Healthcare Link and eSource

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Introduction

Clinical research data follow a life cycle that begins with data capture and ends with the submittal of a data set to the regulatory agency and/or publication in a report or journal. CDISC began its work at the tail end of this cycle by first specifying how data should be submitted for review, then moved through progressively earlier stages of the data life cycle with standards for data acquisition, data management and data analysis. The earliest step in the data progression, the electronic capture of research data directly from healthcare information (at the source), remained an open gap in the CDISC chain of specifications, even though eSource was a key aspect of the driving vision of CDISC's founders. The CDISC Board launched the Healthcare Link initiative several years ago to close this last unspecified gap in the clinical research data life cycle.

The data capture step for clinical research typically takes place at a healthcare site, which has its own set of systems and regulations. So this final gap in the research data cycle is in fact a gap between two industries, medical research and healthcare, each with its own technology, regulations, and culture. CDISC was challenged to close this final gap by working in conjunction with the healthcare information technology community which services the primary needs of the healthcare site.

The first attempts to automate data capture for clinical research resulted in stand-alone electronic data capture (EDC) systems, first deployed at healthcare sites as dedicated laptop computers and then increasingly as web services. But as the electronic medical record (EMR[1]) gained penetration in the healthcare settings, healthcare sites were saddled with multiple of data capture systems: an EMR for their patient care practice and one or more EDC systems for their research studies. And the use of EDC systems did not totally replace paper processes, such as printing documents from the EMR for re-entry into the EDC, and retaining paper copies of source documents. This collision of two industries at healthcare sites resulted in a mishmash of systems and processes that cried out for simplification. But since the essence of the problem was coordination among systems, only a standards-based solution, specified by all participating parties, had any chance of success. By developing standards that connect the EMR and the research systems, CDISC's Healthcare Link sought to ease and simplify the data capture processes that support clinical research as investigative sites.

Approach

Healthcare Link uses the standards development process to drive innovation. Standards are often thought of as reflections of the status quo, as static rules to be adopted. But the process of developing new standards in an open setting with wide participation from many contributors is a creative process of the highest order, and is a fine example of cooperation among competitors. The resulting specifications, along with the first implementations of novel approaches, are the drivers of much new innovation, and the only process that can hope to branch across vendor and industry boundaries.

In its Healthcare Link initiative, CDISC followed five precepts:

1. Meet the EMR vendors more than halfway;
2. Improve the site-based processes that create data;
3. Focus on the notion of a 'form' as the central pivot of data capture;
4. Engineer collaboration among existing systems rather than specifying new development;
5. Incorporate the electronic source into the Healthcare Link solution.

Meet the EMR vendors more than halfway

While the research community is the beneficiary of Healthcare Link, it is the EMR vendors who hold the key to automating patient care processes. It is within the grasp of the EMRs to automate the research processes that currently belong to the EDC systems, but it is not necessarily in their business interests to take on this work. The healthcare industry is a demanding environment, with a regulatory burden that matches or exceeds that of the research space, and with continuous demands for more features and better products. So, to engage this community, CDISC had to step lightly and to make as few demands as possible on this beleaguered community. CDISC reached out to the EMR vendor community by joining IHE[2] and developing integration profiles in the company of the many EMR vendors who populate IHE. The result has been a continuous and ongoing collaboration between IHE and CDISC, a process that continues to expand and grow.

The integration profiles developed as part of Healthcare Link sought to invite the participation of the EMR vendors by keeping the barriers to adoption low, to keep implementation easy, and to protect the EMRs from additional regulatory burden. Whenever possible, the profiles leverage the existing functionality of research systems rather than requiring additional EMR development. This approach is in marked contrast to other industry projects, which define functionality for a fully research enabled EMR, expecting the vendors to pick up the tab on development. Healthcare Link is a collaboration, rather than a competition.

The primary reason to engage IHE was simple: that's where the EMRs vendors go to solve their problems. IHE has created a robust process of specifying profiles, then testing those profiles at annual Connectathons. The testing that goes on at these events provides valuable experience that is fed back into the specifications in a process that hones the specifications over a period of several years until the profile arrives at final text. The core Healthcare Link specifications have been tested at seven IHE Connectathons in North America, Europe, and Japan.

In addition to the Connectathons, IHE has a relationship with the HIMSS Interoperability Showcase, which is put on at the HIMSS annual conference and, most recently in collaboration with CDISC at the DIA Annual Conference. The Healthcare Link work has also been demonstrated at CDISC Interchanges. In all, the work has been demonstrated to public audiences at least 10 times on three continents.

Having been formally tested at Connectathons, and demonstrated at Showcases, some of the specifications have now been implemented in select settings. These implementations have led to changes in the specifications and have developed a body of knowledge and an experienced cadre of implementers. The goal of IHE profiles is to be clear enough to be implemented by competent technicians without any assistance. Two examples speak to the success of this goal: the key Healthcare Link profiles were implemented in Japan by Michio Kimura and in France by Christel Daniel, in both cases without recourse to the profile originators in the US.

The acceptance of Healthcare Link is reflected in the number of EMR vendors who have helped to develop, test, demonstrate and implement the Healthcare Link solution. These include Cerner, GE Healthcare, Epic, Allscripts, Greenway Medical, and commercial and academic implementers in Japan and Europe. The Electronic Health Record Association, the trade organization representing over 95% of the market in the US, wrote a letter of endorsement for the approach[3].

Improve the site-based processes that create data

Mark Arratoon, an engineer at General Electric Healthcare, brings a fresh perspective to healthcare from his work in other industries. He observes that the healthcare and research industry emphasize data over process in pervasive ways that influence the most basic terms: "The terms Electronic Health *Record* and Electronic Medical *Record* are misleadingly used to describe healthcare information systems. The noun in these acronyms is 'record', which as any IT engineer knows, is a specific entry in a database or file. This is not what the healthcare IT vendors of the world are selling with their competing 'EMRs'. They are selling complex software systems that enable customers to create such records in the act of performing healthcare-related functions. The features they compete on are not primarily the nature of the record they produce in their database, but the range and depth of functions associated with typical clinical and financial workflows within a healthcare environment. So a more accurate term for what these vendors sell would be Electronic Health System or Electronic Medical System, which as a by-product produce Electronic Health *Records* and Electronic Medical *Records*."

From the start, Healthcare Link has taken an approach of automating collaborative processes between healthcare and research systems, not just an extractive grab at the data. This focus on process first and data second contrasts with other initiatives such as OMOP[4] and FDA's Sentinel Network[5] which seek to assemble large datasets from EMRs and other sources and mine the data using signal detection algorithms. The process focus looks first at the workflows by which data are created, and retrieves data in small, tightly specified batches that are tightly bound to the data capture processes. The process approach leverages the front end definition of data, using CDISC's CDASH[6] specification and the HL7 CCD[7].

One important implication of the process focus is to recognize the EMR as the primary application for healthcare automation. A healthcare site that has invested time and money into the implementation of

an EMR should be able to leverage that application for research purposes. Any competing data capture systems should be relegated to the background, with workflows integrated into the EMR session to facilitate the activities of a busy clinician.

Focus on the notion of a 'form' as the central pivot of data capture

CDISC uses the notion of a form, in research applications called a case report form, to define the specific, limited data needs of particular interactions. The form defines a reasonable bite of data that allows for the use of reasonably sized semantic approaches. Compared to the many efforts that are underway to develop ontologies or other broad-based semantic solutions, the Healthcare Link uses ad hoc solutions that build on existing standards. Full data normalization is a worthy goal, but it is not necessary for beneficial use of EMRs any more than it is necessary for an English speaker to have a Ph.D. in French to be able to order a croissant in a Paris bakery.

The other benefit of a focus on the form is that it allows for ad hoc data capture in the moment. Research data capture cannot be completely satisfied by re-use of pre-existing EMR data. The research study often requires specific observations to be made that are beyond the scope of the medical record, and in some cases irrelevant to the healthcare process. A pediatric study known as the Fuzzy Navel study tracked the buildup of lint in infant belly buttons. No one expected the medical record to have this information on hand, and it was not deemed necessary to preserve these observations for healthcare needs. The use of a data form that draws on the EMR for basic historic information but which allows for data capture in the moment would accommodate the Fuzzy Navel and other more serious research requirements.

So a research form can be regarded as a data request, some of which can be 'pre-populated' by existing EMR data, and the remainder to be completed by research personnel. By integrating research forms into healthcare workflows, data capture processes are simplified and located where the site wants them.

Engineer collaboration among existing systems rather than specifying new development

The solution offered by the Healthcare Link specifications is a system of systems. Not only is this practical from the point of view of the applications that currently exist in the marketplace, EMRs and EDC systems, but the approach preserves valuable distinctions between healthcare and medical research systems. The regulatory environment requires a clear differentiation between research systems that are under the control of the research sponsor and systems under the purview of the healthcare sites. In designing systems of systems, there must be a clear understanding of the functions of each participating system, and a clear differentiation between the functions of a single system and the interoperability among the systems.

The research systems encapsulate valuable expertise in curating research data. EMRs provide knowledge of healthcare. If one or the other crosses into the other's domain, they find themselves in foreign territory, with different business drivers, cultures, and vocabularies. Since both healthcare and research systems have value in their respective environments, and since it is possible to engineer collaborative approaches that keep all current players in the game, why should such value be displaced?

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By leveraging business process management technologies that have long history in retail and finance, healthcare and research can co-exist and mutually benefit the sites, researchers, and sponsors.

Incorporate the electronic source into the Healthcare Link solution

David Iberson-Hurst, then the CDISC technical lead, envisioned the technical solution to bring together Healthcare Link and CDISC's eSource Data Interchange Initiative. With his input, the IHE specification included an archive step that was specifically designed to create an electronic source document archive to meet the needs of source document verification and electronic record retention per regulation (21CFR11). The creation of the archive off-loaded the burden of electronic source storage and access from the EMRs. It removes the regulatory burden from the EMRs, and the burden of maintaining paper records from the sites.

The eSource archive is, in Iberson-Hurst's analogy, a black box recorder for the clinical study. Like the black box recorder on an aircraft, the eSource archive records and stores data generated by the study, and keeps the data at the site in a clear chain of custody. The eSource archive was designed to be the clinical research black box recorder, recording whatever emerges from the research site, permitting reconstruction should the need arise.

Replacing the paper-based source document with an electronic source will rework and improve the site's processes, and replace on-site monitoring with electronic monitoring and auditing from afar. CDISC's Electronic Source Data Interchange Initiative (eSDI) informed the Healthcare Link specifications so that a solution for data capture became a solution to electronic source documentation as well. This approach has received attention and support from regulators in Europe, Japan and the U.S. and leaders in HIT implementations around the globe; it is poised for widespread adoption.

Specifications

The collaboration between CDISC and IHE has resulted in a set of four IHE profiles and an HITSP Interoperability Specification. Together these documents define a complete technical approach for integrating the clinical research data capture workflow into the existing electronic processes supported by the EMR.

The cornerstone of CDISC's Healthcare Link initiative is the Retrieve Form for Data-capture (RFD) profile, jointly developed by CDISC and IHE. RFD sets up a 'conversation' between the healthcare system, the EMR, and its corresponding research system, the EDC. This conversation develops around the form that the research system needs to have completed. This form, often called a case report form or CRF, defines the data requirements for a particular research encounter. It is not a 'one size fits all' request, but rather a tightly defined data unit that would typically be entered directly into an EDC system by healthcare site personnel. RFD enables the healthcare system to display this form, thereby eliminating the need for multiple data capture systems at the site. But this does not mean that the research system is eliminated. The EDC still retains ownership of the form, and of the data captured through it. The EDC retains its valuable function in the data ecosystem, but works collaboratively with the healthcare system to simplify the experience of the site personnel involved in research data capture.

IHE's Retrieve Form for Data Capture (RFD) profile was developed with CDISC as the first in a series of work products to squarely tackle the clinical research use cases and relevant requirements identified through the eSDI. RFD was written as a simple and powerful architectural tool to allow an EHR to prepopulate, submit, and archive the electronic case report form (eCRF). Here are the technical steps in an RFD-enabled workflow:

1. An EDC system develops an electronic case report form, an eCRF, and exposes the form to an EMR through a URL, i.e. a simple web connection. The EDC associates a Form ID to the eCRF so that the EHR can retrieve the appropriate form. Any EMR with appropriate security credentialing and knowledge of the EDC URL and Form ID can access the eCRF.

2. As the EMR calls the EDC, one of the available options for the EHR to send is known pertinent data. A separate content profile called Clinical Research Data (CRD) defines the content and structure of this pre-population data set. CRD, as with all IHE profiles, rests on core standards from standards development organizations, in this case HL7's CCD and CDISC's CDASH. Once the EDC receives the Form ID and Data, the EDC binds all pertinent data received to the eCRF.

3. The eCRF is then able to be displayed within the EHR as a prepopulated form. The appropriate review and actions can then occur to the eCRF from within the EHR. Additional data, specific to the study, is entered into the form from within the EHR session. Once complete the eCRF can be submitted and archived. Within RFD the ability to separate the submitted data and archived data is achieved by distinctly describing these functions as separate end points and delivering an exact copy to each respectively.

Beyond RFD

Since the original work on the RFD profile, additional profiles have been added to extend and refine the actions of RFD. The Clinical Research Data (CRD) profile specifies the pre-population which is exported from the EMR on the RFD Retrieve Form transactions. A Redaction Services profile was developed to remove sensitive data from the pre-population data set. And a more sophisticated workflow automation profile called Retrieve Process for Execution (RPE), open the door for more collaborative workflow, as the research protocol becomes a process definition that the EMR will execute. The full impact of this subsequent work is still playing out, and will be published in future papers.

Conclusion

The Healthcare Link solution, augmented by electronic archiving of source at the site, will benefit the sites, the research sponsors and the regulators.

- The benefit to the site is the reduction of labor associated with printing and archiving paper documents.
- The benefit to the sponsor is a reduction in the cost of the source data verification process. If the Clinical Research Associate, an employee of the CRO or Sponsor, had access to a legitimate electronic source document, source verification audits could be done by visually comparing two documents side-by-side on a remote computer screen. This opens the possibility of conducting monitoring and/or audits remotely (audit from afar), which could save money on travel and remote posting of CRAs or field auditors.

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- Regulator could also audit from afar, monitoring the progress of a study by reviewing the electronic archive of source documents, the 'black box recorder' of the study.

CDISC's Healthcare Link improves on awkward data capture routines at sites by reducing duplicate data capture and empowering the site's chosen solution, its EMR, to capture data in service of medical research. At the same time it brings forward a new method for eSource creation that minimizes the work that EMR vendors, already dealing with a full plate of healthcare requirements, must do to support research. And the approach allows both EMRs and research systems to continue doing their native functions in a synergistic relationship in which neither competition nor extractive viewpoints predominate.

1. An Electronic Medical Record (EMR) is a system used at a particular healthcare site. An Electronic Health Record is a lifetime record that spans institutions. While this distinction has been blurred in recent usage, it is retained here.

2. Integrating the Healthcare Enterprise (IHE) www.ihe.net

3. The text of the EHRA endorsement letter can be found at www.cdisc.org

4. http://omop.fnih.org/

5. http://www.fda.gov/Safety/FDAsSentinelInitiative/ucm149343.htm

6. http://www.cdisc.org/cdash

7. http://www.hl7.org/implement/standards/cda.cfm

8. http://www.cdisc.org/stuff/contentmgr/files/0/2f6eca8f0df7caac5bbd4fadfd76d575/miscdocs/esdi.pdf

9. http://www.ihe.net/Technical_Framework/upload/IHE_ITI_Suppl_RFD_Rev2-2_TI_2011-08-19.pdf