Annual meeting of the Danish Society for Pharmacoepidemiology 2021

Theme

Pragmatic trials: academic, regulatory, and industry perspective

Date

26th October 2021

Time

12h 30 to 16h 00 (GMT +1h)

Venue

Online

Scope

The theme of this year's annual meeting will be pragmatic trials. Whereas the traditional randomized controlled trial is designed to establish efficacy of a specific drug, i.e. the effect under ideal conditions, the pragmatic trial is designed to establish effectiveness, i.e. how well the drug works in everyday clinical practice. The topic will be addressed by speakers from regulatory agencies, academia, and the industry.

Program

12h 30 to 12h 40	Welcome
12h 40 to 13h 30	Academic perspective on pragmatic trials
	Title: The why and how of pragmatic trials – an academic perspective
	Speaker: Mira G.P. Zuidgeest, Assistant Professor, Julius Center for Health Sciences and Primary Care, University Medical Center Utrecht
13h 30 to 13h 40	Short break
13h 40 to 14h 05	General assembly (only for members of Danish Society for Pharmacoepidemiology)
14h 05 to 14h 50	Regulatory perspective on pragmatic trials
	Title: Pragmatic clinical trials in the context of regulation of medicines
	Speaker: Daniel Morales, Wellcome Trust Clinical Research Fellow, 1 Population Health and Genomics, School of Medicine, University of Dundee. 2 Department of Public Health, University of Southern Denmark.
14h 50 to 15h 00	Short break
15h 00 to 15h 45	Industry perspective on pragmatic trials
	Title: The changing face of clinical trials – pragmatic trials from an industry perspective
	Speaker: Simon Skibsted, Senior Director and Head of Real World Data Science & Innovation, Novo Nordisk Inc
15h 40 to 16h 00	Closing remarks

Presentation of speakers

Mira G.P. Zuidgeest, PhD, PharmD, MSc epidemiology, works as assistant professor at the Julius Center for Health Sciences and Primary Care. Trained both as a pharmacist and epidemiologist and with a PhD in pharmacoepidemiology in the field of paediatric asthma, her current work focuses on clinical trial innovation, both methodological and operational. As core team member of the GetReal Institute, her work focusses on randomised clinical trials integrated into routine clinical practice (also called pragmatic trials) and the methodological and operational consequences of introducing real world elements in trial design, for which she has developed a decision-support tool (www.getrealtrialtool.eu). And as overall scientific lead and WP3 lead for the IMI Trials@Home project (www.trialsathome.com), she looks into the possibilities of centring trials around patients rather than clinical sites by use of innovative technologies (so called Remote Decentralised Clinical Trials).

Simon Skibsted, MD, MPH, PhD, serves as Senior Director and Head of the Real World Data Science & Innovation team at Novo Nordisk Inc. In this capacity, he leads the continued development of data science capabilities and championing innovative approaches to randomized real-world trials to create a fully integrated cross-functional hub of advanced evidence generation relevant to patients, physicians, payers, regulators, and internal decision makers. Dr. Skibsted has spearheaded the cross-functional efforts of implementing novel trials designs including pragmatic trials within his organization across various therapeutic areas and development phases. This has led to the initiation of real world randomized pragmatic trials in employer, health system, and payer settings. Prior to this, Dr. Skibsted worked in a global function where he was medically and scientifically responsible for the conduct of pre and post approval randomized trials including large scale cardiovascular outcomes trials enabling a solid experience in planning, designing, executing, and reporting of trials within the setting of diabetes and cardiovascular disease.

Dr. Skibsted is particularly focused on ways to translate efficacy to effectiveness. This includes the development and implementation of new tools and processes to assist in assessing value of interventions in settings and populations in which the intervention is intended to be used once it is on the market. Dr. Skibsted earned his MD degree at University of Copenhagen and his PhD degree from Aarhus University. Furthermore, Dr. Skibsted has an MPH degree in Clinical Effectiveness from Harvard University.

Daniel R. Morales, PhD, MRGP, MRCP, MBChB, BMSc, works as a primary care physician and epidemiologist. His research focuses on chronic disease epidemiology, drug safety and medicines regulation. He holds a Wellcome Trust Clinical Research Fellowship focusing on understanding differences in trial eligible populatioins. Dr Morales has previously worked within the Department of Pharmacovigilance and Epidemiology at the European Medicines Agency (EMA) and is currently a member of the EMA Pharmacovigilance Risk Assessment Committee (PRAC). He is chair of the PRAC impact group, which coordinates activities related to the PRAC strategy on measuring the impact of pharmacovigilance activities, and is a member of the ENCePP steering group.