



**Health Level Seven, Inc.**

***For Immediate Release***

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**HL7 Announces Industry's First Electronic Health Record System (EHR-S)  
Functional Requirements Standard for Clinical Research**

New ANSI standard identifies functionalities required of EHR systems  
to conduct regulated clinical research

**Ann Arbor, Michigan, U.S.A.— November 5, 2009—**Health Level Seven® (HL7®), the global authority for interoperability and standards in healthcare information technology with members in 57 countries, today announced it has published the healthcare industry's first ANSI (American National Standards Institute)-approved standard that specifies the functional requirements for regulated clinical research in an electronic health record system (EHR-S). The HL7 EHR Clinical Research Functional Profile for EHR systems is based upon the HL7 EHR Work Group's EHR System Functional Model Release 1, which is also an ANSI-approved American National Standard.

The EHR Clinical Research Functional Profile defines high-level requirements critical for using electronic health record data for regulated clinical research, and provides a roadmap for integrating the information environment that must support both the patient care and the downstream clinical research processes. According to Donald Mon, PhD, co-chair of the HL7 EHR Work Group and member of the HL7 Board of Directors, "This profile is an excellent demonstration of how important functional requirements for secondary data use, such as clinical research, can be integrated into the patient care work flow and documented in EHR systems." Pharmaceutical, biotechnology, clinical research technology vendor, healthcare technology vendor, and federal regulatory stakeholders from the United States and the European Union collaborated for two years to identify and address a broad list of data protection, regulatory and ethical research requirements.

The EHR Clinical Research Functional Profile is also a resource for the Certification Commission for Healthcare Information Technology (CCHIT) Clinical Research Work Group as they define new clinical research certification criteria for EHR systems.

This functional profile will be complemented by the EHR-Clinical Research interoperability specification, currently being developed by the Health Information Technology Standards Panel (HITSP). Additionally, Dr. Rebecca Kush, President and CEO of the Clinical Data Interchange Standards Consortium (CDISC), commented that “CDISC is pleased to be a collaborator and to contribute clinical research standards and eSource Data Interchange concepts towards these initiatives. The ultimate goal is to accelerate the pace at which research informs healthcare for the benefit of patients and this functional profile contributes to the achievement of that goal.”

### **About HL7**

Founded in 1987, Health Level Seven, Inc. is the leading global authority for healthcare Information interoperability and standards with members in 57 countries. HL7 is a non-profit, ANSI accredited standards development 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 2,300 members represent approximately 500 corporate members, which include more than 90 percent of the information systems vendors serving healthcare. HL7 collaborates with other standards developers and provider, payer, philanthropic and government agencies at the highest levels to ensure the development of comprehensive and reliable standards and successful interoperability efforts.

HL7's endeavors are sponsored, in part, by the support of its benefactors: Accenture; Booz Allen Hamilton; Centers for Disease Control and Prevention; Duke Translational Medicine Institute (DTMI); Eclipsys Corporation; Eli Lilly & Company; Epic Systems Corporation; European Medicines Agency; the Food and Drug Administration; GE Healthcare Information Technologies; GlaxoSmithKline; Intel Corporation; InterSystems Corporation; Kaiser Permanente; Lockheed Martin; McKesson Provider Technology; Microsoft Corporation; NHS Connecting for Health; NICTIZ National Healthcare; Novartis Pharmaceuticals Corporation; Oracle Corporation; Partners HealthCare System, Inc.; Pfizer, Inc.; Philips Healthcare; QuadraMed Corporation; Quest Diagnostics Inc.; Siemens Healthcare; St. Jude Medical; Thomson Reuters; the U.S. Department of Defense, Military Health System; and the U.S. Department of Veterans Affairs.

Numerous HL7 Affiliates have been established around the globe including Argentina, Australia, Austria, Brazil, Canada, Chile, China, Colombia, Croatia, Czech Republic, Denmark, Finland, France, Germany, Greece, Hong Kong, India, Ireland, Italy, Japan, Korea, Mexico, The Netherlands, New Zealand, Romania, Russia, Singapore, Spain, Sweden, Switzerland, Taiwan, Turkey, United Kingdom, and Uruguay.

**For more information, visit [www.HL7.org](http://www.HL7.org)**

For more information on the EHR Clinical Research working group, visit [www.ehr-cr.org](http://www.ehr-cr.org).

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