

Session 2 Summary

TOPIC 1:

- * How much knowledge/awareness should statisticians have on topics like responsible reuse, privacy and data sharing?**
- * What is the optimal model for data sharing? A separate data sharing group or one integrated within Biometrics part of the organization?**

TOPIC 2: Can Data Sharing have a positive influence on drug development pipelines? If so, what needs to change to maximise the benefits of data sharing.

TOPIC 1: Actions for EFSPI Leaders

- Share knowledge from how different companies are handling on this in the companies
- Generate awareness for all statisticians about what can be done by statisticians on secondary use of data (eg sample size calculation for a new study)
- Support the Data Sharing SIG with recommendations from different companies
- Early planning on potential data sharing to a drug development programme
- To make our teams aware of the data sharing requirements and opportunities
- Trainings material, Working group(s)

TOPIC 1: Actions for EFSPI Council

- Faster model for data sharing platforms – focus at making it easier to set-up, facilitating minimising the hurdles (standardising format, definitions, endpoints)
- Whitepaper on how to do data sharing would be very helpful for companies not seeing these requests that often
- Help promote awareness on data sharing across the industry
- To increase awareness of the Working Groups
- To help in identifying what statisticians are called to do, to provide guide
- To evaluate trainings needs
- Discussion with regulatory authority as partner – to foster the collaboration with stat from regulatory agencies [discussion already ongoing, feedback from Uli]

TOPIC 2: Actions for EFSPI Leaders

- Need to educate broader than within Biostatistics
- Continue securing awareness of the increasing demands (like today)
- Distinguish between internal and external data sharing; actions are different
- Share case studies of internal data sharing from companies who have done that successfully, to help others convince their organisations (could be done via Data Sharing SIG)

TOPIC 2: Actions for EFSPI Council

- Facilitate it's easier to share data between companies
- Collect and share successful case studies (see previous slide)
- Collaborate with EFPIA (who also have a data sharing group)