

Joint BBS-EFSPI Seminar on Data Sharing in Clinical Development

Thursday 13th November 2014, Basel
9:15am to 3:30pm

Draft program

- 9:15-9:30 Uli Burger (Roche, Basel)
Welcome and introduction to data sharing
- 9:30-11:00 **Session 1: What happens outside companies**
Chair: Janice Branson
- 9:30-10:00 Sabine Atzor (Roche, Basel)
The environment and stakeholder expectations: EMA Policy - New Clinical Trials Regulation
- 10:00-10:30 Stefan Driessen (Abbott, Weesp)/Christoph Gerlinger (Bayer, Berlin)
EFSPi input into EMA policy
- 10:30-11:00 Franz König (Medical University Wien)
Big thunder, little rain
- 11:00-11:30 *Coffee break*
- 11:30-13:00 **Session 2: Data sharing within industry**
Chair: Hans Ulrich Burger
- 11:30-12:00 Rebecca Sudlow (Roche, Welwyn)
Overview on data sharing initiatives in industry and current experience
- 12:00-12:30 Janice Branson (Novartis, Basel)
Practicalities of accessing and using data – Advice for Researchers
- 12:30-13:00 Sally Hollis (Astra-Zeneca, Manchester)
Considerations for analysis plans for data sharing requests
- 13:00-14:00 *Lunch break*
- 14:00-14:30 **Session 3: Patient confidentiality and Panel discussion**
Chair: Conny Berlin
- 14:00-14:30 Katherine Tucker (Roche, Welwyn)
Principles to maintain patient confidentiality
- 14:30-15:00 Guillaume Breton (Novartis, Basel)
Implementation aspects
- 15:00-15:30 Panel discussion (with all speakers)
Consequences for us in statistics?
- 15:30 End of the meeting



Data Sharing in Clinical Development is a hot topic since the appearance of the EMA draft guidance last year. Recently EMA released it's policy on the publication of clinical data.

This seminar will invite representatives from academia and industry who will highlight important topics in this area and will close with a panel discussion.

Venue:

Actelion Pharmaceuticals
Hegenheimermattweg 95
4123 Allschwil
Switzerland

Cost:

A nominal fee to cover basic costs will be collected at the registration desk at the meeting:
CHF 100 for industry
CHF 50 for others
Students and Speakers are free

Registration:

No formal registration apart from an e-mail to Fred Sorenson
(e:mail:
fred.sorenson@xcenda.com)