ACRP has joined CDISC to work on the Clinical Data Acquisition Standards Harmonization initiative to develop a new and universal case report form for clinical trials.

Perhaps you have already read in the pages of The Monitor or elsewhere about the need for, and the work being done toward, the establishment of platform-independent data standards that would allow information systems to “talk to” one another freely at great benefit to the medical and healthcare community. I am excited to share with you the news that ACRP has joined a new project with a leader in this endeavor, the multidisciplinary, nonprofit Clinical Data Interchange Standards Consortium (CDISC), and to let you know what you can do to make this a more dynamic process for all who seek to make such standards a reality.

ACRP members are well acquainted with the current state of a typical investigative site that conducts multicenter clinical research studies with more than one sponsor. Given the data technology needs alone, an observer from another industry might rightfully question why an investigative site would agree to add the “burden” of running trials to their existing role of caring for patients. A site may have anywhere from a few to a dozen disparate systems in use at any given time, each using a different data format, different query resolution methods, and different applications and login information—all in addition to the shelves of notebooks for the paper-based studies.

Survey Says . . .

In a survey in 2004–05 (fourth in a series that began at the ACRP Global Conference in 2000), sites were asked if sponsors should collaborate on standards for electronic data capture (EDC) technologies and data collection requirements; the response was overwhelmingly positive. If they are not already posted as you read this, results from the fifth survey will soon be available at www.cdisc.org/surveys/eCRTsurvey/. Furthermore, it should come as no surprise to our members that the U.S. Food and Drug Administration (FDA) identified “consensus on standards for case report forms (CRFs)” as a Critical Path Opportunity (see www.fda.gov/oc/initiatives/criticalpath/reports/opp_list.pdf).

These sentiments form an excellent backdrop for why ACRP members should be involved in the CDASH (Clinical Data Acquisition Standards Harmonization) initiative, which is a collaborative project to address this Critical Path Opportunity. The overarching goals of this initiative are to make it easier for sites to conduct clinical research; to collect data once for multiple purposes; and to improve data quality and patient safety. The initiative is managed by CDISC (www.cdisc.org) and was started by the Association of Clinical Research Organizations (ACRO), which requested (along with FDA) that CDISC assume a leadership role in 2006.

Behind the Scenes

Strategic direction and resources for CDASH are provided through a collaborative group of 16 organizations, includ-
ing ACRP, ACRO, CDISC, and FDA, with the stated goal of developing “a set of 'content standards' (element name, definition, metadata) for a basic set of global data collection fields that will support clinical research studies.” The initial scope is on safety information that supports all clinical research. There is also interest in eventually augmenting these standards with therapeutic-specific standards.

The CDASH project was initiated with an open meeting attended by more than 80 volunteers. Since that meeting, nine subgroups comprised of volunteers from pharma and biotech companies, contract research organizations (including representation from outside the United States), academia, and government have been formed to develop the safety data/domains that are relevant to their particular areas of expertise for a new and universal CRF. Some of the guiding principles for these groups are limiting the variables to those that are required and necessary; complying with applicable regulatory requirements; reducing redundancies; and ensuring that the fields are appropriate for both pre- and postapproval studies.

After each subgroup has reached agreement on basic CRF data elements, added definitions for each field/element, and written completion guidelines/instructions, the next step in the CDISC consensus process is an internal review by the leaders of the other groups. This review will be open to all collaborative group members, including ACRP. Although significant progress has been made, there remains much to be done to ensure that all of the subgroups’ products are ready for an open public review in early 2008.

**What You Can Do**

Meanwhile, the CDASH initiative needs the support of ACRP members to ensure that our voice is heard in the development of standardized CRF data elements. It is obvious that the efficiencies that can be achieved as a result of standardized CRF data elements would greatly benefit all stakeholders in the clinical research enterprise. In fact, an analysis by Gartner Inc. (www.gartner.com) has indicated that there can be significant time and cost savings, not to mention better quality and team communications, when standards are implemented in the CRF development stage of a clinical trial.

ACRP members are therefore encouraged to actively support the CDASH initiative. Support can take several different forms—for example, by contributing funds to the CDASH project, by volunteering to actively participate in a subgroup (new ones are being formed to develop the end of study/disposition, comments/protocol violations, and drug accountability and exposure domains), by reviewing the subgroup products during the collaborative group review and/or the final sets of data collection elements during the public review period, or by joining CDISC. For more information on how you can contribute to this effort, send an e-mail to rfacile@cdisc.org or visit www.cdisc.org/standards/cdash/index.html.