

## 3<sup>RD</sup> 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)  
A Bourke (Center for Advanced Evidence Generation, QuintilesIMS, United Kingdom)  
D Dedman (Clinical Practice Research Datalink (CPRD), MHRA, London, United Kingdom)  
A Lübbecke-Wolff (University of Geneva, Geneva Arthroplasty Registry, Switzerland)  
I Douglas (LSHTM, London, United Kingdom)  
V Ehrenstein (Clinical Epidemiology, Aarhus, Denmark)  
D Robinson (CSM, University of Oxford)  
I Petersen (University College London, United Kingdom)  
A Silman (CSM, University of Oxford)  
S Perez-Gutthann (RTI-HS, Barcelona)  
MS Ali (LSHTM, London, United Kingdom)  
R Pinedo-Villanueva (CSM, University of Oxford)  
E Burn (CSM, University of Oxford)  
G Collins (Centre for Statistics in Medicine, CSM, University of Oxford)  
PR Rijnbeek (Erasmus University Medical Center, Netherlands)  
S Khalid (CSM, Oxford)  
A Delmestri (CSM, University of Oxford)  
P Ryan (Janssen R&D)



A Sena (Janssen R&D)

W Forrester-Barker (NDORMS, University of Oxford)

N Lea (University College London, United Kingdom)

S Hawley (CSM, University of Oxford)

E Molero (SYNAPSE Research Management Partners, Spain)

Katherine Donegan (MHRA, United Kingdom)

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

**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](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**: 25<sup>th</sup> of June to 29<sup>th</sup> 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-residential <sup>0</sup>	Residential*	Non-residential <sup>0</sup>
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

<sup>0</sup> **‘Non-residential’ fees** cover course registration and materials, refreshments, lunch for five days (25<sup>th</sup> to 29<sup>th</sup> of June 2018), and 1 social dinner in college on Monday the 25<sup>th</sup>.

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

For more information about the registration process, please contact the course administrator ([paloma.odogherty@ndorms.ox.ac.uk](mailto: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, QuintilesIMS]
- 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 QuintilesIMS; D Dedman CPRD; D Prieto-Alhambra SIDIAP] 45’;
  - Device Registry/ies [A Lübbecke-Wolff, Oxford] 15’;
  - Hospital data: HES [D Prieto-Alhambra, Oxford] 10’
  - QUESTIONS 5’

#### COFFEE BREAK: 11.00-11.30h

- 11.30-12.30h: INTERACTIVE SESSION 1: conduct a 'live' DUS [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] 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] 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]
- 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 [MS Ali, LSHTM]

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, Oxford; E 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, Oxford]
- 09.30-10.15h – Prediction Modelling using big data [P Rijnbeek, Erasmus]
- 10.15-11.00h – 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, Oxford; G Collins, Oxford]

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, Janssen R&D]
- 14.45-15.15h – CDM analytic tools – OHDSI [P Ryan, Janssen R&D]

TEA BREAK: 15.15h - 15.45h

- 15.45-16.30h – INTERACTIVE SESSION (8): checking data quality outputs [P Rijnbeek, Erasmus; P Ryan, Janssen, R&D]

**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, Oxford; D Prieto-Alhambra, Oxford]

LUNCH: 12.30h-13.30h

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

Chair: D Prieto-Alhambra, Oxford

- 13.30-14.15h - The regulators' perspective [K Donegan, MHRA] 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 [D Prieto-Alhambra, Oxford]