Dear Fellow San Diego CDISC User,

It is with great pleasure that I would like to invite you to the next San Diego CDISC Users Network meeting which will be held on Thursday, December 13th at Pfizer in La Jolla from 12:00 PM – 4:00 PM.

The San Diego CDISC Users Network (SDCUN), is a network that encourages sharing of experiences, education, exchange of ideas, news and career opportunities amongst friends and colleagues in our industry who share an interest in CDISC, submission standards, and regulation.

Based upon the feedback from our last meeting, we have added an additional interactive element to the meeting and are looking forward to the continued sharing and learning amongst our members.

The meeting room will be available at 12:15 at which time you can reconnect with friends and meet new ones during our light lunch provided by Assent Consulting. As with all of our meetings, there is not a fee to attend. If you plan to join us, please e-mail (mgomez@pharmastat.com) by Tuesday, December 11th to allow ample time for food planning and security documentation for our hosts. Please also forward this invitation to anyone who you think may be interested in attending this, or future events.

Thank you to Ren-Yu of Pfizer for coordinating the location for the event! Thank you all for your participation and feedback.

Happy Holidays.

Micky

The Meeting

Light Lunch and Networking

Welcome and News

Presentation: PDUFA V and the 2012 North American CDISC Interchange

Micky Salgado-Gomez – Submission Standards & eCTD Submission Strategies, PharmaStat

On July 9, 2012, the President signed into law the Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012. This new law includes the reauthorization of the Prescription Drug User Fee Act (PDUFA) that provides FDA with the necessary resources to maintain a predictable and efficient review process for human drug and biologic products. This presentation will discuss the changes in regulation and timelines associated with data standardization requirements for submissions. The tenth anniversary CDISC Interchange and updates on CDISC standards will also be discussed.

Micky is a standards implementation and eCTD submission strategies consultant who has worked in the biopharmaceutical industry since 1998 as an associate director of statistical programming, statistical programmer, and consultant. Based in San Diego, she provides submission standards and strategy support for her clients.
Round Table Break Out Session

Round Table 1: Transitioning to CDISC Standards
In this roundtable, Members will discuss challenges confronting companies and departments as they implement CDISC standards. This includes anticipated challenges for those who have not yet started implementation through those who are in the trenches of CDISC implementation and have worked through or are still working out transition obstacles. CRFs (using CDASH), SDTM, ADaM, Controlled Terminology, and Define.xml/Define.pdf will be discussed.

Round Table 2: Developing Tools to Support Standards
In this roundtable, Members will discuss tools that support the production of CDISC conforming deliverables. This includes discussion of what constitutes a tool and when is an optimal time to think about creating tools. Tools for specific deliverables such as CRFs, SDTM, ADaM, Controlled Terminology and Define.xml will be discussed.

Round Table 3: Standardizing Lab Data
In this roundtable, Members will discuss the standardization of lab data to CDISC and Controlled Terminology standards. This will include discussion of the challenges to getting lab data standardized as well as possible and actual solutions.

BREAK

Presentation/Panel Discussion

Closing Remarks

Location
All visitors to the Pfizer campus must be pre-registered and sign in at the Security Desk. See map on next page.

Pfizer
10770 Science Center Drive
San Diego, CA 92121
CB2-1110
Map to Pfizer La Jolla Campus

CB2
(VISITORS Check In)
10770 Science Center Drive
San Diego, CA 92121

VISITORS PARKING
Please Check-In with Security

Directions to the Campus Buildings

Please refer all Contractors and Visitors that will be visiting CB1-CB6, CB10 or The Pfizer Incubator to the CB2 Visitors Check-in Center. A photo ID is required for visitor check in.

Groups of 15 or more will check-in at the lobbies of the buildings visited. Visitors should arrive 15 to 20 minutes early to allow enough time for check-in.

CB2 Visitors Center
10770 Science Center Drive, San Diego, CA 92121

From San Diego International Airport.
Follow signs to I-5 North.
Proceed on I-5 North for approx. 10 miles.
Exit I-5 at Genesee Ave. and make a left at the stop light.
Make a right at the second stop light which will be Science Center Drive.
CB2 Visitors Center is located at the end of the cul-de-sac.
Visitor Parking is to the left. Please follow Visitors Signs.