

The Bay Area CDISC Implementation Network

The Bay Area CDISC Implementation Network will have its next meeting on Thursday, 15 July from 1:30 to 4:30 at Jazz Pharmaceuticals on Porter Drive in Palo Alto.

David Borbas, Director, Data Management at Jazz will give a presentation on

Using ODM Messages to Integrate Clinical Trial Systems and Improve Data Quality

Increasingly, clinical trials have multiple electronic data systems to capture and manage data. These systems often have overlapping information but are currently used as isolated systems. Integrating these systems is one option to streamline data sharing and decrease errors. This presentation will focus on the use of ODM messages and web services to standardize and control data between an IVRS and EDC system currently in use at Jazz Pharmaceuticals. It will include the design, testing, and the practical aspects of the current use of this interface method in a clinical study.

Mark Wheeldon, CEO of Formedix, will give the following presentation:

ODM – the Operational Efficiency Model. Using CDISC ODM to Deliver Proven Cost and Time Savings in Study Set-up

Today, due to regulatory interest by the FDA much of the focus on CDISC standards implementation has centered on the use of the Study Data Tabulation Model (SDTM) for dataset submission.

However, despite minimal regulatory support the ODM is increasingly being adopted by CROs, Pharmaceutical, Biotechnology and (very interestingly) within a range of EDC vendor offerings.

So why is this? Simply because the ODM has been proven to deliver operational efficiencies upstream during study set-up and downstream in dataset conversion, system integration and as a vendor neutral archive format.

Mark will present real-life use cases (with real companies) where CDISC ODM produced a 68% reduction in study specification time and a further reduction of 40-60% in database build times. In addition, we will talk about using ODM to establish and manage vendor neutral global libraries of data elements. This latter use case involved the conversion of multiple proprietary unstructured metadata formats into an ODM library with over 500 forms, 15,000 items and 3,000 code lists. Library management in this case alone reported an 8 month return on investment.