Last year Critical Path Institute (C-Path) and Clinical Data Interchange Standards Consortium (CDISC) launched a landmark joint project to develop a successful Alzheimer's Disease (AD) data standard and research database. Data from eleven AD clinical trials from seven of C-Path's Coalition Against Major Diseases (CAMD) member organizations (who are also CDISC members), was converted into the CDISC SDTM standard. During the process, new formats were added to SDTM to create a resulting new therapeutic area specific standards package, the CDISC AD standard. The data were then ready to be aggregated, and the result was a database incorporating detailed data from over 4,100 individuals afflicted with AD, a groundbreaking achievement that will assist researchers in developing safer and more effective treatments for those suffering with AD.

The collaboration between CDISC, C-Path, government agencies, academia, patient groups and the AD clinical community in developing the CDISC AD standard is a valuable model of how a successful consortium can support faster and safer drug development. In much the same way that CDISC has collaborated with C-Path to develop Alzheimer’s data standards, CDISC and the Innovative Medicines Initiative (IMI) have recently signed a Memorandum of Understanding (MOU), agreeing to collaborate for the shared purpose of accelerating the development of new therapies for patients worldwide.

IMI, the largest public-private partnership in Europe, supports further innovation in healthcare through the formulation of partnerships between industrial and academic experts to aid in the creation of a more cooperative environment for R&D, encouraging the development of safer and more effective drugs for patients. IMI seeks to address certain inadequacies in R&D causing delay in the drug development pipeline through four research priorities: 1) predicting safety, 2) predicting efficacy, 3) knowledge management and 4) education and training. With knowledge management in particular, IMI seeks to more effectively utilize data to determine safety and success.

Equally interested in the efficient use of data is CDISC, whose entire focus is upon the establishment of an accepted and definitive guide for clinical data in the effort to improve medical research and stimulate more rapid drug development. CDISC produces these standards through collaboration with experts from 270 member organizations representing all sectors of the medical research and healthcare industry. In addition to the CDISC AD standard described above, CDISC’s collaborative efforts have successfully produced nine other standards, providing a common language for research findings that promotes easier interpretation by government regulators, greater ability to share data across the industry with less duplication, and improved efficiencies in the drug development timeline.

Much like the successful partnership between C-Path and CDISC for development of Alzheimer’s data standards, IMI and CDISC aspire through the signing of the MOU to share knowledge by bringing together academia, industry, government agencies and non-profit
organizations from both of their wide-reaching membership bases in an effort to further collaborate on research, sharing information and developing additional standards when necessary. Non-competitive collaborative findings developed through this partnership will then be made available for public use. Additionally, the partnership between CDISC and the IMI’s Knowledge Management workgroup (IMI KM), which is tasked with all digital asset management, is working to harmonize the way the IMI collects, uses and reuses the data collected in its projects. The utilization of CDISC standards from the outset of data collection is expected to streamline the process and improve data quality. One of the major motivators for the IMI to use CDISC standards by default from the beginning of the research process is to promote cost-effectiveness, in that this allows greater interoperability and eliminates the need to convert older data into a standard format, a very time- and asset-consuming task.

Enthusiasm for further partnerships like that between CDISC and IMI was evident at the recent conference “Creating Consensus Science,” hosted by C-Path in Silver Spring, Maryland earlier this month. One of the most enlightening roundtable discussions focused on ways in which to spur development of medical products through global partnerships. Dr. Michel Goldman of the IMI, John Castellani of PhRMA, Myrl Weinberg of the National Health Council, Dr. ShaAvhree Buckman-Garner of the FDA, and Dr. Jan Gheuens of the Bill & Melinda Gates Foundation all participated in the panel discussion, following an opening presentation by Dr. Goldman. Interests voiced at the table included a need for further public-private partnerships in order to ensure that there is less duplication among consortia and more innovation in the industry. Another key point discussed was the current reassessment of the research process by the pharmaceutical industry, and the ways in which they have started to look for opportunities to shorten the drug development timeline. Lastly, Dr. ShaAvhree Buckman-Garner praised the achievements of the consortia represented at the conference, but emphasized the need to more broadly articulate these accomplishments and the impact that they have had on the industry.

In this regard, CDISC partnerships, such as the one with IMI and C-Path, motivate greater opportunity for a wider number of public and private organizations in the global healthcare industry to collaborate. This, in addition to the adoption of CDISC standards, will assist in the harmonization and cross-utilization of clinical data, thus advancing higher quality medical research and leading to quicker and more effective cures.

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

**The CDISC Vision:** Informing patient care and safety through higher quality medical research.

Additional information on CDISC can be found on the CDISC website at [www.cdisc.org](http://www.cdisc.org).