## Preliminary Programme of the Conference

### Session 1: Implementation of RWE in regulatory decision making

**Chair: Christine E. Hallgreen, Associate Professor and Director CORS**

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<tbody>
<tr>
<td>08:30 – 09:00</td>
<td><strong>Registration and coffee</strong></td>
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| 09:00 – 09:10 | **Welcome**  
  *Christine E. Hallgreen, Associate Professor and Director CORS* |
| 09:10 – 09:35 | **Preliminary title: EMA’s experiences using RWE to support regulatory decision-making**  
  *Jesper Kjær, Director of the Danish Medicines Agency's Data Analytics Centre and co-chair at EMA/HMA Big Data Steering Group* |
| 09:35 – 10:00 | **Real-world evidence in the EU medicines regulation: enabling use and establishing value**  
  *Peter Arlett, Head of the EMA Data Analytics and Methods Taskforce* |
| 10:00 – 10:30 | **Coffee break**                                                      |
| 10:30 – 11:00 | **(Online)**  
  **RWE in regulatory science**  
  *Britta Hänisch, Head of the research division, Federal Institute for Drugs and Medical Devices (BfArM), Bonn* |
| 11:00 – 11:30 | **(Online)**  
  **Beginning convergence on conducting RWE studies to estimate treatment effects**  
  *Sebastian Schneeweiss, Chief, Division of Pharmacoepidemiology and Pharmacoeconomics, Harvard Medical School; Professor in Epidemiology, Harvard T.H. Chan School of Public Health* |
| 11:30 – 12:00 | **Panel discussion and Q & A**                                        |
| 12:00 -13:00 | **Lunch and poster exhibition of Regulatory Science PhD and Master projects** |
**Session 2: Examples of RWE use**

**Chair:** *Marieke De Bruin*, Professor Utrecht University, Scientific Director of the Utrecht Centre for Pharmaceutical Policy and Regulation

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| 13:00 – 13:30 | Examples of stepped wedge and cluster randomised clinical trials - from the perspective of the clinical researcher.  
*Pernille Brok Nielsen*, Physician and PhD student at Herlev and Gentofte Hospital, Pragmatic trial experience |
| 13:30 – 14:00 | Expanding the use of RWE across the product life cycle                                              
*Alison Cave*, Chief Safety Officer at Medicines and Healthcare products Regulatory Agency (MHRA) |
| 14:00 – 14:30 | Regulatory use of RWE and Industry: the need for T-shaped RWD and X-shaped methods                  
*Nigel Hughes*, Scientific Director of the Observational Health Data Analytics at Janssen, Project Lead for the IMI2 European Health Data & Evidence Network (EHDEN) |
| 14:30 – 15:00 | Coffee break                                                                                     |

**Session 3: Methodologies in RWE**

**Chair:** *Theis Lange*, Head of Department, Professor Department of Public Health UCPH

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| 15:00 – 15:30 | A Bayesian perspective on real-world data analysis                                                  
*Chris Holmes*, Programme Director for Health and Medical Sciences at The Alan Turing Institute and Professor of Biostatistics at the University of Oxford |
| 15:30 – 16:00 | Bounding RWE and a potential new causal pipeline                                                   
*Erin Evelyn Gabriel*, Associate professor in Biostatistics at UCPH, Principal Researcher and Docent in Biostatistics at Karolinska Institutet, and Affiliate Researcher at the National Institute of Allergy and Infectious Diseases (NIH) |
| 16:00 – 16:20 | Panel discussion and Q & A                                                                            |
| 16:20 – 16:30 | Closing remarks                                                                                     
*Nikolai B Brun*, Affiliate Professor CORS, Chief Medical Officer Affibody AB |