Informatics around the World
Duke plays a significant role in the development of international data standards for clinical research and care. Indeed, in the mid 1980s, under the leadership of David Kirby, Duke developed the messaging standard that preceded and influenced the creation of the Health Level Seven (HL7) standard. Through organizational membership in HL7 and the Clinical Data Interchange Standards Consortium (CDISC), Duke has assumed a leadership role in standards development and adoption.

W. Ed Hammond, PhD, director of the Duke Center for Health Informatics, was a founding member of HL7 and chaired HL7’s Board of Directors for three terms since its inception in 1987. During that time, Duke developed the first HL7 website and hosted it for more than 10 years. Barbara Tardiff, MD, assistant consulting professor of anesthesiology, and Meredith Nahm, PhD, associate director of clinical informatics at the Duke Translational Medicine Institute, served on CDISC’s Board of Directors for several years. Still others at Duke have led a wide range of projects that have enabled interoperability in health care and research.

**Data standards for tuberculosis and heart disease**

Data standards refer to an agreed-upon set of common data elements, including how they are defined and how they “look” electronically. In 2005, the Duke Clinical Research Institute (DCRI) launched two projects designed to develop a methodology for engaging clinicians in creating data standards for cardiovascular (CV) disease and tuberculosis (TB). The National Institutes of Health (NIH) Roadmap Program, which aims to eliminate obstacles to the conduct of biomedical research, supported these initiatives. Led by Robert Harrington, MD, professor of cardiology and director of the DCRI, the CV data standards project produced the first-ever efficacy data standards to pass the CDISC and HL7 balloting processes for heart disease. The project balloted 21 acute coronary syndrome data elements in May 2008. Meanwhile, the TB standards project, led by Carol Dukes-Hamilton, MD, associate professor of medicine, balloted 139 pulmonary diagnoses and treatment data elements through HL7 and CDISC in September 2008. All of these elements have been loaded into an open-source data repository at the National Cancer Institute using the Cancer Data Standards Registry and Repository.

Duke facilitated the CV and TB projects over the course of four years. It worked with clinicians, members of federal agencies, pharmaceutical companies, standards development organizations, informaticians, and professional societies to select a set of data elements and decide on standard definitions and permissible value sets, which were then vetted by the research and healthcare communities.

The CV data standards project has since gained momentum. In 2010, the NIH awarded the DCRI another grant to create the National Cardiovascular Research Infrastructure (NCRI). Under the leadership of James Tcheng, MD, director of the bioinformatics core at the Duke Translational Medicine Institute, the NCRI is a partnership between the DCRI and American College of Cardiology (ACC) designed to harmonize CV data standards efforts across multiple organizations. The TB data standards project has likewise generated interest within the federal government and among national TB consortiums.
Developing standards for other therapeutic areas and applications

Following the success of the CV and TB data standards projects, Duke has begun facilitating the development of data standards in other therapeutic areas.

Terri Monk, MD, MS, professor of anesthesiology, is the facilitator for the Preoperative Anesthesia Record Domain Analysis Model project, which is part of the HL7 Generation of Anesthesia Standards (GAS) Working Group. This project, which is being conducted in collaboration with groups in the Netherlands and the United Kingdom, supports the exchange and understanding of anesthesiology data by establishing standard definitions and values for common anesthesiology data elements. The standards will include anesthesiology-specific data elements related to adult and pediatric patients. Subsequent releases will also include demographic, history and physical, and organ system data.

Duke has also made significant contributions in standards development for clinical decision making.
support. Guilherme Del Fiol, MD, PhD, MS, assistant professor of community and family medicine, played a leadership role in developing the International Context-Aware Information Retrieval standard (nicknamed the “Infobutton” standard) through the HL7 Clinical Decision Support Working Group.

The Infobutton standard facilitates the integration of knowledge resources in an electronic health record (EHR) system. An Infobutton manager accessed through an EHR application can obtain a set of standardized information about a patient, a provider, and a specific encounter needed for any case. In most cases, the Infobutton standard has been used to display decision support information for clinicians.

Ken Kawamoto, MD, PhD, an assistant professor of community and family medicine, is co-chair of the Clinical Decision Support Working Group. Kawamoto has led the HL7 Decision Support Service project for several years, and is also actively involved in the development and evaluation of operational standards-based clinical decision support systems at Duke. He continues to be involved in leading applications of the Clinical Document Architecture (CDA) standard to exchange information from patient encounters.

Continuing a long and robust history in national and international standards development, Duke pushes forward with leadership in standards development efforts, academic thought leadership, and pragmatic projects. For example, Michael Russell, MD, associate professor of medicine, leads the development of the Clinical Context Object Workgroup (CCOW) standard. This standard allows multiple software applications to share a patient’s identity so authorized users can access that patient’s medical history, prescribe medication, or obtain radiology images without logging onto multiple programs and navigating through different Internet sites. The Duke University Health System was one of the first institutions to implement this standard, and much of the health system uses it today for patient care and to facilitate secondary data use through semi-automated chart review.

In addition, Duke is heavily involved in the leadership of an international working group within the Clinical Interoperability Council (CIC), which allows clinicians to contribute to data standards development and provides a forum for standards projects to receive input from the clinical community. The HL7 organization created the CIC in 2008 to engage practicing clinicians in data standardization without overwhelming them with technical terms and analysis.

Even as it continues to help define and refine international data standards for clinical research and patient care, Duke is consistently incorporating these standards into its institutional processes. For instance, it is establishing a platform for creating a local International Organization for Standardization (ISO) 11179 data registry to support its systems and databases. The goal is to develop electronic forms that can be used to gather standardized data collected during primary care visits to identify which services patients need. This registry will use a combination of internationally approved standards, as well as standards developed locally with the input of Duke primary care physicians and researchers.