



IBCD 2022 Scientific Programme

10.00-10.15 Introduction
Speaker: Roberto Salgado, EORTC (BE)

10.15-10.45 Biomarkers or Bioassays?
Keynote Speaker: Justin Zook (US)

Session 1: Critical topics in Drug- and Biomarker Validation

Chair: Tracy Lively (US)

10.45-11.05 What are the methodological challenges and pitfalls in biomarker-development in immunotherapy-trials as a model for other biomarkers?
Speaker: Susan Halabi (US)

11.05-11.45 Whole Genome Sequencing: is it practical for standard-of-care?
Speaker for: Phillip Beer (UK)
Speaker against: Michael Hubank (UK)

11.45-12.05 Current role of cfDNA for treatment selection, minimal residual disease, and screening – The academic perspective
Speaker: Chris Abbosh (UK)

12.05-12.25 Current role of cfDNA for treatment selection, minimal residual disease, and screening – The industry and regulatory strategic perspective
Speaker: Geoff Oxnard (USA)

12.25-13.00 Panel Discussion and Q&A:

Panelists: T. Lively, S. Halabi, P. Beer, M. Hubank, C. Abbosh, G. Oxnard, J. Seoane, J. Zook and B. Borisch

13.00-14.00 Lunch Break

Session 2: Can Real-World data help translate drug-biomarker evidence to health care settings.

Chair: David Solit (US)

- 14.00-14.20** FDA's Reform of Regulations on Laboratory Developed Tests (LDTs): Taming the Wild West: the payers perspective
Speaker: Gabriel Willner (US)
- 14.20-14.40** FDA's oversight of laboratory developed tests (LDTs): taming the wild west in daily practice
Speaker: Jochen Lennerz (US)
- 14.40-15.00** Can Real World Data replace control arms in prospective clinical trials? Role of the regulatory?
Speaker: Donna Rivera (US)
- 15.00-15.20** EMA and the Cancer Medicine Forum: how can this help in biomarker-development
Speaker: EMA to be announced
- 15.20-16.00** **Panel Discussion and Q&A:** Payers and Patients perspective
Panelists: D.Solit, EMA rep, J. Lennerz, D. Rivera, G. Willner, E. Rubin, G. Oxnard and B. Borisch
- 16.00-16.30** An Orbis-programme for assays: how would it look like?
Keynote Speaker: Eric Rubin (US)
- 16.30-16.45** Conclusions
Speaker: Roberto Salgado, EORTC (BE)