



Welcome to PhUSE Single Day Event

Copenhagen, 2013





Data transparency and submission standards

Chair: Pia Hjulskov Kristensen, Lundbeck

Co-chair: Åsa Carlsheimer, Ferring





House keeping:

- Turn off your mobile
- Be in time
- Lunch is served in the canteen at 12:30
- Questions and discussions are encouraged
- Networking!





- 6 countries
 - Denmark 53 (66%)
 - Sweden 20 (25%)
 - Rest of Europe 7 (9%)
 - 19 work places
 - Pharmas 52 (65%)
 - CROs 23 (29%)
 - Others 5 (6%)
- } 80



Agenda



- 09:40 – 10:20** **Getting the most out of CDASH and SDTM: Automating the specification and validation process** – Jean-Marc Ferran (*Qualiance*) and Peter van Reusel (*Business&Decision Life Science*)
- 10:20 – 10:55** **SDTM exceptions** – Niels Both and Johannes Ulander (*S-Cubed*)
- 10:55 – 11:15** **Morning coffee break**
- 11:15 – 11:50** **Annotations: Automate or suffer** – Toni Awwad and Rune Kaasen (*Lundbeck*)
- 11:50 – 12:30** **Tame the traceability monster** – Kirsten Langendorf and Mikkel Traun (*Novo Nordisk*)
- 12:30 – 13:30** **Lunch**





Agenda



- 12:30 – 13:30** **Lunch**
- 13:30 – 13:45** **News from PhUSE and Brussels conference – Sascha Ahrweiler (*UCB*)**
- 13:45 – 14:20** **Moving to Define.xml V2.0.0 – Davy Baele (*Business&Decision Life Science*)**
- 14:20 – 14:55** **Getting your skeletons out of the closet – Parag Naithani (*Ferring*)**
- 14:55 – 15:25** **Afternoon coffee break**
- 15:25 – 16:00** **Update@SAS (9.4, STAT, Toolkit, CDI and JMP® Clinical - Kristina Birch and Anders Helmø Larsen (*SAS*))**
- 16:00 – 16:15** **Closure and summary – (Pia and Åsa)**



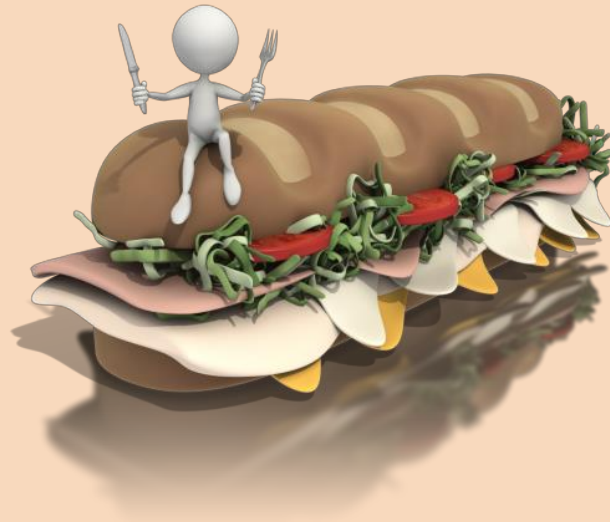


Morning break





Lunch break until 13:30



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Afternoon break





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