PhUSE Single Day Events

Foster City, CA

December 2nd 2015

Overview

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- Program Overview
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Theme

Building High Quality Clinical and Nonclinical e-Data Submissions for FDA Review

Why Getting it Right Matters

Why this event and why now?

Help the FDA and industry *successfully and cost-effectively* implement standards-based exchange of "*fit for purpose*" clinical and nonclinical data

- FDA's mandate requiring submissions using CDISC standards starts in a year – *not much time left to get it right*
- PMDA in Japan is following the FDA's lead. Others expected to follow
- Foster a community to share lessons learned, best practices and business processes

Data Quality Considerations

"Fit for purpose" means that submitted data should be:

- ✓ *Technically conformant* to evolving CDISC and FDA specific requirements – new models, terminologies, rules, …
- ✓ *Consistent* with regard to data submitted by sponsors (e.g., study and trial reports)
- ✓ *Sufficient* with respect to what should be included
- ✓ Able to meet *Agency review* needs

Failure to meet these criteria will cause delays, increased costs and missed opportunities

Opportunities for Sponsors & CROs

- ✓ Better and new ways to build repositories and exploit standardized data beyond just individual trials and nonclinical studies
- ✓ Longer-term productivity gains

Requires practical ways to integrate data, R&D and regulatory submission processes across the development lifecycle

Agenda

Time	Presentation	Presenter
8:30 - 9:00	***Welcome Refreshments***	
9:00 - 9:15	Welcome	SDE Co-Leads
9:15 - 9:30	Overview of PhUSE	
9:30 - 10:00	Optimizing Standards Implementation for Successful e-data Submissions to the FDA	Dhananjay Chhatre, *Gilead*
10:00 - 10:30	Standardizing Data Cuts	Mercidita Navarro, *Genentech*
10:30 - 11:00	***Morning Break***	Sponsored by: CHILTERN
11:00 - 11:30	Common Errors in Loading SDTM Data to the Clinical Trials Repository and Why Getting it Right Matters	Crystal Allard, *FDA*
11:30 - 12:00	A Need for Prescriptive Define.xml	Sergiy Sirichenko, *Pinnacle 21*
12:00 - 1:00	***Lunch & Networking***	Sponsored by: Cytel
1:00 - 1:30	PhUSE–FDA Working Group on Standardizing Data Elements for the Site Selection Process	Patty Gerend, *Genentech*
1:30 - 2:00	SEND Compliance – Challenges and Opportunities for Sponsors	Sandor Schoichet, *Meridian Management Consultants*
2:00 - 2:30	Non-clinical Study Data Specifications and CRO-Sponsor Workflows for FDA SEND Compliance	Kristi Johnson, *PointCross Life Sciences* & Michael Dorato, *Smithers Avanza*
2:30 - 2:45	***Afternoon Break***	Sponsored by: Sycamore Informatics
2:45 - 3:00	PhUSE-FDA 2015 CS Working Group Update	SDE Co-Leads
3:00 - 3:40	Panel Discussion Q&A	SDE Co-Leads
3:40 - 4:00	Wrap Up & Closing Remarks	SDE Co-Leads

Some Perspectives to keep in mind…

Build the Plane as You are Flying it

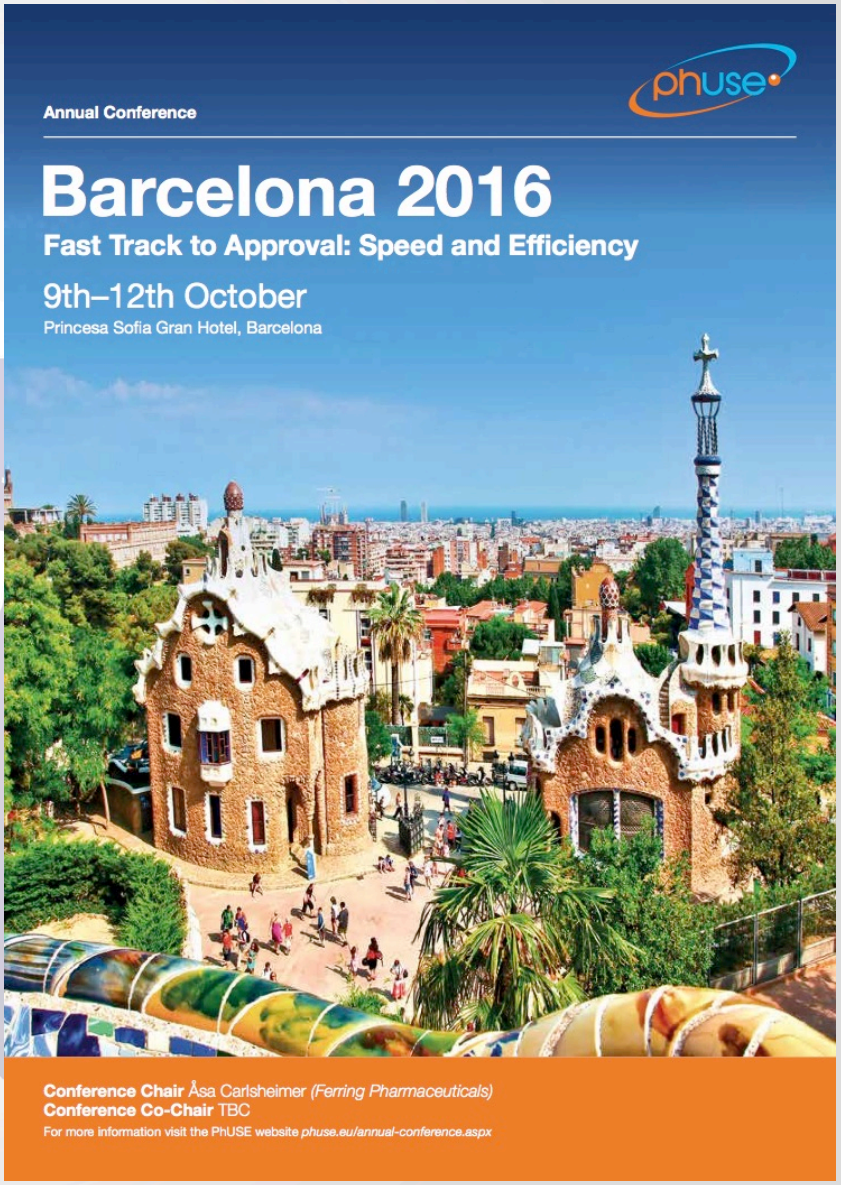
We have the answers, it is the questions we don't know

House Keeping Notes

Sponsors

We would like to thank our sponsors for their support:

PhUSE Future Events



Let’s get started!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