**3RD Real world data epidemiology –**

**Oxford summer school**

*Lady Margaret Hall, Oxford*

 25/06/2018 – 29/06/2018

CONFIRMED SPEAKERS

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

PR Rijnbeek (Erasmus University Medical Center, Netherlands)

I Petersen (University College London, United Kingdom)

I Douglas (LSHTM, London, United Kingdom)

R Pinedo-Villanueva (CSM, University of Oxford)

E Molero (SYNAPSE Research Management Partners, Spain)

Bart Vannieuwenhuyse (IMI-EMIF and Janssen Research and Development)

A Silman (CSM, University of Oxford)

S Perez-Gutthann (RTI-HS, Barcelona)

A Delmestri (CSM, University of Oxford)

MS Ali (LSHTM, London, United Kingdom)

A Bourke (IQVIA, United Kingdom)

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

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

N Lea (University College London, United Kingdom)

D Dedman (Clinical Practice Research Datalink (CPRD), MHRA, London, United Kingdom)

S Khalid (CSM, Oxford)

V Ehrenstein (Clinical Epidemiology, Aarhus, Denmark)

P Ryan (Janssen R&D)

A Sena (Janssen R&D)

D Robinson (CSM, University of Oxford)

E Burn (CSM, University of Oxford)

S Hawley (CSM, University of Oxford)

**Course Director:**

Prof D Prieto-Alhambra, Associate Professor and Co-Chair of the Big Health Data User Group, NDORMS, University of Oxford.

**Course administrator:**

Ms Paloma O’Dogherty (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**: 25th of June to 29th of June 2018

**Venue**: Lady Margaret Hall college, Oxford ([www.lmh.ox.ac.uk](http://www.lmh.ox.ac.uk))

Registration will be on a ‘first arrived first served’ basis. Fees are as follows:

|  |  |  |
| --- | --- | --- |
|  | **Non-for-profit organization** | **For-profit organization** |
|  | Residential\* | Non-residentialθ | Residential\* | Non-residentialθ |
| Early Bird (before 30/04/2018) | £ 1,300 | £ 850 | £ 1,550 | £ 1,000 |
| Regular Fee(from 01/05/2018) | £ 1,500 | £ 1,100 | £ 1,800 | £ 1,350 |

θ ‘Non-residential’ fees cover course registration and materials, refreshments, lunch for five days (25th to 29th of June 2018), and 1 social dinner in college on Monday the 25th.

\* ‘Residential’ fees cover additional bed & breakfast accommodation and dinner for five days (24th to 28th of June) at Lady Margaret Hall.

For more information about the registration process, please contact the course administrator (paloma.odogherty@ndorms.ox.ac.uk).

**PRELIMINARY PROGRAMME**

**DAY 1 (25/06/2018)**

***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 [A Bourke, IQVIA]
* 9.30-11.00h: Real world data sources. Chair: Daniel Prieto-Alhambra, Oxford.
	+ Drug Utilisation Databases [D Prieto-Alhambra, Oxford] 15’;
	+ Primary Care records databases: a few examples [A Bourke, IQVIA; D Dedman CPRD; D Prieto-Alhambra SIDIAP] 45’;
	+ Device Registry/ies [A Lübbeke-Wolff, Oxford] 15’;
	+ Hospital data: HES [tbc] 10’
	+ QUESTIONS 5’

*COFFEE BREAK: 11.00-11.30h*

* 11.30-12.30h: INTERACTIVE SESSION 1: conduct a ‘live’ DUS [DPA, 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] 60’

*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 (26/06/2018)**

***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] 60’
* 10.00h to 11.00h – Data characterization and validation studies [V Ehrenstein, Aarhus Univ Clinical Epidemiology] 60’

*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; D Robinson, Oxford]

*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 (27/06/2018):**

***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 [MS Ali, LSHTM]

*COFFEE BREAK: 11.00-11.30h*

* 11.30-12.30h – INTERACTIVE SESSION (5): designing a pharmaco-epi study [S Perez-Gutthann, RTI-HS; MS Ali]

*LUNCH: 12.30h-13.30h*

***AFTERNOON SESSION – HEALTH ECONOMICS***

* 13.30h to 14.30h - Introduction to RW Health Economics [R Pinedo-Villanueva, Oxford]

*TEA BREAK: 14.30-15.00h*

* 15.00h to 16.00h - INTERACTIVE SESSION (6): Real World Health Economics [R Pinedo-Villanueva & Ed Burn, Oxford]

**DAY 4 (28/06/2018)**

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

* 08.00-08.30h – REGISTRATION
* 08.30-09.30h – Introduction to Prediction Modelling [G Collins]
* 09.00-10.00h – Prediction Modelling using big data [P Rijnbeek]
* 10.00-11.00h – Big Data Methods for Real World Epidemiology [S Khalid, Oxford]

*COFFEE BREAK: 11.00-11.30h*

* 11.30-12.30h – INTERACTIVE SESSION (7): interpreting predictive models performance [S Khalid & G Collins]

*LUNCH: 12.30h-13.30h*

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

* 13.30-14.00h - Data models for real world data [A Delmestri, Oxford].
* 14.00-14.45h – Common Data Models for multinational RWE studies [P Ryan]
* 14.45-15.15h – CDM analytic tools – OHDSI [P Ryan]

*TEA BREAK: 15.15h - 15.45h*

* 15.45-16.30h – INTERACTIVE SESSION (8): checking data quality outputs [P Rijnbeek & P Ryan]

**DAY 5 (29/06/2017)**

***MORNING SESSION – DEVICE EPIDEMIOLOGY & TIME SERIES ANALYSES***

* 09.00-09.30h – REGISTRATION
* 09.30-10.30h – Time series analyses [S Hawley, Oxford]
* 10.30-11.00h – Project Management in Real World Epidemiology [E Molero, SYNAPSE Managers]

*COFFEE BREAK: 11.00 – 11.30 h*

* 11.30-12.30h – INTERACTIVE SESSION (9): analysing risk minimisation measures effectiveness using interrupted time series methods [S Hawley & D Prieto-Alhambra, Oxford]

*LUNCH: 12.30h-13.30h*

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

Chair: DPA, Oxford

* 13.30-14.15h - The regulators’ perspective [tbc] 30’
* 14.15-14.45h - The industry’s perspective [B Vannieuwenhuyse, IMI-EMIF and Janssen Research and Development] 30’
* 14.45h - Conclusions, Closure, and Departure [DPA]