

10th NorPEN congress 1st–3rd November 2017

Safety of Drugs and Vaccines - defining exposures and outcomes

Venue: The Finnish Social Insurance Institution (Kela), Nordensköldinkatu 12, Helsinki, Finland

Wednesday 1st of November

Practical workshop on statistical analyses of register data (own laptops)

This practical workshop includes hands on sessions on how to handle Nordic register-based data and conduct analyses with statistical software. The session is designed to include example dataset, and instructions and codes with three most commonly used statistical software; SAS, STATA and R. Participants may proceed according to their own skills with the help of the teachers. The idea is to bring your own laptop with one or several statistical software (if your university does not have license for these software you can install R free-of-charge from the internet: www.r-project.org). Participants can attempt analyses first with the software that they are most familiar to work with, and then follow the logic with another software and develop skills on how these software differ, what has to be taken into account when working with a different software etc. The solutions with each software are provided at the end.

12:00- 13:00 Introduction to methods, professor, statistician Reijo Sund, University of Eastern Finland and University of Helsinki

Practical sessions by using R, SAS and STATA, professor Reijo Sund and PhD, statistician Piia Lavikainen, University of Eastern Finland. Bring your own laptop!

13:15–14:00 Describing the data

14:00-14:20 Break with coffee and fruit

14:30-16:30 Defining the study population, exposed and non-exposed

Thursday 2nd of November

09:00 Practical session with R, STATA and SAS continues: Outcome analyses (sensitivity analyses)

10:00-10:20 Break with coffee

10:20-12:00 Outcome analyses continues (sensitivity analyses) **and closing the workshop**

12:00-13:00 Lunch

Welcome to NorPEN congress

13:00-13:15 Director Elli Aaltonen, Kela and professor Sirpa Hartikainen, University of Eastern Finland

Vaccine safety

Chair: Miia Artama

13:15-14:00 Case narcolepsy and swine influenza vaccine in Finland

Speaker: Hanna Nohynek, Chief Physician, Team leader, National Institute for Health and Welfare, Vaccine Programme Development, Helsinki, Finland

14:00-14:30 Coffee

14:30-15:15 Safety of HPV vaccines – A case-control study

Speaker: Kåre Mølbak, MD, DMSc, Director, Statens Serum Institut, Department of Infectious Disease Epidemiology, Copenhagen, Denmark

15:15-16:00 Approaches to vaccine safety research

Speaker: Miia Artama, senior researcher, PhD, National Institute for Health and Welfare, Impact Assessment Unit, Tampere, Finland

16:00-17:00 Pharmacoepi slam (3 min presentations)

Chair: Johanna Jyrkkä, Fimea

Friday 3rd of November

Drug exposure and safety outcomes

Chair: Sirpa Hartikainen

09:00-09:45 Drug exposure modelling from register-based data –methodological problems with different approaches

Speaker: PhD Helga Gardarsdottir, Utrecht University, The Netherlands

09:45-10:15 Second generation method (PRE2DUP) for drug exposure modelling

Speaker: Adjunct professor, PhD Pharm Heidi Taipale, University of Eastern Finland

10:15-10:30 Break with coffee

10:30-11:00 Choosing the outcome measures used in register-based research

Speaker: Academy Researcher, Associate professor Anna-Maija Tolppanen, University of Eastern Finland

11:00-11:30 Validity of outcomes in Swedish registers

Speaker from Sweden, name open

11:30- 12:00 Assessing real-world effectiveness with within-individual models

Speaker: Head of Statistics, PhD Fabian Hoti, Epid Research, Finland

12:00-13:00 Lunch

Nordic presentations

Chair: Leena Saastamoinen, Kela

13:00-14:15 Biosimilars in the Nordic countries – country presentations

Speakers from Finland (name open, Fimea), and from other Nordic countries, names open

14:15-14:45 NorPEN presentations (Results from and plans for Nordic studies) with coffee in between

14:45-15:00 Closing and introduction of next NorPEN meeting in 2018