For Immediate Release

Contacts:
Jonathan Himlin, Director of Communications, HL7
(734) 677-7777
jhimlin@HL7.org

Frank Newby, Vice President, Education and Member Relations
(610) 942-2464
fnewby@cdisc.org

HL7 and CDISC Mark First Anniversary of Renewed Associate Charter Agreement,
Joint Projects Result from Important Healthcare-Clinical Research Industry Collaboration

ANN ARBOR, Mich. / AUSTIN, Texas — October 12, 2005—Health Level Seven, Inc. (HL7) and The Clinical Data Interchange Standards Consortium (CDISC) recently celebrated the one-year anniversary of their renewed associate charter agreement (initial agreement 2001) and report that several joint projects have been initiated as a result of this strengthened collaboration.

These projects include:

- **BRIDG**

  CDISC initiated and managed the early development of a clinical research domain model, the Biomedical Research Integrated Domain Group (BRIDG) model. The development of this model quickly became a collaborative effort among CDISC, the National Cancer Institute (NCI), HL7, the Food and Drug Administration (FDA) and others. The modeling was led by HL7 Board Member Charlie Mead and followed the HL7 Development Framework. The HL7 Regulated Clinical Research Information Management (RCRIM) Technical Committee (TC) voted in January 2005 to adopt BRIDG as their domain analysis model, and specifications/messages are in progress based upon this model, including one for trial registries/protocol tracking and one for an electronic data collection instrument (e.g. case report form).

  “This particular collaboration provides an opportunity to bring together the standards that have been developed for clinical research via CDISC, the International Conference for Harmonization (ICH), FDA, and HL7 RCRIM under one model,” said Dr. David Hardison, CDISC Board Chair-elect. “We feel confident that those companies implementing these standards in the biopharmaceutical industry and medical research area will especially appreciate the BRIDG project.”
Meanwhile, CDISC and NCI have made this model freely available on an open-source website (www.bridgproject.org). Recently, Sue Dubman, a director of informatics initiatives at NCI, and CDISC President Becky Kush presented on the NCI-CDISC collaborations with HL7 at the September HL7 Plenary Session in San Diego.

- **OCCR**
  The HL7 Board of Directors initiated an Outreach Committee for Clinical Research (OCCR) so that HL7 could reach out to the medical/clinical research community. This Board-appointed committee is chaired by Charles Jaffe, MD, PhD., and as chair of OCCR, he participates in HL7 Board meetings. Dr. Jaffe is also a Director on the CDISC Board.

- **CDISC/HL7 Day**
  CDISC organized a CDISC-HL7 Day in Paris, France following the European CDISC Interchange. Presentations were given by: Prof. Joachim Dudeck of HL7 Germany; HL7 Board Members, Liora Alschuler, Charlie Mead, and Randy Levin; Meredith Nahm of Duke Clinical Research Institute (DCRI) and Pat Wise of the Healthcare Information and Management Systems Society (HIMSS).

- **Single Source**
  A collaboration of CDISC, HL7, and a number of other supporting companies (including technology providers and global biopharmaceutical companies) completed a proof-of-concept named Single Source. This project demonstrated synergistic use of the HL7 Clinical Document Architecture (CDA) and CDISC standards to capture data once for use with electronic health records and clinical trial databases. The concept was demonstrated by Microsoft and many of their partners at the Drug Information Association Conference in June 2005. CDISC is seeking to expand this concept into pilots in the near future.

In addition, the two organizations have established an incentive plan that includes the exchange of discounted memberships for companies that join both organizations. Companies that have taken advantage of this joint membership incentive thus far include: Eli Lilly, First Consulting Group, IBM, Johnson & Johnson, Merck, Microsoft, Pfizer, Raining Data, and SAIC.

**About CDISC**

CDISC is an open, multidisciplinary, non-profit organization. The mission of CDISC is to develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare. CDISC is made possible through the work of many volunteers and the generous support of its corporate members, which include major global biopharmaceutical and technology providers, contract research organizations, government, academia and others. CDISC standards are referenced as specifications in FDA Guidance for eSubmissions. Additional information on CDISC and the CDISC open standards/models can be found on the CDISC website at [http://www.cdisc.org](http://www.cdisc.org).
About HL7

Founded in 1987, Health Level Seven, Inc. (http://www.HL7.org/) is a not-for-profit, ANSI-accredited standards developing organization dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services. HL7’s more than 2,000 members represent approximately 500 corporate members, including 90 percent of the largest information systems vendors serving healthcare.

HL7’s endeavors are sponsored, in part, by the support of its benefactors: Accenture; Centers for Disease Control and Prevention (CDC); Duke Clinical Research Institute (DCRI); Eclipsys Corporation; Eli Lilly & Company; the Food and Drug Administration; GE Medical Systems; Guidant Corporation; IBM; IDX Systems Corporation; Intel Corporation; Digital Health; InterSystems Corporation; Kaiser Permanente; McKesson Provider Technologies; Microsoft Corporation; Misys Healthcare Systems; NHS Connecting for Health; NICTIZ National ICT Institute for Healthcare in The Netherlands; Oracle Corporation; Partners HealthCare System, Inc.; Pfizer, Inc.; Philips Medical Systems; Quest Diagnostics Inc.; Science Applications International Corporation; Siemens Medical Solutions Health Services; Solucient, LLC; the U.S. Department of Defense, Military Health System; the U.S. Department of Veterans Affairs; and Wyeth Pharmaceuticals.

International affiliates have also been established in 25 countries throughout the globe including Argentina, Australia, Brazil, Canada, China, Croatia, Czech Republic, Denmark, Finland, France, Germany, Greece, India, Ireland, Italy, Japan, Korea, Mexico, The Netherlands, New Zealand, Spain, Switzerland, Taiwan, Turkey and the United Kingdom. Recently, the HL7 Board approved the establishment of two new affiliates in Malaysia and Uruguay.

###