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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)

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)

With the support of SYNAPSE RESEARCH MANAGEMENT PARTNERS

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)

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

	Non-for-profit organization		**For-profit organization**	
	Residential*	Non-residential$^{\theta}$	Residential*	Non-residential$^{\theta}$
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

$^{\theta}$ '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 [tbc]
- 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]

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]