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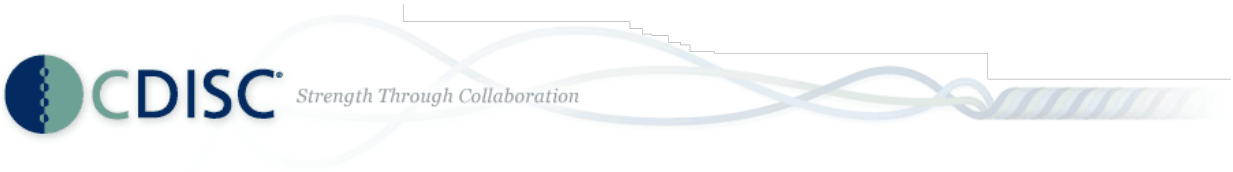

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Healthcare Link Initiative

Healthcare Link User Guide Available Here.

CDISC Healthcare Link Profiles

The CDISC Healthcare Link Initiative is one of the most rapidly developing areas of work being conducted by CDISC. Leveraging standards to improve the methods by which investigative sites can conduct medical research and capture data for clinical research studies is vital for a number of reasons; one very important reason is that clinicians frequently do one research study and no more due to the unwieldy nature of clinical research processes today. The increasing presence of an electronic health record (EHR) at healthcare sites opens new opportunities to integrate the processes of clinical care and clinical research. This will, in turn, expand the capacity for

--Public Review--

Controlled Terminology Package 23
Comments due 17 July 2015

ADaM Integration-IADSL v1 Draft
Comments due 10 July 2015

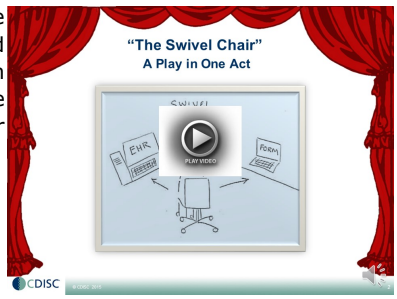
CDISC and IHE Linking Research Data Capture to Electronic Health Records

research and increase patient participation.

The overarching goals for CDISC Healthcare Link have been to:

- Make it easier for physicians to conduct clinical research,
- Collect data only once in an industry standard format for multiple downstream uses
- Improve data quality and patient safety

Since the CDISC Healthcare Link Initiative was conceived in ~ 1997 and officially launched in 2004, CDISC has developed: a suite of foundational standards (detailed in other chapters), various means to leverage these standards and a series of 'enablers' to improve the workflow of clinicians doing research. The Initiative has taken steps to ensure that the link between clinical research and healthcare takes into account existing regulations, privacy and security concerns, and current practices to provide practical pathways to achieve the vision through a stepwise approach. These enablers were developed in conjunctions with EHR vendors, and respect the limited amount of resource that these vendors can devote to a problem that is secondary to their main concern. These enablers are available now and have already proven to significantly decrease the time and effort to provide data for certain use cases, such as safety reporting, using EHRs.



Healthcare Link Program Plan / Gantt Chart

Table listing the CDISC-IHE Healthcare Link profiles

CDISC Healthcare Link Chapter (updated from the CDISC Primer)

For information on other CDISC enabling standards used with Healthcare Link see CDISC CDASH, Protocol Representation Model, Study Design Model-XML and ODM.

Download the Healthcare Link User Guide Here.

Challenge: Interoperability between Healthcare and Clinical Research

For years now, researchers have dreamed of accessing the data held within electronic health records (EHRs) and using it for research purposes. And site investigators, who provide the data, have dreamed of a solution that eliminates double data entry of research data.

The CDISC Healthcare Link project began in 2005 and focuses on the mission of interoperability between healthcare (the EHR) and clinical research. The roots of the Healthcare Link project come from the collaborative work of a preceding initiative--the eSDI project, an FDA-CDISC project to encourage the use of eSource data (e.g. EHRs) in regulated clinical research, leveraging CDISC standards.

Solution: Integration Standards to connect disparate systems and data

The solution is here. CDISC and IHE (Integrating the Healthcare Enterprise) have created the inaugural working link between EHRs and clinical research systems. This groundbreaking approach uses the CDISC/IHE developed integration profile,

Healthcare Link Downloads

Healthcare Link Profiles

IHE Retrieve Form for Data Capture Profile

Healthcare Link Introduction Document

eSDI Document

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Retrieve Form for Data-capture profile (RFD), along with CDISC standards to collect relevant data from the electronic health record for critical secondary uses such as Safety Reporting (and Biosurveillance), Clinical Research, and Disease Registries. Reaching through to the EHR in this way to pull key data of interest to clinical research that is already existing in the EHR creates system interoperability and improves data quality and most importantly timeliness of data sharing (key in safety reporting) while alleviating the Investigator site from supporting and entering data in to multiple redundant (from the investigator's perspective) data collection tools for the purpose of the secondary uses.
This integration creates the first 'sticky parts' that connect healthcare and clinical research data workflow.

IHE Retrieve Form for Data Capture Profile

Case Studies

RFD has also been useful in debunking both the overly facile illusions of turnkey access to EHR data, and the overly pessimistic view that such access is twenty years off.

CDISC received a letter of endorsement from EHRA (the Electronic Health Record Association) in 2008 for the development work with IHE and the resulting RDF integration profile.

Connecting Clinical Research and Health Care — The Time Is Now! by Joe Dustin

Contact

For information or inquiries, please contact CDISC Healthcare Link Program Manager, info@cdisc.org