology, Saryga*<br><br>Rigorous Type I error control for randomized BOP2-TE designs under minimal assumptions - *Alexander Ooms, GSK*<br><br>A ballad of a basket trial and historical information borrowing: Application in neurodegenerative diseases - *Libby Daniells, MRC Biostatistics Unit, University of Cambridge*<br><br>Technical rating = 2 | Technical rating = 3<br><br>***Sponsored by RSS***<br><br>ROYAL STATISTICAL SOCIETY | trial power - *James Wason, Newcastle University*<br><br>Beyond Dichotomization: Efficient estimation of response rates using continuous outcomes - *Michael Sweeting, GSK*<br><br>A robustness assessment of the latent variable framework for composite endpoints: With application to late-stage trials - *Paul Newcombe, GSK*<br><br>Technical rating = 2.5 |
| 13:35 | Departure with grab and go lunches in registration area | | | |

# MONDAY 15 JUNE | POSTER REVIEW AND GONE IN 45 SECONDS

| Poster ID | Title | Presenting Author | Gone in 45 Seconds |
|---|---|---|---|
| P001 | Network Meta Analysis in R: Satisfying the Statistical Criteria for Health Care Decision Makers | Rebecca Tilston | Y |
| P002 | Bayesian Building Blocks: The Key to Successful Validation | Moaaz Sidat | Y |
| P003 | Individual Patient Data (IPD) Network Meta Analysis (NMA) without IPD sharing | Federico Bonofiglio | Y |
| P005 | A Tutorial on tidymodels | Jason Nicholas | Y |
| P006 | Structural Equation Models to Model Digital Measures, Patient-Centred Outcomes, and Clinical Variables: Illustration Using SPIROMICS Data | Prathiba Batley | N |
| P008 | Effectiveness of Cannabidiol in Patients With Rare Epilepsies Compared With External Placebo Control: A Post Hoc Analysis From the Expanded Access Program | Teresa Greco | N |
| P009 | Use conditional Hellinger distances with cumulative link mixed model with nested random effects on questionnaire variables for univariate and multi variate risk detection in clinical trial | Lawson Wang | N |
| P010 | Arm Wrestling with Uncertainty: Meta-Analysis for Survival Estimation | Isabelle Smith and Emily Wood | Y |
| P011 | Double Trouble: Tackling Expectations, Challenges and AI in Double Programming | Avie-Lee Tillotson | Y |
| P013 | Continuous Monitoring in Early Phase Oncology: A Standardized, Patient-Centric Approach | Tessa Lloyd | Y |
| P014 | Leveraging Predicted Interval Plots (PIPs) to Predict the Outcome of an Oncology Study through Interim Monitoring of Event Accrual | Valeria Mazzanti | Y |
| P015 | Love It or HTA It: Exploring Variability in Submission Requirements and Implications for Global Strategy | Daria Shamaida | Y |
| P016 | Forecasting the process of screened/randomized patients and optimal screening stopping time to minimize over-enrollment in clinical trials | Vlad Anisimov | Y |
| P017 | Temporal Deep Learning for Predicting Intensive Care Unit Readmissions from Electronic Health Records | Paola Berchialla | N |
| P018 | Shaping Europe’s Demographic Future: The Role of Clinical Trials | Daria Vynohradova | N |
| P020 | Innovative Trial Design Through Bayesian Dynamic Borrowing: Industry Lessons and Applications | Lesedi Ledwaba-Chapman | N |
| P021 | Assessing the Likelihood of Success in Phase 3 Vaccine Clinical Trials: A Strategical Approach Derived from Phase 2 Efficacy Results. | Fabian Tibaldi | N |

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| P022 | Real-world evidence for dose–response relationships between weight loss and clinical outcomes in obesity-related comorbidities | Tzviel Frostig | Y |
| P023 | Walking the tightrope: Balancing the needs of all stakeholders for biotech survival | Kimberley Hacquoil | Y |
| P024 | Optimizing BOIN with Bayesian posteriors: a simple, flexible, and accurate phase I design | Yaron Racah | Y |
| P025 | Designing phase I trials with backfilling to mitigate screening and treatment delays | Andrew Hall | Y |
| P028 | Recurrence: An Analysis of Adverse Events Whose Time Has Come in the Evaluation of Patient Safety in Clinical Trials | Richard Zink | Y |
| P029 | Maximizing insight and efficiency: Comparison of Rate of decline in FVC and change from baseline in FVC analysed using frequentist and model-based approaches in idiopathic pulmonary fibrosis trials | Beatriz Seoane | Y |
| P030 | Effective Study Closeout Following Early Termination: Points to Consider as a Biostatistician | Tessa Lloyd | N |
| P031 | Exploring PSI's Introduction to Industry Training (ITIT) Course: Benefits for Participants and Hosts | Laura White | N |
| P032 | The Versatile Statistician: Driving Value beyond Clinical Trial Conduct | Parveen Kumar | Y |
| P033 | Bayesian Meta-Analysis for Phase 2 Endpoint Selection: Predicting Phase 3 Outcomes to Optimize Trial Design | Enti Spata | Y |
| P034 | Recurrent Events made simple: translating disease burden into five scenarios | Tomoko Iwata | Y |
| P036 | Using Influence Science to Communicate and Advocate for Innovative Bayesian Trial Designs | Claire Smith | Y |
| P037 | Balancing Complexity in EU-HTA – A simulation study to assess the impact of treatment effect estimates from incomplete PRO collection data | Alexandra Lauer | Y |
| P038 | Between-Study Heterogeneity in Two-Study Bayesian Meta-Analyses of German HTA Dossiers: Empirical Evidence on the Appropriateness of τ Priors - FRIEND OR FOE? | Annett Kucka | N |
| P039 | From junior to lead: Key skills developed working in an IDAC | Rhys Jones | N |
| P040 | Real-World Data (RWD) to Influence Clinical Trial Drug Supply Forecasting | Sandra Joksaite | Y |
| P041 | Absolute standardized Differences – an objective tool for checking similarity in indirect treatment comparisons? | Janik Beuermann | Y |
| P043 | What are multi-state models and how are they useful in our industry? | Victoria López Dittmar | N |
| P044 | Characterizing FEV1 Variability from Historical Early-Phase Asthma Trials to Shape Future Designs | Alese Halvorson | N |
| P045 | From Conventional Trials to Ultra Rare Diseases: Adapting Classical Statistical Methods to Extremely Small Populations | Benoit Sansas | Y |
| P046 | GAM plots, AI, SAS and R: a tutorial exploring baseline associations and negative binomial responses | Kacper Kowalczyk | N |
| P047 | Why Radioconjugates Demand New Statistical Thinking | Benjamin Webb | N |
| P048 | Automated generation of SAP multiplicity appendices via the {appendMCP} R package | Michael Grayling | Y |

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| P049 | Beyond Dichotomization: Optimizing Composite Endpoints in Atopic Dermatitis Using a Bayesian Latent Variable Framework | Arina Kazimianec | Y |
| P050 | Benchmarking Statistical Methods of Dynamic Borrowing Information from Historical Data | Xiang Zhang | Y |
| P051 | FDA Bayesian Guidance: A Software Testing Procedure | Pravin Madhavan | N |
| P053 | Applying the Estimand Framework to Dose-Ranging Trials: A Case Study | Chun-Hang Tang | Y |
| P054 | Agenda of the novel SIG Special Interest Group for Medical Devices - Finding similarity within the diversity of medical devices | Emilie Gerard | N |
| P055 | Delivering interim analyses in blinded randomized clinical trials: plan, protect, adapt, align | Elisabet Garcia | N |
| P056 | Discrete-Time Modelling of Sustained eGFR Decline in CKD Trials: Simulation-Based Comparison of Cox, Gompertz and Weibull Approaches | José Sánchez | Y |
| P057 | When to Weight, When to Match: Considerations from Two Real-World Evidence Case Studies | Lucy Clark | Y |
| P058 | Multiple imputations of range-restricted data – to ignore the range or not to ignore, that is the question | Kacper Kowalczyk and Beata Pawlikowska | Y |
| P059 | Predicting the Unpredictable: How Event Prediction Succeeds, and Fails | Bastiaan Jansen | N |
| P060 | APT-SAP: Enhancing the design, conduct and analysis of Adaptive and Platform Trials through consensus-driven Statistical Analysis Plan guidance. | Sue Todd | Y |
| P061 | Interim Decision-Making in Two Parallel Pivotal Studies | Saswati Saha | Y |
| P062 | Estimating eGFR-Decline Event Times Under Intermittent Observation: Bias, Precision, and Implications for CKD Trial Design | Sasha Tatum | Y |
| P063 | Weighted longitudinal summaries of PRO data across treatment phases: a simulation study with potential relevance for HTA | Emanuele Del Fava | Y |
| P064 | What drug do we want to develop? Interpretation of results from proof-of-concept trials and de-risking of phase 3. | Oliver Sailer | Y |
| P065 | Innovating Biostatistics: Strategic Pathways for R Migration | Parsa Mohammadian | Y |
| P066 | Combination of non-parametric analysis results after multiple imputation | Stefano Vezzoli | Y |
| P067 | Morgana: Lessons learnt using Agentic AI to generate real time study report tables from raw data | Philip Young | Y |
| P068 | A statistical perspective on early and late-stage clinical development in oncology trials | Lydia Dickson | N |
| P069 | Scientific Surveillance as a Pillar of Risk-Based Quality Management within Centralized Monitoring | Megan Hewitt | N |
| P070 | A Gene Therapy Trial for Type 1 Diabetes: Dose Escalation Guided by Continuous Glucose Monitoring and Bayesian Beta Regression | Matt Chapman-Rounds | Y |
| P071 | SAS vs. R Infographic: Documenting Important Differences (PHUSE CAMIS Project) | Martin Brown | Y |

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| P072 | Priors and decision thresholds in Bayesian Phase II and Phase III clinical trials: a methodological scoping review | Oswald Dallimore | Y |
| P073 | Comparing hypothesis testing routines for adaptive designs | Samuel Williams | Y |
| P075 | PRO Endpoints: Power and interpretation for analysis of mean changes in continuous scores vs responder analysis of dichotomised scores | Rachael Lawrance | Y |
| P076 | From Signals to Insight: Integrated Approaches for Improved IDMC Safety Evaluation | Nicolas Dubois | Y |
| P077 | Does the winner take it all? The win ratio method – an alternative approach to analyse composite endpoints. | Corinna Miede | N |
| P078 | Beyond Tables: Visualization as a Decision-Support Tool for IDMCs | Samantha Cambier | Y |
| P079 | Medication adherence - a measurable indicator of childcare at home associated with post-discharge outcomes in Kenyan children. | Dearbhala Quinn | Y |
| P080 | Synthetic Patient Generation as a Framework for Robustness Assessment, Sensitivity Analysis, and Exploratory Decision Support | Sofia Azevedo | Y |
| P081 | Advancing Diversity, Equity, Inclusion & Belonging at PSI: Updates from the DEIB Advisory Group | Karen Smith | Y |
| P082 | A Modelling Framework for Regulatory-Aligned Extrapolation in Paediatric Diseases | Rejina Verghis | Y |
| P083 | OPTIMUS journey - From MTD to Optimal Dose: A Multi-Domain Quantitative Strategy for Early-Phase Oncology Trials | David Jegou | Y |
| P084 | Model-informed early decision making in oncology: case study in MM, when Clinical Pharmacology and Biostatistics work together. | Federico Mattiello | Y |
| P085 | A simulation based comparison of CART survival trees and traditional Cox models in oncology trial settings | Conan Liang | Y |
| P086 | PFS – Sensitivity Analyses through a Regulatory Lens | Callum Dickson | Y |
| P088 | How Sensitive Are Interim Decisions? A Simulation Study of Conditional Power Thresholds in Adaptive Trial Design | Lida Fallah | Y |
| P089 | The use of estimands in real world evidence studies | Andrew Elders | Y |