



December 2008 - F2F

Jason Housley
(EUG co-lead)



Agenda

- 10.00 - 10.10 - Meeting opening & Introduction (Jason Housley)
- 10.10 - 10.30 - Update on Education & survey download (Veronica Martin)
- 10.30 - 11.15 - EUG Strategy and Direction
- 11.15 - 11.30 - Coffee
- 11.30 - 12.30 - CDISC Experience Exchange
- 12.30 - 13.15 - Lunch
- 13.30 - 14.15 - ADaM Overview presentation (Mike Nessly)
- 14.15 - 14.45 - ADaM Case study (Zoe Williams)
- 14.45 - 15.30 - ADaM round-table (Zoe Williams)
- 15.30 - 15.45 - Meeting Close

What's new - 2008

- Change in leadership
 - May 2008 - Jason Housley / Lauren Shinaberry take co-lead from Simon Bishop
 - May 2008 – EUG committee announced
 - Oct 2008 - Veronica Martin takes the place of Lauren Shinaberry

- Partnership proposed with PhUSE – this meeting is a pilot (feedback very welcome)



2008 in Reflection

'A year of Transition'

- March 2008 – F2F Implementation of the CDISC standards.
- July 2008 T/C focussed on Trial Design Domains
- Dec 2008 – F2F CDISC Exchange and ADaM workshop

2009 – The plan

January	Overview of CDASH and implementation options
March	Overview of BRIDG and implementation options
May	SDTM day : Practical application of SDTM - Delegates assigned to map data groups Using CDISC Standards to optimise the clinical trial process
July	Overview of xml (define.xml, ODM, LAB) and implementation options
September	Overview of HL7 and CDISC project and consideration issues
November	Regulatory perspective: What are all the regulatory requirements and mandates? (i.e. SPL, PIMS, eCTD, HL7 messaging)