4TH REAL WORLD EPIDEMIOLOGY –

OXFORD SUMMER SCHOOL

Lady Margaret Hall, Oxford

24/06/2019 – 28/06/2019

CONFIRMED SPEAKERS

D Prieto-Alhambra (Centre for Statistics in Medicine (CSM), University of Oxford, United Kingdom)

H Bhullar (IQVIA, United Kingdom)

A Lübbeke-Wolff (University of Geneva, Geneva Arthroplasty Registry, Switzerland)

I Douglas (LSHTM, United Kingdom)

V Ehrenstein (Clinical Epidemiology, Aarhus, Denmark)

I Petersen (University College London, United Kingdom)

A Silman (CSM, University of Oxford, United Kingdom)

S Perez-Gutthann (RTI-HS, Barcelona, Spain)

S Hawley (CSM, University of Oxford, United Kingdom)

G Collins (Centre for Statistics in Medicine, CSM, University of Oxford, United Kingdom)

PR Rijnbeek (Erasmus University Medical Center, Netherlands)

S Khalid (CSM, University of Oxford, United Kingdom)

A Delmestri (CSM, University of Oxford, United Kingdom)

P Ryan (Janssen R&D, US)

E Molero (SYNAPSE Research Management Partners, Spain)

R Pinedo-Villanueva (CSM, University of Oxford, United Kingdom)
E Burn (CSM, University of Oxford, United Kingdom)

V Strauss (CSM, University of Oxford, United Kingdom)

Nigel Hughes (IMI-EHDEN and Janssen Research and Development, Belgium)

E Rönnemaa (Uppsala University, Sweden)

**Course Directors:**

**Prof D Prieto-Alhambra**, Professor of Pharmaco- and Device Epidemiology; Theme Lead for Observational Research, Centre for Statistics in Medicine; Chair of the Big Health Data User Group, NDORMS, University of Oxford

**Dr V Strauss**, Senior Medical Statistician; Senior Research Associate in Pharmaco- and Device Epidemiology, Centre for Statistics in Medicine, NDORMS, University of Oxford

**Course administrator:**

Ms Paloma O’Dogherty ([paloma.odogherty@ndorms.ox.ac.uk](mailto:paloma.odogherty@ndorms.ox.ac.uk))

**Target audience:** Pharmacists, clinicians, academics (including statisticians, epidemiologists, and related MSc/PhD students); Industry (pharmacy or device) or Regulatory staff with an interest in the use of routinely collected data for research.

**Learning Goals:** By the end of the course, delegates will:

1. **DATA DISCOVERY AND CHARACTERIZATION:** Gain an understanding of the existing sources of routinely collected data for epidemiological research, and on how to characterize whether they are fit for purpose to answer your research question/s

2. **EPIDEMIOLOGICAL STUDY DESIGN/S:** Be able to discuss common and advanced study designs and their implementation using real world data.

3. **PHARMACO- AND DEVICE EPIDEMIOLOGY:** Be aware of the applications of real world data in both pharmaco and device epidemiology, including drug/device utilisation, comparative effectiveness, and post-marketing safety research.
4. **PREDICTION MODELLING**: Learn basic concepts on the design and evaluation of prognostic/prediction models developed using real world data.

5. **BIG DATA METHODS**: Be familiar with the basics of big data methods, including a) machine learning, b) principles of common data models for multi-database studies, and c) digital epidemiology/patient data collection.

6. **“REAL WORLD” SOLUTIONS**: Understand relevant issues and learn potential solutions applied to the use of ‘real world’ epidemiology: a) data management, information governance, b) missing information and multiple imputation, and c) interaction with industry and regulators.

**Dates**: 24th of June to 28th of June 2019

**Venue**: Simpkins Lee Theatre and Monson room, Lady Margaret Hall, Oxford ([www.lmh.ox.ac.uk](http://www.lmh.ox.ac.uk))

To book a place, please follow [this link](http://www.lmh.ox.ac.uk). Registration will be on a ‘first arrived first served’ basis.

Fees are as follows:

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<th>Non-for-profit organization</th>
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<tr>
<td></td>
<td>Residential*</td>
<td>Non-residential*</td>
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<tr>
<td>Early Bird (before 30/04/2019)</td>
<td>£1,300</td>
<td>£850</td>
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<td>Regular Fee (from 01/05/2019)</td>
<td>£1,500</td>
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* ‘Non-residential’ fees cover course registration and materials, refreshments, lunch for five days (24th to 28th of June 2019), and 1 social dinner in college on Monday the 25th.

* ‘Residential’ fees cover additional bed & breakfast accommodation and dinner for five days (23rd to 29th of June) at Lady Margaret Hall.
For more information about the registration process, please contact the course administrator (paloma.odogherty@ndorms.ox.ac.uk).
PROGRAMME

DAY 1 (24/06/2019)

MORNING SESSION – INTRODUCTION AND DATA DISCOVERY

- 08.30-09.00h: Registration, Housekeeping, and Introductions [D Prieto-Alhambra, Oxford]
- 09.00-9.30h: 'Real world' data: strengths and limitations D Prieto-Alhambra, Oxford]
  - Primary Care records databases: a few examples [H Bhullar, IQVIA; TBC; D Prieto-Alhambra SIDIAP] 45';
  - Device Registry/ies [A Lübbeke-Wolff, University of Geneva] 15';
  - Hospital data: HES [D Prieto-Alhambra, Oxford], 5';
  - Nation-wide Nordic Registries [V Ehrenstein, Aarhus], 20'
  - QUESTIONS 5'

COFFEE BREAK: 11.00-11.30h

- 11.30-12.30h: INTERACTIVE SESSION 1: conduct a ‘live’ Drug Utilisation Study Using Aggregated Drug Utilisation Data [D Prieto-Alhambra, Oxford]

LUNCH: 12.30h-13.30h

AFTERNOON SESSION – STUDY DESIGNS USING REAL WORLD DATA 1

- 13.30-14.30h: Study Designs in RWD Epidemiology 1: Case-control and Cohort studies [I Douglas, LSHTM]

TEA BREAK: 14.30-15.00h

- 15.00-16.00h: INTERACTIVE SESSION 2 (in groups): design a RWD study [D Prieto-Alhambra, Oxford; I Douglas, LSHTM]
DAY 2 (25/06/2019)

**MORNING SESSION – STUDY DESIGNS (2)**

- 08.30h-09.00h – REGISTRATION
- 09.00h to 10.00h - Study Designs in RWD Epidemiology 2: Case only designs [I Douglas, LSHTM]
- 10.00h to 11.00h – Data characterization and validation studies [V Ehrenstein, Aarhus]

**COFFEE BREAK: 11.00-11.30h**

- 11.30h to 12.30h - INTERACTIVE SESSION 3 (in groups): design a case only / a validation study [I Douglas, LSHTM]

**LUNCH: 12.30h-13.30h**

**AFTERNOON SESSION – HANDLING MISSING DATA**

- 13.30-14.00h: Introduction and group discussion: What are your experiences of dealing with missing data [I Petersen, UCL]
- 14:00 – 14:45: Lecture A and group discussion: Missing data and missing data mechanisms [I Petersen, UCL]
- 14:45 – 16:00: Lecture B and discussion: Ad-hoc methods to deal with missing data and Multiple Imputation [I Petersen, UCL]
DAY 3 (26/06/2019):

**MORNING SESSION – PHARMACO-EPIDEMIOLOGY**

Chair: A Silman, Oxford.

- 08.30h-09.00h – REGISTRATION
- 09.00-10.00h – Introduction to pharmaco-epidemiology: Drug Utilisation, Drug Safety, and RMM Effectiveness [S Perez-Gutthann, RTI-HS]
- 10.00-11.00h - Advanced Methods in Pharmaco-epidemiology [TBC]

**COFFEE BREAK: 11.00-11.30h**

- 11.30-12.30h – INTERACTIVE SESSION (5): designing a pharmaco-epi study [TBC; A Silman, Oxford; D Prieto-Alhambra, Oxford]

**LUNCH: 12.30h-13.30h**

**AFTERNOON SESSION – TIME SERIES AND PREDICTION MODELLING**

- 13.30h to 14.30h - Time series and longitudinal analyses [V Strauss; S Hawley, Oxford]

**TEA BREAK: 14.30-15.00h**

- 15.00h to 16.00h - Introduction to Prediction Modelling [G Collins, Oxford]
DAY 4 (27/06/2019)

**MORNING SESSION – DATA MODELS, PREDICTION MODELLING & BIG DATA**

- 08.30-09.00h – REGISTRATION
- 09.00-9.45h – Big Data Methods for Real World Epidemiology [S Khalid, Oxford]
- 9.45-10.30h – Data models for real world data [A Delmestri, Oxford]

**COFFEE BREAK: 10.30-11.00h**

- 11.00-12.00h – INTERACTIVE SESSION (6): choosing a prediction modelling research question [P Rijnbeek, Erasmus; P Ryan, Janssen]

**LUNCH: 12.00h-13.00h**

**AFTERNOON SESSION – COMMON DATA MODELS, AND CDM TOOLS**

- 13.00-13.30h – The OMOP Common Data Model: application/s to multinational, multi-database RWE studies [P Ryan, Janssen]
- 13.30-14.15h – Introduction to the OHDSI community & tools [P Ryan, Janssen]
- 14.15-14.45h – Multi-database prediction modelling [P Rijnbeek, Erasmus]

**TEA BREAK: 14.45h - 15.15h**

- 15.15-16.30h – INTERACTIVE SESSION (7): Hands on! [P Rijnbeek, Erasmus; P Ryan, Janssen]
DAY 5 (28/06/2019)

**MORNING SESSION – INFORMATION GOVERNANCE & HEALTH ECONOMICS**

- 08.30-09.00 – REGISTRATION
- 09.00-09.30h – Information Governance in RWD Epidemiology [TBC]
- 09.30-10.00h – Project Management in Real World Epidemiology [E Molero, SYNAPSE Managers]
- 10.00-11.00h – Introduction to RW Health Economics [R Pinedo-Villanueva, Oxford]

*COFFEE BREAK: 11.00 – 11.30 h*

- 11.30-12.30h – INTERACTIVE SESSION (8): Real World Health Economics [R Pinedo-Villanueva and E Burn, Oxford]

*LUNCH: 12.30h-13.30h*

**AFTERNOON SESSION – REAL WORLD EPIDEMIOLOGY: WORKING WITH INDUSTRY AND REGULATORS. INFORMATION GOVERNANCE**

Chair: D Prieto-Alhambra, Oxford

- 13.30-14.30h - The regulators' perspective [E Rönnemaa, MPE Sweden; TBC]
- 14.30-15.00h - The industry's perspective – public-private partnership/s [N Hughes, IMI-EHDEN and Janssen Research and Development]
- 15.00h - Conclusions, Closure, and Departure [D Prieto-Alhambra, Oxford]