

## Interoperability Scenarios

### Care Theme: Clinical Research

**Act 28 - Adverse Event Reporting – Physician Office:** The scenario demonstrates how drug utilization and adverse reaction information are exchanged and used to expediently trigger action by the Food and Drug Administration (FDA) to support drug safety in the industry.

**Scenario Primary Goal:** To demonstrate drug safety reporting process.

### Key Points

- Electronic form maintained and provided from the manufacturer or drug safety intermediary
- Provider submits clinical data to a drug safety registry
- The Nationwide Health Information Network (NHIN) has capabilities to support drug safety through the exchange of data between drug safety oversight entities and the FDA
- The demonstration will use IHE Profiles and HITSP constructs to demonstrate expedient drug safety reporting from the provider's office to the FDA.

### Meaningful Use Relevance

#### MU Objective 4: Improving Population & Public Health

#### Clinical Workflow:

The manufacturer or regulatory agency has established an electronic form for drug safety reporting. The electronic form is used to collect adverse drug event data from the clinician during documentation in the patient's EHR. The form is also configured to enable pre-population of the form by leveraging routine clinical content that the EHR may generate as part of clinical care information exchange. Electronic forms are created, managed, and versioned by the Form Manager system.

In the normal course of patient care a clinician suspects that the patient suffers from an adverse reaction to a commercially marketed drug. The clinician then initiates the transaction (Form Manager) to retrieve the appropriate data capture form. The form is pre-populated with the relevant data 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 it to the form receiver at a drug safety intermediary.

When the clinician selects the submit button on the form, the EHR system sends the completed form to the drug safety intermediary. The intermediary, a drug safety registry, reviews and codes the event, and forwards it to the manufacturer of record and to the regulatory authority. The federal agency receives the completed form from the drug safety intermediary and initiates actions to announce the problem with the drug to the health care industry.

Care Scenario Steps:	Care Setting From	Care Setting To	IHE Profiles*	Title	HITSP Constructs	Title
<b>28-1</b> Electronic forms for capture of drug safety reporting are created, managed, and versioned by the Form Manager system. The clinician then initiates the Retrieve Form for Data Capture (RFD) transaction (Form Manager) to retrieve the appropriate data capture form.	Manufacturer / Regulatory Agency	Provider's Office	RFD (ITI)	Retrieve Form for Data Capture	HITSP/CAP135 HITSP/TP50	Retrieve and Populate Form  Retrieve Form for Data Capture
<b>28-2</b> The form is pre-populated with the relevant data from information obtained from the EHR. The clinician then reviews and verifies the data in the form, completes the form, and submits it to the form receiver at a drug safety intermediary	Provider's Office	Drug Safety Registry	RFD (ITI)	Retrieve Form for Data Capture	HITSP/CAP135 HITSP/TP50	Retrieve and Populate Form  Retrieve Form for Data Capture
<b>28-3</b> The intermediary, a drug safety registry, reviews and codes the event, and forwards it to the manufacturer of record and to the regulatory authority.	Drug Safety Registry	FDA	RFD (ITI)	Retrieve Form for Data Capture	HITSP/CAP135 HITSP/TP50	Retrieve and Populate Form  Retrieve Form for Data Capture