



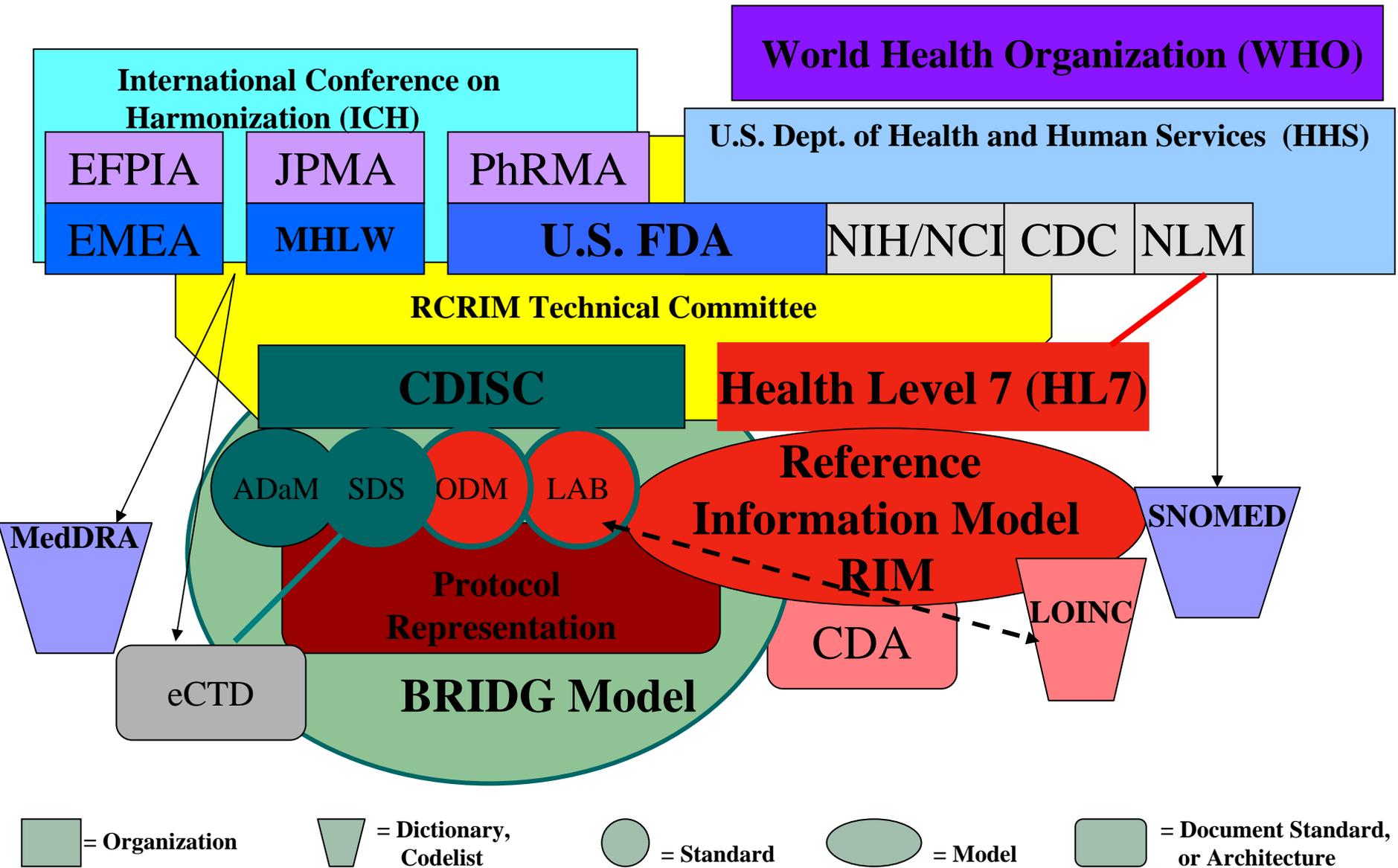
Setting the  
Global Standard  
for Clinical Data

A Lifecycle Approach to Safety:  
Leveraging the Electronic Health Record  
for Adverse Event Reporting,  
and Clinical Research

**CLINICAL DATA INTERCHANGE  
STANDARDS CONSORTIUM**

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CDISC Board of Directors Chair-Elect,  
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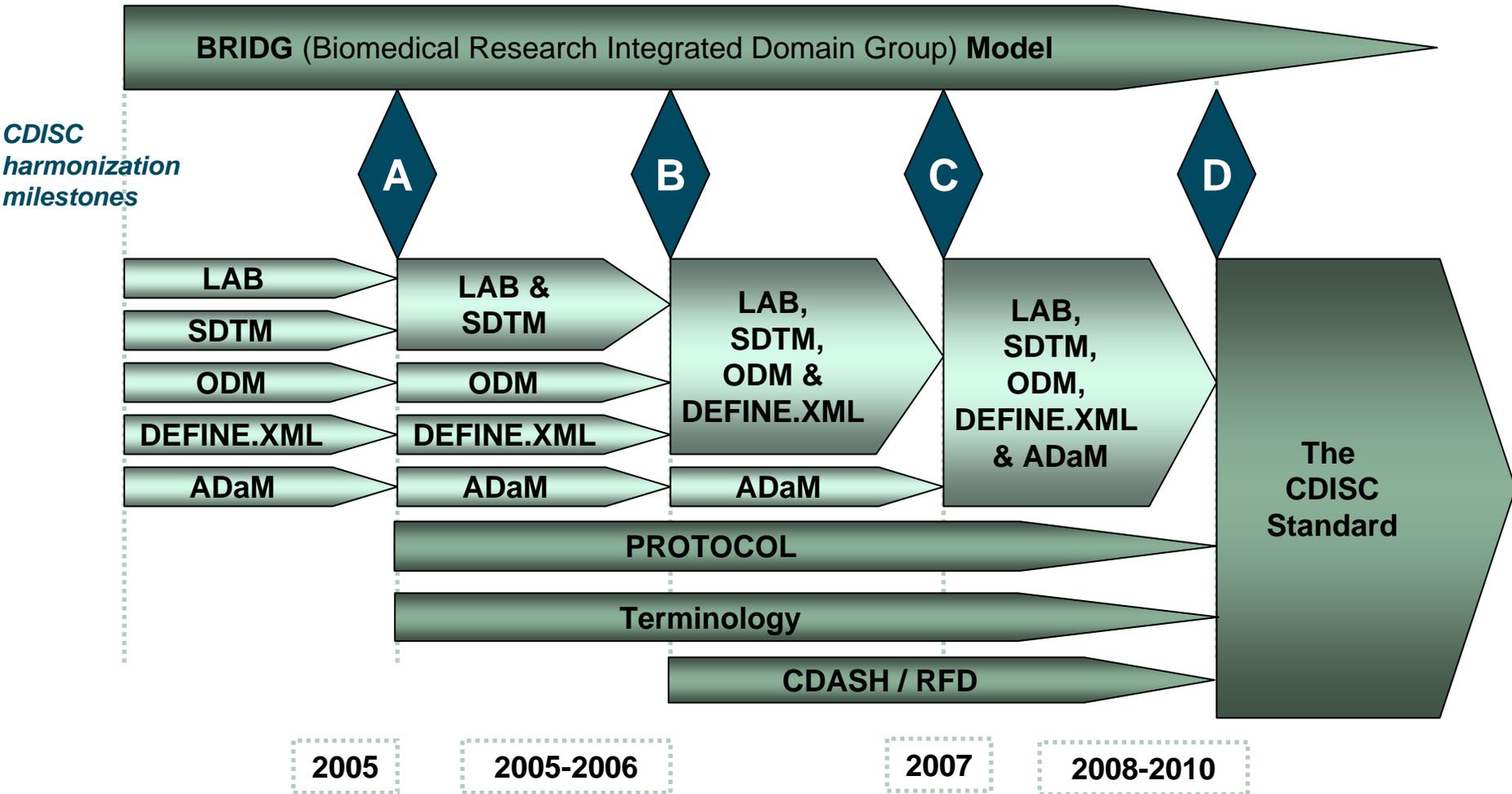
# CDISC in the “World of Standards” 2007



# Standards to Support Safety Surveillance – Adverse Event Reporting

- **CDISC Study Data Tabulation Model (SDTM)**
  - CDISC Operational Data Model xml schema
  - HL7 V3 message in progress
  - Case Report Forms can use SDTM-based data collection formats
  - Adverse events during clinical studies
- **ICH E2B = Individual Case Safety Report (ICSR)**
  - HL7 V3 Message
  - Post-marketing adverse events on approved products
- **Federal AE Task Force Basal Adverse Event Report (BAER)**
  - based on ICSR/ICH E2B(AHRQ, CDC, NIH, VA, DoD, FDA, OHRP)
  - Reporting to Institutional Review Boards and other Safety Surveillance
- **Note:** These 3 standards are currently being harmonized within the BRIDG.

# CDISC Technical Roadmap





Setting the  
Global Standard  
for Clinical Data

**RFD: A Useful Approach for Data  
Capture in a Sentinel Network**

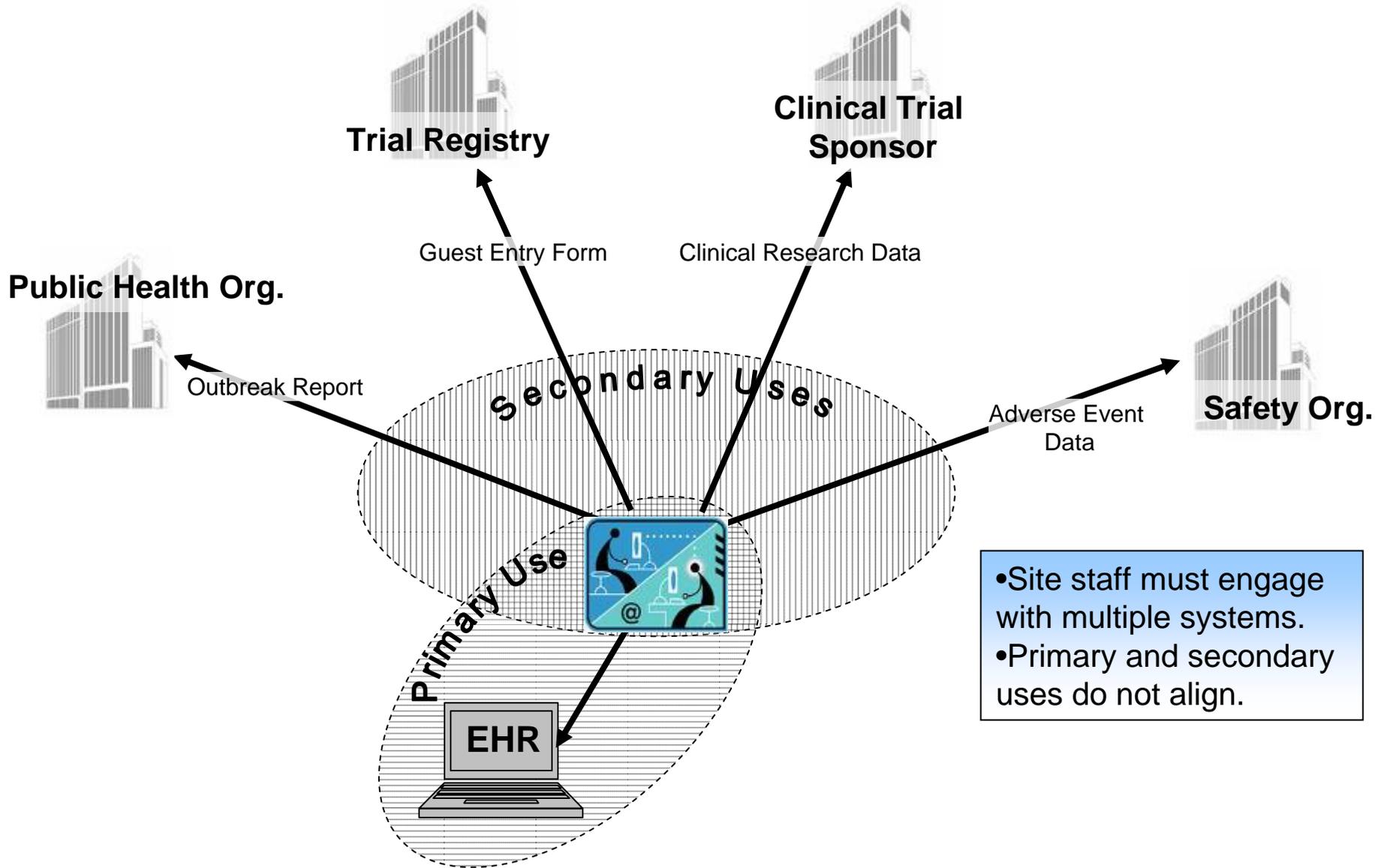
**CLINICAL DATA INTERCHANGE  
STANDARDS CONSORTIUM**

**Landen Bain  
CDISC Liaison to Healthcare**

# Retrieve Form for Data-capture

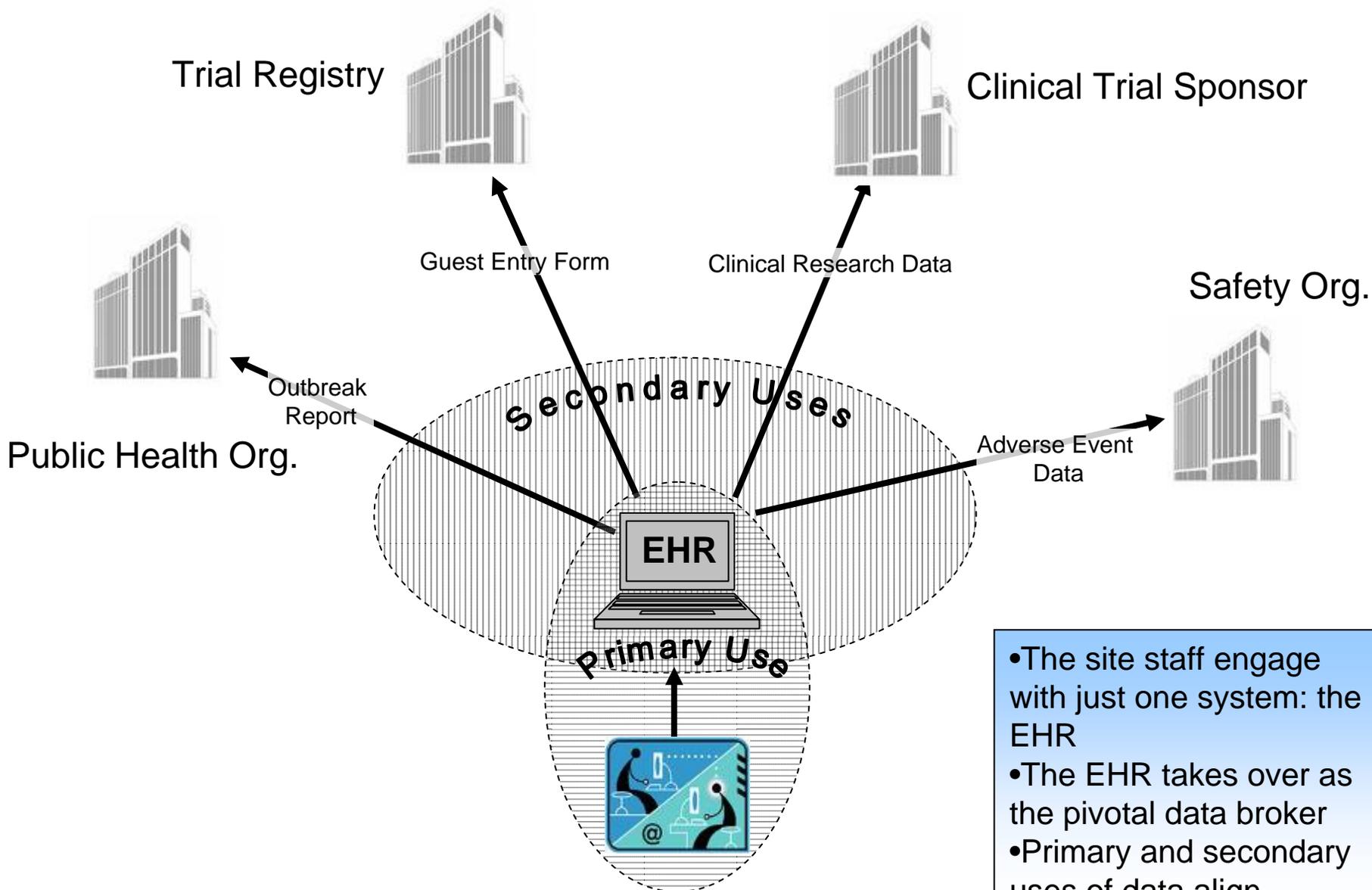
- Retrieve Form for Data Capture (RFD), is an integration profile jointly developed by CDISC and IHE, which addresses the problem of integrated data capture for patient care and clinical research.
- RFD addresses question 2: “How can post-market medical product safety data collection be integrated into the workflow of clinical practice at the point-of-care while avoiding the imposition of undue burdens on health care practitioners, patients, and health care institutions?”
- RFD is in the spirit of question 9: a “worthwhile small-scale projects that could be readily achievable”.

# Before RFD



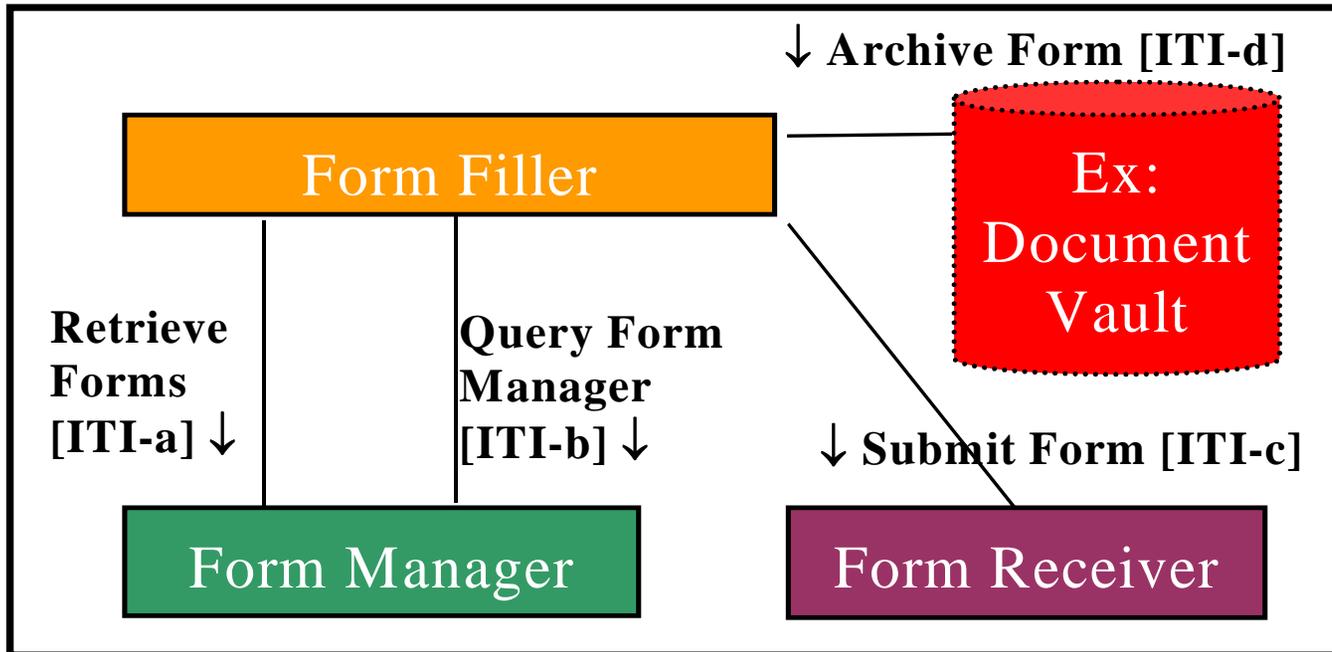
- Site staff must engage with multiple systems.
- Primary and secondary uses do not align.

# After RFD



- The site staff engage with just one system: the EHR
- The EHR takes over as the pivotal data broker
- Primary and secondary uses of data align

# RFD Actors and Transactions



RFD uses the XForms standard to present data capture forms from external agencies to an EHR.

# Five RFD Scenarios shown at HIMSS 07

**Drug  
Safety**



**Clinical  
Trial: Lab &  
Image Data**



**Clinical  
Trial: Visit  
Workflow**



**Disease  
Registry**



**Bio-  
Surveillance**



The Drug Safety and Bio Surveillance scenarios have particular application to the Sentinel Network.

# Biosurveillance Scenario

## *Standardizing and Facilitating Data Collection for Enhanced Biosurveillance*

### Roles:

**SAIC with CDC**

**Cerner Millennium™**

**Allscripts Touchworks**

**SAS**

**IBM**

**University of Washington**

Scenario developer and orchestrator

EHR system at hospital

EHR system at physician practice

Forms archiver

Forms manager

State Health Department

# Drug Safety Scenario

## *Supporting Physician Reporting of Adverse Reactions and Public Health Threats*

### Roles:

**Pfizer Inc.**

**Allscripts TouchWorks™**

**Sentrx**

**Relsys Argus Safety™**

**SAS**

Pharmacovigilance Scenario Sponsor

EHR system at Clinical Site

Repository for adverse events form

Safety System used by Sentrx

Forms archive for Clinical Site