



## CDISC 2010 Strategy Document

### **Introduction**

The Clinical Data Interchange Standards Consortium (CDISC) has established standards to support the acquisition, exchange, submission and archiving of data for protocol-driven research.

*The mission of CDISC is to develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare.*

This mission pertains to all CDISC global initiatives. In particular, the CDISC Strategic Plan *focuses on areas that highlight the unique value CDISC brings to the global health care industry.*

### **Five Strategic Themes**

*CDISC has the skills at the intersection of the “triangle” of domain expertise, standards expertise and business knowledge.*

Specific to the CDISC Strategy for 2010 and beyond, we recognize that CDISC brings unique value to the health care industry in the following ways. Each of these themes is further delineated in the paragraphs that follow.

- Ensure the existence, harmonization, acceptance and support of standards for medical research
- Promote and provide education on the use and benefits of standards
- Facilitate the integration with Electronic Health Record (EHR) / Health Information Technology (HIT)
- Use CDISC standards to support data collection and reporting with a focus on data aggregation for the purposes of scientific investigation and comparative effectiveness
- Leverage our global, nonprofit, vendor neutral, independent status to forge productive collaborations with other Standards Development Organizations (SDOs) and key stakeholder communities including regulators and health agencies



**Ensure the Existence, Harmonization, Acceptance and Support of Integrated Standards for Medical Research**

As the science around discovery and development of therapies, medical research and personalized medicine progress, new measurements of patient status and disease state will be introduced. These will range from biomarkers and laboratory values to measure early activity of molecules to primary endpoints for clinical studies that are pivotal to approval. Recent examples include imaging, pharmacogenomics, and patient reported outcomes. CDISC plays a role in determining the necessity for and timing of standards creation around such parameters, influencing key stakeholders and other appropriate groups. CDISC will rely on the CDISC Advisory Board (CAB), Board Strategy Committee and others to identify and raise awareness of new standards-related opportunities and needs.

Biomedical research standards development is the domain expertise of CDISC, whether CDISC acts as a doer, influencer, facilitator or enabler. CDISC must track new developments and act nimbly to partner with important stakeholders to develop, influence, approve, harmonize, and lifecycle manage new and existing standards. CDISC must input views into public debate at the time of greatest potential impact.

In addition to influencing decisions about emerging standards, CDISC must ensure its standards are harmonized with one another and with other healthcare standards, specifically the HL7 Reference Information Model (RIM). This can be accomplished by employing the domain analysis model, specifically the BRIDG (Biomedical Research Integrated Domain Group) model. CDISC must maintain, support and enhance, as appropriate, the standards it develops; and, CDISC must promote acceptance of its standards through various methods and implementation services.

This strategic theme needs to balance the old with the new. CDISC will support standards maintenance, but CDISC will not be expected to provide maintenance *a priori*. This decision should be made each time new work is considered.

The long-term benefit of any standards organization is measured through widespread adoption of its standards. A significant challenge for potential adopters of CDISC data standards, especially large organizations, is determining how best to implement those standards within the organization's overall plans for business transformation and technology management. It is difficult for organizations to change their business practices, and CDISC should support all degrees of conformance to standards. CDISC should support standard data content (semantic interoperability) as expressed in BRIDG and the core concepts of existing standards, standard data transport (application and data interoperability) through work with HL7 and support of CDISC define.xml. CDISC must explore standard architectures that support common user interfaces and work processes (application integration). Distinguishing between data content, data transport, and data architecture will allow businesses to use CDISC standards to the extent they support their business objectives. CDISC should make clear these distinctions and support all degrees of business and technology standardization.



CDISC has had tremendous success in developing standards in several areas due in large part to the efforts of volunteer subject matter experts (SMEs). CDISC standards are strong because of the relative simplicity of their structures and because of their intuitive design aimed at meeting the users' needs. CDISC standards are continuously evolving within a stable process targeting compliance with existing and future regulatory requirements. CDISC standards simplify data collection and end-to-end data handling processes. CDISC has also successfully developed controlled terminology and best practices across its various models all of which can be viewed as a complete package that addresses both format and content. Therefore, CDISC has a responsibility to ensure these standards, related terminology and best practices are properly maintained with continued support from the industry SMEs who have helped bring about success.

### **Promote and Provide Education on the Use and Benefits of Standards**

CDISC has a key role in facilitating education for its standards, and seeking additional SMEs in new areas aligned with its mission. It is especially important that CDISC establishes an international network of experts to provide education in regions outside the US. This educational effort is important both to medical researchers and to key stakeholders in the implementation of the CDISC standards.

We recognize that there are different levels of stakeholder education. High level policy making and funding bodies require education around business use cases and benefits that are aligned with the Communications Plan for CDISC. Education of technical and application-focused users of CDISC tools and standards necessitates a more comprehensive program. And, the U.S. FDA has sought education from CDISC for its reviewers. CDISC Education should continue to be managed and implemented through the work of the CDISC Operations staff and instructors and the training programs they offer.

CDISC needs to promote standards usage to ensure smooth integration across the healthcare domain. CDISC should be aligned with further development and/or enhancement of best practices and terminology. A well designed Education and Communication Plan will support and promote more advocates in the medical research community.

CDISC needs to be proactive toward decisions that provide education about its initiatives. It needs to ensure education but can decide to defer operational aspects of education to other organizations. CDISC also needs to accept that part of our leadership role is to educate the world about "Standards" and not just "CDISC standards".



**Facilitate the Integration Clinical Research Standards and Processes with Electronic Health Records (EHR) / Health Information Technology (HIT)**

CDISC and other opinion leaders envision that the future of clinical data capture will be integrated into the broader world of healthcare information technology and the EHR.

This integration will have a profound impact by:

- Improving a sponsor's ability to recruit patients into trials
- Enhancing accessibility to data for research
- Streamlining the data capture process by reducing data entry and transcription errors while reducing associated costs/resources to resolve such discrepancies
- Improving pharmacovigilance
- Facilitating decision support
- Decreasing the number of systems required at an investigator site

An equally relevant issue is the ability of clinicians to provide care that is evidence-based and predicated on safety where knowledge can be derived from medical databases. As part of this vision, CDISC expects to take a leading role on behalf of the medical research industry by linking biomedical research and healthcare standards efforts. This will require continued involvement by CDISC and its Board in worldwide healthcare IT initiatives, at the technical and political levels.

CDISC has been actively engaged with the pharmaceutical industry and Integrating the Healthcare Enterprise (IHE) and various HIT initiatives operated through the Department of Health and Human Services (HHS) Office of the National Coordinator (ONC) in an effort to identify how data can be harvested from the EHR for safety and medical research. This work promises to bring about process improvements and contribute to the aggregation of data for safety reporting, signal detection and evaluation, including but not limited to comparative effectiveness and to streamlining biomedical research processes.

**Use CDISC Standards to Support Data Collection and Reporting with a Focus on Data Aggregation for the Purposes of Scientific Investigation and Comparative Effectiveness**

With increasing demands for aggregated data for comparative effectiveness evaluations, biosurveillance and drug safety surveillance, the knowledge base supporting pharmacovigilance data is growing. There are increasing pressures to enhance the access to information for such purposes to improve evaluations of safety and efficacy for biopharmaceutical products and other therapies. Requirements are generated at the legislative level as well as from regulatory authorities.

CDISC has an opportunity to leverage its experience to great advantage. The use or application of existing CDISC standards can contribute to several key domains, including biomedical research, adverse event reporting, post-marketing pharmacovigilance, and



potentially certified supply chain documentation. Coordination with regulatory agencies is paramount, but support of other co-existing standards is essential for success.

Appropriate areas of expansion for CDISC may include: a) the implementation of the CDISC Integrating the Healthcare Enterprise (IHE) Retrieve Form for Data Capture (RFD) integration profile to support drug safety reporting, clinical research, and population of registries using EHRs (through the CDISC Healthcare Link Initiative), b) the FDA Integrated Safety Data pilot and c) the harmonization of AE standards, including National Institutes of Health (NIH) and cancer Bioinformatics Grid (caBIG) models into BRIDG. These should be areas of focus for TAC and our EHR/HIT programs.

CDISC should remain both agile and forward-looking in support of the evolving, complex environment. Since one of the principle benefits of the use of consistent standards is the ability to aggregate and “re-use” data, this feature will be highlighted to stakeholders in the execution of this part of the strategy.

**Leverage Our Global, Non-profit, Vendor Neutral, Independent Status to Forge Productive Collaborations with Other Standards Development Organizations (SDOs) and Key Stakeholder Communities including Regulators and Health Agencies**

CDISC plays many vital roles in the business of standards development, implementation, and maintenance. CDISC has the ability to visibly and compellingly enter into public debates about standards issues without fear of conflict of interest because of its non-profit, vendor neutral, independent status. This status, along with subject matter expertise contributed by its membership, contributes to the credible voice it enjoys in the medical research community. CDISC’s independence and its record of accomplishments elevate the organization to a leadership role that carries the responsibility of driving change.

Independent, neutral views and consensus-building are vital to the advancement of global standards that are in the best interest of science and patients in the long run. This approach requires clear vision, policy statements, and a communications strategy from the Executive Committee, Board of Directors and Operations when speaking on behalf of CDISC and its constituents on relevant issues. At every meeting, the Board should review CDISC’s position on emerging relevant issues and its strategy for communicating to its membership, stakeholders and the public at large. CDISC should continue to actively engage in industry trade groups and national standards/HIT groups to leverage its credibility.

*Relationship to the Food and Drug Administration (FDA), European Medicines Agency (EMA), and Japan’s Ministry of Health Labor and Welfare (MHLW) and Pharmaceutical and Medical Devices Agency (PMDA) other regulatory and health agencies*



CDISC has a long-standing and admirable relationship with the FDA. Because the FDA is the only agency that requires submission of raw data in standard format, the relationship is unique. Moreover, the United States is the single largest market for ethical pharmaceuticals, representing better than 50% of pharmaceutical sales. It is important, therefore, that CDISC continue to cultivate its relationship with the FDA on behalf of its constituents.

It is also important to understand the pace of emerging markets in the European Union and Asia. CDISC has been given an advisory role to EMEA for its eSource Data Interchange (eSDI) work that is being referenced in EMEA documents. Additionally, the Japanese MHLW has now included CDISC as a part of its 5-year plan and CDISC has a project planned with PMDA. CDISC has also met with the State FDA (SFDA) in China and should assess how best to develop a relationship with that agency. CDISC must balance its efforts to interact with these organizations and evolve its role in these regions. This may require influencing the adoption of existing standards to speed new therapies to patients worldwide.

There are other government agencies that may have interest in standards for healthcare and biomedical research, such as the U.S. Department of Defense (DoD) or Department of Veteran Affairs (VA), the National Health Services (NHS) in the UK, and other governmental agencies throughout the world. Certain of these entities play the role of being the payer of services, provider of services, and a government agency. As a result, their needs may be different than those of regulatory authorities (e.g. more related to business-to-business standards); these may need to be satisfied in the greater healthcare domain.

#### *Collaborations with other Standards Development Organizations (SDOs) and other key stakeholder organizations*

Since 2001, with the initiation of an Associate Charter Agreement (Memorandum of Understanding or MOU), CDISC has built a formal and strong relationship with Health Level Seven (HL7). This collaboration was further strengthened through CDISC's initiation of the BRIDG model, which has now been adopted by the HL7 Regulated Clinical Research Information Management (RCRIM) Workgroup as its domain analysis model and serves to link the biomedical research standards with the healthcare standards from HL7. CDISC also has a position on the HL7 Board of Directors.

CDISC is **the** expert on Biomedical Research Standards and thus brings value to HL7 and other SDOs as a separate but collaborative organization. CDISC continues to see the HL7 relationship as a top priority. However, CDISC will also seek to strengthen its global reach through direct collaboration with the International Organization for Standardization (ISO) (leveraging its new Liaison A status), Comité Européen de Normalisation (CEN) and other international organizations, particularly through its role as a member of the Joint Initiative Council (JIC). CDISC will work with other key stakeholder organizations as appropriate, including but not limited to the Pharmaceutical Research and Manufacturers of America (PhRMA), the European Federation of Pharmaceutical



Industries and Associations (EFPIA) and the Japan Pharmaceutical Manufacturing Association (JPMA). CDISC is also now a charter member of the US Standards Developing Charter Organization (SCO).

Routine, detailed submission of data for regulatory review remains primarily a requirement for US New Drug Applications (NDAs). Other agencies around the world have not adopted such requirements. As a key stakeholder, PhRMA represents a large contingent of industry focusing on discussions with FDA regarding drug development and regulatory submissions. As a standards development organization, CDISC focuses on meeting industry and Agency submission requirements for data content and format. As a result of these realities, it is imperative that CDISC maintains a collaborative relationship with PhRMA to define, develop and implement data standards for regulatory submissions and for information exchange with business partners. CDISC will have working liaisons as appropriate to PhRMA initiatives. CDISC will continue its relationship to other areas of PhRMA through its work on CDASH data collection standards and other relevant CDISC projects.

CDISC will continue to build an awareness of EFPIA activities and priorities, while developing a long-term policy regarding meaningful relationships with this association. CDISC will continue to strengthen its relationship with JPMA since their data management group has now explicitly endorsed CDISC standards and has initiated relationship with CDISC and the CDISC Japan CDISC Coordinating Committee (J3C).

Given the growth and influence of CDISC, the Board and a Collaborations team have begun to set a more structured approach for collaborations since 2008. This should be reviewed annually to manage the resources needed to maintain these relationships.

### **Conclusion**

We believe this document provides necessary direction for CDISC over the next five years by maximizing *its unique value to the global health care community and capitalizing on the concepts of borderless innovation and strength through collaboration.*

This document will be a “living document” that will be reviewed regularly and changed as appropriate to the evolving environment.