Bay Area CDISC Implementation Network November Meeting - PLEASE REPLY

Please reserve the afternoon of **Thursday, November 19 from 1:00 to 4:30** for the last Bay Area CDISC Implementation Network meeting of 2009. It will be held at the South San Francisco Conference Center on South Airport Blvd. Directions are at the end of this document. Thanks to Patty Gerend and Genentech for hosting the meeting and reserving the conference facility. Doors will open at 1:00 and the meeting will start promptly at 1:30. As usual, I encourage you to come early to chat.

If you plan to attend **PLEASE REPLY** so we'll have a count of attendees.

**The Meeting**

- **CDISC Implementation on a Rheumatoid Arthritis Project Partnership**  
  Patricia Gerend, Senior Manager, Statistical Programming & Analysis, Genentech
  
  Roche’s acquisition of Genentech has given the two companies fresh opportunities to work together on submissions. Patty first made this presentation at the WUSS Conference this year. She and her co-authors, Olivier LeConte and Chris Price from Roche Products Limited, and Michelle Zhang from Genentech, have distilled their experience with pulling together a multi-company submission based on CDISC data standards.

- **Strategies for a CDISC Submission Using CROs**  
  John Brega, CDISC Implementation and eCTD Submissions, PharmaStat
  
  It used to be that any company preparing for a submission would staff up to do the heavy lifting. Many sponsors these days choose instead to engage CROs to produce all of the data and documentation deliverables for a submission. This is a brave new world for both the sponsors and their CROs. How do you get your vendors to produce conforming and consistent submission-ready deliverables? How can you be sure they got it right? How do you hold to your timeline and keep the costs from ballooning? This presentation provides practical tips on how to work with your vendors to plan and produce the Biometrics parts of a successful CDISC submission.

- **News from the CDISC Interchange**  
  The CDISC Interchange, held this year in Baltimore the week of November 9, is always a source of late-breaking news. We will hear perspectives on it from several of the Bay Area attendees.

- **Panel Discussion: Practical Real-world Experiences with Define.xml**
  
  Sy Truong, President, Meta-Xceed  
  Phil Liu, Associate Director of Clinical Programming, Theravance  
  John Brega, CDISC Implementation and eCTD Submissions, PharmaStat
  
  Define.xml is the prescribed method for documenting data in a CDISC eCTD submission. We will hear from a few Bay Area companies that have accumulated some experience producing define.xml for submissions. The panelists will share their experiences, methods and insights on how to produce rigorous and conforming Define documents.
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 Area), 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, at the Hungry Hunter Restaurant, onto South Airport Boulevard. The South San Francisco Conference Center is located on the left between the Good Nite Inn and the Holiday Inn.

See you there!

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