

## ADMTP Workshop 2023 – Scientific Program Overview

**Wednesday 19<sup>th</sup> April**

12:30 – 13:00	Registration
13:00 – 13:15	<p>Welcome</p> <ul style="list-style-type: none"> <li>• Lisa Hampson (Chair of local organizing committee)</li> <li>• Thomas Asendorf (Chair of IBS-DR and ROeS ADMTP working group)</li> <li>• Marisa Bacchi (Basel Biometric Society)</li> </ul>
13:15 – 14:15	<p>Invited Session I Chair: Marisa Bacchi</p> <p style="text-align: center;"><b>Tobias Mielke:</b> <i>Adaptive platform trials: complex and innovative – but how useful?</i></p>
14:15 – 15:15	<p>Session I: Platform trials Chair: Marta Bofill Roig</p> <ol style="list-style-type: none"> <li>1. <b>Peter Greenstreet</b>, Thomas Jaki, Alun Bedding, Pavel Mozgunov: <i>Why keeping previous data can be detrimental in platform trials with a change in standard of care</i></li> <li>2. <b>Michaela Maria Freitag</b>, Dario Zocholl, Stefan Gold, Martin Posch, Franz König: <i>Early stopping, allocation ratios and power: how to tailor design options for a platform trial in Major Depressive Disorder</i></li> </ol>
15:15 – 15:45	Coffee Break
15:45 – 17:45	<p>Invited Session II: Platform trials – findings from the EU-PEARL initiative Chair: Ekkehard Glimm</p> <ol style="list-style-type: none"> <li>1. <b>Pavla Krotka</b>, Katharina Hees, Peter Jacko, Dominic Magirr, Martin Posch, Marta Bofill Roig: <i>NCC: An R-package for analysis and simulation of platform trials with non-concurrent controls</i></li> <li>2. <b>Quynh Nguyen</b>, Hue Kästel, Katharina Hees, Benjamin Hofner: <i>The use of complex clinical trials: A regulatory review</i></li> <li>3. <b>Marta Bofill Roig</b>, Ekkehard Glimm, Tobias Mielke and Martin Posch: <i>Optimal allocation strategies for platform trials</i></li> <li>4. <b>Sonja Zehetmayer</b>: <i>Looking forward and benefiting from the past: Sample size estimation for new arms in platform trials</i></li> </ol> <p><b>Discussion panel:</b> Benjamin Hofner, Tobias Mielke, Tom Parke and presenters (30 minutes) <b>Audience Q&amp;A:</b> 10 minutes</p>
19:30	Workshop Dinner

## Thursday 20<sup>th</sup> April

09:00 – 11:00	<p>Session II: Adaptive designs and multiple testing in a confirmatory setting Chair: Ekkehard Glimm</p> <ol style="list-style-type: none"> <li>1. <b>Frank Bretz</b>, Uli Burger: <i>Principles of adaptive clinical trials - a personal view</i></li> <li>2. Marie Louise Østerdal, Kyle Raymond, <b>Christian Bressen Pippert</b>: <i>Properties of a confirmatory two-stage adaptive procedure for assessing average bioequivalence</i></li> <li>3. <b>Leonhard Held</b>: <i>Sequential alternatives to the two-trials rule</i></li> <li>4. <b>Akshay Patil</b>: <i>Checklist and reporting guidelines for estimands in adaptive or innovative clinical trial designs</i></li> </ol>
11:00 – 11:30	Coffee Break
11:30 – 13:00	<p>Session III: Adaptive designs for clinical trials with time-to-event endpoints Chair: Dominic Magirr</p> <ol style="list-style-type: none"> <li>1. <b>Moritz Fabian Danzer</b>, Andreas Faldum, Rene Schmidt: <i>Adaptive designs for multiple time-to-event outcomes in Markovian multi-state models</i></li> <li>2. <b>Pantelis Vlachos</b>: <i>A new approach to trial design and probabilistic risk assessment for trials with dual survival endpoints</i></li> <li>3. <b>Deepak Parashar</b>: <i>A predictive biomarker enrichment design for Phase II oncology trials</i></li> </ol>
13:00 – 14:00	Lunch
14:00 – 15:30	<p>Session IV: Group sequential and adaptive designs Chair: Anh Nguyen Duc</p> <ol style="list-style-type: none"> <li>1. <b>Kelly Van Lancker</b>, Josh Betz, and Michael Rosenblum: <i>Combining covariate adjustment with group sequential, information adaptive designs to improve randomized trial efficiency</i></li> <li>2. <b>Cornelia Ursula Kunz</b>, Shannon Amy Zellner, Sonja Drescher, Johannes Krisam: <i>An adaptive balance-ensuring big stick randomization procedure for equal and unequal allocation ratios</i></li> <li>3. <b>Maria Vittoria Chiaruttini</b>, Jacopo Gallochio, Alessandro Desideri, Danila Azzolina, Dario Gregori: <i>Resampling algorithm for calculation of sample size of two-stage and three-arm sequential non-inferiority clinical trials when applied to skewed outcome: a simulation study</i></li> </ol>
15:30 – 16:00	Coffee Break
16:00 – 17:30	<p>Session V: Multiple Testing Procedures Chair: Tobias Mielke</p> <ol style="list-style-type: none"> <li>1. <b>Jixian Wang</b>, Ram Tiwari: <i>Toward optimal graphic tests</i></li> <li>2. <b>Lasse Fischer</b>, Marta Bofill Roig and Werner Brannath: <i>Online closed procedures</i></li> <li>3. <b>Remi Luschei</b>: <i>The effect of estimating prevalences on the population-wise error rate</i></li> </ol>

## Friday 21<sup>st</sup> April

09:00 – 10:00	<p>Session VI: Adaptive designs permitting sample size re-estimation Chair: Lisa Hampson</p> <ol style="list-style-type: none"><li>1. <b>Arunava Chakravarty</b>, Xiaodong Li, Shoubhik Mondal, Pabak Mukhopadhyay: <i>Sample size re-estimation for long term time to event trials- A case study and practical considerations</i></li><li>2. <b>Lara Vankelecom</b>, Tom Loeys &amp; Beatrijs Moerkerke: <i>How to safely re-assess variability and adapt sample size? A primer for the two-sample the t-test</i></li></ol>
10:00 – 11:00	<p>Invited Session III Chair: Robbie Peck</p> <p><b>Chris Jennison</b>: <i>Optimising sequential and adaptive designs: the power of dynamic programming</i></p>
11:00 – 11:30	<p>Coffee Break and Workshop Photo</p>
11:30 – 12:00	<p>Session VII: History of the IBS-DR and ROeS ADMTP working group Chair: Thomas Asendorf</p> <p><b>Gerhard Hommel</b>, Gernot Wassmer: <i>Adaptive designs and multiple testing procedures before the ADMTP Working Group</i></p>
12:00 – 12:30	<p>Meeting of the IBS-DR / ROeS Working Group on ADMTP Chairs: Thomas Asendorf and Marta Bofill Roig</p>
12:30 – 12:40	<p>Close of workshop Lisa Hampson and Marta Bofill Roig</p>