

**PRE/POST CONFERENCE
FULL-DAY
SAS® TRAINING COURSES**



Western Users of SAS Software (WUSS) is **seeking information from qualified providers of SAS Software training who are interested in teaching full-day courses in conjunction with the WUSS annual user group meeting *November 3-5, 2010 in San Diego.***

INFORMATION

Individual/Company name: Sy Truong
Meta-Xceed, Inc.

Address, City, State, Zip: 42978 Osgood Rd
Fremont, CA 94539-5627

Work Phone: 510-979-9333

Cell Phone: 510-366-9918

Email address: sy.truong@meta-x.com

Please describe or give an outline of the full-day training course you want to present:

Course Title: Implementing CDISC SDTM and DEFINE.XML

Course Description/Outline:

Topics covered in this course include:

- CDISC SDTM and DEFINE.XML data models
- Data Standard Analysis and Review
- Data Transformation Specification and Definition
- Performing Data Transformation to Standards
- Review and Validation of Transformations against CDISC guidelines
- Generating DEFINE.PDF and DEFINE.XML for data definition documentation

The regulatory requirements are going to include CDISC in the near future and the benefits are obvious. It is therefore wise and prudent to implement with techniques and processes refined from lessons learned based on real life implementations.

CDISC standards have been in development for many years. There have been structural changes to the recommended standards going forward from version 2 to 3. It is still an evolving process but it has reached a point of critical mass that organizations are recognizing the benefits of taking the proposed standard data model out of the theoretical and putting it into real life applications. The complexity of clinical data coupled with technologies involved can make implementation of a new standard challenging. This paper will explore the pitfalls and present methodologies and technologies that would make the transformation of nonstandard data into CDISC efficient and accurate.

It is important to have a clear vision of the processes for the project before you start. This provides the ability to resource and plan for all the processes. This is an important step since the projects can push deadlines and break budgets due to the resource intensive nature of this effort. The organization and planning for this undertaking can become an essential first step towards an effective implementation.

Instructor: Sy Truong

Biography: Sy Truong is the cofounder and president of MXI (Meta-Xceed, Inc.) since 1997. MXI provides software solutions within the Pharmaceutical Industry specializing in CDISC data standards, SAS validation, electronic submission, data analysis and reporting. Sy is on the editorial board and contributor to the "Pharmaceutical Programming" journal. He is a frequent contributor and presenter at PharmaSUG, WUSS, and SAS Global Forum. He's currently writing a book for entitled Analyzing Clinical Data.

Please check the method by which training will be delivered (Check one):

☒ Lecture ☒ Hands-on (Instructor to provide software/hardware) ☐ Other (please describe)

Please check materials that course attendees would receive (Check all that apply):

☐ Book ☐ Book, Extra Fee (amount?) ☒ Course Notes ☒ Power Point slides
☐ Other (please describe)

Please check audience level required for class (Check all that apply):

☒ Beginner ☐ Intermediate ☐ Advanced ☐ Other (please describe)

Any other information you would like us to know?

Although part of the course will be lecture, there are many exercises that would require using the PC. If possible, I would like to request access to the PC in advance to install example data in preparation for course.