Dear San Diego and Southern California CDISC Users,

Happy New Year! I am pleased to announce a San Diego CDISC Users Network meeting on February 20th, 2020 from 12:15p-4:30p at Pfizer in La Jolla.

There is no charge to attend this meeting which is only possible thanks to our Network supporters. Many thanks to **PharmaStat** for organizing the event along with the generous support of Dave D'Attilio **(TalentMine),** Sheila Leaman **(CDISC)**, and Ren-Yu Tzeng **(Pfizer)**.

To register, visit: https://www.eventbrite.com/e/86060085031 . Please register by ***Thursday, February 13th***.

Updates about this event and upcoming events will be made available

- via e-mail if we have your current e-mail address,
- on LinkedIn if you are a member of the San Diego CDISC Users Network https://www.linkedin.com/groups/4055118/ , and
- the CDISC Wiki for the San Diego CDISC User Network https://wiki.cdisc.org/display/SDUN/San+Diego+User+Network+Home

Please forward this invitation to your colleagues and friends as many work e-mail addresses have changed since our last meeting. Thanks in advance for this favor!

As usual, we're leaving extra time in this meeting for people to chat with colleagues and catch up with old friends. We encourage you to come early to start your networking. The room will be open at 12:15 and the first presentation will start promptly at 1:00.

THE MEETING

We will have the following presentations

Trial Sets in Human Clinical Trials

Fred Wood, Vice President, Consulting Services, Data Standards Consulting Group, A Division of TalentMine

Abstract

The Trial Sets table has been included in the SDTM since Version 1.3, published in 2012. The only implementation guide in which it appears, however, is the SEND Implementation Guide (SENDIG). The Trial Sets dataset (TX) allows for the subsetting of subjects within an Arm (treatment path) and facilitates the "grouping" multiple Arms together. A Trial Set represents the most granular subdivision of all the experimental factors, treatment factors, inherent characteristics, and distinct sponsor designations as specified in the design of the study.

Within a nonclinical trial, each animal is assigned to a Set in addition to an Arm. The Set Code (SETCD) variable is Required in the SEND DM dataset. While there is no such requirement in the SDTMIG DM dataset, Trial Sets has potential uses in human clinical trials, particularly when the randomization or the study design is based on factors other than treatment (e.g., subjects who have undergone previous heart surgery vs. those who have not). This presentation will provide an introduction to Trial Sets as it's used in nonclinical studies as well as examples of how this dataset could be used in human clinical trials.

Bio

Fred has been a leader in the development of CDISC standards since 1999. Fred is Vice President for Consulting Services at TalentMine. He leads the Data Standards Consulting Group, and is an SDTM and SEND Implementation Advisor. He has been active in leading the development of CDISC standards since 1999, and is one of the principal contributors to the CDISC Study Data Tabulation Model (SDTM). Fred is a founding member of the SDS (Study Data Standards) Team (1999), the SEND Team (2002), and the Medical Devices Team (2007), and has led or co-led these for many years; he currently serves on the Leadership Teams of all three. Fred served for more than fifteen years on the CDISC Technical Leadership Committee and five years on the CDISC Standards Review Council. He is currently a member of the CDISC Global Governance Group, which oversees the development and publication of all CDISC standards and documents.

Why Are There So Many ADaM Documents, and How Do I Know Which to Use?

Sandra Minjoe, Senior Principal Clinical Data Standards Consultant, PRA Health Sciences

Abstract

As of this writing, the CDISC website has the following ADaM documents for download: a model document, three versions of the implementation guide, an adverse event data structure, an occurrence data structure, a time-to-event document, a document with examples in commonly used statistical analysis methods, an analysis result metadata document, conformance rules, and an important considerations document. Additionally, you can download three release packages, each containing a subset of these documents. This presentation describes why there are so many documents, walks through basic information contained in each, and makes recommendations of which set of documents to use in which circumstances.

Bio

Sandra Minjoe started programming in the pharma/biotech industry in 1993. She is a Senior Principal Clinical Data Standards Consultant at PRA Health Sciences. Sandra is the former CDISC ADaM Team Lead, has been part of the ADaM team since 2001, proposed structures that became ADSL and OCCDS, and continues to lead and work on sub-teams. Her focus is the fundamental principle of traceability.

CDISC Library

Anthony Chow, Director Data Science CDISC

Abstract

CDISC introduced CDISC Library in 2019, available to all gold & platinum members. CDISC Library is the single, trusted, authoritative source of CDISC standards metadata and represents a new way of creating, maintaining, and publishing this metadata. CDISC Library has two main components: Application Programming Interface (API) and CDISC Library Browser. The presenter will provide the audience a high-level overview of CDISC Library and an interactive demonstration of both API and Browser.

Bio
Anthony Chow serves as Director of Data Science at CDISC. He plays a leadership role in defining and administering processes and policies for governing the metadata that becomes CDISC standards. Anthony's primary duties include creating, maintaining, curating, and ensuring high-quality metadata in CDISC Library, the single, trusted, authoritative source of CDISC standards metadata. He also co-leads the Controlled Terminology Relationship team to develop detailed metadata about codelist usage and rules.

Previously, Anthony held essential IT roles at Allergan and Octagon Research Solutions, focused on delivering data integration and migration systems. He holds a bachelor's degree in Computer Science from Northeastern University.

Is your organization ready for CDISC 360 View and Challenges?

Sunil Gupta Executive Director of Data Sciences at TalentMine

Abstract
Like many organizations, manual double programming is applied to create SDTMs and ADaMs with automated variable attributes. The next step to more fully automate SDTM mapping and creation with minimum customized programming is still in the planning stages.

Welcome CDISC 360. CDISC 360's mission is to guide the industry to apply a metadata design to control and automate the process of SDTM and ADaM development. Along with SDTM and ADaM specs, new metadata design datasets are planned to be introduced for organizations to utilize and apply for program automation. This presentation will explore current CDISC 360 metadata design model and how evaluation is progressing. In addition, key updates to Control Terminology will also be reviewed.

Bio
Sunil Gupta, MS, is an international speaker, best-selling SAS author, and a global SAS and CDISC corporate trainer. Sunil is Executive Director of Data Sciences at TalentMine and has over twenty-five years of experience in the pharmaceutical industry. Most recently, Sunil is on several CDISC and PhUSE working groups and has taught his CDISC online class at the University of California at San Diego and SAS Institute India. Sunil also developed a new class on Data Science using SAS for UCLA and UCSD Extension. In 2011, Sunil launched his unique SAS mentoring blog, SASSavvy.com, for smarter SAS searches. Sunil has MS in Bioengineering from Clemson University and a BS in Applied Mathematics from the College of Charleston.

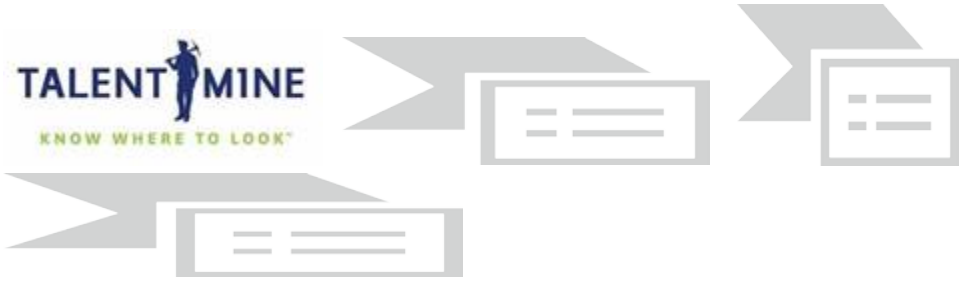
News from CDISC and Other News

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

Micky will share current CDISC updates about recent accomplishments, upcoming developments, and notable topics. This should be extremely informative for those of you who were not able to attend the CDISC Interchange in San Diego in October and will also provide new information since the Interchange.

Wrap Up

Meeting Sponsors



See you at the meeting!

Micky