A number of CDISC stakeholders contributed articles to the CDISC eJournal 2012; these articles were distributed via a CD during the International Interchange 2012 and will be posted on the website next week. CDISC is the leading standards developing organization (SDO) focusing on data standards for medical research. These eJournal articles represent case studies and success stories reflecting the implementation of CDISC standards and their value and adoption towards our CDISC vision to inform patient care and safety through higher quality medical research. If you would like to contribute an article for the CDISC eJournal 2013, please contact Diana Harakeh [1].

CDISC eJournal 2012

Extracting the value of standards: The role of CDISC in a pharmaceutical research strategy - Article by Frank W. Rockhold and Simon Bishop

Abstract - Regardless of your role in drug development (Clinical, Statistics, Data Management, Safety, etc.), the importance of information that is of high quality and open to immediate and reliable access has never been more apparent. The ultimate utility of the information is directly related to how it is collected, stored and able to be located. That is to say, it has little value if not retrievable. The need for clear, useable and available standards to accomplish this is essential. The true value of standards is only seen when they are absent and information cannot be used. Not only is information our most expensive and valuable resource, when patients are asked to sign an informed consent to enroll in one of our clinical trials, they are assured the information gathered will be used to better the health of future patients. If we cannot store, find and retrieve the information in a reliable way, not only are we wasting valuable time and money, we are not meeting our commitment to patients or supporting the research goals. CDISC (Clinical Data Interchange Standards Consortium) is an organization that was created and is tasked with being in the middle of solving this most critical piece of transforming the data from trials into a true information-based model that will allow subject matter experts to derive practical wisdom on behalf of patients. This paper outlines both at a strategic and tactical level how standards in general and CDISC in particular help us be more efficient in our handling of research data and sustain valuable contributions to science. Follow the link for full details. [2]

Continuing Efforts Toward Data Standardization - Article by Paula Brown Stafford

The Last Word. PharmaVoice September 2012

PV: Why is data standardization so important?

BROWN STAFFORD: Lack of standardization often leads to undesirable outcomes. One simple example that is often cited in such discussions is the fact that electrical outlets in different countries for example, the United States and countries in Europe, require different plugs, and hence an electrical device purchased in one country may well not work in another. Fortunately, this particular issue is easily remedied by using a converter, a device that effectively facilitates standardization and interoperability. Follow the link for the full article. [3]

Position Paper 1.0: Surveying and Navigating the CDE Landscape - Article by Maryann Martone, Theresa L. Frangiosa, Bron Kisler, Jyotishman Pathak, Melissa Haendel, Jennifer Bretz, and Magali Haas
The following position paper has been created based on the outcomes of a workshop sponsored by One Mind for Research (Table 1). The workshop focused on evaluating the common data elements (CDE) landscape in brain diseases and was held May 22nd, 2012 at the University of California, Los Angeles.

This document represents the workshop attendee’s initial thoughts on the opportunities and challenges in establishing CDEs, as well as, the potential for One Mind to advance the study of brain diseases through data curation initiatives. This document is version 1.0 and will evolve as additional information is gathered regarding the CDE landscape and as One Mind’s support of data curation efforts are further formalized. Follow the link for full details. [4]

CDISC Standards and Innovations - Article by Andrea Vadakin and Rebecca D. Kush

Abstract - The Clinical Data Interchange Standards Consortium (CDISC) is an open, multidisciplinary neutral non-profit standards developing organization (SDO) that has been working through productive, consensus-based collaborative teams, since its formation in 1997, to develop global standards and innovations to streamline medical research and ensure a link with healthcare. The CDISC mission is to develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare. The CDISC vision is informing patient care and safety through higher quality medical research. The CDISC suite of standards supports medical research of any type from protocol through analysis and reporting of results. They have been shown to decrease resources needed by 60% overall and 70-90% in the start-up stages when they are implemented at the beginning of the research process. They are harmonized through a model that is now not only a CDISC standard but also an HL7 (Health Level 7) standard on the path to becoming an ISO (International Organization for Standardization) /CEN (European Committee for Standardization) standard, thus giving the CDISC standards (harmonized together through BRIDG (Biomedical Research Integrated Domain Group)) an international status and accreditation. This publication provides a summary of each of the primary CDISC standards in addition to two CDISC innovations that are designed to improve the value of the standards in terms of enabling higher quality medical research done faster and with fewer resources. Follow the link for the full article. [5]

Current status and future scope of CDISC standards - Article by Rebecca D. Kush

1. Introduction

In translational research, research information is used to inform healthcare decisions, and healthcare information is used for research. This cycle, however, is too long and inefficient and needs to be shortened, which is basically the vision of CDISC (Clinical Data Interchange Standards Consortium).

The CDISC vision is ‘to inform patient care and safety through higher quality medical research’. CDISC is a standards developing organization. It is global, open, multidisciplinary, vendor-neutral, and nonprofit, and it was founded in 1997. There are approximately 300 member organizations from academia, biopharmaceutical companies, device companies, technology and service providers and other companies. Follow the link for the full article. [6]

Success Stories: “Ask the Expert” Session at the CDISC European Interchange - Article by Diana Harakeh

“Ask the Expert” session of the CDISC European Interchange 2012 was quite remarkable. Stimulating questions related to the CDISC achievements and other issues grabbed the attention of the audience. In fact, this was arguably the best session of 2012 CDISC Interchange since the two excellent Plenary Sessions had not allowed time for Q&A, while this session gave the audience plenty of opportunity to ask many of these Plenary speakers about issues they really wanted to understand.

The panel was formed of international experts in the healthcare/research industry: Charles Cooper of FDA, Bernard De Bono of the European Bioinformatics Institute, Bron Kisler and Wayne Kubick of CDISC and Pierre-Yves Lastic of Sanofi and the E3C answered inquiries from the attendees. Follow the link to read the full article. [7]

Business and Decision Life Sciences Adopted CDISC Standards from the Start - Article by
Diana Harakeh

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. Follow the link for the full article. [8]

Notes from the Field: Implementation of CDISC Standards at AstraZeneca - Article by Andrea Vadakin

“There is an increasing demand for standardized clinical information, as well as an increasing need to scale our CDISC standards capabilities,” noted Alex Hromcenco and Sam Hume of AstraZeneca (AZ) at the beginning of their presentation at the 2011 CDISC International Interchange in Baltimore, Maryland. Mr. Hromcenco and Mr. Hume went on to discuss these issues as well as how AZ had successfully implemented CDISC standards and become a major contributor to CDISC. Follow the link for the full article. [9]

The Major Impacts of CDISC on Clinical Data Lifecycle - Article by Chengxin Li and Nancy Bauer

Abstract - CDISC has defined a series of standards covering the entire clinical data lifecycle, from data collection to submission. This paper describes the major impacts of CDISC on the clinical data lifecycle within data management and programming such as interoperability, metadata repository, controlled terminology, formats, traceability, programming model, macroitized programming, and object oriented clinical programming. This paper reflects authors’ current understandings of CDISC and visions of clinical data processing. Follow the link for full details. [10]

Organizing and Accelerating the Clinical Research Process from the Beginning: The CDISC Protocol Representation Model and Toolkit - Article by Andrea Vadakin, Brooke Hinkson, and Members of the Protocol Representation Group

Overview - What is the Protocol Representation Model, and how does it affect the success of a clinical study? As we will see in this article, the Protocol Representation Model, or PRM, is of great importance, not only to data managers and statisticians, but to individuals and entities across the realm of clinical research: from the clinician, to the medical writer, to the study coordinator, to federal agencies, and eventually and most importantly, to the patient. The PRM was developed to a) support the generation of a protocol document, b) to support research study (clinical trial) registration and tracking, c) to support regulatory needs, and d) facilitate single-sourced, downstream electronic consumption of the protocol content. This article offers background information on the history of the Protocol Representation Model and generation of PRM V 1.0, recent developments in the model, use cases for the PRM describing the business value of the PRM, description of a new Toolkit made available to users of the PRM and anticipated future progress in this area. Follow the link for the full article. [11]

Biogen Idec Adoption of CDISC Standards to Create Standard Case Report Form Libraries - Article by Diana Harakeh

The Case Report form (CRF) is a tool used to record data in a clinical study. Data in a CRF should be collected in a specific format in harmony with the protocol and in agreement with regulatory requirements. The importance of standardized CRFs is revealed in facilitating the exchange of data across drug compounds, disease indications as well as across companies. Standardized CRFs which are harmonized with the CDISC CDASH model require minimal mapping (if at all) in order to exchange the data. If a well-designed CRF is adopted, it will provide improved productivity in processing and analyzing clinical data from start-up throughout all down-stream processes. Saving time and money in collecting and analyzing clinical trial data is the main outcome of using well-designed CRFs where data could be reused effectively. Follow the link for the full article. [12]
Using EHRs for Research

An Interview with Susan Mitchell, RN, Florida Hospital - Article by Andrea Vadakin

Using EHRs for research is not a thing of the future. It is being done in the present. Read below about the success Florida Hospital has had in utilizing EHRs for research. On 19 June, CDISC (Landen Bain, CDISC Liaison to Healthcare) participated in a meeting with representatives of FDA Office of Scientific Investigation, CDER, where Susan Mitchell, Senior Manager of Research Information Systems at Florida Hospital, spoke about how her organization is already utilizing EHRs for research. Jane Griffin from Cerner and representatives from Quintiles also participated in this meeting at FDA. FDA representatives who attended this meeting were very pleased with this progress and the opportunity that is afforded by using EHRs for research, including the ability to support ‘auditing/monitoring from afar’. Follow the link for full article. [13]

CDISC eJournal 2011

Generating a caBIG Patient Study Calendar from a Study Design in ODM with Study Design Model Extension - Article by Jozef Aerts [14]

The Study Design Model (SDM) extension for ODM is currently being developed by a working group consisting of members of the XML Technologies Team and of the Protocol Representation Group (PRG). The major features of this extension are being presented. The SDM-XML extension has been used to generate an example study design instance which has then been transformed to a caBIG Patient Study Calendar (PSC). Follow the link [14] for the full article.

Healthcare Link and eSource - Article by Landen Bain [15]

Clinical research data follow a life cycle that begins with data capture and ends with the submittal of a data set to the regulatory agency and/or publication in a report or journal. CDISC began its work at the tail end of this cycle by first specifying how data should be submitted for review, then moved through progressively earlier stages of the data life cycle with standards for data acquisition, data management and data analysis. The earliest step in the data progression, the electronic capture of research data directly from healthcare information (at the source), remained an open gap in the CDISC chain of specifications, even though eSource was a key aspect of the driving vision of CDISC’s founders. The CDISC Board launched the Healthcare Link initiative several years ago to close this last unspecified gap in the clinical research data life cycle. Please follow the link [15].

Genzyme’s GetSMART Program: Implementing Standards End-to-End - Article by Sue Dubman, Brooke Hinkson, Dana Soloff, David Fritsche and PK Tandon [16]

At the end of 2008 Genzyme initiated GetSMART, a Strategic, Measurable, Achievable, Realistic, and Time-based program, to implement global clinical information standards. The GetSMART vision is to consistently define, use, and reuse clinical information across the development lifecycle through the use of standards in order to facilitate the exchange of information (data and content), streamline our business processes and prepare to comply with existing regulations, current regulatory requests and likely future mandates. Follow the link [16].

The BRIDG Model and a “Model” Implementation: The Clinical Trial Registration and Results HL7 Message - Article by Julie Evans and Abdul-Malik Shakir [17]

The Biomedical Research Integrated Domain Group (BRIDG) Model is a Domain Analysis Model (DAM) representing protocol-driven research. A DAM is a conceptual, abstract representation of an area of interest, which can be used as input to the technical design of software, data interchange specifications, and databases. A DAM should be understandable and usable by domain experts and technology developers alike. Having been in existence for over five years, BRIDG is alive and well: semantic content is being added and an increasing number of projects are using BRIDG for the basis of their information requirements. One such project is the HL7 V3 Clinical Trials Registration and Results message. This article
gives a brief summary of BRIDG followed by a description of the CTRR project. Follow the link [17].

**CDISC: Adoption Trends, Benefits and Addressing Barriers - Article by William Friggle, Feng Li, Shannon Labout, Rebecca Kush [18]**

Results of an online survey of CDISC stakeholders indicates that the CDISC standards continue to gain traction among clinical researchers. Among the 641 respondents who answered the demographics section, the Study Data Tabulation Model (SDTM) is the most widely used and the Clinical Data Acquisition Standards Harmonization (CDASH) standard for case report forms has the most users piloting as of the end of the survey period, March 2010. CDISC Healthcare Link Initiative was largely unknown by the respondent community. Clinical Research Organizations (CROs) are consistently adopting the standards more readily than are biopharmaceutical companies. The greatest benefits from the use of the CDISC standards were cited as: a) to improve data exchange; b) to improve study efficiency and c) to improve data quality. Perceived barriers include: a) a lack of understanding of the CDISC standards; b) cost of implementation and c) that the existing domains do not cover a sufficient amount of the data. Of the 475 respondents to a question about eSubmissions, 166 replied that their organizations have submitted at least one. When survey participants were asked how CDISC can assist in improving the adoption of the CDISC standards, the top responses were: a) to work with regulators to provide greater clarity; b) provide more case studies; and c) produce more therapeutic/efficacy standards. Significant progress has been made in terms of addressing these areas since the survey was conducted. This progress is shared in depth in the Discussion section. Follow the link [18].

**The Value of CDISC: Results of a Brief Survey - Article by Diana Harakeh, Saad Yousef, Rebecca Kush [19]**

The word 'value' in English is defined as relative worth, merit, or importance. John Perry Barlow, lyricist of the band 'The Grateful Dead' wrote “...here’s the thing: if I give my song away to 20 people and they give it to 20 people, pretty soon they know me, and my value as a creator is dramatically enhanced”. In another interview with Wired Magazine he stated: “The best way to raise demand for your product is to give it away”. (Joshua Green, March 2010, The Atlantic, “Management Secret of the Grateful Dead”). Oddly enough, the Dead’s influence on the business world may turn out to be a significant part of its legacy. The Dead were masters of creating and delivering superior customer value. One idea was to focus intensely on its most loyal fans. This premise of creating value by giving products away is analogous to the practice of the Clinical Data Interchange Standards Consortium (CDISC). While other standards developing organizations (SDOs) in the related area of healthcare still require fees or membership to access their standards, CDISC has held strongly with the belief that these should remain open and free to encourage adoption and participation--and to create value. Follow the link [19].

**Data Model - the trials and tribulations of implementing BRIDG in an Information Technology Environment - Article by Terry Hardin and Isabelle deZegher [20]**

Over the past several years there has been much discussion regarding BRIDG (Biomedical Research Integrated Domain Group) within CDISC and HL7 as a Domain Analysis Model (DAM). These discussions center on ways that BRIDG can be used as semantic "glue" across evolving and established standards. However, there has been little work in moving BRIDG from "glue" to a common data model (CDM) that could be implemented within an IT infrastructure. In this new role BRIDG 3.0.1 would be used to move from a conceptual model with abstract data types to an implementable data model with simple data types that, in combination with business process rules, would allow for flexible system integration. Follow the link [20].

**Regulatory Submissions for Medical Devices and Diagnostics: The Basics - Article by Carey G. Smoak [21]**

Medical devices and diagnostics are an important part of the healthcare industry. The number of device approvals by the FDA has increased by 52% in the past decade. Devices are different than pharmaceutical products in terms of the FDA approval process, and the use of CDISC standards. In May 2006 an SDTM Device sub-team was formed. The team was expanded in February 2009 to include CDASH. The Device sub-team is working towards the goal of modifying existing domains (as needed) and developing new domains, which will be incorporated into CDASH and SDTM standards. Follow the link [21].

**Using CDISC ODM to Migrate Data - Article by Alan Yeomans [22]**

The migration of data from a legacy system to a new EDC system poses both technical and regulatory challenges. System architectures differ widely, database structures are not compatible and it is rare that a simple copy-paste type of solution
can be applied. This paper describes the choice of CDISC ODM as a mechanism to migrate data from a legacy system that did not support CDISC standards, and the work entailed. Conversion, cleaning, archiving, migration, export to a legacy data analysis system and validation of the data were all aspects that were included in the migration project. The migration took approximately 6 months to prepare, and 3 days to perform. Follow the link [22].

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