Introduction to the CDISC Standards

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ABSTRACT

The Clinical Data Interchange Standards Consortium (CDISC) encompasses a suite of standards across the clinical space. The Study Data Tabulation Model (SDTM) and Analysis Data Model (ADaM) are probably the two standards most familiar to SAS User Group attendees, but there are many others. This paper and presentation focus on the foundational standards of CDISC, from protocol to analysis reporting, along with data exchange and controlled terminology. Each of these standards is introduced, emphasizing how it fits into the big picture.

If you want to learn about these standards that are becoming common in the pharmaceutical, biotech, and medical device industries, or just add a few acronyms (such as PRM, CDASH, SDTM, SEND, ADaM, ODM, and NCI EVS) to your vocabulary, then this is for you!

DISCLAIMER

The views and opinions expressed in this paper are the author's interpretation and should not be attributed to the CDISC organization or any other group.

INTRODUCTION

As stated on the CDISC website, CDISC is

> a global, open, multidisciplinary, non-profit organization that has established standards to support the acquisition, exchange, submission and archive of clinical research data and metadata. 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. CDISC standards are vendor-neutral, platform-independent and freely available via the CDISC website.[1]

This means that CDISC works to develop standards that are free for everyone and useful for all players in the industry, regardless of what software and tools they use and where in the world they are located.

The CDISC brochure, found on their website, states that "CDISC standards catalyze information flow through the entire pre-clinical and clinical research process, from study protocol and various sources of data collection to analysis and reporting through regulatory submission and electronic data archive."[1] For those of us working in the world of clinical and pre-clinical trials, that covers pretty much everything we do!

CDISC doesn't operate in a vacuum, but keeps in tune with other industry groups and standards organizations. The current Board of Directors includes representation from pharmaceutical and biotechnology companies, educators, vendors, and government agencies.

There are a handful of CDISC employees who keep the process moving, but the bulk of the work is done by volunteers. Volunteers include representatives from pharmaceutical and biotech companies, vendor companies (such as Contract Research Organizations, or CROs), and even the FDA. Work includes developing, maintaining, and improving standards, plus training.

The underlying goal of CDISC is to help the drug development process become more efficient. Efficiencies are gained by improving the data flow process within a company, allowing sharing/combining of data across companies, and potentially reducing questions from a reviewer.

CDISC FOUNDATIONAL STANDARDS

As stated on the CDISC website, the foundational standards

> provide the basis for the complete CDISC suite of standards, supporting the clinical research process from protocol through data collection, data management, data analysis and reporting. These standards focus on the core principles for defining research data standards, and generally represent interest areas that are common across all research studies such as demographics, medical history, medication history and concomitant medications, adverse events and other common domains. [1]

The standards shown in the diagram below, from the CDISC website, include those at the data content level, plus additional standards that help us exchange/share data, further clarify data, and make implementation choices that are appropriate for specific therapeutic areas. This diagram serves as a visual guide for all of the standards in the CDISC arena, and each is further explained within this paper.

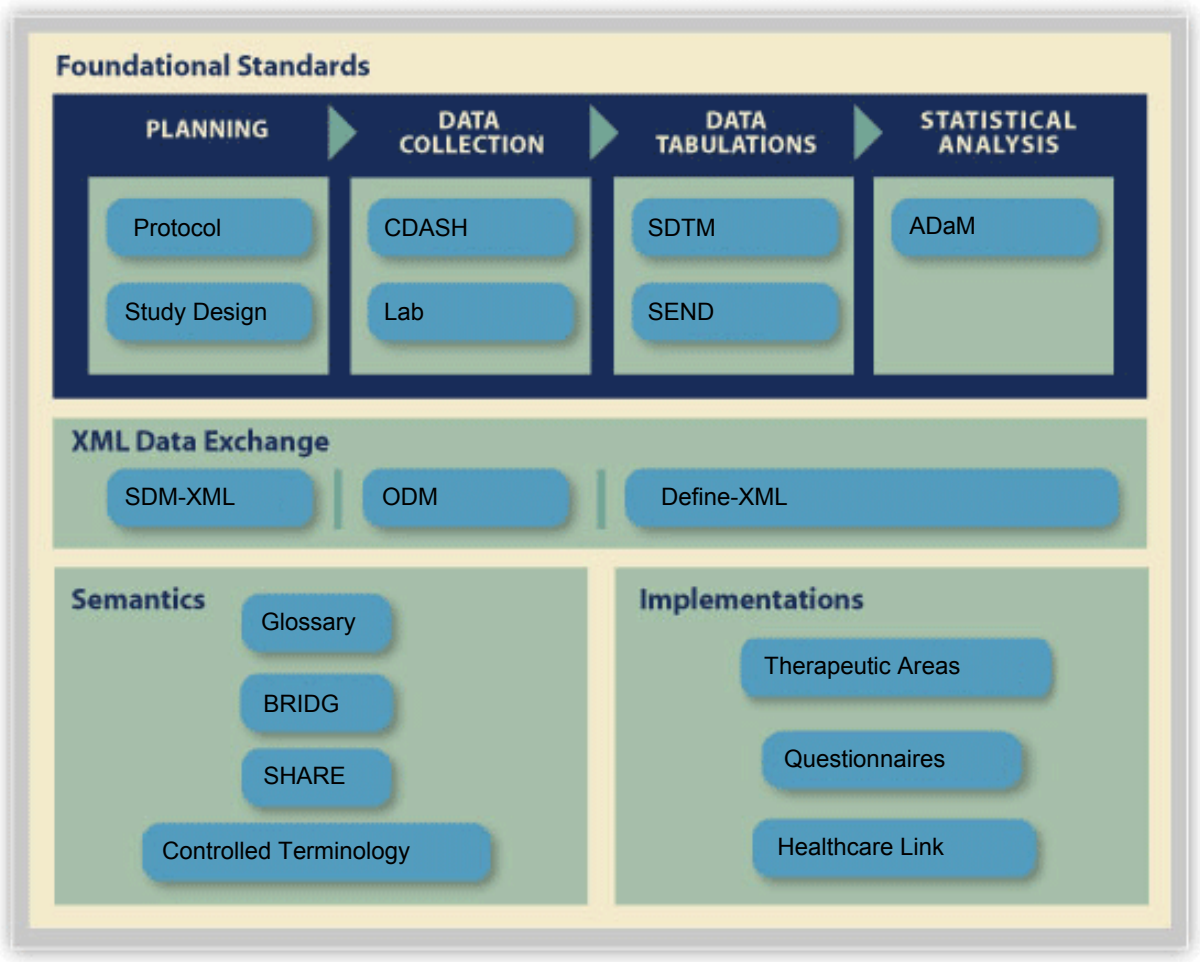

Figure 1: CDISC Foundational Standards[1]

THE DATA CONTENT STANDARDS

The top section of **Figure 1: CDISC Foundational Standards** shows all the models used to standardize data content throughout the clinical process, from planning, through data collection and data tabulation, and into statistical analysis.

PROTOCOL REPRESENTATION MODEL (PRM)

The PRM takes what we typically think of as text documents and pulls out the data components. The PRM is used not only for capturing protocol content, but also for that in the Statistical Analysis Plan (SAP).

A protocol is typically the first document created when starting a clinical trial. Although content differs from study to study, most protocols contain similar types of information. For example, protocols have a title and contain information about the drug under study, study objective(s), the study design (e.g., blinded, crossover), inclusion and exclusion criteria, and a schedule of visits with planned activities at each visit. When this type of information is captured as data, rather than as simple text, it can be used throughout all stages of the process, such as when setting up the database, creating data set metadata, and generating tables in study reports. As stated on the CDISC website, "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."[1]

The SAP is a document that describes the analyses to be done for the study. Statisticians are working with the PRM team to help define common information included within a SAP.

As of this writing, CDISC has released version 1.0 of the PRM. It now includes a toolset, with a template that allows companies to standardize the structure of their protocols, plus a study outline concepts list to show the connections between the protocol and the other parts of CDISC. This toolset is free to download from the CDISC website[1].

STUDY DESIGN MODEL

The Study/Trial Design Model was developed to allow companies a means "to provide rigorous, machine-readable, interchangeable descriptions of the designs of their clinical studies."[1] It is an Extensible Markup Language (XML) model, and built as an extension to the previously-existing CDISC Operational Data Model (ODM) described later in this paper.

Version 1.0 of the Study/Trial Design Model is available to download from the CDISC website[1] as a PDF and/or a zip file containing XML schemas, examples, and references.

CLINICAL DATA ACQUITISION STANDARDS HARMONIZATION (CDASH)

CDASH describes a standard set of data-collection elements. Included are dataset- and variable-naming conventions, as well as references to controlled terminology within variables. CDASH doesn't define Case Report Form (CRF) or electronic (e)CRF design.

CDASH was developed after the Study Data Tabulation Model (SDTM), described later in this paper, was already in production. Because CDASH is a pre-cursor to SDTM, as shown in **Figure 1: CDISC Foundational Standards,** it was designed to match the SDTM standard as much as possible.

For those familiar with SDTM, the CDASH content will look familiar. There are, however, a handful of differences between CDASH and SDTM, since the needs of collection are not always the same as those for submission. Some of the most notable are:

- Dates and times are captured as individual numeric components (year, month, day, hour, minute, second) in CDASH, but as a single text variable using the ISO-8601 format in SDTM-based data.
- Some data collected in CDASH, such as questions used as prompts or for data cleaning (e.g., whether the subject took any concomitant medications), aren't included in SDTM-based data.
- CDASH collects relationships in distinct variables (e.g., CMAENO for the adverse-event line number), while the SDTM represents such relationships in RELREC.

CDASH version 1.1 is available for download on the CDISC website[1].

LABORATORY DATA MODEL (LAB)

Lab was developed to standardize the format of data transfers from a laboratory (such as a central lab) to a client (such as the study sponsor). Prior to the existence of this model, central labs were spending a lot of time customizing data transfers for every client, so that each could upload into their own internal database. This was a major effort on the part of the labs. After the CDISC Lab model was developed, central labs started offering a discount if the client would receive their data in the CDISC Lab structure rather than their own internal standard. Clients found it to be cost-effective to take advantage of the discount, even if it meant someone internally had to either reformat the data or redesign their internal database. Many companies are now using the CDISC Lab model.

Very little has changed with the Lab model since its first release, and the current release is version 1.0.1. As of this writing there are draft extensions open for comment that allow microbiology data, ECG data, and reference ranges to all be used within the Lab model.

There are several documents available for download on the CDISC website[1]. These include pdf, zip, xls, dat, and xml files for the current version, plus documents for comment on the draft versions.

STUDY DATA TABULATION MODEL (SDTM)

SDTM is probably the most familiar of all the CDISC models. It was created by the CDISC Submission Data Standards (SDS) team to provide a model for the submission of tabulation data in a study.

Clinical data can be captured via several means. An example of data flow into SDTM, from both the CDISC standards described thus far and other possible non-CDISC sources, such as an Interactive Voice Randomization System (IVRS) or an Independent Review Facility (IRF), is shown here:

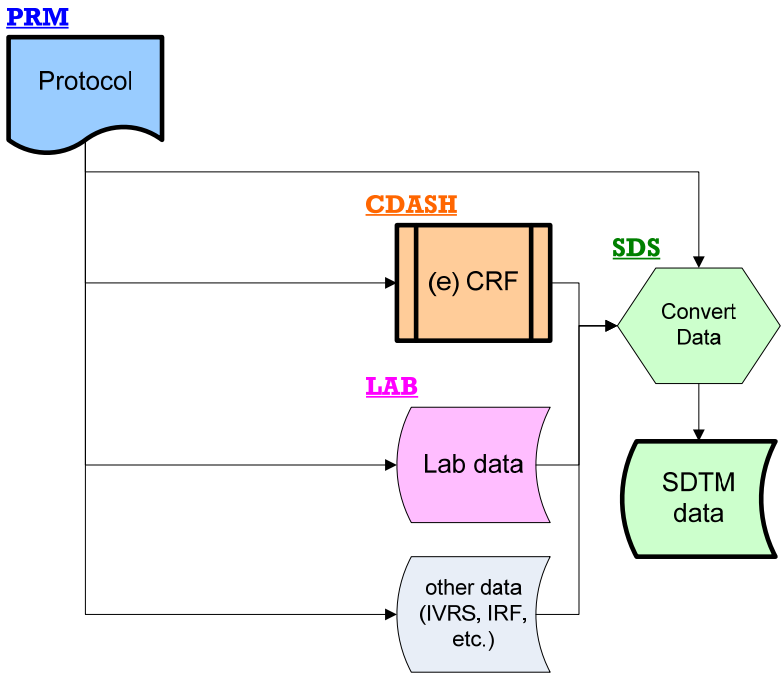

Figure 2: Data Flow into the SDTM Standard

SDTM has three basic structures, called General Observation Classes, based on the type of data that was collected. These classes are events, interventions, and findings. The SDTM document describes these observation classes and includes naming conventions for their variables. It also includes an overview of some data that doesn't fit into the general observation classes, such as demographics, comments, and trial design. The SDTM document provides the "big picture" of the standard, and is applied not only to SDTM but also to the Standard Exchange of Non-Clinical Data (SEND) Model, described later in this paper. There are few examples and not a lot of detail in the SDTM document, 35 pages in SDTM version 1.2.

The SDTM Implementation Guide (SDTMIG) supplements the SDTM document and includes a lot more detail about the common types of data for each of these classes. The SDTMIG is much longer than the SDTM document, 298 pages for version 3.1.2. Within each observation class, the SDTMIG shows how most common domains are mapped, and includes not only dataset and variable metadata, but also assumptions and examples. For example, the Adverse Event (AE) domain in the SDTMIG v3.1.2 has three pages of metadata, including a description of the dataset and all the common variables that are required, expected, or permitted in the tabulation dataset. Following that, there are three pages of assumptions and four different examples of applications. When determining how to map collected data into SDTM, the SDTMIG is an extremely valuable tool.

There are different versions of the SDTM and SDTMIG available for download from the CDISC website[1]. They should be used in pairs. As of this writing, these are:

- SDTM version 1.2 and SDTMIG version 3.1.2
- SDTM version 1.3 and SDTMIG version 3.1.3

Also available from this section of the CDISC website[1] is the Medical Device Supplement to the Study Data Tabulation Model version 1.0. This implementation guide contains domains useful for the submission of device data, in support of a drug application or a device application.

Finally, the SDTM section of the CDISC web page includes information about the versions of SDTM that the FDA will accept. As of this writing, the FDA is now accepting SDTM versions 1.2 and 1.3 and SDTMIG versions 3.1.2 and 3.1.3[2].

STANDARD EXCHANGE OF NON-CLINICAL DATA (SEND) MODEL

SEND is an implementation of the SDTM used for animal studies. SEND shares many of the same fundamentals and assumptions as SDTM. While there is overlap in the domains described in the SDTMIG and SENDIG, there are cases where the data collected for animals is a bit different than that collected for humans.

The current version of the SEND Implementation Guide (SENDIG), as of this writing, is 3.0, and is available on the CDISC website[1]. It is consistent with SDTM version 1.3.

IMPLEMENTATIONS OF SDTM

As described above, the SDTM document is the base for the SDTMIG, the Medical Devices Implementation, and the SENDIG. Below is a figure that shows the relationship between these documents:

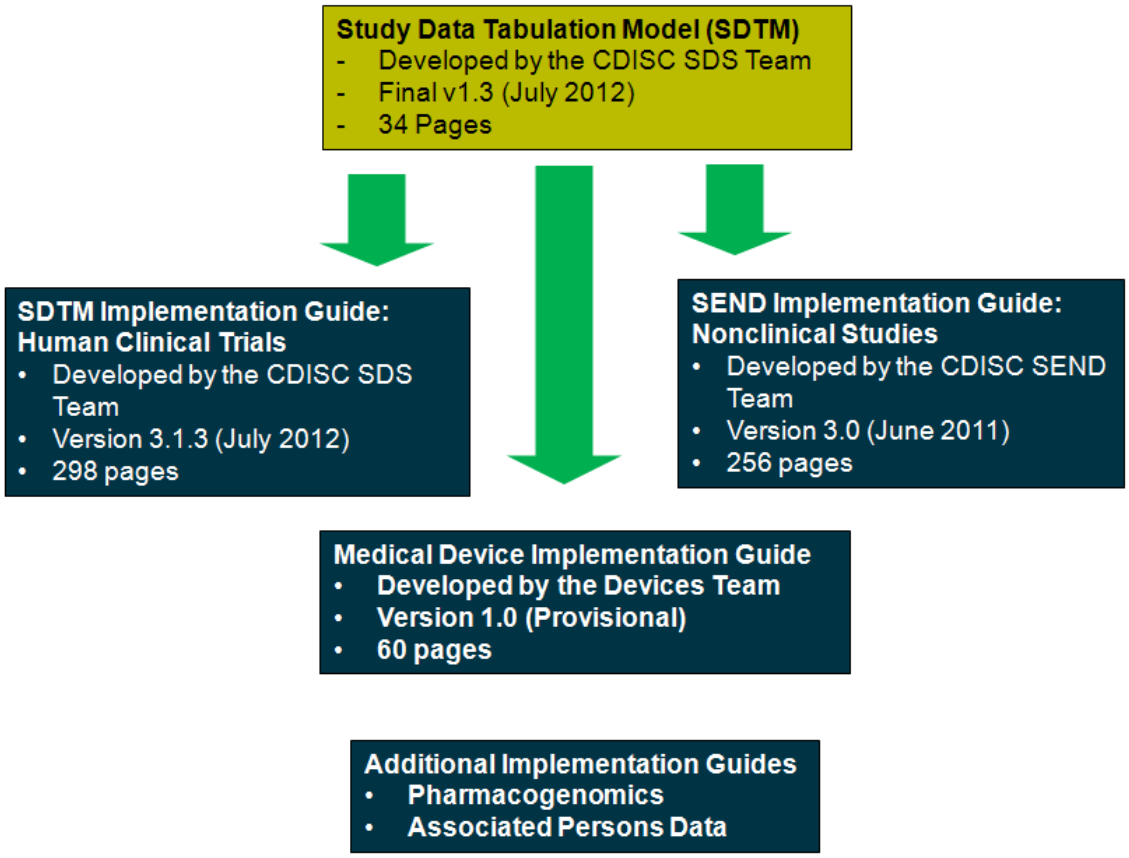

Figure 3: SDTM and Implementations

For additional clarification, the SDTM document includes a set of tables showing which variables in each observation class apply to which of the Implementation Guides.

ANALYIS DATA MODEL (ADAM)

ADaM provides another representation of clinical data. Where SDTM contains all clinical data we collected about every subject in the study, ADaM reconfigures the data as needed for analysis. ADaM structures are based on SDTM data as input, but are also dependent on analysis needs. Expanding on **Figure 2: Data Flow into the SDTM Standard**, then:

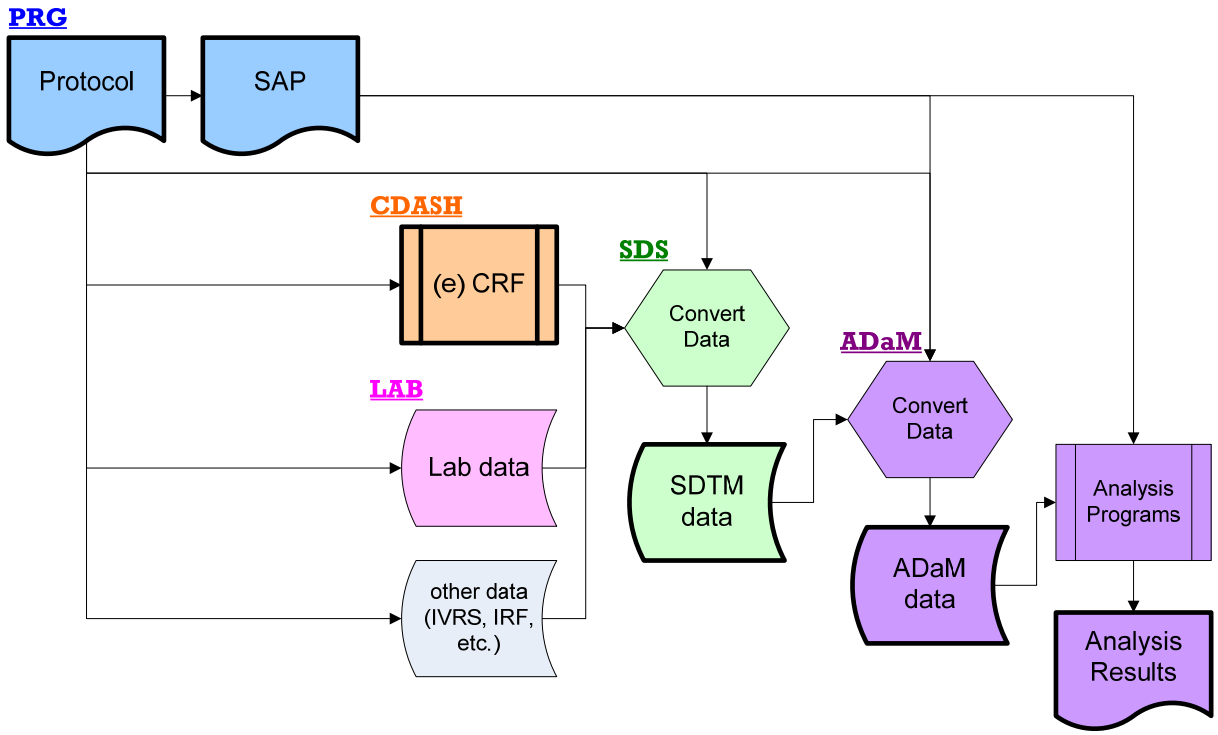

Figure 4: Data Flow into the ADaM Standard

ADaM has three defined structures: the Subject Level Analysis Dataset (ADSL), the Basic Data Structure (BDS) and the Adverse Events Analysis Dataset (ADAE). Most analysis results can be quickly derived using data in these structures.

The ADaM document contains some basic information about the structures, but similar to SDTM, the ADaM Implementation Guide (ADaMIG) contains the bulk of the details and examples. At the time of this writing, ADaM version 2.1 and ADaMIG version 1.0 were posted on the website[1], along with the following three appendices:

- ADaM Examples in Commonly Used Statistical Analysis Methods (Examples)
- ADaM Basic Data Structure for Time-to-Event (TTE) Analyses
- The Adverse Event Analysis Document (ADAE)

The Examples and TTE appendices both make use of the BDS structure, but the ADAE appendix defines a new structure. At the time of this writing, the ADaM team is working on a new version of the ADaM and ADaMIG that will incorporate these appendices.

Also available in the members-only section of the website[1] is a list of validation checks. We can make use of these checks to determine whether our analysis datasets are compliant with the ADaM specifications.

DATA STANDARDS - SUMMARY

The CDISC data standards give us a common way across the industry to represent information collected when running a clinical study and producing results about the study. This includes information about study design, such as seen in the PRM and Study Design standards and the SDTM trial design domains. It also includes information about the subject and/or device under study, as captured in CDASH, Lab, SDTM, SEND, and ADaM.

Not all companies have adopted all of these standards. The Lab standard and SDTM are probably the most commonly used of all the CDISC data standards.

SDTM, and less often ADaM, are being adopted in some form by many companies. Some are starting to replace internal standards with these CDISC standards. Other companies are choosing to produce SDTM and ADaM at the time of submission, because changing internal tools and processes has been deemed too labor-intensive. However, producing SDTM and ADaM only for submission means keeping track of two sets of data (CDISC and non-CDISC version), which has its own risks.

To get the most benefit from standards, companies should consider using all of the CDISC models as part of their internal processes. The standards were developed to sync together nicely, so adopting all of them means a reduction in the effort when moving through all the deliverables shown in **Figure 4: Data Flow into the ADaM Standard**.

DATA EXCHANGE STANDARDS

CDISC uses XML to handle exchange of standards. XML is an open international standard in itself, used for far more than just clinical data. Typically XML code is used with one or more schemas to display content in a human-friendly way. Tools have been developed across the industry to create and use XML data.

CDISC uses XML in two different ways to exchange data: the Operational Data Model (ODM) is used to transfer data, and the define.xml is used to describe metadata.

OPERATIONAL DATA MODEL (ODM)

ODM was developed to transfer data, between standards (such as from CDASH to SDTM) or between companies. As stated on the CDISC website,

> ODM is a vendor neutral, platform independent format for interchange and archive of clinical study data. The model includes the clinical data along with its associated metadata, administrative data, reference data and audit information. All of the information that needs to be shared among different software systems during the setup, operation, analysis, submission or for long term retention as part of an archive is included in the model. [1]

ODM is also a potential replacement for the current SAS® version 5 transport file when submitting data to the FDA. Version 5 of the SAS transport file has been made open (free) by SAS, but the technology is quite old and has limitations. For example, SAS version 5 transport files require that dataset and variable names not be longer than 8 characters, labels not be longer than 40 characters, and text strings not be longer than 200 characters. The FDA has been working with CDISC and other standards organizations to choose a replacement for SAS version 5 transport files as a means of data delivery, but it is not yet known whether that replacement will be ODM.

Some vendors have developed tools that make use of ODM in transferring data into and across the CDISC standards. CDISC has an ODM Certification program, and all companies that pass that certification are posted on the website[1].

As of this writing, ODM version 1.3.1 is available on the CDISC website[1].

DEFINE.XML

XML is also used to describe metadata. Define.xml, also called Case Report Tabulation Data Definition Specification (CRT-DDS), is the CDISC standard.

In recent years, companies submitted a *define.pdf* with their data to describe the metadata, and prior to that it was *define.doc*. CDISC *define.xml* allows this same type of information to render in a website-like display, with lots of links to other information.

CRT-DDS version 1.0 has been available since 2005, and can be used to represent metadata at the dataset and variable levels. That has been sufficient for SDTM submissions, and define.xml has become the standard for submitting SDTM metadata to the FDA. The CDISC website[1] contains more information about how to use define.xml for SDTM metadata, including a reference to the FDA's Study Data Specifications website[2].

Version 1.0 was not easily used to represent ADaM data, since ADaM also requires metadata at the parameter value level. An extension to the define.xml 1.0 can be added to enable this, and CDISC has now released version 2.0 with parameter value level metadata capabilities. As of this writing, the FDA is accepting both versions 1.0 and 2.0[2].

SEMANTICS STANDARDS

Semantics is defined as the study of meaning, and thus the CDISC semantics standards are used to provide additional meaning to the other standards.

CDISC GLOSSARY

The CDISC Glossary includes terminology and acronyms used across the industry. It's a great resource for the many acronyms and terms used on the CDISC website[1] and within our industry work.

BIOMEDICAL RESEARCH INTEGRATED DOMAIN GROUP (BRIDG)

BRIDG is a joint effort by CDISC, Health Level Seven (HL7), the FDA, and the U.S. National Cancer Institute (NCI). BRIDG is "a domain analysis model"[1]. The website explains that it "was developed to provide an overarching model that could readily be understood by domain experts and would provide the basis for harmonization among standards within the clinical research domain and between biomedical/clinical research and healthcare."[1] BRIDG involves more than just CDISC, but the CDISC standards map into BRIDG.

SHARED HEALTH AND CLINICAL RESEARCH ELECTRONIC (SHARE)

The SHARE library supplements the data standards by providing additional metadata in machine-readable elements. The first version of SHARE is focused on CDASH and SDTM, but the goal is to add the remaining data standards.

CONTROLLED TERMINOLOGY

Controlled terminology spans across all the CDISC data standards. Clicking on the Controlled Terminology link on the CDISC website[1] actually redirects to the NCI Enterprise Vocabulary Services (EVS) website[3]. NCI EVS is where all CDISC controlled terminology is stored.

From the NCI EVS website[3], there are links to controlled terminology for CDISC data standards SDTM, ADaM, SEND, and CDASH. Each set of standards can be downloaded in a variety of different formats, such as xls, xml, or pdf. Additionally, there are controlled terminology downloads available for questionnaires and a few therapeutic areas.

As part of the NCI EVS website[3], there is a link to request additional terminology, and we can even suggest new terminology. This is a great way to make the standard more robust and applicable to our specific work needs.

Controlled terminology updates happen quarterly. It's a rolling update, so anything that is ready by the quarter cut-off is included. It's important to check back frequently to take advantage of additional terms.

IMPLEMENTATION STANDARDS

CDISC is currently focusing on two major implementation areas. One is the development of many therapeutic area standards to help align data specific for each indication. The other is to connect data between clinical trials and the electronic health record so that data can be entered once for both purposes.

THERAPEUTIC AREA STANDARDS

One of the biggest complaints heard about CDISC is that the standards aren't stringent enough, and companies can make different decisions when applying a standard. To help make implementations consistent across specific indications, the therapeutic area standards were born.

The therapeutic standards implementations are a large effort, involving not only expertise in CDISC but across each therapeutic area. As stated on the CDISC website, they are "actively collaborating with a variety of partners, including the National Cancer Institute, Critical Path Institute, the FDA, other National Institutes of Health and TransCelerate Biopharma Inc. on the development of Therapeutic Area Data Standards."[1] It also states that the "Coalition for the Advancement of Standards and Therapies (CFAST), a joint initiative of CDISC and the Critical Path Institute, has established a program to develop therapeutic area standards along with the FDA and TransCelerate Biopharma, Inc. which is governed by a program steering committee."[1]

At the time of this writing, the group has initiated work on several therapeutic areas, including Alzheimer's Disease, Tuberculosis, Pain, Virology, Parkinson's Disease, and Polycystic Kidney Disease. As they are developed, provisional and then final implementations are made available on the CDISC website[1]. Several questionnaires are included as part of these therapeutic areas. Other therapeutic area implementations are in progress, and this website[1] is updated regularly.

Modeling of the therapeutic area standards thus far has been focused on data collection (CDASH) and tabulation (SDTM).

HEALTHCARE LINK

The Healthcare Link is an initiative to connect clinical trials to the Electronic Health Record (EHR). CDISC has been working with another industry group called the Integrating Healthcare Enterprise (IHE), and the CDISC website[1] includes a link the IHE wiki for remote data capture[4].

As of this writing, CDISC had developed an "inaugural working link between EHRs and clinical research systems".[1] Continuing, the site states

> This groundbreaking approach uses the CDISC/IHE developed integration profile, Retrieve Form for Data-capture profile (RFD), along with CDISC standards to collect relevant data from the electronic health record for critical secondary uses such as Safety Reporting (and Biosurveillance), Clinical Research, and Disease Registries. Reaching through to the EHR in this way to pull key data of interest to clinical research that is already existing in the EHR creates system interoperability and improves data quality and most importantly timeliness of data sharing (key in safety reporting) while alleviating the Investigator site from supporting and entering data in to multiple redundant (from the investigator's perspective) data collection tools for the purpose of the secondary uses. [1]

Patient confidentiality issues were a major obstacle to overcome. In clinical trials, we work very hard to mask subjects, going so far in many countries as to disallow collection of birthdates because that might make it too easy to determine patient information. The EHR, though, has a lot of patient information, because it is needed by the treating physician. Thus a significant effort has been made to allow clinical trials systems to get at parts of the EHR that are needed, without disclosing patient identifying information.

MORE INFORMATION ON CDISC

In the spirit of open information, CDISC now has regular (as frequently as monthly) webinars where they present information about new or updated standards. Information about these free webinars can be found on their Education and Events tab. Also on that tab is information about training and conferences, where you can learn more about the CDISC standards.

You can also join the CDISC email list. This will allow you to receive their monthly newsletter and get updates on what's new and what's coming.

Finally, there is an opportunity for membership. While all content needed to make use of the CDISC standards is free, some additional content, available to members only, can aid in making implementation more efficient. CDISC membership is at the company-level, meaning that once a company has become a CDISC member all employees will have access to additional materials on the "members only" portion of the website[1]. This "members only" section contains, for example, an Excel version of variable metadata that can be used to quickly set up internal specs and define documents. Companies who are members are helping defray the cost of developing these free standards.

CDISC EFFORTS IN INDUSTRY

FDA AND CDISC

CDISC has been working with the FDA for years at various levels. Many individuals who work at the FDA are members of different CDISC teams and are helping to develop the standards.

The FDA is helping drive CDISC adoption, since they are now requesting CDISC structured data. They have already developed tools to help reviewers load and use CDISC data and metadata, and are currently developing a data warehouse to store this content. Reviewers at the FDA are receiving training to become familiar with the standard models.

As of this writing, a search for "CDISC" on fda.gov found 356 documents that mention it, including several hits in their Study Data Standards Resources website[2]. According to a presentation made by the FDA at the CDISC Interchange in November, 2012 and summarized in a blog on the CDISC website[1], the FDA will be expected to require standards by 2017 and must by June, 2013 publish a plan of how they will get there. The FDA website on Study Data Standards[2], including the spreadsheet attachment titled "FDA Study Standards Catalog," has information on all standards the agency will accept, including timing of when older versions of the standards will no longer be accepted.

An advantage of the whole industry using a single standard is that it will allow the FDA to use data across multiple sponsors for answering questions related to an indication or drug class. This has been a huge struggle for them, since their data is now stored in a variety of structures. As presented at the Computational Sciences Symposium in March, 2013, the agency has now successfully had some legacy data converted to SDTM, pushed into their data warehouse, extracted, and analyzed.

As data is increasingly delivered to the FDA in the CDISC standards, the FDA will be able to more efficiently review individual submissions and do ad hoc analyses across companies.

OPENCDISC

Although "CDISC" is used in the name of the tool OpenCDISC Validator[5], it is not part of the CDISC suite of deliverables. OpenCDISC Validator is a free tool written by a consulting group to check for compliance of various versions of SDTM, ADaM, and SDTM's define.xml. These same consultants also sell services to help fix or explain any issues found by the checks.

The FDA, a big supporter of open/free tools, is using OpenCDISC Validator to check for CDISC compliance. Since the tool is free, companies can run material through OpenCDISC Validator prior to submission, seeing exactly what the FDA reviewer would see, and use the output to help them fix issues or explain any messages that are generated.

Because OpenCDISC Validator automated checks are written by an external vendor and not CDISC, users must check results to ensure they are accurate. For example, at the time of this writing the author has noticed there are some ADaM checks not programmed in OpenCDISC Validator, and some OpenCDISC Validator ADaM checks produce incorrect output messages.

Also, just because a dataset passes a suite of automated compliance checks, such as those in OpenCDISC Validator, that doesn't mean it is necessarily CDISC-compliant. There are many things an automated tool is not able to check, and human eyes are always an essential component of any review.

CONCLUSION

CDISC has been around since the late '90s, the standards are continuing to grow and evolve, and implementation is continuing to increase. Within the industry, the "hot" jobs, demanding some of the highest salaries, are for people with CDISC expertise. Individuals who want to learn more about CDISC can do so by reading the CDISC website[1], downloading the free materials, attending free webinars, paying for CDISC training, and even volunteering to help on a CDISC team to develop standards.

REFERENCES

[1] CDISC: http://www.cdisc.org, 08MAR2013.

[2] US FDA's Study Data Standards: http://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/default.htm, 20SEP2013.

[3] Controlled Terminology, on NCI-EVS: http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/cdisc, 08MAR2013.

[4] IHE's RFD, part of CDISC Healthcare Link: http://wiki.ihe.net/index.php?title=Retrieve_Form_for_Data_Capture, 08MAR2013.

[5] OpenCDISC Validator: http://www.opencdisc.org/projects/validator, 20SEP2013.

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