



PhUSE Single Day Events

Gaithersburg, MD

June 2nd 2016



House Keeping Notes



Metadata Repositories – Promises and Realities

The Pharmaceutical industry recognizes the value of metadata but has been slow to develop Metadata Repositories (MDRs). The technology has taken time to develop. Fortunately, we now have better tools to automate and manage metadata. Metadata that has historically been saved in excel spreadsheets can now be moved into metadata repository applications. As more MDRs are adopted, the usefulness of metadata is becoming more apparent. This SDE will focus on learning from those that have or are about to implement MDRs.



PhUSE Metadata Definition Workgroup 2013/2014

- Led by Dr. Isabelle De Zegher, Mitra Rocca and Marcelina Hungria.
- Members included Terek Peterson, Susan Zhao, Yun Oldshue, Sam Hume, Tim Church, Kenneth Stolfus, Julie James, Praveen Garg and Aimee Basil
- The project focused on developing common definitions around metadata and related aspects across the industry
- http://www.phusewiki.org/wiki/index.php?title=Metadata_Definition_Project



Sponsors

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Agenda – Morning – Session 1

Time	Presentation	Speaker
8:30 – 9:00	--- Breakfast ----	
8:55 – 9:00	House Keeping	Frank Senk, AstraZeneca Thejo Annareddy, AstraZeneca Alex Batkhan, MedImmune
9:00 – 9:15	Keynote	Nevine Zariffa, AstraZeneca
9:30 – 9:55	Metadata-driven, Standards-based Clinical Analysis and Reporting Environment	Alex Hromcenco, AstraZeneca James Miller, AstraZeneca
9:55 – 10:30	Metadata-driven Analysis – How Users Can Benefit from Metadata	Peter Schaefer, Validated Cloud Applications
10:30 – 10:45	--- Morning Break ---	



Agenda – Morning – Session 2

Time	Presentation	Speaker
10:45 – 11:15	How to Find the Best MDR Solution for Your Organization	Kevin Lee, Clindata Insight
11:15 – 11:45	The Chicken and the Egg Dilemma: Why Metadata Solutions have Struggled	Chris Decker, d-Wise Ian Fleming, d-Wise
11:45 – 12:00	PhUSE Future Forum Update	Chris Hurley, MMS Holdings
12:00 – 1:00	--- Lunch ---	



Agenda – Afternoon – Session 1

Time	Presentation	Speaker
1:00 – 1:30	Automating CDISC Deliverables through Processing Metadata	Paul Slagle, inVentiv Health Eric Larson, inVentiv Health
1:30 – 2:00	Moving from Data Collection to Data Visualization Analytics: Leveraging CDISC SDTM Standards to Support Data Marts	Steve Kirby, Chiltern Terek Peterson, Chiltern
2:00 – 2:30	CDER, Regulatory Science Informatics and Metadata: What We've Learnt	Salvatore Pepe, CDER, FDA
2:30 – 2:45	--- Afternoon Break ---	



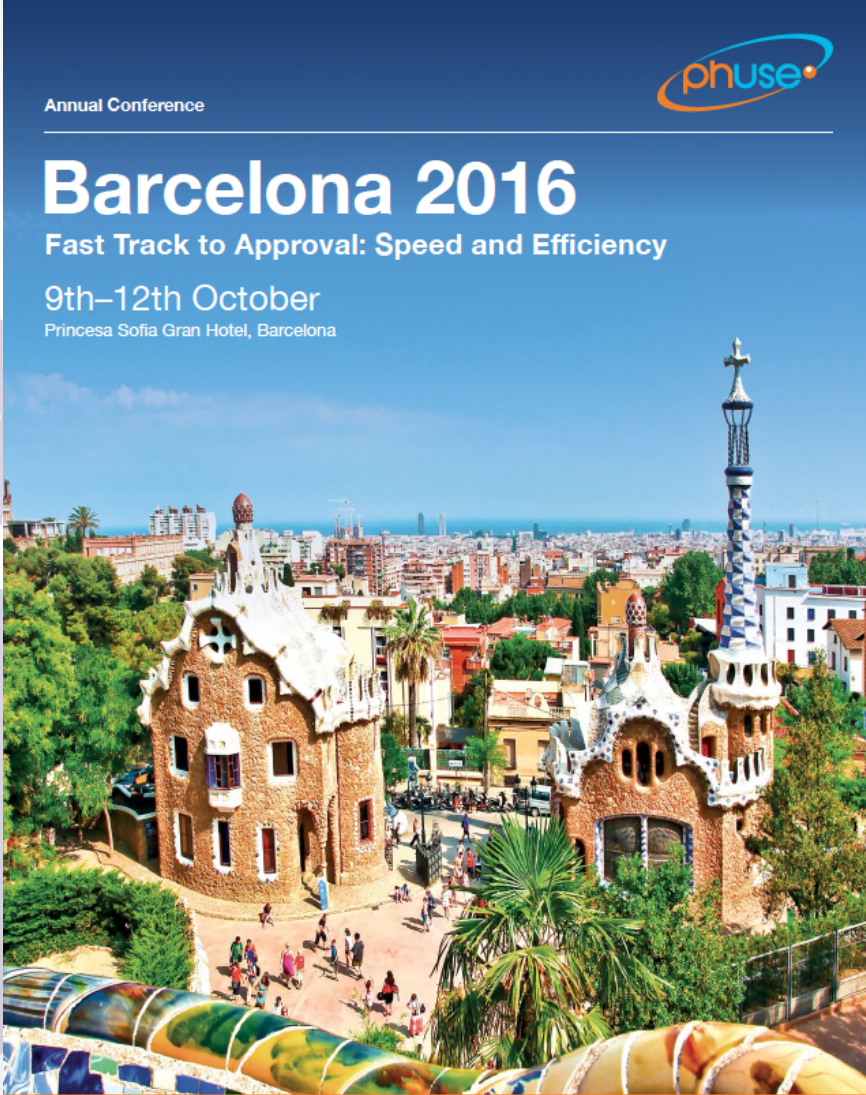
Agenda – Afternoon – Session 2

Time	Presentation	Speaker
2:45 – 3:15	Implementing End-to-End Data Standards from a Metadata and Technology Perspective	Michael Goedde, Parexel
3:15 – 3:45	CDISC Share: The Road Ahead	Sam Hume, CDISC
3:45 – 4:30	Panel Discussion	All Speakers
4:30	--- Closing Remarks ---	



PhUSE Future Events

SDE	Date
PhUSE EU CSS Basel, Switzerland	June 21 st & 22 nd
Deerfield, Illinois	July 21 st
Frenchtown, NJ	August 4 th
PhUSE Annual Conference Barcelona, Spain	October 9 th – 12 th
Durham, NC	November 10 th



The poster for the PhUSE Annual Conference Barcelona 2016 features a vibrant photograph of Park Güell in Barcelona, Spain, with its iconic mosaic and towers overlooking the city. The PhUSE logo is in the top right corner. The text on the poster includes the event title, dates, location, and chair/co-chair information.

Annual Conference

Barcelona 2016

Fast Track to Approval: Speed and Efficiency

9th–12th October
Princesa Sofia Gran Hotel, Barcelona

Conference Chair Åsa Carlshelmer, *Trialbee*
Conference Co-Chair Jules van der Zalm, *OCS Consulting*
For more information visit the PhUSE website phuse.eu/annual-conference.aspx





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