Business and Decision Life Sciences Adopted CDISC Standards from the Start

Business and Decision Life Sciences is one of the well-known consulting companies and CROs in Europe that supports the adoption of CDISC standards. Their involvement with CDISC is very broad and not only limited to using data standards. They are active team members, leaders in the CDISC Advisory Board and the CDISC European Coordinating Committee and are authorized CDISC trainers. With their profound awareness of the CDISC data standards and their interest in improving healthcare and patient safety, B&D recognized that there is a strong need for adopting data standards. As a CRO/Service provider, they felt that there is a promising opportunity to help companies understand and adopt CDISC standards within their work environments. CDISC has now acknowledged B&D as a Registered Solutions Provider, which provides consultancy on implementing the various CDISC standards.

Business and Decision Life Sciences is also one of the invaluable CDISC Platinum-level organizational members who are actively involved in the development and implementation of CDISC standards. Through their consulting services, they play key role in helping companies implement the CDISC standards in their work environments, they assist these companies in creating their CRF libraries based on CDASH and they create their internal data standards library based on SDTM and ADaM. In addition, they provide guidance on implementing CDISC standards according to the data standards governance process; they also offer a clear understanding on the metadata repository and how to generate reports out of that.

Peter Van Reusel, Business Unit Director CRO Services at Business and Decision states: “Over the past 2 decades and in the near future, we are witnessing how pharmaceutical companies and other sponsors are changing the way they conduct clinical studies. All activities between data collection and regulatory submissions used to be performed by in-house experts from the sponsors. Today and in the near future, companies are changing their collaboration models by outsourcing specialists’ work to CROs and strategic service providers. The efficiency in collaboration between a CRO and a sponsor has vastly increased through the use of CDISC standards. CDISC standards have become the de-facto standard between sponsors, CROs and regulatory agencies”.

Business and Decision Experience with CDISC Standards

B&D started its CRO activities in 2004. Upon their establishment, they made a decision to implement the CDISC standards. In 2005-2006, experts in the CDISC standards from B&D became members of various CDISC teams. Peter Van Reusel is a member of the CDISC SDTM team and an SDTM trainer, and over the years staff from B&D started joining other CDISC teams such as ADaM, Define.xml, Terminology and CDASH. These teams work towards the development and advancement of the CDISC standards.
The main involvement for Business and Decision with the CDISC standards began with the SDTM submission data standard. The SDTM is a specification for the submission of pre-clinical and clinical data to the U.S. Food and Drug Administration in support of marketing applications. Some of the staff at B&D became authorized CDISC trainers with a goal to broaden the adoption of CDISC standards in Europe and to train companies around the world on the implementation of these standards within their actual work. Another major involvement that B&D has with CDISC standards is through the Analysis Dataset Model (ADaM). Business and Decision provides authorized training on the ADaM standard within the European region and in Japan. The Analysis Dataset Model specifies principles for analysis datasets and standards for a subject-level analysis file and for a basic data structure, which can be used for a wide variety of analysis methods. They also provide CDASH authorized training; this standard describes the basic data collection fields that are common to all therapeutic areas and all types of clinical research.

B&D are always present at the CDISC international interchanges in Europe, United States and Asia. Their representatives provide presentations on CDISC standards development and updates within the European region. B&D has always played a significant role in leading and participating in the CDISC Legacy Data Conversion workshops; these workshops are usually held at CDISC interchanges every year. Representatives of Business and Decision have been organizing these workshops for the past three years.

**Business and Decision Experiences with the CDISC Advisory Board (CAB) and the European CDISC Coordinating Committee (E3C)**

The CDISC Advisory Board (CAB) is formed of representatives from CDISC Platinum Member companies. Each CDISC Platinum Member organization may have one representative in the CDISC Advisory Board; the B&D current representative is Lauren Shinaberry, who is also the current Chair of the CDISC Advisory Board.

The CDISC Advisory Board holds regular teleconferences that include presentations on CDISC standards technical roadmap, experiences with CDISC standards and latest updates. In addition, it offers an instrument to the industry to provide comments on the direction of CDISC. One of the major benefits of the CAB is the Town Hall meeting that they have held for the most recent CDISC interchanges, with the presence of FDA representatives, CDISC Board Members and Leadership, IMI representatives and others to respond to questions from the CAB attendees. Lauren was also a key participant in a CAB Validation Task Force that evaluated various tools for SDTM Validation.

Business and Decision is a vital participant of the European CDISC Coordinating Committee (E3C). As of just last week, the E3C Chair-elect is Peter Van Reusel of B&D; he was voted as the E3C Chair after being a member of this committee since 2010. The current E3C chair, Pierre-Yves Lastic of Sanofi, is departing the chairmanship of the E3C to become the Chair of the CDISC Board of Directors.
Business and Decision is a CDISC Registered Solutions Provider

Last but not least, Business and Decision is a CDISC Registered Solutions Provider (RSP http://www.cdisc.org/rsp). RSPs are considered consultants, system integrators, and subject matter experts that have sufficient knowledge and experience in implementing various CDISC standards. As a CDISC RSP, Business and Decision provides expertise mainly in Define.XML, Terminology and SDTM CDISC Standards.

CDISC is honored to have the invaluable contribution of Business and Decision Life Sciences in the CDISC mission and vision. And as a valued CDISC Platinum Member, we would like to thank them for their continued support of CDISC and the global health care industry.

By Diana Harakeh
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