

# Joint BBS-EFSPI Seminar on Data Sharing in Clinical Development

*Thursday 13<sup>th</sup> November 2014, Basel*  
**9:15am to 3:30pm**

## ***Draft program***



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|-------------|--|
| 9:15-9:30   | Uli Burger (Roche, Basel)<br><i>Welcome and introduction to data sharing</i>                                     |
| 9:30-11:00  | <b>Session 1: What happens outside companies</b><br>Chair: Janice Branson  |
| 9:30-10:00  | Sabine Atzor (Roche, Basel)<br><i>Overview on EMA actions and EFPIA</i>  |
| 10:00-10:30 | Stefan Driessen (Abbott, Weesp)/Christoph Gerlinger (Bayer, Berlin)<br><i>Statistical input into EMA policy</i>  |
| 10:30-11:00 | (to be confirmed)<br><i>Viewpoint from academia</i>  |
| 11:00-11:30 | <i>Coffee break</i>  |
| 11:30-13:00 | <b>Session 2: Data sharing within industry</b><br>Chair: Hans Ulrich Burger                                      |
| 11:30-12:00 | Rebecca Sudlow (Roche, Welwyn)<br><i>Overview on data sharing initiatives in industry and current experience</i> |
| 12:00-12:30 | Janice Branson (Novartis, Basel)<br><i>Data sharing concepts</i>   |
| 12:30-13:00 | (to be confirmed)<br><i>Requirements for analysis plans for data sharing</i>                                     |
| 13:00-14:00 | <i>Lunch break</i>   |
| 14:00-14:30 | <b>Session 3: Patient confidentiality and Panel discussion</b><br>Chair: Conny Berlin                            |
| 14:00-14:30 | Katherine Tucker (Roche, Welwyn)<br><i>Maintaining patient confidentiality</i>                                   |
| 14:30-15:00 | Guillaume Breton (Novartis, Basel, tbc)<br><i>to be determined</i>   |
| 15:00-15:30 | Panel discussion (all speakers)<br><i>Consequences for us in statistics?</i>                                     |
| 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*Data Sharing in Clinical Development is a hot topic since the appearance of the EMA draft guidance last year.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 91  
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 are free

### **Registration:**

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