Strategic Partnership with NCI EVS

As this is the first time to spotlight a CDISC partnership, it is only fitting to focus on one of our longest running and most fruitful partnerships; that is with the National Cancer Institute Enterprise Vocabulary Services (NCI EVS) organization, spanning nearly 10 years. This partnership has proved pivotal to CDISC’s success in providing controlled terminology and the semantic underpinnings for our global data standards. We have come a long way since releasing the initial set of several hundred terms for SDTM (Study Data Tabulation Model), CDISC’s standard for FDA Regulatory Submissions of Human Clinical Trial Information. There are now over 10,000 CDISC terms maintained and published in NCI Thesaurus supporting our core data standards: SDTM, CDASH (data collection), ADaM (analysis) as well as the SEND standard for non-clinical data collected in animal toxicology studies. This terminology is completely open for use in global clinical trials and can be accessed and downloaded via either the CDISC website http://www.cdisc.org/terminology or directly through the NCI website http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/cdisc

Terminology Services

There is so much more to controlled terminology than what meets the eye. There is an incredible amount of work going on behind the scenes. The bundling of Controlled Terminology with Terminology Services is critical to meet the growing needs of CDISC’s global user community. NCI EVS provides an important suite of terminology services to CDISC as well as other Federal and International Partners:

- Subject Matter Expertise
- Definition Writing and Analysis
- Terminology Coding, Tagging and Subset Bundling
- Terminology Maintenance and Versioning
- Links to other Controlled Terminologies (e.g. MedDRA, LOINC, SNOMED-CT)
- Terminology Harmonization and Cross-Sharing between Partner Organizations such as FDA and NIH Institutes
- Facilitation of New Terminology Requests

These services are the backbone of the NCI EVS. With dedicated terminology experts, NCI Thesaurus developers have consistently responded to the evolving needs of a user community that spans the globe. The NCI EVS team is always seeking to improve terminology access and use. A perfect example is the New Term Request capability that was brought online several years ago. This enables users of CDISC standards around the world to request new terminology and terminology subsets. 400-500 new terms are being requested and processed each quarter.

Having central terminology services also enables CDISC and other key terminology stakeholders (e.g. FDA, NIH Institutes) to easily reuse and cross-share terms. This is an important capability and resource that helps ensure harmonization. Detailed terminology analysis often accompanies this work.
The Future

In addition to supporting the terminology needs for CDISC’s core data standards, the NCI EVS team has been supporting new standards development projects for key Therapeutic Areas identified as federal and international priorities – Cardiovascular Disease, Infectious Diseases, Neurological Disorders and Oncology. This work is being recognized around the world by Health Regulators (e.g. US FDA), Europe’s Innovative Medicines Initiative (IMI) http://www.imi.europa.eu, and global biopharmaceutical companies as well as by foundations such as the Bill & Melinda Gates Foundation.

On July 9, 2012, the President of the United States signed into law the Food and Drug Administration Safety and Innovation Act of 2012. This new law includes the reauthorization of the Prescription Drug User Fee Act (PDUFA) that provides FDA with necessary resources to maintain a predictable and efficient review process for human drug and biologic products. “Clinical Terminology Standards” across review divisions and for 57 prioritized Therapeutic Areas is a pivotal component of a key PDUFA V Performance Goal to... Improve Regulatory Decision-Making and the Efficiency of Human Drug Review through Required Electronic Submissions and Standardization (section XII, page 28). Working with NCI EVS, The Critical Path Institute, and others, CDISC is aligning therapeutic area priorities and opportunities in the US, Europe and Asia, among global biopharmaceutical companies, academia, institutions and key patient foundations.

With a roll out plan to address many more Therapeutic Areas, including numerous cancers in the next 5 years, and the need for standards updates and maintenance, NCI EVS services and support are critical to ensure an ongoing, long-term sustainable model for terminology development, production and evolution.

CDISC looks forward to continuing this partnership with a shared vision and common objectives that strengthen both organizations for many years to come.

Strength Through Collaboration