

# Education Work stream Update

English Speaking User Network

F2F Meeting

15<sup>th</sup> of December 2008

Veronica Martin

# About the work stream ...



- Team members:
  - Donald Paterson (Amgen)
  - Neil Yolland (Eisai)
  - Veronica Martin (GSK)
- Work stream goal:
  - *Serve as a link between CDISC and the English Speaking User Group (EUG)*
    - *Raise awareness of training needs*
    - *Provide feedback on training*
  - *Understand and then start to address the educational needs of the EUG*
  - *Schedule the 'Educational' sessions for EUG*
  - *Establish links with other professional bodies (i.e. PhUSE, PSI) to deliver CDISC training*
  - *Proactively explore opportunities for potential sessions of interest*
- Team established in early August

# Accomplishments to date ...

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- Education survey
  - Provided results to CDISC
- Established links with Frank Newby
- Drafted the '2009 Education Plan'
  - Plans for TC and F2F meetings in 2009
    - 4 TCs (Jan, Mar, Jul, Sep)
    - 2 F2F meetings (May, Nov)
  - Our first TC in 2009 is on CDASH
- Developed a 'CDISC Courses' overview document
  - Provides participants with detailed information about courses
  - Still in 'draft' format ; will be shared with CDISC



Date	Format	Topic	Presenter
January	TC – 1 hour	CDASH Overview and implementation	Liz Nulton-Bodiford (GSK) with support from Ricky Dolphin and Sean Cronin (Shire)
March	TC – 1 hour	Overview of BRIDG and implementation options  <a href="#">Other suggestions: Future of ODM in the context of FDAs submissions, More about JANUS</a>	TBD
May	F2F meeting	SDTM day : Practical application of SDTM- Delegates assigned to map data groups  Using CDISC Standards to optimise the clinical trial process	TBD
July	TC – 1 hour	Overview of xml (define.xml, ODM, LAB) and implementation options	TBD
September	TC – 1 hour	Overview of HL7 and CDISC project and consideration issues	TBD
November	F2F meeting	Regulatory perspective: What are all the regulatory requirements and mandates? (i.e. SPL, PIMS, eCTD, HL7 messaging)	TBD

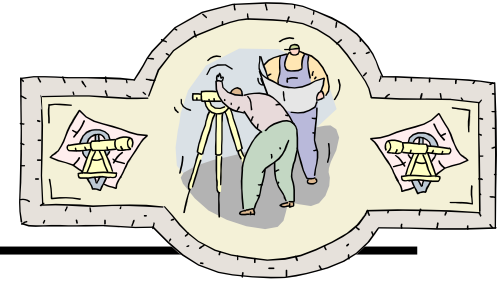
# Our objectives for 2009

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- Partner with CDISC and/or other professional bodies (eg. PhUSE, PSI) to deliver at least one “one day” CDISC event in 2009
- Identify and then maintain a list of ES CDISC trainers in the EU
- Draft and deliver the 2009 Education Plan for EUG
  - Identify ways to involve the EUG members in the planning and delivery of the Education Plan (i.e. presentations at the TCs for F2F meetings)
- Re-run the education work stream survey in 2009
- Partner with other Regional User Networks on education topics (i.e. share presentations and topics)
- Increase awareness in the EUG of upcoming educational opportunities
- Proactively engage with Frank Newby on CDISC education topics, such as:
  - Feedback on the CDISC website and improvements that CDISC may wish to consider
  - Establish links between the EUG and CDISC education

# Survey results

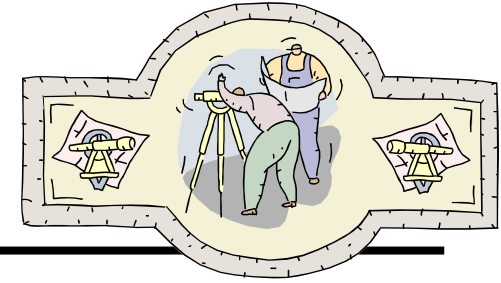
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- Completed by 71 members
  - Out of 259 members
  - Response rate = 27.4%
  - Very low rate – why?
- **Highlights:**
  - 10 out of the 71 participants are members of CDISC standard teams, some names listed below:
    - Jason Housley - Terminology and CDASH
    - Stephen Harrison - Terminology and SDS
    - Peter Van Reusel - SDTM
    - Siju John - CDASH
    - Flavie Stucker - ADaM
    - Jon Roth - ADaM
  - Good network of people we can call upon!

# Survey results - contd

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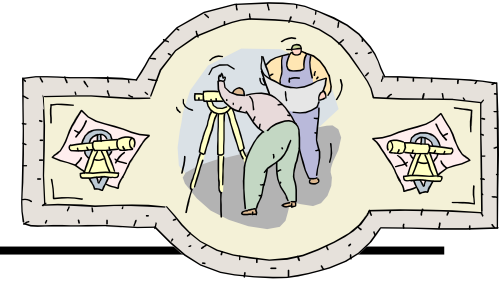


- **Highlights:**

- 48 (66%) received CDISC training
- Mainly through public training provided by CDISC (76%)
  - F2F seems to be the preferred method
- Top 3 training topics are :
  - SDTM Theory & Application (78%)
  - Introduction to CDISC (64%)
  - ADaM Implementation (38%)
- 75% have applied the knowledge gained at the training on a project or submission

# Survey results - contd

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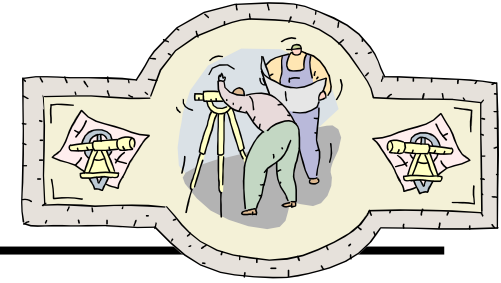


- **Highlights:**

- 47% of participants said that internal training is offered:
  - SDTM Theory and Application (71%)
  - Introduction to CDISC (51%)
  - ADaM Implementation (26%)
  
- 90% of participants asked for EUG to offer CDISC training:
  - Submission Data Standards [SDTM] (83%)
  - Analysis Dataset Model [ADaM] (79%)
  - Case Report Tabulation Data Definition Specification [define.xml] (60%)
  - Clinical Data Acquisition Standards Harmonization [CDASH] (46%)

# Survey results - contd

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- **Reasons for joining EUG:**
  - Learn more about CDISC
    - Training
    - Keeping up to date with CDISC
  - Expand CDISC network
  - Learn more about how to implement CDISC standard
    - Sharing of experiences
  - Hear real-world examples and solutions
  - Find out more about emerging standards
    - HL7 messaging

What are your thoughts on the  
survey results?