You are cordially invited to the next meeting of the Bay Area Implementation Network on Tuesday, May 24, 2011 at the South San Francisco Conference Center (see directions below). Many thanks to Medidata Solutions for hosting the meeting at the Conference Center, and to Vidhi Goel and Joshua Pines of Medidata’s Marketing group for making it all happen.

If you plan to attend, please reply to the following e-mail amy.caron@omnicarecr.com so we can get an accurate count for planning purposes.

As usual, please come early to find parking and say hello to your colleagues. The room will be open at 13:00 hr, the meeting will start at 13:30 and will end at 16:00.

You will be able to attend the following presentations

Introducing the CDISC Protocol Representation Model

David Gemzik, Vice President, Implementation Services, Medidata Solutions

CDISC recently released the Final version 1.0 of the Protocol Representation Model (PRM). The scope of this model includes protocol content including Study Design, Eligibility Criteria, and the requirements from the ClinicalTrials.gov and World Health Organization (WHO) registries. There is some overlap between the PRM and the SDTM Trial Design datasets. David Gemzik is the team lead for the CDISC Protocol Representation group. He will introduce the PRM and discuss the benefits of structured protocol authoring with PRM to gain efficiencies in the trial design process. To highlight the design and implementation challenges and operational considerations, David will demonstrate with real world examples and case studies.

Using the CDISC Protocol Representation Model

Michelle Marlborough, Senior Manager, Product Management, Medidata Solutions

Michelle Marlborough, a colleague of David’s at Medidata, will expand on David’s presentation by examining the relationship between PRM and other standards, including SDTM, ODM and CDASH. She will give examples and best practices for using CDISC standards to gain efficiency across trial design and execution, and present the case for end-to-end support for CDISC standards in order to maximize efficiency.
Using OpenCDISC Validator to Check SDTM datasets – Mechanics and Case Studies

David Borbas, Senior Director, Data Management, Jazz Pharmaceuticals
The FDA has made it abundantly clear that OpenCDISC is the SDTM conformance validator they intend to use going forward to evaluate submitted data. They expect sponsors to run it themselves first, and either fix the conformance issues or explain which ones cannot or should not be addressed. David will talk about what OpenCDISC is, how to use it, and how to interpret its diagnostics.

News from the DIA/FDA CDER/CBER Computational Science Annual Meeting

Lisa Brooks, Independent Consultant
Attendees of the conference

The second Computational Science Annual Meeting was a watershed event in the evolution of the FDA’s adoption of the CDISC standards. Attendees were treated to a rare candid glimpse into how the FDA uses the data we provide. They offered the clearest statements to date about what they consider important, what they want to get from sponsors, and what they do with what we send them. For those of us who implement CDISC standards, this meeting promises to be one of the most important events on our calendars going forward. Lisa Brooks, a local independent consultant, will start the discussion with a brief overview of the meeting. 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 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. As usual, leave yourself plenty of time for parking.
ABOUT CDISC

CDISC is a global, open, multidisciplinary, non-profit organization that has established standards to support the acquisition, exchange, submission and archive of clinical research data and metadata. The CDISC mission is to develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare. CDISC standards are vendor-neutral, platform-independent and freely available via the CDISC website. Additional information on CDISC can be found on the CDISC website at www.cdisc.org.

*The CDISC Vision: Informing patient care and safety through higher quality medical research*