CDISC Contact:
Diana El Harakeh
+1 512 436 8455
dharakeh@cdisc.org

IMI Contact:
Kim De Rijck
+32 484 89 62 27
kim.derijck@imi.europa.eu

PRESS RELEASE

CDISC and IMI Partner in Knowledge Management Towards Development of Innovative Medicines

Brussels – 15 December 2011 – The Innovative Medicines Initiative Joint Undertaking (IMI) and the Clinical Data Interchange Standards Consortium (CDISC) are pleased to announce that they have signed an agreement and initiated activities to enhance the use of information gathered for the purpose of developing safer, more effective innovative medicines for patients. The agreement was spearheaded by Ann Martin, Principal Scientific Manager for Knowledge Management at IMI. "To effectively manage information across a variety of projects requires a common format at the elemental level," stated Ms. Martin. "Our stakeholders felt strongly that it is good practice to adopt data standards. CDISC already provides such standards enjoying wide adoption in the pharmaceutical industry. The CDISC standards therefore could be considered as a default standard for research conducted through the IMI projects. Moreover, CDISC not only focuses on global clinical research, but also collaborates to harmonise with global healthcare standards bodies such as the International Organization for Standardization (ISO), Health Level Seven International (HL7) and the European Committee for Standardization (CEN) through a Joint Initiative Council (JIC)."

IMI, a joint undertaking between the European Union and the European Federation of Pharmaceutical Industries and Associations (EFPIA), is the world's largest public-private partnership initiative aiming to speed up the development of better and safer medicines. With its €2 billion research fund, IMI supports collaborative projects through consortia comprising academic experts, small and medium-sized enterprises, patients' organisations, pharmaceutical companies, and regulators to support innovation in research and development in Europe. The IMI projects range from finding new biomarkers for the development of safer and more effective treatments for patients, to educating researchers and using electronic health records for various research purposes.

CDISC has developed consensus-based data formats that provide a common global 'language' and enablers for obtaining, using and sharing information to enhance science and improve research and healthcare. The CDISC suite spans the research process from the study plan (protocol) through data analysis and reporting. CDISC also provides enablers for using electronic health records (EHRs) for research. CDISC has become increasingly involved during the past few years in developing data formats to support specific disease areas such as tuberculosis (working with the TB Alliance, Gates Foundation and Critical Path Institute), Alzheimer's disease, Parkinson's disease, pain, oncology and other such therapeutic areas.

The agreement between CDISC and IMI provides CDISC education and materials for IMI consortia members, as well as a CDISC membership and access to the CDISC Members Only Area and portals for all academic institutions, small and medium-sized enterprises and other organisations receiving IMI funding in IMI projects. The EFPIA partners involved in IMI projects are already CDISC members. IMI project teams will use CDISC formats and standards where applicable and, when not available, they will participate in developing new ones.

"CDISC is extremely pleased to formalise this relationship with IMI," said Dr Rebecca Kush, President and CEO of CDISC. "We have thoroughly enjoyed working with IMI to date, and we feel that this will be an invaluable mutually beneficial partnership that can generate standards-based innovations to streamline the development of new therapies and medical knowledge that will benefit patients worldwide." CDISC is also now a full participant in several IMI consortia through its CDISC Europe Foundation.

IMI Executive Director Professor Michel Goldman commented: "The agreement between IMI and CDISC will greatly enhance the standardisation of data management in IMI projects, and will therefore help IMI to achieve its goal: speeding up the development of more effective and safer treatments for patients. As IMI projects will be more and more based on the analysis of large data sets, the harmonisation and standardisation of data made possible through the collaboration with CDISC will be critical to the success of IMI."

This partnership will allow IMI and CDISC to further develop tools that will advance the development of better and safer treatments for patients. In addition, their collaboration will open new opportunities for a wider number of public and private organisations in the healthcare sector and research industries to collaborate. The partnership broadens the adoption and use of common CDISC standards, and facilitates the harmonisation and cross-utilisation of clinical data, thus advancing higher quality medical research and leading more rapidly to innovative and effective cures.

ABOUT IMI

The Innovative Medicines Initiative (IMI) is the world's largest public-private partnership in drug research. By linking industry, academic teams, regulators and patients' organisations in joint research and training projects, IMI is transforming the EU's ecosystem for pharmaceutical R&D, making Europe a more attractive place for private investment in innovation.
By sharing research results that have not been brought together previously, IMI project partners are building new methods, models and tools that will speed up the development of novel therapies. IMI is funded jointly by the European Union (€1 billion in cash) and EFPIA, the European Federation of Pharmaceutical Industries and Associations (€1 billion in in-kind contributions).
www.imi.europa.eu

ABOUT CDISC

CDISC is a global, open, multidisciplinary, neutral non-profit organisation that has established standards to support the acquisition, exchange, submission and archive of clinical/medical research data and metadata through a consensus-based process. The CDISC mission is 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.*** CDISC standards are platform-independent and freely available via the CDISC website. Additional information on CDISC can be accessed at www.cdisc.org.