



Satellite Symposium Getting the dose right first!

Regulatory perspective and impact of Project Optimus on RP2D selection in oncology

Preliminary Programme

13:00 – Welcome: Oscar Della Pasqua & Salvatore D'Agate, UCL

- Title: Getting the dose right first!

13:10 – Speaker 1: Julie Bullock, Certara

- Title: Project Optimus overview: What has changed and how are we adapting to the new expectations?

Industry Experience in Dose Selection in Oncology

13:30 – Speaker 2: Dinesh De Alwis, Generate Biomedicines

- Title: Pembrolizumab case study: a successful story

13:50 – Speaker 3: Stefan Zajic, GSK

- Title: Dose selection vs. dose optimization for checkpoint inhibitors in oncology

14:10 – Speaker 4: Kris Jansen, Parexel

- Project Optimus: learnings and modern approaches from a pharmacometrics perspective

14:30 – *Coffee break (20 min)*

Clinical and Regulatory Perspectives on Dose Selection in Oncology

14:50 – Speaker 5: Anna Dorothea Wagner, University of Lausanne

- Title: The implications of personalised therapy for oncology drugs

15:15 – Speaker 6: Mark J. Ratain, University of Chicago

- Title: Implications of Project Optimus for clinicians and investigators

15:40 – Speaker 7: Jiang Liu, FDA Division of Pharmacometrics

- Title: FDA perspective on the Optimus project

16:05 – Speaker 8: Flora Musuamba, EMA Methodology Working Party

- Title: EMA perspective on dose selection in oncology clinical trials

16:30 – *Coffee break (20 min)*

16:50 – Start panel discussion

Moderators: Oscar Della Pasqua, Salvatore D'Agate (UCL)

Panel participants: Paolo Mazzei (Menarini Group), Dinesh De Alwis (Generate Biomedicines), Stefan Zajic (GSK), Dorothea Wagner (University of Lausanne), Mark Ratain (University of Chicago), Flora Musuamba (EMA), Jiang Liu (FDA)

17:50 – Wrap up & Closure