CDISC Partnerships

CDISC is known for **Strength** through Collaboration and convening teams in productive collaboration. Our relationships with other organizations are extremely important and meaningful and we would not have made the same progress without them. We would like to highlight key relationships in this area of the website, acknowledging that there is no way we can mention all of the important ones that come into play daily for CDISC.

### Innovative Medicines Initiative (IMI)

a. In 2012, CDISC continued an extremely valuable partnership with IMI and provided a second educational session at the IMI central offices in Brussels. All IMI consortia were encouraged to send participants. CDISC is currently a partner on three major project consortia.

i. The EHR4CR project (Electronic Health Records for Clinical Research [http://www.ehr4cr.eu](http://www.ehr4cr.eu)) is in its third year and CDISC is contributing to the semantic interoperability and pilot work packages. EHR4CR is, to date, one of the largest public-private partnerships aiming at providing adaptable, reusable and scalable solutions (tools and services) for reusing data from Electronic Health Record systems for Clinical Research.

ii. The BioVacSafe project (Biomarkers for Enhanced Vaccine ImmunoSafety [http://www.biovacsafe.eu](http://www.biovacsafe.eu)) kicked off March 2012 with the first annual meeting. The goal of BioVacSafe is to develop cutting edge tools to speed up and improve the testing and monitoring of vaccine safety, both before and after release to the market. CDISC is working with Charité University in Berlin on the data collection and management system to ensure conformance with CDASH, SDTM and Controlled Terminology standards.

iii. The eTRIKS project (European Translational Information & Knowledge Management Services [http://www.etriks.org](http://www.etriks.org)) was launched in November. CDISC is leading the data standards work package with Roche and IDBS. Building upon the open source tranSMART system, eTRIKS will provide 1) a sustainable Knowledge Management Platform and Service to support Private/Public Translational Research (TR) across IMI and 2) a single access point to standardized curated TR study information. eTRIKS will bring data together from key IMI projects, many focused on Therapeutic Areas such as severe asthma, rheumatoid arthritis, depression and schizophrenia, tuberculosis, as well as breast, colon, prostate and lung cancer.

### The Coalition for Accelerating Standards and Therapies (CFAST)

The Coalition For Accelerating Standards and Therapies (CFAST) is an initiative formed to accelerate clinical research and medical product development by creating and maintaining data standards, tools and methods for conducting research in therapeutic areas that are important to public health. CFAST was initiated as a partnership between CDISC and the
Critical Path Institute (C-Path). Since launching CFAST, CDISC and C-Path have worked to expand the TA Program Steering Committee (TAPSC) to ensure input from US FDA, the National Cancer Institute Enterprise Vocabulary Services (NCI EVS) and TransCelerate BioPharma. CDISC also initiated the CFAST Scientific advisory Committee, which brings advice from the TAPSC organizations and also IMI and the Association of Clinical Research Organizations (ACRO) . Through the CFAST initiative, 7 new therapeutic area standards projects were launched in 2013 and 3 were completed. For more information on the standards developed through the CFAST initiative, please visit pages 6-7, the CDISC Timeline.

The Critical Path Institute (C-Path)

C-Path remains a strong partner with CDISC. C-Path makes the CDISC standards tangible by testing them through development of valuable research databases that are aggregated using CDISC standards to ensure scientific integrity of the content. In 2012, CDISC and C-Path launched a new initiative called Coalition For Accelerating Standards and Therapies (CFAST), described under our 2012 Milestones. Through the CFAST initiative, a new process for accelerating the development of therapeutic area standards was created (based upon lessons learned from previous therapeutic area projects where CDISC and C-Path collaborated). This is now being tested in a new area, Asthma.

TransCelerate BioPharma, Inc.

TransCelerate is a non-profit organization focused on advancing innovation in research and development (R&D), identifying and solving common R&D challenges and further improving patient safety, with the goal of delivering more high quality medicines to patients. TransCelerate launched in September 2012 with the support of the original 10 founding biopharmaceutical company members. Today 19 of the world’s leading biopharmaceutical organizations are members.

TransCelerate currently has 12 critical initiatives all designed to drive the efficient, effective and high quality delivery of new medicines. One of the initiatives is the Clinical Data Standards project which is an incentive for the CFAST partnership between CDISC and C-Path, to speed Therapeutic Area data standards development. TransCelerate provides resources from their 19 participating Member Companies to the development of the TA data standards.

National Cancer Institute Enterprise Vocabulary Services (NCI EVS)

NCI EVS has been providing CDISC with expert services to develop and maintain its controlled terminology since 2005. This invaluable and essential partnership continues to expand with NCI EVS providing critical terminology support and resources for CFAST therapeutic area projects. Additionally, NCI EVS provides terminology services to other key partners such as US FDA and many NIH Institutes (e.g. National Institute of Child Health & Human Development). NCI is also a key stakeholder organization for the BRIDG model.
The Learning Health Community

CDISC was involved in the planning of the first Learning Health System Summit, which was held in May 2012 at the National Press Club and was sponsored by the Joseph H. Kanter Family Foundation. The outcome of this Summit was a set of Core values for a Learning Health System (which CDISC has endorsed along with 59 other organizations) and a growing Learning Health Community (LHC). The LHC aims to mobilize and empower multiple and diverse stakeholders to collaboratively realize a national-scale (and ultimately global), person-centered, continuous and rapid learning health system (LHS). The Essential Standards to Enable Learning (ESTEL) initiative, led by CDISC, was launched in the CDISC Offices in Austin, TX in February 2013 and held another face-to-face meeting at Duke in September 2013. CDISC was invited to host the LHC in terms of providing a non-profit tax deductible mechanism for their fund-raising and a link to their website; we were honored to sign such an MOU with the LHC this year in addition to continuing to lead the ESTEL Initiative.

CDISC Healthcare Link Collaborations

One of the five CDISC 2013-15 Strategic Goals is to enable interoperability between clinical care and clinical research, in such a way as to accelerate the cycle through which healthcare informs research and research informs clinical decisions. CDISC has been working with Integrating the Healthcare Enterprise (IHE) and the IHE Quality, Research and Public Health (QRPH) group (led by Landen Bain, CDISC Healthcare Liaison), to develop a number of CDISC-inspired IHE profiles. By the end of 2013, CDISC and IHE developed a total of eight CDISC-inspired IHE profiles, and the relationship between CDISC and IHE continues to grow.

To further accomplish this strategic goal, CDISC has been fortunate to have representation both on the U.S. Health IT Standards Committee and the Structured Data Capture (SDC) Initiative, an initiative of the Health and Human Services (HHS) Office of the National Coordinator for Health IT. Through collaborative efforts on the SDC initiative, it was terminated to develop an SDC/IHE Profile under QRPH in 2013. This profile will specify Retrieve Form for Data Capture (RFD) and allows Data Element Exchange (DEX) as an option. It appears that CDISC SHARE will be considered an SDC-compliant metadata repository, and ODM and CDASH are well positioned to be SDC-compliant forms.

Furthermore, another attempt to create linkages between the worlds of healthcare and research has been through our collaboration with the PhUSE Computational Science Symposium (CSS). This collaboration brings together CDISC with the PhUSE CSS group, and has created the opportunity for a new semantic web-oriented project, keyCRF, which was presented and approved by the CSS group in 2013.

Another project in this area has been to demonstrate the alignment of CDISC standards and CDISC-inspired IHE profiles with the IMI EHR4CR clinical study execution and drug safety scenarios. The goal of this effort has been to express, through this collaboration, the availability of standards-based EHR-enabled applications for clinical research and patient safety.

Through these initiatives, CDISC and the LHC will continue to align with and support movement toward informed healthcare IT.