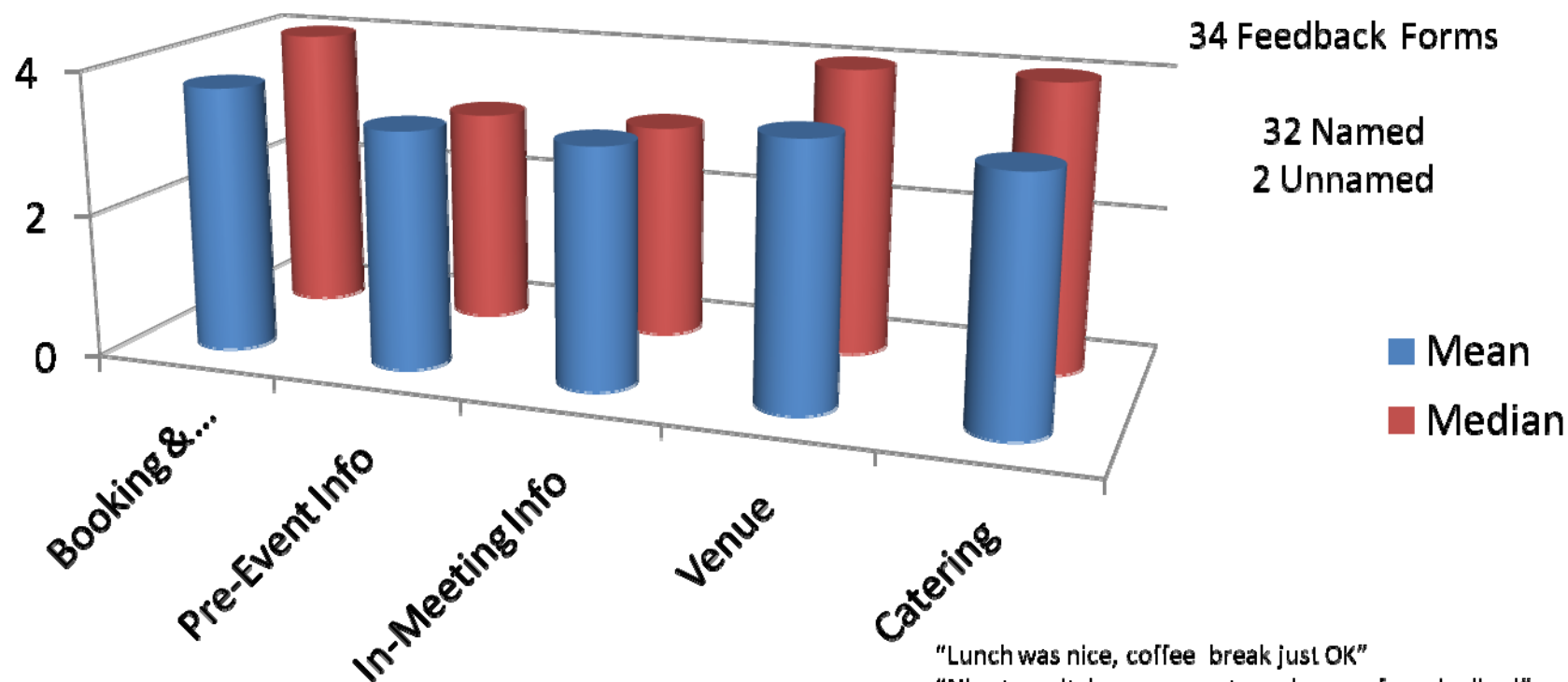


Feedback Analysis

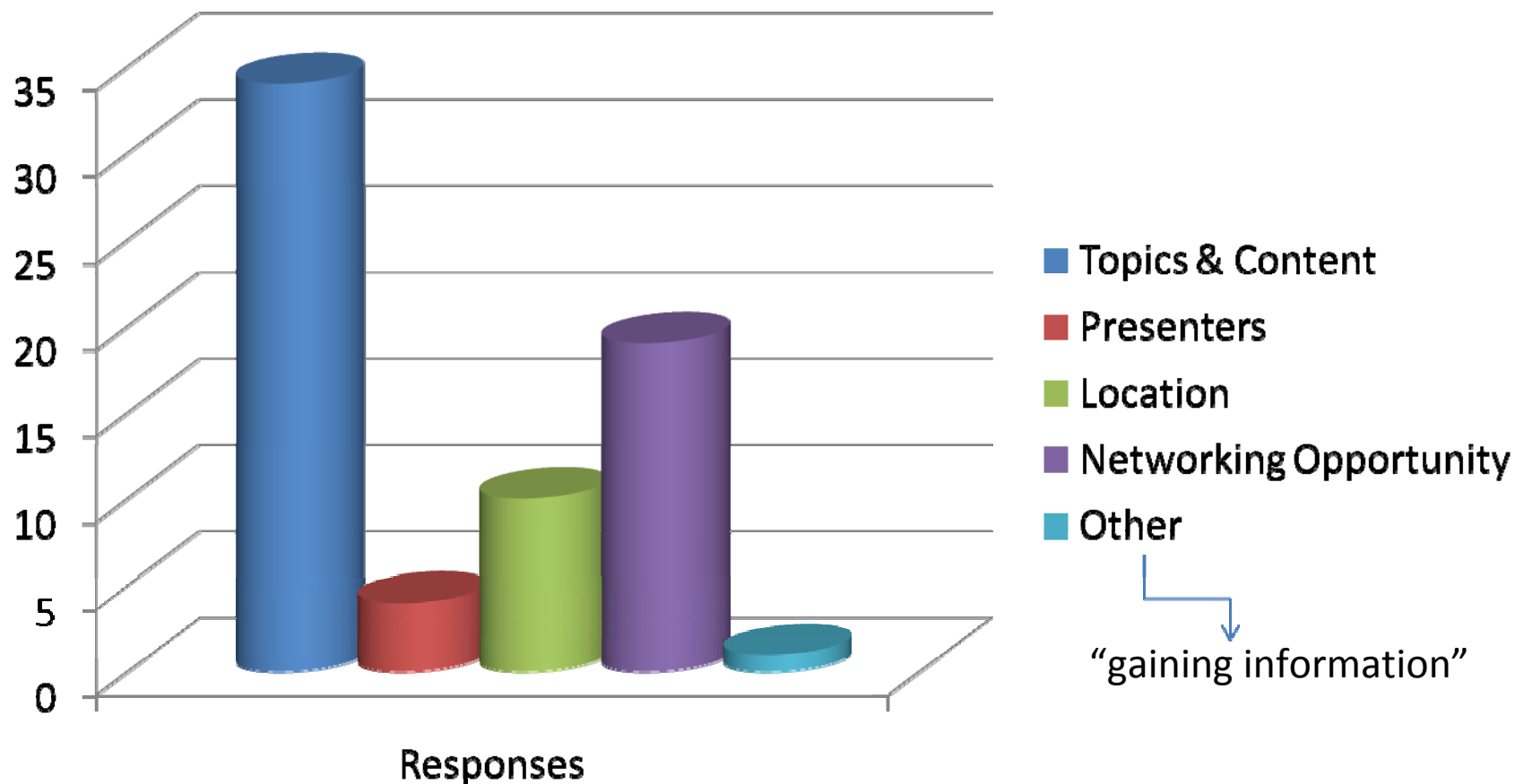
CDISC ESUG Meeting 27th May 2009

Meeting Administration



"Lunch was nice, coffee break just OK"
 "Nice to switch rooms - not much room for mingling!"
 "Labels for vegetarians"
 "Day very well chaired by Jason"
 "should mark vegetarian options"

Influences on Attending (?)



Changes to Improve Future Events

Meeting Management & Timekeeping

- “Maybe start a bit later to accommodate those of us commuting from far away”
- “Time Keeping!”
- “Start later or promptly”
- “10am start to ensure on time start and travel”
- “Start later!”
- “Better adherence to timings - more time for questions for presenters”
- “Program to run on time. Allow time for tech changes.”

Meeting Administration & Preparation

- “Paper and writing material for everybody”
- “Provide some more info beforehand so that beginners could research before event if they wish”
- “1) Possibly integrate standards Implementation Workshop ; 2) discuss breakout feedback”

Changes to Improve Future Events (2)

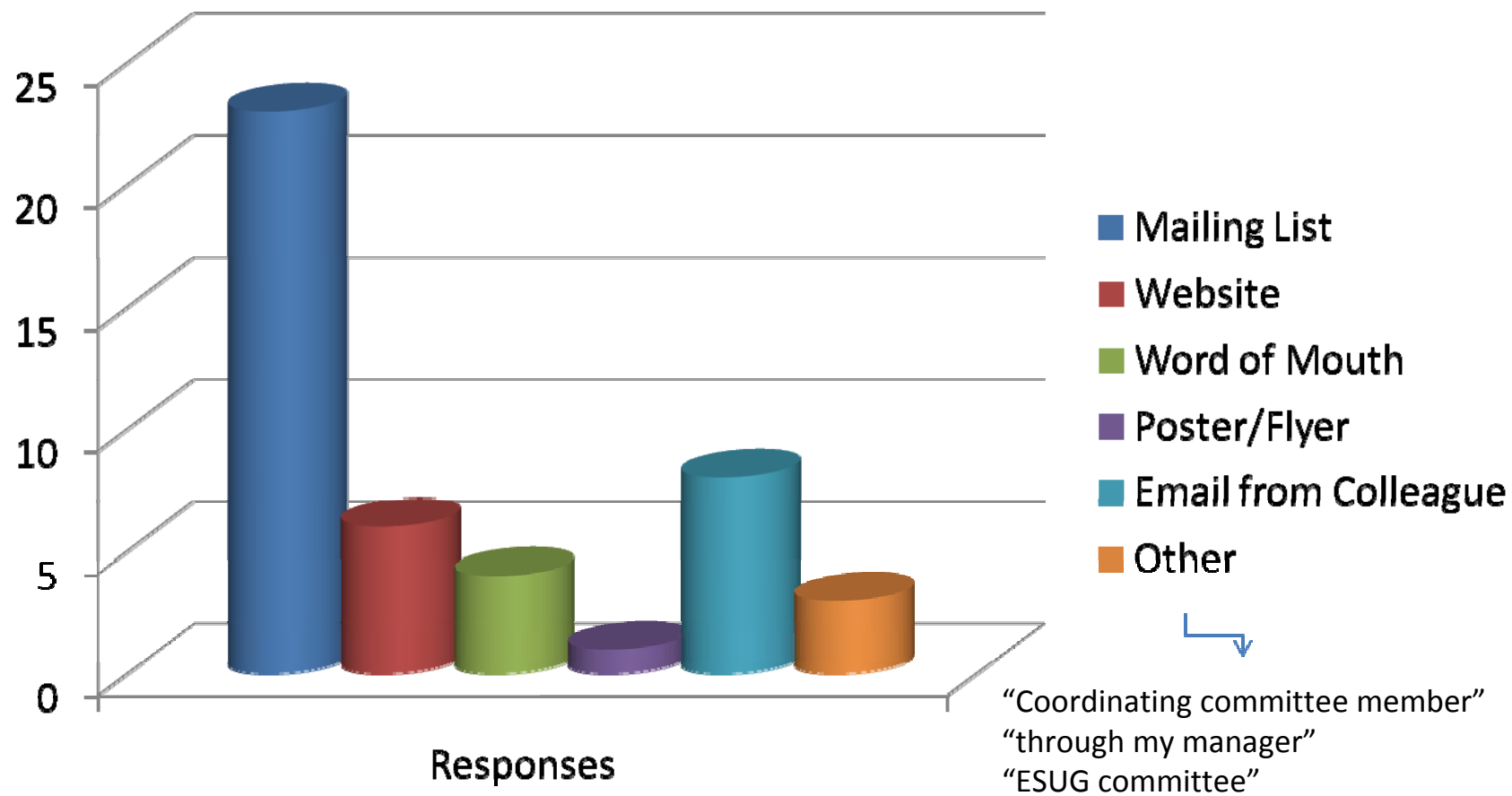
Content

- “Maybe fewer presentations with a little longer for each”
- “Got very technical at times, feel that people in the early phases of implementing CDISC/Define.xml struggled to follow at times”
- “Presentation content focused not so ambitious. Software vendors tend to flick quickly through their products/slides”
- “More on problems that people encounter - more interactive sessions around these”

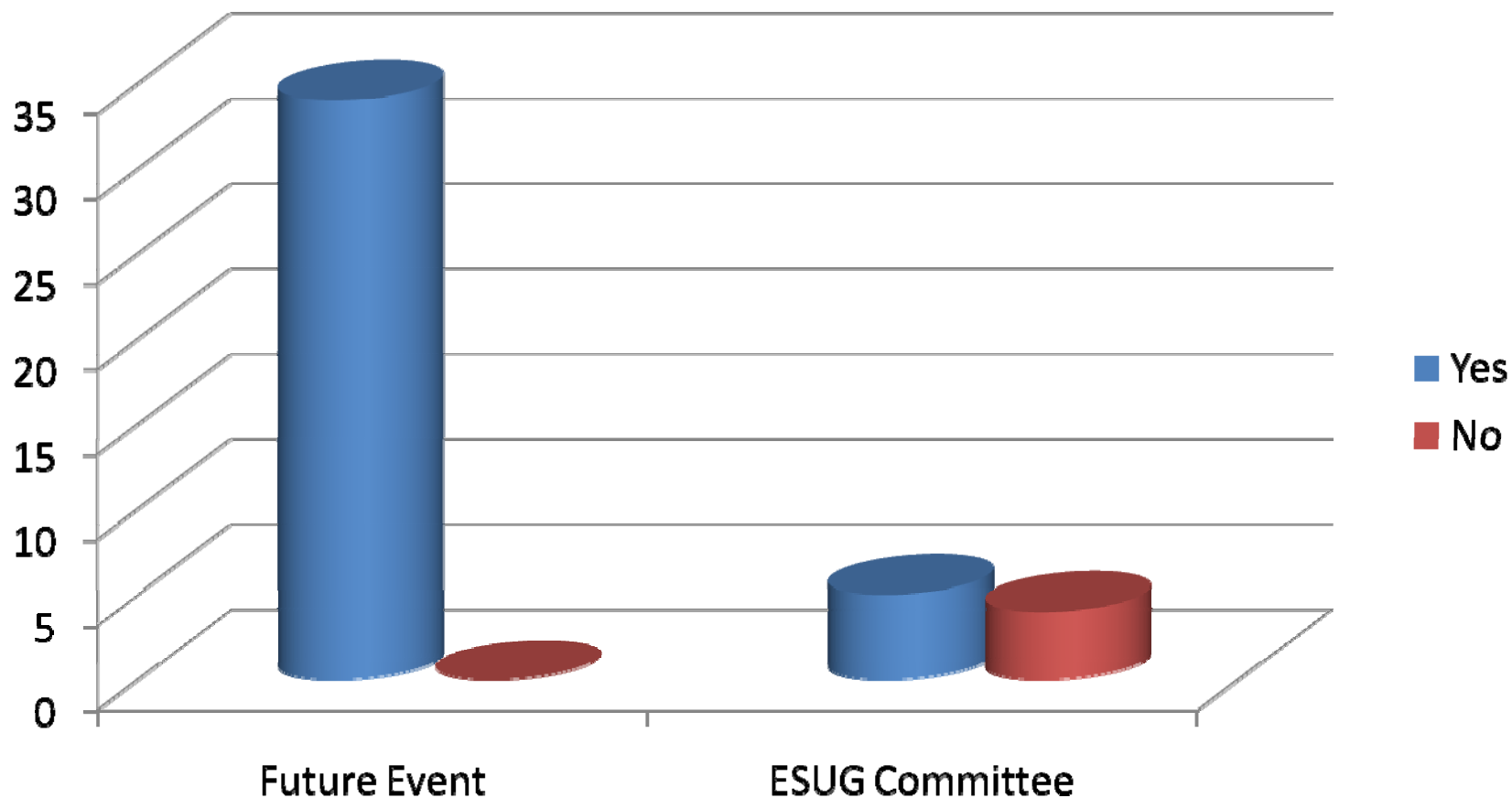
Other

- “None”
- “I think the event looked very attractive - no changes need to be made”
- “Extend TC's to 2 hours”
- “Difficult to think of any”

How did you hear about the meeting?



Interested:
in attending a Future ESUG/Phuse Event?
in getting more involved with the ESUG Committee?

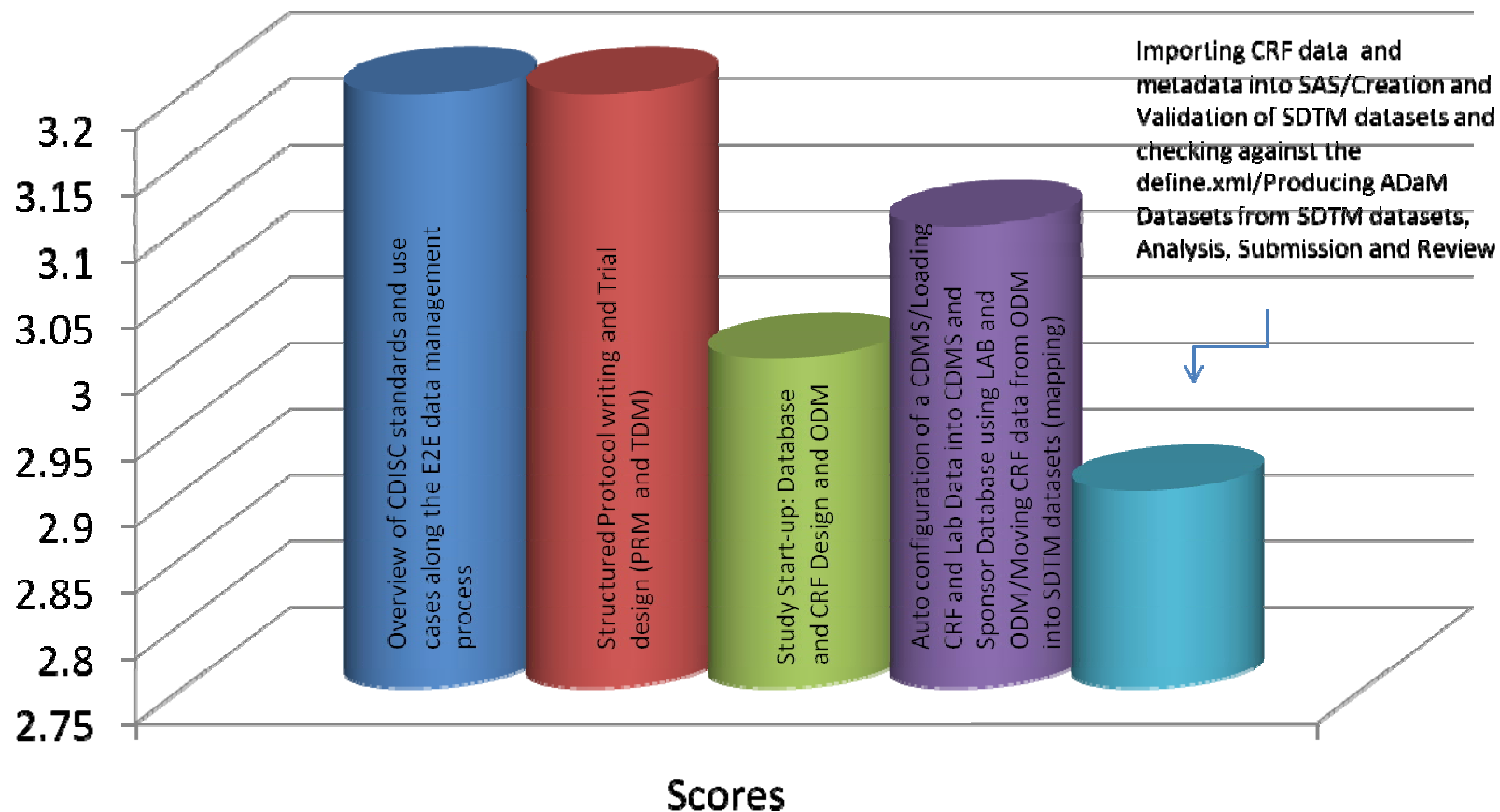




What topics would you like to see covered at the next ESUG F2F meeting or TC?

- “Productions of TFL's”
- “Stylesheets, SAS changes for handling CDISC”
- “Philippe's presentation that was dropped from today's schedule. Real life implementation problems and solutions presented by users/implementers rather than vendors”
- “More on terminology - how can we help each other with extensive codelists etc.”
- “DI Studio”
- “HL7 and link to CDISC”
- “Basic CDISC - I still don't understand the point other than FDA require it”
- “Continue with practical demonstrations”
- “Best Practice Guides”

Presentation Scores



Comments on Presentations

Overview of CDISC standards and use cases along the E2E data management process

- “not enough detailed information”
- “would have liked to see more detail”

Structured Protocol writing and Trial design (PRM and TDM)

- “would have been good to mention ability to share across protocols”
- “not totally applicable at moment but good to get feel for it”
- “integrated curve off line”
- “would have liked to see more detail”
- “demo would be more useful”
- “very well explained”

Comments on Presentations (2)

Study Start-up: Database and CRF Design and ODM

- “good information - a bit rushed”
- “longer demo would be a 4”
- “too much too quick”
- “too fast! Was difficult to follow at times”
- “too rushed however trying to fit in too much info into the time available”
- “a lot of content put into a short time. Would have been better with more time to add more detail and explanation”
- “needs to slow down - a lot of information so hard to take it all in”
- “would have liked to see more detail”
- “rather too much info, lots of valuable info but needs more time allocated”

Auto configuration of a CDMS>Loading CRF and Lab Data into CDMS and Sponsor Database using LAB and DM/Moving CRF data from ODM into SDTM datasets (mapping)

- “would have liked to see more detail ”
- “demo was difficult to see as was sat around the table”
- “shown at table - was in small group so very interactive”

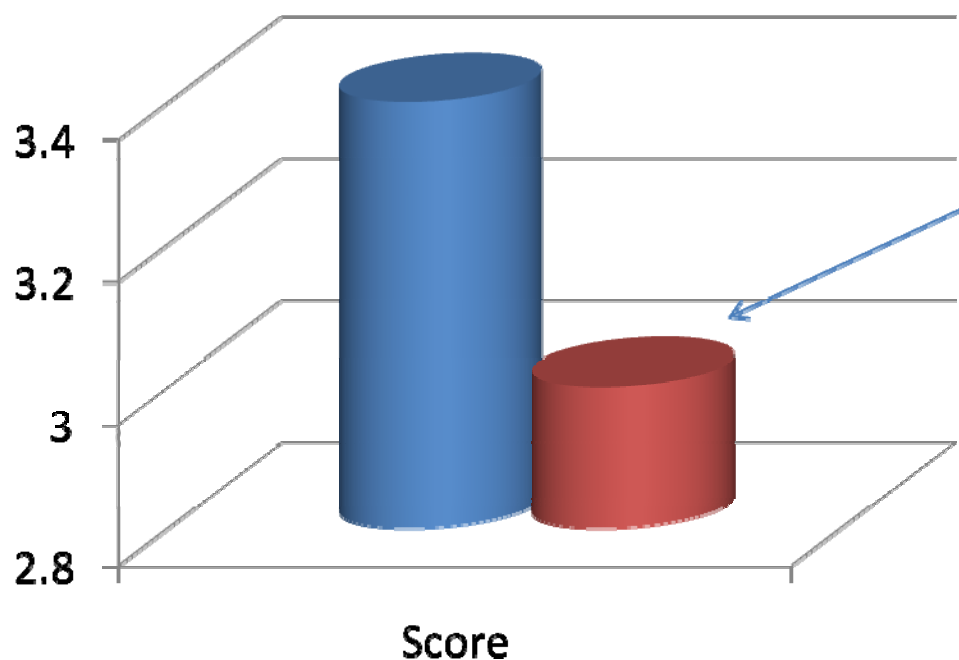
Comments on Presentations (3)

Importing CRF data and metadata into SAS/Creation and Validation of SDTM datasets and checking against the define.xml/Producing ADaM Datasets from SDTM datasets, Analysis, Submission and Review

- “would have liked to see more detail”
- “very good talk, I would like to hear more about the End-to-End SAS approach”
- “too much packed into time available”
- “demo was slightly too quick”
- “complex ideas of functions quickly demonstrated”
- “good information - a bit rushed”

Group Discussion & Final Presentation

“dominated by a few!”
 “good opportunity to share feedback with others”
 “more of this please!”
 “good to hear other companies issues and resolutions”
 “a bit too long!”



“admitted to problems, issues involved which was helpful”
 “first part a bit too general”
 “really helpful to have the time to look at CDISC from a very basic/beginners point of view”
 “ - Too long for a last session. Suggest last session is a summary Q & A etc”
 “ slides too cluttered (did not really add to content of what was said)”

■ **Group Discussion**

■ **The Vision**

CDISC Metadata Data
 Repository (CMDR) - The vision
 moving forward

Any Other Comments

- “For EC3: would like to see CDISC address the disconnection between SDTM IG and define.xml ”
- “Maybe try to split discussion groups up more - not more than 1 or 2 from one company on a given table, otherwise it can turn into an internal company meeting and discussion becomes too specific to that company. Discussion and experience will vary for Pharma and CRO's - try to get balance on tables.”
- “The group discussion would be better either split up during the day or not too long, people with not much experience don't have a great deal to discuss at the moment”