

Biomarkers, Biostatistics and Novel Clinical Trial Design

A workshop hosted by the NCRI Biomarkers and Imaging Clinical Studies Group
& supported by Imperial Cancer Research UK Centre

W12 Conference Centre, Artillery Lane, Du Cane Road, London, W12 0HS

Thursday 27th September 2012

10:00 – 16:00

10:00 - 10:30 Registration and Coffee/Tea

Chair: Professor Bob Brown, Imperial College London

- 10:30 - 10:35 **Introduction to the workshop**
Professor Bob Brown, Imperial College London
- 10:35 - 11:00 **Introduction to challenges in clinical trial design incorporating biomarkers**
Mr Jim Paul, Cancer Research UK Clinical Trials Unit, University of Glasgow
- 11:00 - 11:30 **Phase I: Adaptive design of dose escalation phase I trials**
Dr Adrian Mander, Medical Research Council Biostatistics Unit
- 11:30 - 12:00 **Phase II: Review of novel clinical trial designs using biomarkers in phase II trials**
Mr Roger A'Hern, Institute of Cancer Research
- 12:00 - 12:30 **Phase III: A new comprehensive, molecularly stratified trial design for a common cancer: the FOCUS 4 trial programme for colorectal cancer**
Professor Rick Kaplan, Medical Research Council Clinical Trials Unit

12:30 - 13:30 Networking Lunch

- 13:30 - 15:00 **Breakout Sessions:**
- Session 1: Biostatistical challenges: How to define validation**
Chaired by Professor Jorge Reis-Filho, Institute of Cancer Research & Mr Matt Sydes, Medical Research Council Clinical Trials Unit
- Session 2: Design challenges: How to incorporate biomarkers into phase II clinical trials**
Chaired by Mr Jim Paul, Cancer Research UK Clinical Trials Unit, University of Glasgow, Mr Roger A'Hern, Institute of Cancer Research & Dr Robert Jones, Beatson Oncology Centre & University of Glasgow
- Session 3: Bioinformatic challenges: How to integrate complex data sets using different molecular endpoints**
Chaired Dr Ed Curry, Imperial College London & Professor Yike Guo, Imperial College London

- 15:00 - 15:30 **Summaries of breakout sessions**
Breakout Session Chairs
- 15:30 - 15:55 **General discussion**
Chaired by Professor Bob Brown, Imperial College London
- 15:55 - 16:00 **Closing remarks**
Professor Bob Brown, Imperial College London

CPD credits applied for at the Royal College of Physicians

For more information on Imperial Cancer Research UK Centre, please visit
www1.imperial.ac.uk/surgeryandcancer/crukcentre/