



43rd
Annual Meeting



Atlanta - 2007

Retrieve Form for Data-capture:

*An Integration Profile to Enable
Electronic Health Record (EHR)
Capture of Clinical Trial Data.*

Landen Bain
CDISC Liaison to Healthcare



Point of Departure

“Data are not just waiting to be gathered, collected or recorded. Data are created.”

- Paul Taylor, *From Patient Data to Medical Knowledge*, Blackwell Publishing 2006, p. 12.



Retrieve Form for Data-capture

- **Retrieve Form for Data-Capture**, is an *integration profile* jointly developed by **CDISC** and **IHE**, which enables data capture for clinical research, drug safety, and other purposes within an EHR session.



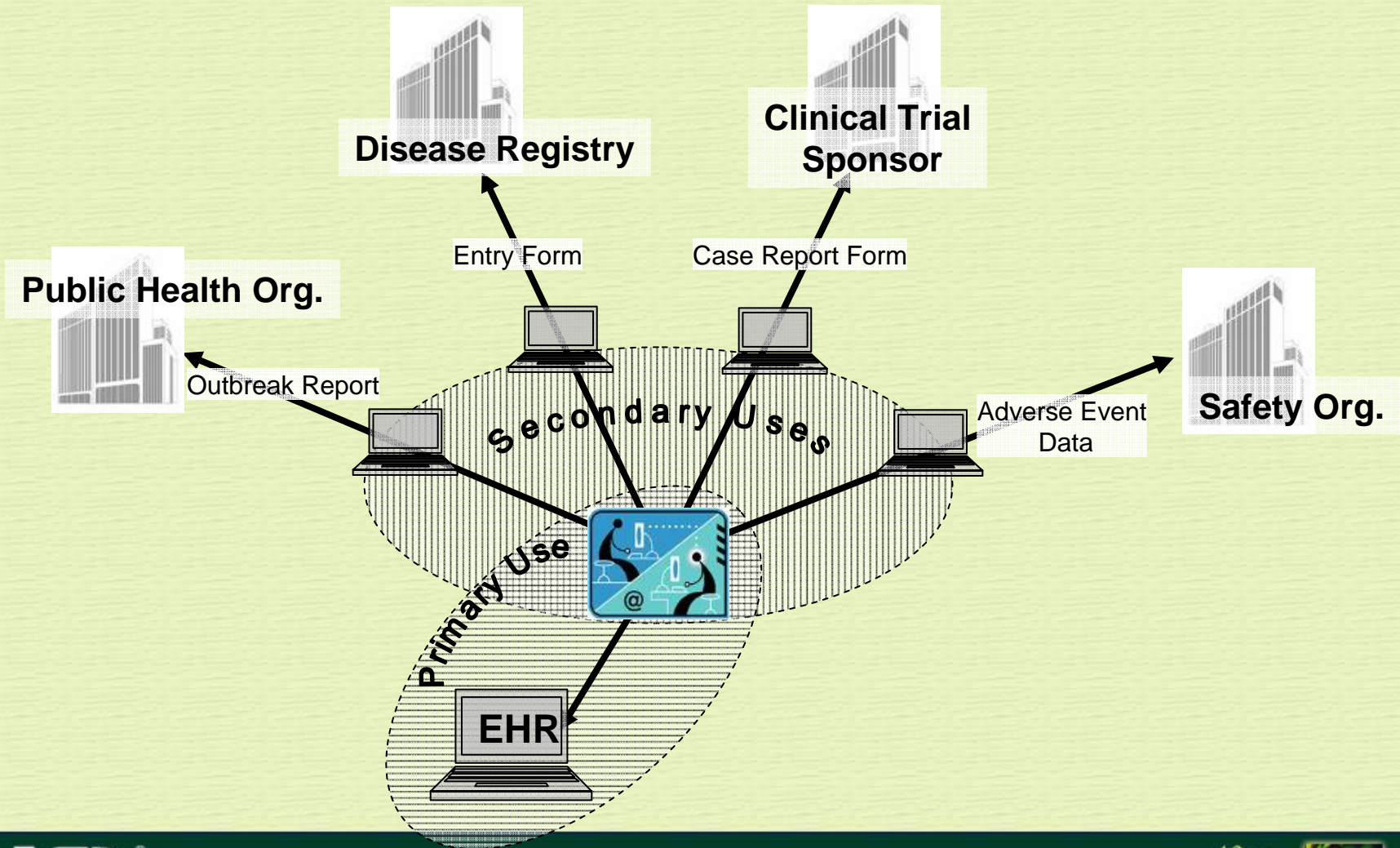
CDISC & IHE

IHE --

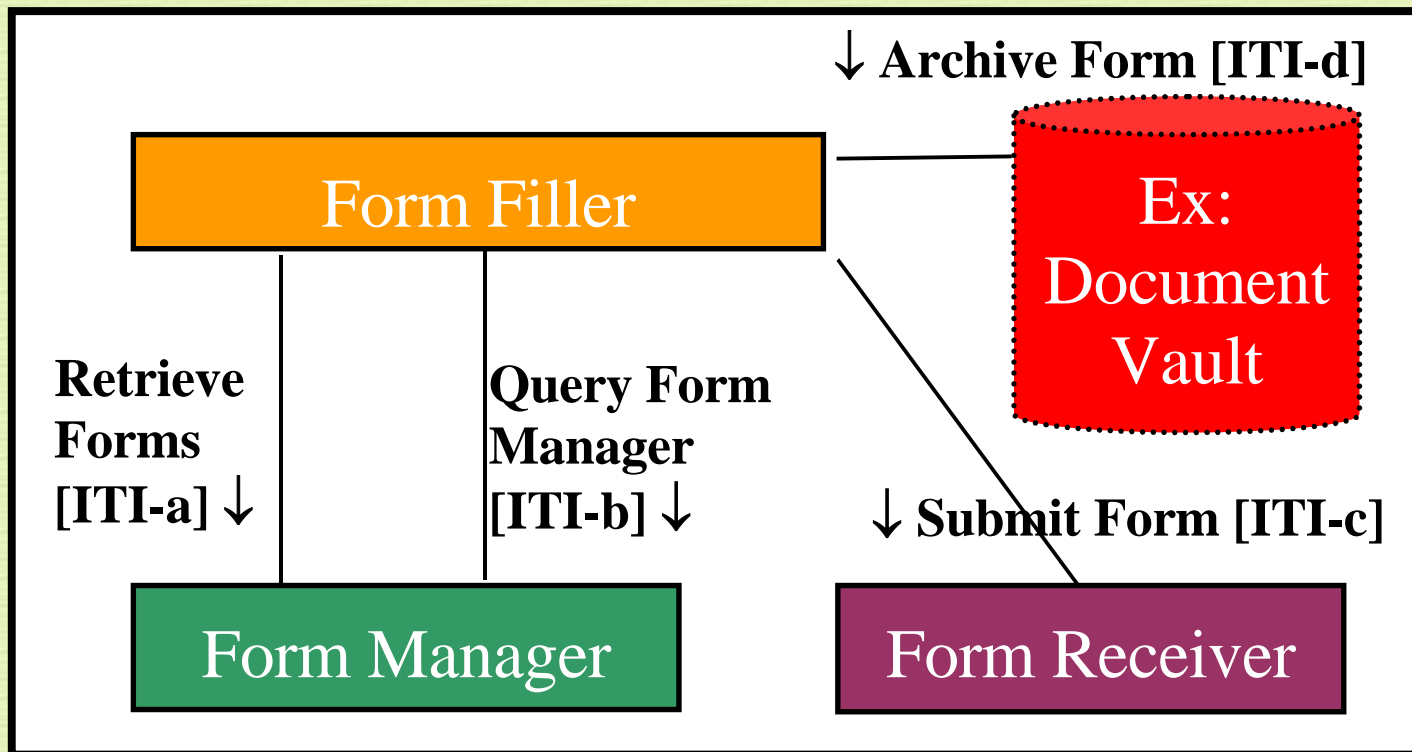
- **a collaborative response to healthcare information technology market requirements for system integration.**
 - **Develop standards-based implementation specifications called *profiles*.**
 - **Useful subsets of one or more standards**
 - **Tested at *Connectathons***
 - **Demonstrated at *HIMSS, RSNA, and ACC* shows**



Plight of the Site



Retrieve Form Architecture



Problem Focus

- Retrieve form is *problem focused*:
 - Address the multiple data entry systems at sites.
- Retrieve form is *experimental* :
 - Introduce the technique into a site and observe what happens.
- Retrieve form is *developmental*:
 - Start simple and iterate improvements.



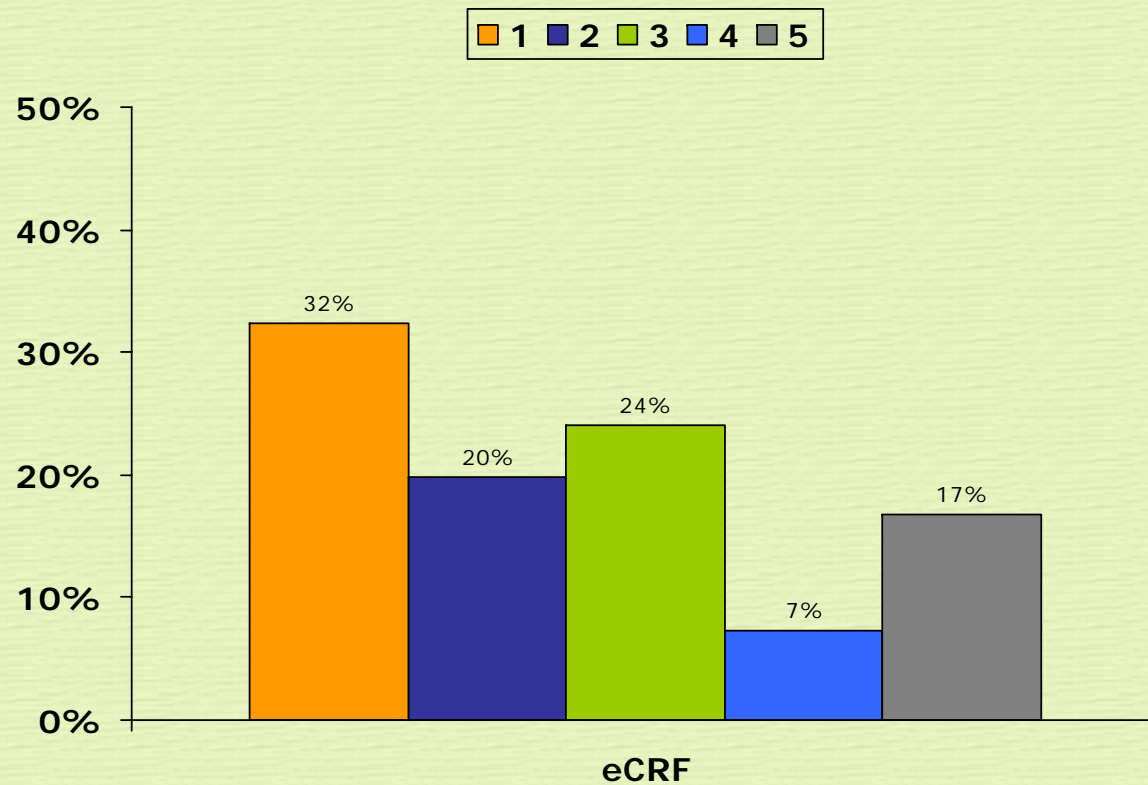
The Problem is Obvious



AP / Damian Dovarganes



17% of Sites have 5 or more data capture systems



Root Cause

- EDC was introduced to the sites without adequate regard for the existing Information eco-system.



CDISC and IHE

PROUDLY PRESENT

New Directions

Life Sciences Bridging to Healthcare

**Drug
Safety**

Sponsored by



**Clinical
Trial: Lab &
Image Data**

Sponsored by



**Clinical
Trial: Visit
Workflow**

Sponsored by



**Disease
Registry**

Sponsored by



**Bio-
Surveillance**

Sponsored by

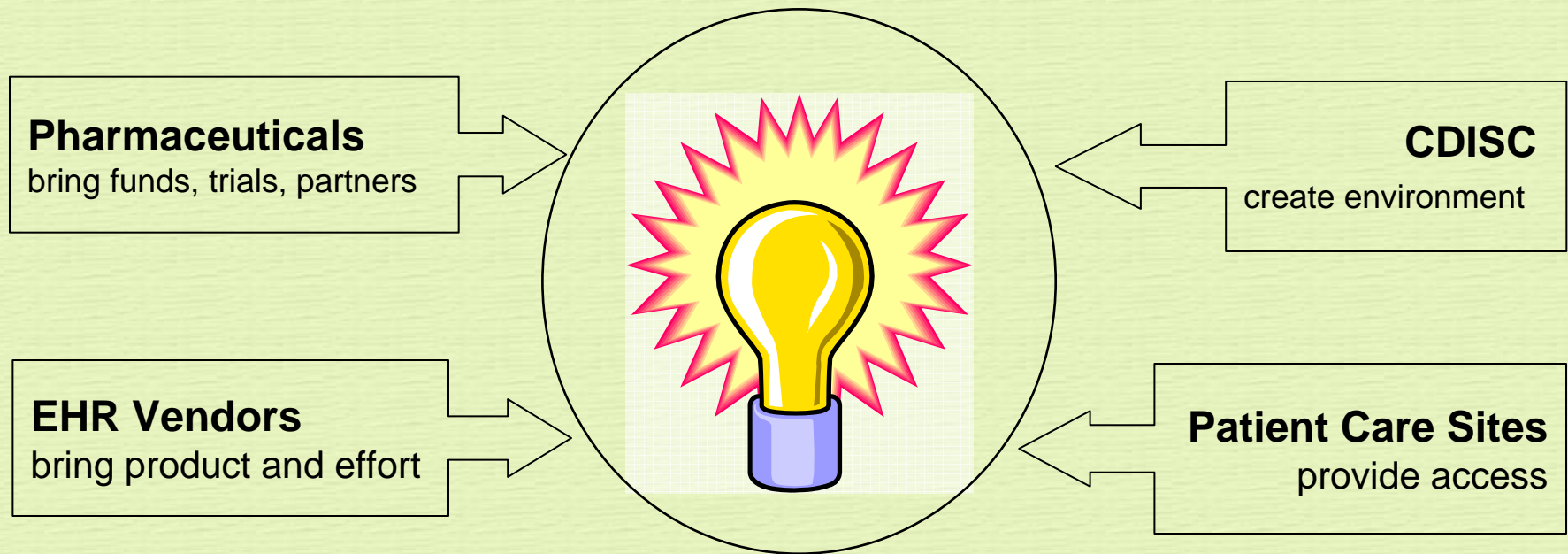


Profile Expansion

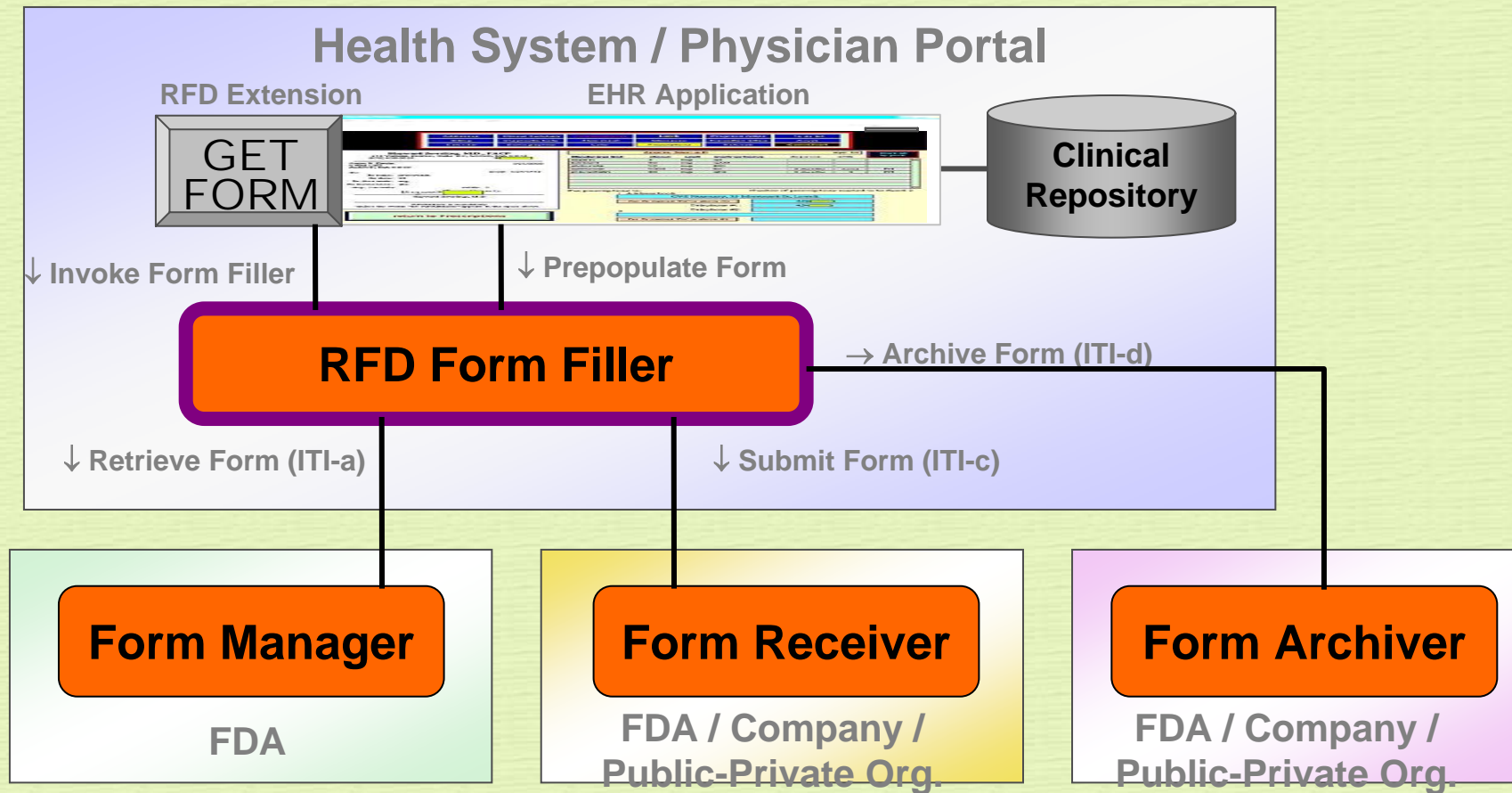
- Goals: auto-population of form, data clarification.
- Infrastructure work (IHE - ITI)
 - Add data clarification transaction
 - Beef up security
 - Formally test @ Connectathon
- Content work (IHE - PCC)
 - PV: ICSR, BAER
 - CDASH will define data elements for electronic case report forms.
 - CDISC's Terminology project will define code lists for standard data elements.
 - Query for Existing Data will enable data extraction without a form.



Real World Pilots



Pfizer Pilot



IHE



CDIS
C

ONLY CONNECT

lbain@cdisc.org

