

DATA STANDARDS CONSULTING

Octagon's **Data Standards Consulting** experts have the practical experience to support the development, understanding and implementation of the Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model (SDTM) with both clinical and non-clinical data across a wide variety of therapeutic areas. As the leader in the electronic transformation of Clinical R&D, Octagon provides a unique suite of offerings combined with expert consulting services to ensure organizations effectively integrate new data standards.

DATA STANDARDS CONSULTING SERVICES INCLUDE:

STANDARDS DEVELOPMENT

- Creation and/or review of modeled and custom SDTM compliant domains
- Non-modeled safety domains
- Efficacy domains across a wide variety of therapeutic areas
- Nonclinical toxicology and pharmacology data
- Development of data-transfer specifications that facilitate integration with either legacy or SDTM databases
- Lab Data
- PK Data
- ECG Data

SDTM and SEND (Standard for the Exchange of Nonclinical Data) COMPLIANCE REVIEW

- Data-conversion specifications
- Annotated CRFs
- Datasets
- Interpretation and remedies for results from automated checks

REVIEW of CRF DESIGN FOR SAFETY and EFFICACY DOMAINS

- CDASH Compliance
- Maximum efficiency for creating SDTM compliant datasets

TRAINING on CDISC STANDARDS

- SDTM
- SEND
- Customized and/or Advanced Training

DATA STANDARDS STEWARDSHIP and GOVERNANCE

- Ongoing development and expert review of data standards from collection through reporting and submission
- Development of processes for data standards development and maintenance

DSC BACKGROUND AND EXPERIENCE

Fred Wood, Vice President

As one of the principal contributors to the SDTM, Fred served as the primary editor for v3.1.2 of the SDTM Implementation Guide. He leads the team for the CDISC Submission Data Standards (SDS) Team, of which he was founding member. Fred also holds a leadership role on the SEND (Standards for the Exchange of Nonclinical Data) Team since its inception in 2002, serving as a co-lead through 2008. He remains on the SEND Leadership Team, supporting domains for general toxicology, reproductive toxicology, and safety pharmacology. He is additionally involved in the CDISC Technical Leadership Committee, as well as numerous SDS subteams for PK data, device data, pharmacogenomics data, and mapping the SDTM to BRIDG. Furthermore, Fred participates in the PhRMA SDTM Implementation Group and the HL7 RCRIM Technical Committee. Prior to joining Octagon in 2006, Fred acted as the Global Data Standards Manager for Procter & Gamble Pharmaceuticals, a position he held for eight years. Before holding this title at P&G, Fred worked as a toxicologist in the areas of health care (OTC and Rx) and food additives. Fred has a B.S. in Biology from Springfield College, and M.S. and Ph.D. degrees in Biochemistry from the University of Massachusetts at Amherst.

Mary Lenzen, Principal Consultant

Mary is an extensively experienced contributor to CDISC standards. She has been a member of the CDISC Submission Data Standards (SDS) Team since its inception in 1999, as one of the SDTM principal contributors as well as the primary editor for v1.2 of the SDTM. She was also a leader of the Controlled Terminology Team and continues to be a key contributor. Mary is actively involved in other CDISC standards teams, including Trial Design, Protocol Representation Group, CDASH (Clinical Data Standards Acquisition and Handling), and HL-7 (Health Level 7). The numerous accolades she has received for her contributions to CDISC include the prestigious FDA Leveraging/Collaboration Award in 2005.

Prior to joining Octagon in 2006, Mary served as the leader of global Clinical Data Standards at Pfizer, Inc., where she managed and led technical staff to support data standards. Previous positions include Oracle DBA (Database Administrator), Clinical Data Manager, and Laboratory Technician. In her 24-year career at Pfizer, Mary also worked at BBN Software Products for five years, where she managed the highly successful Health Industry Professional Services Group. Mary has over 32 years of pharmaceutical industry experience combined with a Master's degree in Computer Science and a B.S degree in Biology.

Richard Lewis, Senior Consultant

Richard has been with Octagon since 2001 when he began as a manager in Regulatory Operations. From there, Robert became the primary team member responsible for starting and developing Octagon's Data Integration and Standardization (DIS) department, which provides SDTM data-conversion services. Richard joined DSC in 2005. Richard has been a member of the SDS Team since 2004, and is the co-lead for the SDS Metadata subteam. He is a current member of the CDISC/FDA Integrated Data Pilot, the lead of the CGUN Educational Committee, and the lead of the Midwest CDISC User Group. He also served as a "core" member of the initial SDTM/ADaM Pilot team, responsible for converting all of the legacy data to SDTM, and also for publishing the submission. His programming skills include Java, C++, and web programming, and he holds a BS in Chemistry.

Jerry Salyers, Consultant

Jerry came to Octagon in January of 2009, after 18 years at Procter and Gamble Pharmaceuticals, where he held the position of data manager for 15 years. At P&GP, Jerry was a member of the Data Standards Team, working across a number of therapeutic areas. He was the lead data manager on a number of Phase III projects whose submissions resulted in FDA approval. Jerry has extensive experience in EDC, from designing and creating standard and custom eCRFs to mapping the data to Oracle Clinical and SDTM-based SAS datasets. He is also experienced in the creation of data definition ("define") files in PDF and XML. Jerry was based in the UK for three years, where he worked with study sites and CROs in Europe and the US to harmonize data-management practices and standards. Additionally, Jerry conducted numerous EDC-training sessions for site personnel and CRAs, as well as shared both paper and electronic CRFs at numerous Phase III investigator meetings. He has broad experience in presenting at clinical data management forums and EDC user groups, both in the US and in Europe. Jerry has a BS in biology as well as a degree in computer science. He is a member of the CDISC CDASH Team.