Please reserve Thursday, May 23 from 12:30 - 4:30 for a meeting of the Bay Area CDISC Network at the South San Francisco Conference Center (see directions below). Many thanks to Formedix for hosting the meeting at the Conference Center, and to Mark Wheeldon and Nicola Rogerson of Formedix for making it happen. This meeting has been months in the planning and we have quite an agenda.

If you plan to attend, Please reply to this e-mail (jbrega@pharmastat.com) so we can get an accurate count for planning purposes.

Please come early to find parking and say hello to your colleagues. The room will be open at 12:30 and the meeting will start at 1:00.

If you cannot attend in person, you have the option of joining our web conference meeting. A meeting link and teleconference number are provided below.

The Meeting

The following presentations will be offered:

Practical Uses of Define.xml for End-to-End Processing of Clinical Trial Data

Mark Wheeldon, CEO and Founder, Formedix

Formedix has been a key supporter of CDISC for many years. Mark is a member of the CDISC Industry Advisory Board, and Formedix engineers did much of the heavy lifting to develop Define.xml v2.0, which was published in March. CDISC standards are the underpinnings for a suite of software that Formedix developed to manage metadata repositories and drive clinical data management and documentation processes from the development of specifications through delivery of the data submission.

Define.xml is an underused and undervalued standard that can support a variety of applications across the continuum of clinical data operations. Mark will show how Define can be used to manage libraries of dataset designs, or to produce detailed dataset specifications for sharing internally or with CROs.

New Domains and Features of the SDTM IG Draft v3.1.4

Barrie Nelson, CDISC SDS Leadership team member and SDS Oncology Team co-lead,
Director of Biomedical Data Stewardship, Amgen

Development of version 3.1.4 of the SDTM Implementation Guide has been such a large production that the team has had to publish the draft version in three batches of documents, which include at least 12 new standard domains. Barrie has played a leading role in the development, review and publication of this opus.

The new domains are so useful and practical that many sponsors are already implementing them even though they are still drafts for public comment. He will give us an overview of the new domains and their intended uses, and an update on the status of the package.
Update from CDISC on current initiatives and plans
Rebecca Kush, President and CEO, CDISC

Yes! Rebecca Kush, the CEO of CDISC, will be attending the meeting in person! She has kindly agreed to provide an update of CDISC’s current initiatives and plans.

OpenCDISC Validator v1.4 – what to expect from the new version
David Borbas, Senior Director, Data Management, Jazz Pharmaceuticals

Pinnacle 21 released version 1.4 of OpenCDISC in March, just before the Computational Sciences Symposium. The FDA has hired Pinnacle 21 to help them implement a new version of Janus and develop the software to qualify SDTM data for submissions. Consequently, CDER is now taking an active role in defining the checks that OpenCDISC performs, and diagnostics in the new version go well beyond SDTM conformance. David will explain the differences between version 1.3 and 1.4 of OpenCDISC, and how to interpret its diagnostics.

Study Data Reviewer’s Guide (SDRG) v1.0 from the FDA/PhUSE CSS collaboration
Scott Bahlavooni, Global Data Standards Manager/Information Architect, Data Standards Office, Biometrics Strategic Operations, Genentech/Roche

The FDA/PhUSE Computational Sciences Symposium (CSS) supports FDA/industry collaborations that promote the use of data and documentation standards within FDA. One of last year’s successful collaborations was Working Group 4, which recently published version 1.0 of the Study Data Reviewer’s Guide.

Scott was a co-lead of the group, which also included Helena Sviglin, Doug Warfield and Steve Wilson from FDA, and Gail Stoner (J&J), John Brega (PharmaStat) and Joanna Koft (Biogen Idec) from industry. The package includes an SDRG template, guidelines for document production, and examples of submission-ready documents. It was presented at the FDA/PhUSE CSS in March and the FDA is now evaluating it for inclusion in submission specifications. Scott will give us a cook’s tour of the package, which is available for download on the PhUSE Wiki at http://www.phusewiki.org/wiki/index.php?title=Study_Data_Reviewer%27s_Guide.

News from the FDA/Phuse Computational Sciences Symposium
Scott Bahlavooni, Genentech/Roche
Sandra Minjoe, Accenture
John Brega, PharmaStat

Attendees of the conference

The 2013 FDA/PhUSE Computational Sciences Symposium annual meeting was held in March in Silver Spring, MD. This year’s meeting was organized to focus on specific projects rather than general topics. About 300 attendees were treated to updates on FDA’s progress in implementing data standards, and then rolled up their sleeves for 2 days of intense sessions aimed at producing project deliverables. This meeting has become one of the year’s most important events for those of us involved in data submissions. Scott, Sandra and John will bring us up to date on the news and activities at the conference. Attendees of the conference will also share their observations and experiences.
Directions to the South San Francisco Conference Center

The meeting will be held at the South San Francisco Conference Center at 255 South Airport Blvd in South San Francisco. You will find directions and a map on the Conference Center’s website at http://www.ssfconf.com/getting_here/map_and_directions.html. Free parking is available at the conference center and at the two neighboring hotels. There will be signs and/or people to direct you inside the conference center.

If you are coming from Highway 101 heading North (from San Jose/Palo Alto/Redwood City), take Highway 101 north to the South Airport Boulevard exit, which is two miles north of the San Francisco International Airport. At the first stop light, drive straight across the intersection and directly into the Holiday Inn parking lot. The South San Francisco Conference Center is on the left.

From Highway 101 heading South (from San Francisco), take Highway 101 South to the South Airport Boulevard exit in South San Francisco. Stay to the right and turn east under the freeway overpass. Make a right onto South Airport Boulevard. The South San Francisco Conference Center is located on the left next to the Holiday Inn.

As usual, leave yourself plenty of time for parking.

Web Conferencing information

If you are unable to attend in person, you may dial into the web conference as follows

1. Dial in to the Conference Call:
   - Call-in toll-free number: 1-888-804-6796 (US)
   - Call-in number: 1-706-679-0931 (US)
   - Conference Code: 136 109 1091

2. Join the Web Conference:
   - Click the Web Conference Link: https://amgen.webex.com/amgen/j.php?ED=235251247&UID=482483707&RT=MIM0
   - OR – Launch Meeting Center: http://amgen.webex.com
   - Enter the Meeting Number: 598 221 929

3. Enter your name and email address. This meeting does not require a password.

NEW USERS: Prepare your computer in advance of the meeting by clicking New User on the navigation bar after launching Meeting Center (http://amgen.webex.com)