



IRISH MEDICINES BOARD

Agenda for the Irish Medicines Board (IMB) Clinical Trials Seminar for Medical Practitioner Sponsors and Investigators

Date: 19th June 2012
Location: Irish Medicines Board, Earlsfort Terrace, Dublin 2.
Time: Registration will take place from 16.30 to 17.00

17.00 – 17.05 Welcome and introduction

Ms. Ann O'Connor, Director Human Products Authorisation and Registration, IMB

17.05 – 17.25 The application process, legislation, guidelines and the protocol template

Dr Elaine Breslin, Clinical Assessment Manager, IMB

17.25 – 17.30 Q&A session

17.30 – 17.50 Lifecycle of the clinical trial – substantial amendments, end of trial declarations/reports, development safety update reports (DSURs), urgent safety restrictions, premature terminations, recent updates to the legislation

Dr Agnieszka Przybyszewska, Clinical Assessor, IMB

17.50 – 17.55 Q&A session

17.55 – 18.15 Adverse Reaction reporting requirements for clinical trials

Dr. Clare Brennan, Pharmacovigilance Scientific Officer, IMB

18.15 – 18.20 Q&A session

18.20 – 18.40 Good Clinical Practice Inspections – expectations for compliance with sponsor responsibilities Part I

GCP Inspector IMB

18.40 – 18.45 Q&A session

18.45 – 19.05 Good Clinical Practice Inspections – expectations for compliance with sponsor responsibilities Part II

GCP Inspector IMB

19.05 – 19.10 Q&A session

19.10 – 19.30 Panel Q&A session, Key messages and Final Conclusions

19.30 Close of Meeting