Enabling EHR Use in Clinical Research

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Health information collected in electronic health records (EHRs) can support a variety of initiatives, including clinical research. However, technical standards are needed to enable EHRs to communicate with clinical research applications.

Work from the American National Standards Institute (ANSI) EHR Clinical Research Value Case Workgroup and the Healthcare Information Technology Standards Panel (HITSP) has helped spur the development of numerous standards and profiles that enable interoperability between EHRs and clinical research applications.

Identifying the Standards Requirements

In November 2008 ANSI formed the EHR Clinical Research Value Case Workgroup to promote convergence between clinical research and healthcare. One of the workgroup's charges was to identify priorities for harmonizing the technical standards necessary to ensure interoperability between EHRs and clinical research applications.

The workgroup first identified a set of data elements required by most protocols that are commonly present in EHRs.[1] It then identified the highest priority for EHR-clinical research technical standards: the exchange of this core set of research data elements from EHRs into clinical research systems.

The workgroup limited the scope of the standards harmonization work to three scenarios:

- Data exchange from EHR to sponsor for submission to regulatory, public health, and other agencies
- Exchange of information from EHR to registries or other databases
- Exchange of information from EHR in a distributed network

It also developed a detailed use case for the technical standards, which featured the following scope:

- The ability to communicate study parameters, eligibility information, results, and case report forms within the research community
- The ability to exchange a core data set of de-identified or anonymized information from the EHR for use in clinical research[2]

The Standards and Profiles

The use case then went to the HITSP EHR Clinical Research Tiger Team, which identified the harmonized standards to be developed.

The team created the Clinical Research Interface Specification (IS158), a document that integrates all constructs to meet the business needs of a use case.[3] Constructs specify how to integrate and constrain selected standards and define a road map to use emerging standards and harmonize overlapping standards when resolved.

The specification also focused on the information flows associated with the use case scenarios (see the sidebar below).

Information Flow

The use case identified several detailed information flows for the processes and workflows associated with the three scenarios. The initial Clinical Research Interface Specification addressed a subset of those information flows.

The specifications for the three scenarios included the following events:

Data exchange from EHR to sponsor for submission to regulatory, public health, and other agencies (also referred to as protocol-driven sponsored research scenario)

- A subject is enrolled in a study, and the subject's EHR is updated with a study identifier.
- The case report form from the sponsor's electronic data capture system is presented to the site personnel within the subject's EHR. Data from the EHR or other electronic source system are prepopulated on the CRF. The site personnel complete the CRF with additional data not available in the EHR or source system.
- Diagnostic information such as laboratory or radiology results is sent from the lab or imaging center to either the EHR or directly to the EDC system.

Exchange of information from EHR to registries or other databases

- For retrospective studies EHR data are sent to patient registries or research databases

Exchange of information from EHR in a distributed network

- EHR data are sent to a data repository where they are aggregated and used in longitudinal studies

The specification draws on existing HITSP constructs and communication methodologies and incorporates existing standards from healthcare (such as Health Level Seven and Integrating the Healthcare Enterprise) and clinical research (such as the Clinical Data Interchange Standards Consortium). It identifies a set of standards and profiles that enable EHRs to send data to clinical research systems.

Data Capture Standards

- Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework Supplement, Retrieve Form for Data Capture, Draft for Trial Implementation
- HITSP Retrieve Form for Data Capture Transaction Package (HITSP/TP50)
- HITSP Retrieve and Populate Form (HITSP/CAP135)

These documents support the concept of entering healthcare data once for many purposes. This is accomplished when a form from an outside system, such as a case report form from a sponsor system, is presented within the EHR.

The form is prepopulated with EHR data originating with the care given to the patient. The healthcare provider then enters data required by the outside system that are not available within the EHR.

Workflow Standards

- HITSP Clinical Research Workflow Component (HITSP/C156)

In order for EHR and electronic data capture systems to interact it is necessary to define common identifier variables. This component identifies those variables and provides the mapping between the Clinical Data Interchange Standards Consortium's Clinical Data Acquisition Standards Harmonization (CDASH) and the HITSP Data Dictionary (HITSP/C154). The data elements include:

- Sponsor ID
- Protocol study ID
- Study site ID
- Person ID
- Investigator ID

Data Element Standards

- IHE Quality, Research, and Public Health Technical Framework Supplement Clinical Research Document Trial Implementation Supplement
- HITSP Clinical Research Document Component (HITSP/C151)

The purpose of this IHE profile and HITSP component is to support a standard set of data elements that would be prepopulated in a case report form, a document (electronic or paper) designed to record all of the clinical study data required by the protocol.

The nine content modules identified in the component are in line with CDASH and are included in Health Level Seven's Continuity of Care Document format. The data elements were also updated in the HITSP CDA Content Modules Component (HITSP/C83) and the HITSP Data Dictionary (HITSP/C154).

Interoperability Standards

- HITSP Communicate Lab Results Document (HITSP/CAP127)
- HITSP Communicate Imaging Information (HITSP/CAP128)

These capabilities address the interoperability requirements to support the communication of structured laboratory results and imaging results. These capabilities are not unique to the clinical research application. This is an example of how HITSP constructs are reused for multiple purposes.

Patient Consent Standards

- HITSP Manage Consumer Preference and Consents (HITSP/CAP143)

This capability is used to capture a patient's agreement to a privacy policy, such as an authorization to participate in a clinical study.

The appropriate confidentiality and privacy requirements must be addressed for each of the three scenarios. Only data identified in the protocol should be included in the data exchange. All data extracted from an EHR or other source system must be anonymized before submission to the sponsor's database.

Clinical Research Profile and CCHIT Criteria

Health Level Seven published the Clinical Research Functional Profile in November 2009.[4] The standard defines high-level requirements for using EHR data in regulated clinical research.

The Certification Commission for Health Information Technology is also in the process of identifying clinical research criteria that will supplement the ambulatory care criteria for its EHR certifcation program. The first draft went out for public comment December 2009.

Notes

1. American National Standards Institute (ANSI). "Value Case for the Use of Electronic Health Records in Clinical Research: Process to Support Core Research Data Element Exchange." Available online at http://publicaa.ansi.org/sites/apdl/EHR%20Clinical%20Research/Forms/AllItems.aspx.
2. ANSI. "Detailed Clinical Research Use Case." Available online at http://publicaa.ansi.org/sites/apdl/EHR%20Clinical%20Research/Forms/AllItems.aspx.
3. Healthcare Information Technology Standards Panel. "Clinical Research Interface Specification." Available online at www.hitsp.org/ConstructSet_Details.aspx?&PrefixAlpha=1&PrefixNumeric=158.
4. Health Level Seven. "Functional Profile-Electronic Health Record (EHR)/Clinical Research (CR) Profile." Available online at www.hl7.org/implement/standards/ehrphr.cfm.

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