

Interoperability Scenarios

Care Theme: Clinical Research

Act 23 - Clinical Research

Scenario Primary Goal: To demonstrate improved Clinical Research information exchange processes via use of IHE Profiles and HITSP Constructs.

Key Points:

- The scenario demonstrates how clinical research information can be gathered at Site Investigators' site where patient care is delivered alongside pharmaceutical-sponsored clinical studies. The information so gathered is authenticated at the trial site, forwarded to the sponsor and archived in the site clinical trial document vault as part of the permanent source record of the trial. Below describes the clinical scenario that will be demonstrated
- Electronic form maintained and provided from the sponsor; Provider submits clinical data to the sponsor's EDC

Meaningful Use Relevance

MU Objective 4: Improving Population and Public Health

Clinical Workflow:

A Clinical Research Sponsor has established an Electronic Data Capture system (EDC) for documenting clinical trial activities. Functionality for retrieval of electronic forms (RFD), their content, format and archive transaction specifications to support pre-population and workflow data (CRD) are configured. This leverages routine clinical content that the EHR may generate as part of clinical care information exchanges. The electronic form (eCRF) is used to collect study data from the clinician through their own EHRs. Electronic forms are created, managed, and versioned by the Form Manager system.

Patient care is delivered side-by-side with clinical research activities at the physician practice. The Electronic Health Record system (EHR) which can provide only a portion of the data for the study is used to supplement information gathered through the Case Report Form (CRF) for the specific study. The clinician initiates the RFD transaction (Form Manager) to retrieve the appropriate data capture form. The form is pre-populated with the relevant data from the information obtained from the EHR and is displayed within the EHR user interface. The clinician then reviews and verifies the data in the form, completes the form, and submits the data to the form receiver.

When the clinician selects the submit button on the form, the EHR system submits the completed form to the EDC system using RFD. A copy of the document is archived in the site clinical trial document vault as part of the permanent source of record of the trial.

Care Scenario Steps	Care Setting From	Care Setting To	IHE Profiles*	Title	HITSP Constructs	Title
23-1: A Clinical Research Sponsor creates electronic forms that are created, managed, and versioned by the Form Manager system. The data will be collected through Site Investigators' own EHR systems. The form is also configured to enable form pre-population by leveraging routine clinical content that the EHR may generate as part of clinical care info exchanges.	Clinical Research Sponsor	Provider's Office	RFD (ITI) CRD (QRPH)	Retrieve Form for Data Capture Clinical Research Data Capture	HITSP/CAP135 HITSP/TP50 HITSP/C151	Retrieve and Populate Form Retrieve Form for Data Capture Clinical Research Document
23-2: Clinical research instructions (protocol definitions) are retrieved from the Clinical Trial Management System (CTMS) by the EHR system. A new patient presents and based on the established criteria is selected as a clinical study participant. Upon linking the patient to the study, the information is sent to the CTMS, which returns the enrollment ID. Optional step.	Provider's Office	Clinical Research Sponsor	RPE (QRPH)	Retrieve Protocol for Execution		
23-3 The clinical study participant has arrived for a visit and the clinician has documented assessments and procedures in the patient's chart in the EHR system (the Form Filler). The research coordinator or clinician initiates the RFD transaction to retrieve the appropriate data capture form. The form is pre-populated with the relevant EHR data and displayed within the EHR user interface. The user reviews and verifies the data in the form, completes the form and submits the data to the Form Receiver and Archiver.	Provider's Office	Clinical Research Sponsor	RFD (ITI) CRD (QRPH)	Retrieve Form for Data Capture Clinical Research Data Capture	HITSP/CAP135 HITSP/TP50 HITSP/C151	Retrieve and Populate Form Retrieve Form for Data Capture Clinical Research Document
23-4: When the user selects the submit button on the form, the EHR system submits the completed form to the system responsible for aggregating study or registry data from multiple sites (Form Receiver). The form simultaneously submits to the site's clinical study data archive (the Form Archiver).	Provider's Office	Clinical Research Sponsor	RFD (ITI)	Retrieve Form for Data Capture	HITSP/CAP135 HITSP/TP50	Retrieve and Populate Form Retrieve Form for Data Capture
23-5: The data in the investigator's site archive (not the EHR) is now established as the electronic source record for the study and the data sent to the form receiver is eSource data. Documentation of lab procedures is included in this initial data submission and the record is then updated when lab results become available.	Clinical Research Sponsor	Clinical Research Sponsor				