Business Case for Standards

2014 CDISC Business Case

CDISC is pleased to announce the completion of an extensive update to its Business Case for the use of its global, consensus-based standards. Below is an excerpt from the Executive Summary of the 2014 Business Case. A full version of the 2014 CDISC Business Case is available online in the CDISC Members Only area. Members can log in here [1].

Executive Summary

Since its inception in 1997, the Clinical Data Interchange Standards Consortium (CDISC) has worked to develop global, consensus-based standards to support the acquisition, exchange, archive and reporting of electronic clinical research data, in addition to related standards and tools to realize its Mission and Vision. Since the last update to the CDISC Business Case in 2006 (Stage IV), CDISC has been encouraged by its members and supporters to continue to develop standards for clinical research data, with the aim of developing “all of the standards” – in other words, those that are specific to various disease areas. CDISC has also been encouraged to continue to develop synergies with standards for healthcare to realize the Mission and Vision of CDISC. Below is a snapshot of the CDISC standards and products as they exist today, as well as associated findings that are the focus of this updated version of the CDISC Business Case (Stage V).

The CDISC Foundational Standards are now a complete, complementary suite of standards that support clinical research from end-to-end, from protocol and data collection through analysis and reporting, as well as the use of EHRs for research. These standards are harmonized through the Biomedical Research Integrated Domain Group (BRIDG) model, a collaborative model that also serves as a link with healthcare standards (HL7 RIM) and is on the path to become an ISO standard.

Through updated research on the potential time/cost benefits of using CDISC standards from the beginning of a research study, it has been found that former estimates dating from the Stage IV Business Case have not only remained consistent, but have increased in some cases. This is due largely to increasing baseline numbers in the overall time and costs of conducting a clinical research study. Findings suggest that by using CDISC standards from the start, researchers can save 70-90% of time and resources during the Study Start Up stage (time to first patient enrolled), and ~75% of non-patient participation time during Study Conduct and Analysis.

For those developing regulatory eSubmissions, using updated baseline numbers for the time and cost of getting a drug to market, it can be found that ~ $180M can be saved per submission (18% of the total cost). An average of two years can be saved off of an average 12-year clinical development program lifecycle – just by standardizing data. In addition, regulators have stated they will begin requiring CDISC standards for eSubmissions in the U.S. (FDA) and in Japan (PMDA) because standards enable them to use sophisticated review tools and conduct higher quality reviews. Regulators do not plan to require CDISC standards for data collection; however, they are encouraging the use of standards from the start because this helps in maintaining traceability and improves data quality at the end of the study (therefore in the eSubmission).

The CDISC Standards are downloaded by users in over 90 countries. Adoption continues to increase, with the Study Data Tabulation Model (SDTM) adoption as of 2014 estimated to be approaching 90% by ~ 600 respondents in a recent Tufts survey (including biopharma, CROs, academia and vendors).

As certain study data is not addressed by the Foundational Standards, CDISC has developed and is continuing to build Therapeutic Area (TA) Standards for specific disease areas through the Coalition For Accelerating Standards and Therapies, a partnership between CDISC, the Critical Path Institute, and others. Through the TA standards, it is now possible to use sophisticated tools to analyze and aggregate data across studies for specific disease areas, and potentially enable the creation of databases that can serve as a repository for cross-consortia data. This type of shared data leads to opportunities for disease modeling and biomarker qualification that was previously impossible with non-standardized data.
The CDISC Healthcare Link Initiative focuses on streamlining the research process and realizing the mission of interoperability between healthcare (the EHR) and clinical research. CDISC and IHE (Integrating the Healthcare Enterprise) have created the inaugural working link between EHRs and clinical research systems. This groundbreaking approach uses the CDISC/IHE developed integration profile, Retrieve Form for Data-capture (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 already exists in the EHR while allowing for entry of research data that will not be in the EHR creates system interoperability and dramatically improves workflow. All this, while alleviating the need for re-entry of data (which improves data quality as well as saving time) has been shown to have a significant ROI. In the case of safety reporting, it was found that the time to complete an ADE report was reduced from 35 minutes to less than 1 minute, on average.

CDISC Shared Health And Research Electronic Library (SHARE) is a metadata repository that supports the development, governance, publishing and consumption of the CDISC standards in human and machine-readable formats. The ability to retrieve metadata and terminologies in electronic format enables anyone, not just those focused on data management, to understand and utilize the standards. SHARE relates to the existing CDISC standards through storing, managing and governing the standards, meaning and structures of data.

SHARE is essential in accelerating the development of the CDISC therapeutic area standards. In particular, it reduces the cost of standards development and maintenance while encouraging re-use across disease areas that require common information. SHARE will transform what used to be a manual standards development process, allowing for the ability to capture patterns of data, match controlled terminologies, and reuse research concepts across different therapeutic areas.

SHARE also makes the standards electronically available for users, thus streamlining the research process. While SHARE has only recently been released for use by CDISC Platinum Members, a 2013 study conducted by a major pharmaceutical company has found that controlled use of a system such as SHARE (i.e. a standards and metadata repository) could save an estimated $240K per study. With increased automation in more areas of the process, this number could reach over $700K. The costs of allocating standards maintenance to CDISC (vs. internal maintenance costs) will avail organizations using SHARE of additional benefits.

The full version of the 2014 CDISC Business Case offers further detail on how this harmonized suite of CDISC global standards facilitate clinical research from end-to-end; from protocol through analysis and reporting, including standards for specific therapeutic areas and standards linking research with healthcare, as well as offers further illumination of the value that can be realized through utilization of the CDISC standards from the start. The full version of the 2014 CDISC Business Case is available to CDISC Members in the Members Only Area. Members can log in here [1].

2006 CDISC Business Case

Data standards bring about more than just savings in time and money, companies will see additional benefits when they implement CDISC standards:

- Communication among project teams and partners is easier
- A greater level of accuracy and less training with a constant process
- Decision making is simplified
- Scientists can do the science rather than being concerned with the data
- Easier transfer of data between partners
- Opens up a wider choice of tools/technology (as long as they are standards compliant)

If you need information that outlines the value of standards for your company, please take a look at this summary slide set from the 2006 Business Case for Standards [2] prepared by, and based on research conducted by, CDISC and Gartner.

If you have any questions, or if we can provide support to help outline the advantages of CDISC membership for your organization, please contact Shirley Williams [3], CDISC.