



## CDISC is 'SHAREing'!

CDISC is moving forward on a project called SHARE. This article describes why we feel that the time is right for this project (which has long been of interest in CDISC), why CDISC is poised to lead SHARE and why SHARE will increase the value of an investment in adopting the global CDISC standards for medical research.

For more information on what SHARE is and on the design and status of the current SHARE pilot, please refer to the [archived webinar](#) of 6 October 2009.

### Background

CDISC has been trying to determine the optimal means to accomplish SHARE for quite some time, especially in light of the fact that we have been essentially working on terminology for the past 10 years. One of our first efforts was to form the Glossary Team, which has focused on terms and dictionary-type definitions since CDISC was initiated in 1997. When other CDISC standards, including SDTM, were approached, it is fortunate that we focused on the metadata (contextual information) first; in fact, significant progress was made on the development of the CDISC standards suite for medical research before tackling the associated terminology (codelists in this case). Terminology seems to bring with it an entirely new set of issues for standards development, but by the time CDISC was ready to tackle codelists, our stakeholders were clamoring for it. CDISC has now developed significant terminology, which is housed in the National Cancer Institute (NCI) Enterprise Vocabulary Services System (EVS), along with the FDA terminology and that for other organizations. Our NCI colleagues are experts in the area of controlled terminology and believe in global and free access, thus sharing CDISC principles in this regard.

At this point, CDISC stakeholders are anxious to have terminology that goes beyond the safety domains that form the core of the CDISC standards. There is an interest in developing efficacy (therapeutic area) standards as quickly as possible. And, there is current awareness that it would be valuable to ensure that terminology for clinical research is aligned with that for related areas of healthcare. Fortunately, it appears that new sophisticated technology, (and perhaps realization of the need and willingness to contribute to global standards for research and healthcare), have progressed to the point that this is the right time to embark on the SHARE project. As with all CDISC standards development, collaboration will be at the very core of this project. CDISC will lead the project but will work with others who believe in *strength through collaboration!*

### What is SHARE and why is it different from an electronic dictionary or repository?

SHARE is defined as: *a global, accessible electronic library, which through advanced technology, enables precise and standardised data element definitions that can be used in applications and studies to improve biomedical research and its link with healthcare.*

Therefore, SHARE is different from just a dictionary, repository or catalog of terms because it leverages sophisticated technology, an intelligent 'semantic wiki', to identify duplications of terms and

relationships between terms. This advanced technology can automate harmonization processes across dictionaries or terminologies to propose what can become a 'draft standard', which should then be vetted publicly by a standards developing organization like CDISC to create a new standard when one is needed. Conversely, a term or standard already in an existing terminology could be referenced instead of creating a new standard when one is not needed.

SHARE is based upon on the principles behind computable semantic interoperability, i.e. the ability for computer systems to be able to exchange information while retaining the meaning of this information. Hence, a common information model (such as BRIDG) and robust datatypes are necessary.

### Why are we poised for SHARE now?

Significant progress in standards and technology have occurred over the past ~ 8 years that have dramatically improved the feasibility of a shared electronic library as a "reference standard" for medical research and related areas of healthcare, thus positioning the medical research community to be successful with SHARE. In addition to the availability of semantic wikis, the progress includes but is not limited to the following:

- Production versions of the CDISC standards (from protocol through analysis and reporting) are available for safety domains; new domains for efficacy-specific data are desired and could now be developed more rapidly and also concurrently (e.g. CDASH, SDTM and Terminology) in a collaborative environment.
- The [BRIDG model](#) for biomedical research has progressed to a state of maturity such that all CDISC standards are being better harmonized using this domain analysis model (scope = protocol-driven research). Release 3 of the BRIDG Model (due out this month) will include a layer that domain experts can comprehend and a layer that is mapped directly to the HL7 Reference Information Model (RIM). Robust datatypes agreed by ISO and HL7 are also available now.
- Sharing the goal to make standards openly available globally, CDISC has been working since 2003 with NCI, which has produced and hosted CDISC terminology (and FDA terminology) through its Enterprise Vocabulary Services (EVS). NCI is migrating to new tools for semantic management including a new metadata repository (MDR). NCI has offered to include all CDISC requirements for SHARE in its repository development process and has requested direct CDISC participation in the development team. We can use the lessons learned from our experiences to date in developing these new tools. CDISC can bring its standards development experience and process, its global reach, its interest in many therapeutic areas and its expertise as a catalyst for productive collaboration to the relationship. Other organizations are now expressing an interest in partnering as well.
- And, there is a renewed and broader realization that it is important for clinical research standards to be aligned with those for related areas of healthcare. EHR data should support areas in addition to patient care, including patient safety, research, quality reporting and public health – for the benefit of patients (*which means each and every one of us*).

### What does SHARE mean to existing CDISC standards and terminology?

The concept of SHARE is not new; rather, the processes and technology are the new aspects in SHARE. Here are some of the benefits we expect from SHARE.

- We intend to load all the existing CDISC standards/terminology into SHARE as an initial step. Thus, the existing CDISC standards will still be available, but in a more useful and user – friendly format, e.g. electronic and ‘downloadable’ internally within different organizations.
- The CDISC standards will also be more closely harmonized with refined definitions for improved data quality.
- Refined definitions/terminology will enable and facilitate data integration and aggregation without ‘back-end mapping’.
- Maintenance could become less of an internal burden for those who wish to adopt the SHARE reference standard rather than maintaining their own proprietary metadata repositories.
- The research standards will be more closely aligned with healthcare IT standards.
- Those who have adopted CDISC standards should reap a greater value for this investment. Others can perhaps more easily adopt them through SHARE in a readily accessible format.

### What are the next steps?

This project is big and it will not be easy; it will require support and participation from our wonderful volunteers and other organizations if we wish to keep SHARE open, global and free, as are the rest of the CDISC standards. In keeping with the CDISC philosophy of “Strength through Collaboration”, CDISC will be partnering with NCI and others (hopefully around the globe) in the next stages of SHARE. We are seeking organizations willing to commit resources to this project and there are various ways to become involved. These include making sure your organization is a member of CDISC, joining teams, allocating resources (personnel time or funds) for harmonization of specific efficacy-related areas or other ideas we may not have yet considered.

If you are willing to volunteer, collaborate or provide resources towards this project, please contact: Tanyss Mason ([tmason@cdisc.org](mailto:tmason@cdisc.org)).

Again, for more details on SHARE, please see the [archived webinar](#) from 6 October 2009.