Washington DC CDISC Implementation Network Meeting

Place and Date:
Friday, November 17, 2006 (10-12),
SAS Consulting, 111 Rockville Pike, Rockville MD

Attending:

Bob Abelson  
HGSI
Nicole Close*  
Army MeRITS
Jane Diefenbach*,**  
Pharmastat
Amram Ewoo  
Cerner Galt
Heidi Grossman  
HGSI
Heather Hill  
EMMES
Mina Hohlen***  
FDA
Chris Holland*  
FDA
Devin Hunt  
Wellstat Therapeutics
Deborah Leung  
Otsuka
Bob Lyons  
NexTrial
Bob Mangold  
EMMES
Hemang Maniar  
EMMES
Alan Meier  
Medimmune
Scott Mund  
Cerner Galt
Lori Ovington  
Army MeRITS
Amy Palmer  
Independent
Linda Peng  
HGSI
Ujjwala Powers*  
HGS
David Styers  
EMMES
Tom Turlington  
Otsuka

*Steering Committee, **Moderator, ***Minutes

Proceedings

Jane began the meeting by acknowledging the gracious contribution of the meeting room, coffee and snacks by SAS.

The purpose of the meeting was to discuss how the DC Implementation Group should be organized and what the focus should be. It was agreed that meetings would be held at least quarterly, with the possibility of additional meetings if appropriate (for example, additional introductory presentations if new people joined the group who were not experienced in SDTM). The primary focus of the group will be education. The next meeting will be an introductory overview of SDTM. Other topics mentioned were ODM, DEFINE.XML, LAB, ADaM.

There was some discussion about how long the meetings should be; it was generally agreed that half a day was optimal (with the option of longer meetings if appropriate).
It was felt that the Implementation Network should supplement the commercial training available with a focus on discussing experience with implementation, always allowing time for questions, and encouraging very basic questions if appropriate.

There was a discussion about how/if to combine a technical/strategic session. It was felt that a combined approach might be less than optimal for either group and that a strategic-only session might be appropriate.

We discussed the possibility of having introductory webinars. It was agreed that we are not equipped to support webinars at this time but that we would consider putting links on the site for webinars and other educational opportunities. It was also agreed that if we use any electronic forum (webinar, teleconference) we would set it up so that participants have to identify themselves to all attending (maybe use advance registration or something).

Jane asked if any organizations would be willing to host a meeting. There were several potential offers: MedImmune, HGS, Otsuka, Emmes, among others. The volunteers agreed to find out if their employers would be willing to host a meeting. The possibility of asking SAS Institute about continuing or occasional use of their facilities was mentioned. An FDA attendee expressed concern that FDA employees might not be able to attend a meeting held at a pharma company. This issue will be investigated by an FDA employee.

Several suggestions for a name were made. It was decided that we will revisit this issue at the next meeting with the intention of selecting a permanent name at that time.

There was a question about CDASH, initiated by Lori Covington. We used the last few minutes of the meeting to trade information about the purpose of this group.

**Actions:**

1. Steering Committee (SC) to add all meeting attendee emails to the Google communication list
2. SC to create point person/email and add link to the group's website so that folks can ask general questions and get a response (info@...)
3. Alan Meier to begin discussion on website for possible names of our group, to be discussed at the next meeting
4. Use current communication strategies as outlined in the meeting and discuss at the next meeting on how it is working (make improvements if needed)
5. SC to line up venues and speakers for next 1-2 meetings (e.g. Becky Kush on the Business Case for CDISC Implementation, SDTM intro, Steve Wilson on FDA use of the standard, etc.)

The meeting was adjourned at 11:45.

**References:**

Jane’s Powerpoint Presentation