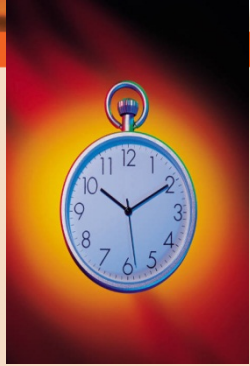




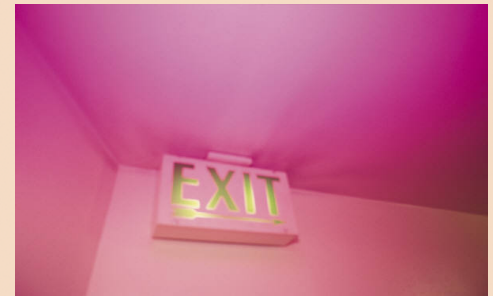
PhUSE Raleigh-Durham Single Day Event

ADaM

April 18, 2013



Housekeeping





Morning Agenda

Time	Topic	Speaker	Affiliation
9:00 – 9:15	Welcome and Introductions	Susan Kenny Gustav Bernard	Amgen Quintiles
9:15 – 10:00	Considerations for an ADaM Submission	Jack Shostak Chris Holland	DCRI Amgen
10:00 – 10:45	You Can't Spell ADaM without Metadata	Jeff Abolafia Ryan Burns	Rho, Inc
10:45 – 11:00	Break		
11:00 – 11:30	CDISC Journey in Solid Tumor using RECIST 1.1	Kevin Lee	Cytel, Inc
11:30 – 12:15	PDUFA V, 21st Century Review, CDER Data Standards, PhUSE/FDA and ADaM: Getting It All Right	Stephen Wilson	FDA
12:15 – 1:15	Lunch		



Afternoon Agenda

Time	Topic	Speaker	Affiliation
1:15 – 2:00	ADaM Review from a CDER Statistical Reviewer's Perspective	Behrang Vali	FDA
2:00 – 2:30	Challenges in Validating Analysis Data	Sergiy Sirichenko Max Kanevsky	Pinnacle 21, LLC
2:30 – 2:45	Break		
2:45 – 3:30	Moving your ADaM Metadata into Define 2.0	Geoff Mann	SAS Institute
3:30 – 4:15	Define-XML v2: Good for ADaM!	Lex Jansen	SAS Institute
4:15 – 4:40	PhUSE Membership and Upcoming Events	Chris Decker	d-Wise Technologies
4:40 – 4:50	Closing Remarks	Susan Kenny Gustav Bernard	Amgen Quintiles



Thank You!

- Many thanks to:
 - ❖ Terrific Speakers
 - ❖ Duke Clinical Research Institute
 - ❖ PhUSE Committee
 - ❖ Sponsors
 - ❖ Attendees



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General Contributors

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