



PhUSE Single Day Events

Copenhagen,
Denmark

14th June 2018



LEO paves the way for PhUSE



SDTM Revisited

The PhUSE EU Connect theme this year is Future Forward, with many presentations on the new digital era. We still face many challenges in using the CDISC foundational standards. For this reason, we have decided this year to concentrate on retrospectives when applying SDTM, ADaM, and Define-XML standards. The focus will be on sharing our learnings, best practices, and strategies in applying these standards. In recent years, roles in biometrics have changed, with better insight into submission deliverables. We aim to cover global submissions with implementation guides, interpretations and regulatory technical conformance guides.



House Keeping Notes



Agenda

Time	Title and Speaker
08:45–09:30	Registration and Welcome Refreshments
09:30–09:40	Welcome Jørgen Mangor Iversen, <i>LEO Pharma</i> & Pia Hjulskov Kristensen, <i>H. Lundbeck</i>
09:40–10:10	Embracing Change: A Journey in SDTM Creation Dennis Jørgensen & Aik Hoe Seah, <i>H. Lundbeck</i>
10:10–10:40	SDTM at LEO Pharma Mette Marie Anderson, <i>LEO Pharma</i>
10:40–11:00	Morning Break
11:00–12:00	Is it Possible to Make a Global Submission; And What are the Top Five Challenges in Complying with CDISC Standards? Marianne Carames, Trine Danø Klingberg & Mikkel Traun, <i>Novo Nordisk</i>
12:00–12:30	Lessons Learned from Two Different FDA Filings Carey Smoak, <i>S-CUBED</i>
12:30–13:30	Lunch & Networking
13:30–14:30	Panel Discussion: How Implementation of SDTM has Changed Over Time
14:30–15:00	Afternoon Break
15:00–15:30	Where Did My Terminology Go? Johannes Ulander, <i>S-CUBED</i>
15:30–16:00	The Ferring Data Model (FDM) Omar Hamidi, <i>Ferring</i>
16:00–16:30	Pinnacle 21 Enterprise Edition Malathi Hari, <i>Larix</i>
16:30–16:50	PhUSE Update Yvonne Moores, <i>PhUSE Strategy & Innovation Director</i>
16:50–17:00	Wrap-up & Closing Remarks Jørgen Mangor Iversen, <i>LEO Pharma</i> & Pia Hjulskov Kristensen, <i>H. Lundbeck</i>



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PhUSE 2018 EMEA Dates

SDE	Date
Basel, Switzerland	28 th June 2018
Brussels, Belgium	21 st September 2018
Warsaw, Poland	October 2018
South Africa	November 2018
Full details and event dates can be found on the PhUSE website	





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