Programme of the Conference

08:30 – 09:00	**Registration and coffee**
09:00 – 09:10	**Welcome** ***Christine E. Hallgreen,*** *Associate Professor and Director CORS*

Session 1: Implementation of RWE in regulatory decision making
Chair: *Christine E. Hallgreen,* *Associate Professor and Director CORS*

09:10 -09:35	**PHAIR: Pharmacovigilance by AI Real-time Analysis.** ***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	**Clinical Evidence 2030** ***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*

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*

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*