



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)

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

I Douglas (LSHTM, London, United Kingdom)

V Ehrenstein (Clinical Epidemiology, Aarhus, Denmark)

I Petersen (University College London, United Kingdom)

S Perez-Gutthann (RTI-HS, Barcelona)

S Hawley (CSM, University of Oxford)

S Khalid (CSM, Oxford)

A Delmestri (CSM, University of Oxford)

PR Rijnbeek (Erasmus University Medical Center, Netherlands)

P Ryan (Janssen R&D)

E Molero (SYNAPSE Research Management Partners, Spain)

R Pinedo-Villanueva (CSM, University of Oxford)

E Burn (CSM, University of Oxford)

V Strauss (CSM, Oxford)

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

E Rönnemaa, Uppsala, 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 Pharmacoand Device Epidemiology, Centre for Statistics in Medicine, NDORMS, University of Oxford

Course administrator:

Ms Paloma O'Dogherty (paloma.odogherty@ndorms.ox.ac.uk)

<u>Target audience</u>: 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.

<u>Learning Goals</u>: By the end of the course, delegates will:

- 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.
- 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)

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

	Non-for-profit organization		For-profit organization	
	Residential*	Non-	Residential*	Non-
		residential $^{\theta}$		residential $^{\theta}$
Early Bird	£ 1,300	£ 850	£ 1,550	£ 1,100
(before 30/04/2019)				
Regular Fee	£ 1,500	£ 1,100	£ 1,800	£ 1,350
(from 01/05/2019)				

⁶ '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.

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





^{* &#}x27;Residential' fees cover additional bed & breakfast accommodation and dinner for five days (23th to 29th of June) at Lady Margaret Hall.





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]
- 9.30-11.00h: Real world data sources. Chair: Daniel Prieto-Alhambra, Oxford.
 - Primary Care records databases: a few examples [TBC; D Prieto-Alhambra SIDIAP] 45';
 - Device Registry/ies [A Lübbeke-Wolff, University of Geneva] 15';
 - o 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;
 D Prieto-Alhambra, Oxford]

LUNCH: 12.30h-13.30h

AFTERNOON SESSION - TIME SERIES ANALYSES

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 - INTERACTIVE SESSION (6): analysing risk minimisation measures effectiveness using interrupted time series methods [V Strauss and D Prieto-Alhambra, Oxford]









DAY 4 (27/06/2019)

MORNING SESSION - DATA MODELS, PREDICTION MODELLING & BIG DATA

- 08.00-08.30h REGISTRATION
- 08.30-09.30h Introduction to Prediction Modelling [TBC]
- 09.30-10.15h Big Data Methods for Real World Epidemiology [S Khalid, Oxford]
- 10.15-11.00h Data models for real world data [A Delmestri, Oxford]

COFFEE BREAK: 11.00-11.30h

 11.30-12.30h – INTERACTIVE SESSION (7): choosing a prediction modelling research question [P Rijnbeek, Erasmus; P Ryan, Janssen]

LUNCH: 12.30h-13.30h

AFTERNOON SESSION - COMMON DATA MODELS, AND CDM TOOLS

- 13.30-14.00h The OMOP Common Data Model: application/s to multinational, multidatabase RWE studies [P Ryan, Janssen]
- 14.00-14.45h Introduction to the OHDSI community & tools [P Ryan, Janssen]
- 14.45-15.15h Multi-database prediction modelling [P Rijnbeek, Erasmus]

TEA BREAK: 15.15h - 15.45h

15.45-17.00h – INTERACTIVE SESSION (8)*: 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 (9): 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]



