



CARDIFF UNIVERSITY/BRAPP POSTGRADUATE COURSE IN PHARMACEUTICAL MEDICINE

Drug Safety, Pharmacovigilance and Pharmacoepidemiology

Wednesday 17 October 2018

etc venues Marble Arch

08:00 Breakfast available for all delegates

08:30 Welcome and Registration

09:00 Introduction to Module 6

Dr Kristina Strutt

Basics of PV Regulation
ICH, CIOMS – terms and definitions
Brief background history

10:00 Pre-marketing drug safety/clinical trials

Tina

11:00 Coffee

11:15 Post-marketing pharmacovigilance

Dr Cheryl Key

12:15 Lunch

13:00 Risk Mitigation

Tina

14:15 From Signal to ADR – Detection and Evaluation

Tina

Break

15:30 Mechanisms and Classification of ADRs

Tina

17:00 Depart

Thursday 18 October 2018

etc venues Marble Arch

08:30 Welcome and breakfast

09:00 Benefit Risk

Tina

10:30 Coffee

11.00 Pharmacoepidemiology

Prof Madhu Davies

12:15 Lunch

**13.00 Maintaining a PV system
(including regulatory inspections and importance of
end-to-end cross-functional processes)**

Ruth Casserley

14.15 Safety Workshop

Madhu and Tina

With refreshment break

15:30 Review of Module and exam prep

Madhu (if time)

16:00 Depart