New CDISC Training Initiative

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ABSTRACT

The U.S. Food and Drug Administration's recommendations in July 2004 and March 2005 that study data submissions use CDISC standards created an industry need for training in CDISC standards. Every company expecting to make a submission within the next three years should understand the role of CDISC standards in submissions and in study database design and many, if not most, will look for training. In January 2006, CDISC, Destiny Corporation and Zurich Biostatistics, Inc. (ZBI) signed an agreement to jointly develop flexible, web or CD-ROM based, on-demand training that will be distributed by CDISC itself, as well as by the other two partners.

INTRODUCTION

Destiny Corporation's Virtual Learning technology will provide a platform for new CDISC training and the expertise that ZBI has accumulated co-authoring, training and consulting on CDISC standards will provide the training content. The prospect of on-demand training has been met with enthusiasm by both current CDISC users and CDISC neophytes and the aim of this paper is to show that this enthusiasm is justified by both the Virtual Learning platform and the training content.

The introduction explains the purpose and scope of your paper and provides readers with any general information they need to understand your paper.

CDISC TRAINING

The business of clinical R&D in pharma and biotech companies and CROs is to submit approvable marketing applications, such as NDAs, to the FDA. The purpose of the new training is to enable companies to achieve submission readiness. To this end, the training will work from three complementary perspectives,

- The FDA perspective - FDA's expectations,
- The CDISC perspective - CDISC offerings and how they help to meet FDA expectations,
- The industry perspective - fitting all this into real life in commercial enterprises that do not have infinite resources.

Understanding these three perspectives will enable a company to recognize,

- Which of their current practices are "best practices" for a CDISC submission,
- Internal barriers to efficient submissions, and
- Potential compliance problems.

Destiny's Virtual Learning platform is based on the latest research in effective training technology. That research has found that training topics should reflect real-life problems. This makes training relevant as it's presented initially and later when it's implemented on the job. The CDISC training content has been organized to reflect real-life issues. It is organized into nine units and each unit covers a related set of issues that CDISC implementers often encounter together. The unit design is based on ZBI's experience working with companies as they implemented CDISC standards for specific submissions.

Each unit in turn has four or five chapters and each chapter is a comprehensive solution to a common CDISC implementation issue. Experienced trainers know that training works best when it uses real-life situations and examples and the unit-chapter structure of the Virtual Learning platform facilitates that real-life, real-issue training content.

The table of contents, in its current draft, is

Unit 1. FDA submission data requirements and CDISC standards facilitate efficient review
Unit 2. CDISC universal concepts
Unit 3. CDISC in the business process
Unit 4. Matching your case report forms to CDISC domains
Unit 5. Creating new domains
Unit 6. Representing relationships
Unit 7. define.xml
Unit 8. Trial design datasets
Unit 9. Analysis data

The first three units provide the regulatory context and the theoretical background in CDISC concepts that everyone working on a submission should understand, whether they are individual contributors, managers, or executives. Units 4, 5, and 6 give individual contributors and their managers the facts and conceptual tools necessary to bridge the gap between in-house data management and statistical analysis and submission data delivered to the FDA. Unit 7 on CDISC's define.xml standard for

metadata will aid XML experts involved in clinical data submissions. Units 8 and 9 explain the specialized topics of trial design as it is seen in CDISC and of analysis datasets for FDA statistical review.

As an example of how the unit-chapter structure delivers bite-size answers to real-life issues, consider the chapters of the define.xml chapter:

Chapter 1. CDISC documentation and resources
Chapter 2. Why CDISC define.xml is replacing define.pdf
Chapter 3. Information content is the same for both define.pdf and define.xml
Chapter 4. Creating define.xml instances in XML
Chapter 5. Flowchart for creating CDISC-compliant data definition

These five chapters show the paradigm planned for all units. First, in chapter 1, there is a guide to CDISC resources. Following that, an explanation of how to transition from the pre-CDISC way of doing business to the new CDISC standards (chapters 2 and 3 in this example unit) and then a "how-to" guide on implementing CDISC.

Chapter 1, in this and in all units, will be a guide to CDISC documentation and resources. The philosophy of the training includes the principle that people should be trained to find the answers to their own questions, if those answers are in readily available. That means knowing how to efficiently locate and use CDISC resources. Therefore, each unit will include a guide to those resources. Chapter 2 explains the motivation for the "CDISC-ing" of data definitions. Chapter 3 explains what the pre-CDISC and CDISC ways of handling metadata for submissions have in common. Chapters 4 and 5 explain how define.xml can be created.

Using the Virtual Learning platform, each chapter has two segments - an instructional segment and a workshop. Video and audio tracks are integral to the Virtual Learning platform. So, each user receives the training content several ways - by listening to the instructor, by seeing the instructor's notes in Power Point, and by participating in the workshop. Such multi-channel training optimizes retention of the material and its application on the job.

CONTACT INFORMATION

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