HEALTHCARE LINK

By Michael Ibara, Head of Digital Healthcare

Healthcare delivery and healthcare research are "two parallel universes" (as described recently by Dr. Robert Califf, FDA Commissioner). They are parallel because they are both concerned with patients, healthcare data, and improving public and individual health. They are separate universes because over time they have developed separate ways of dealing with data: from regulatory concerns to coding schemes to database structures and vocabularies, even to the vendors and products that serve them. Taken together, these two systems form what may be the most complex human-created system on earth.

Every day, the delivery of healthcare to patients generates a tremendous amount of data providing routine and emergency care to patients, and every day, healthcare research is engaged in testing new drug and device entities, seeking to improve quality, addressing errors, finding trends, and more. In the past this data was often trapped paper or siloed in databases with only a small flow of information moving between individuals. Large research investments were, and often are still required simply to collect, process and standardize the data before it can be reviewed as a coherent whole. But today, with rapid adoption of electronic healthcare records (EHRs), and with a massive digitization of additional healthcare data through use of mobile devices and sensors, we have an amazing opportunity to find smarter ways to use the data that is potentially easier to collect and process.

Unleashing the potential of our healthcare data, however, is not yet realized. Our historical investments in systems developed over many years, our need to modernize our regulatory approaches and our industry practices, the lack of the best methods to deal with extremely large sets of data, and a valid concern around patient privacy all pose challenges we need to address. An additional challenge, which is key to Healthcare Link, is the challenge of creating standards and methods that can serve to link the parallel universes of healthcare delivery and research.

Since its original inception in 1997 and official launch in 2004, the original focus of Healtcare Link was on EHRs as the primary source of healthcare data that could be leveraged to enable simpler and higher quality collection of data for research. Toward that goal CDISC developed a suite of foundational standards, various means to leverage these standards and a series of 'enablers' to improve the workflow of clinicians doing research. CDISC Healthcare Link profiles.

Today, as sources of healthcare data proliferate, costs for research continue to rise, and new approaches and methods evolve, CDISC is seeking to build on past work to address the challenges of today.

Retrieve Form for Data Capture (RFD)

RFD is an "integration profile" jointly developed by CDISC and IHE (Integrating the Healthcare Enterprise). RFD, along with CDISC standards is used to collect relevant data from the EHR that can be used in research and public health, such as safety and bio surveillance, clinical research, and disease registries. CDISC is working today with IHE and other partners to modernize RFD, bringing it in line with current web technologies and approaches, and continue its usefulness.

eSource

Creating useful links between the universes of healthcare delivery and healthcare research certainly requires us to improve our standards frameworks, but before we can even discuss what standards we'll use, we must address long-standing challenges in (mis)alignment of stakeholder incentives and a lack of shared understanding. CDISC recognized this challenge in its work with eSource - using electronic sources of healthcare data for regulated research, and is committed to solving the problem at hand - the need for a coherent approach to all of the stakeholders involved and interested in eSource.

eSource involves myriad data sources, including EHRs, clinical trials, claims and quality registries, data from wearables, social media - anywhere healthcare data is generated from an electronic source. And it involves myriad stakeholders as well: physicians, medical centers, sponsors, CROS, EHR vendors, EDC vendors, government, patients... a large and diverse set!

CDISC has initiated and is coordinating the eSource Stakeholders Group (http://www.cdisc.org/CDISC-eSource-Stakeholders-Convene) which is an open, inclusive forum which will provide coordination and focus to the increasing community of stakeholders interested in realizing the benefits of using eSource, also known as electronic source data, in clinical trials and meeting regulatory requirements for eSource data, provenance and electronic records. This group and CDISC's work to help establish it is in recognition of that fact that as stakeholders in healthcare, we are often in our day to day silos, dictated to by our immediate business concerns, and rarely do we get a chance to learn what others are concerned about and working on. Our hope for this group is that it serves as a venue for open, inclusive discussion and work on implementing an eSource approach to bringing together healthcare and research.

Healthcare Link: Building on the past to work toward the future

Healthcare Link began with the recognition of the great promise of better linking healthcare sites to research. It continues with the recognition that this link is one part of a much broader effort underway today to bring together the "parallel universes" of all of healthcare delivery with clinical research. This interface is where Healthcare Link will continues its work.

At this early stage, there are fundamental challenges to understand and more cooperation is needed to meet them, and we are working 'on the ground' with projects and review of past work, as well as at higher levels, with collaborations and policy, to make a fundamental contribution to realizing the original vision of connecting healthcare delivery and healthcare research in meaningful ways that will improve individual patient and public health.