

Retrieve Form for Data-capture: *An Integration Profile to Enable Electronic Health Record (EHR) Capture of Clinical Trial Data.*

And pharmacovigilance data

And public health data

And quality reporting data

And registry reporting data

Landen Bain
CDISC Liaison to Healthcare

“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**, 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

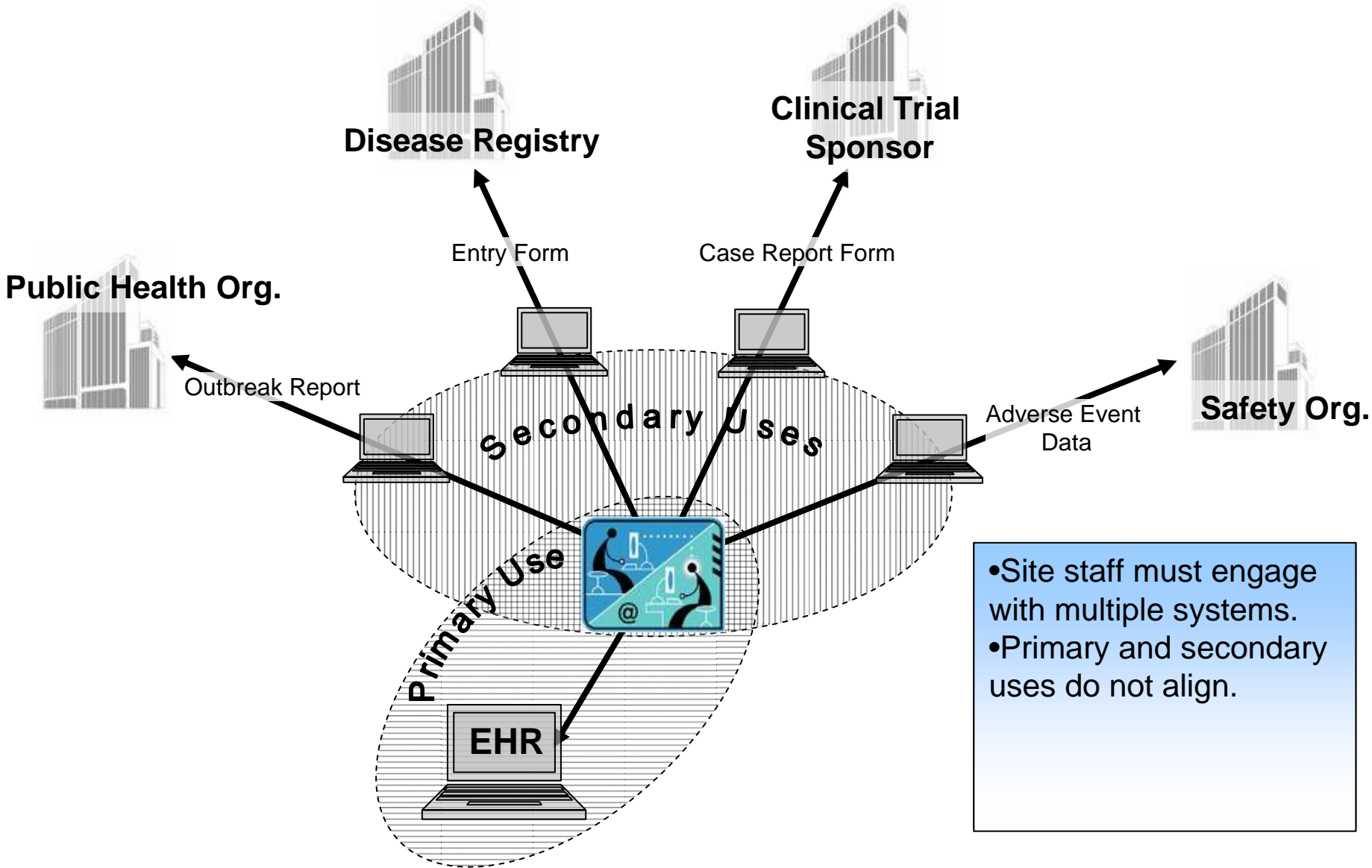
The mission of CDISC is to develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare.

IHE

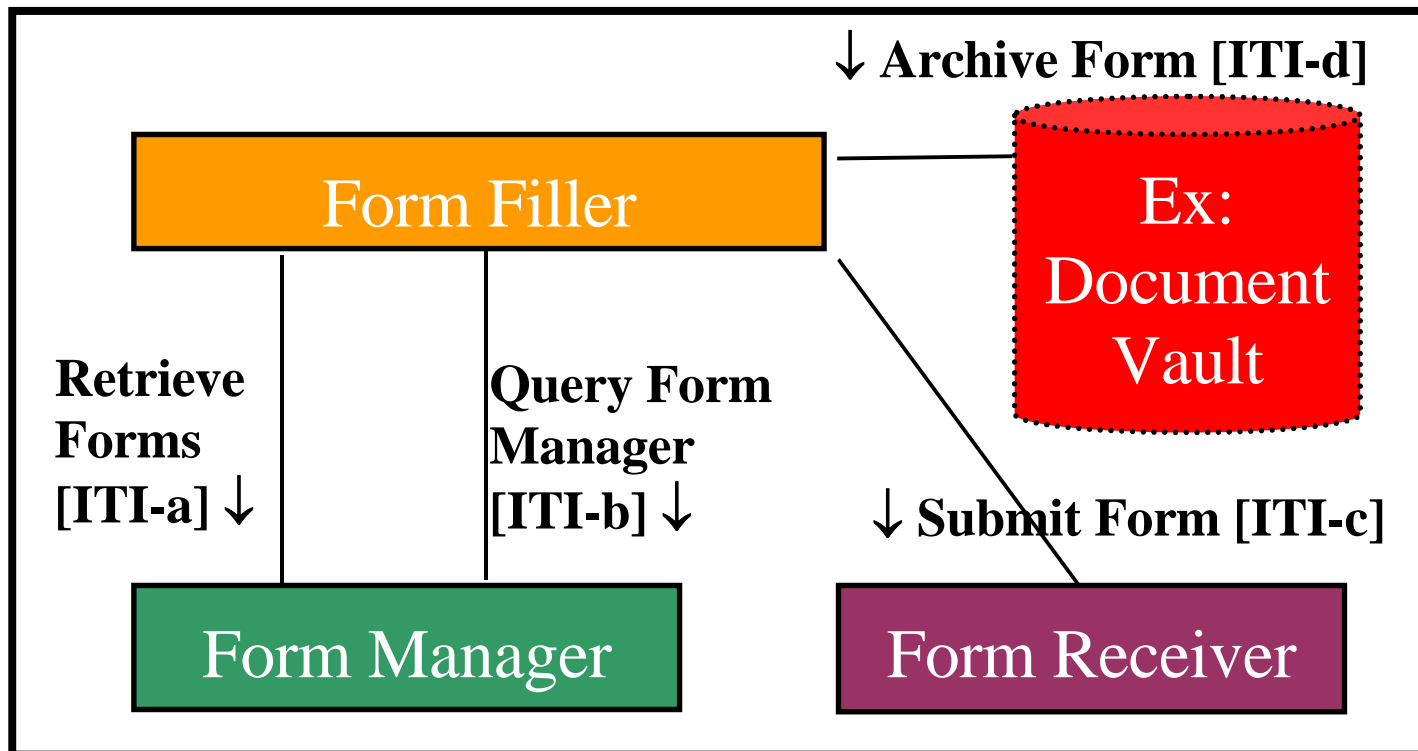
is a collaborative response to healthcare information technology market requirements for system integration.

Develop standards-based implementation specifications called *profiles*.

- **Useful subsets of one or more standards**
- **Tested at *Connectathons***
- **Demonstrated at *HIMSS, RSNA, and ACC* shows**



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



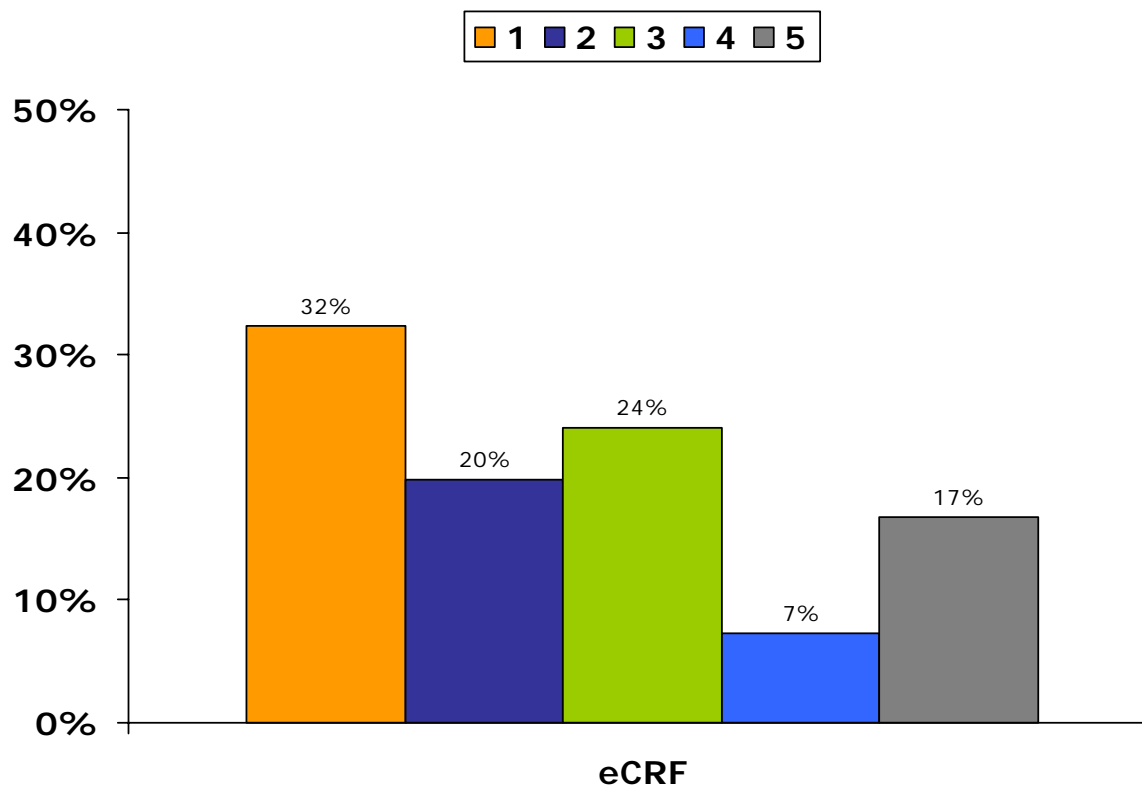
RFD uses the XForms standard to present data capture forms from external agencies to an EHR.

- Retrieve form takes on a single, well known problem, the ‘plight of the site’: multiple data entry systems.
- Retrieve form takes an experimental approach: Introduce the technique into a site and observe what happens.
- Retrieve form takes a developmental approach: a ‘disruptive innovation’.

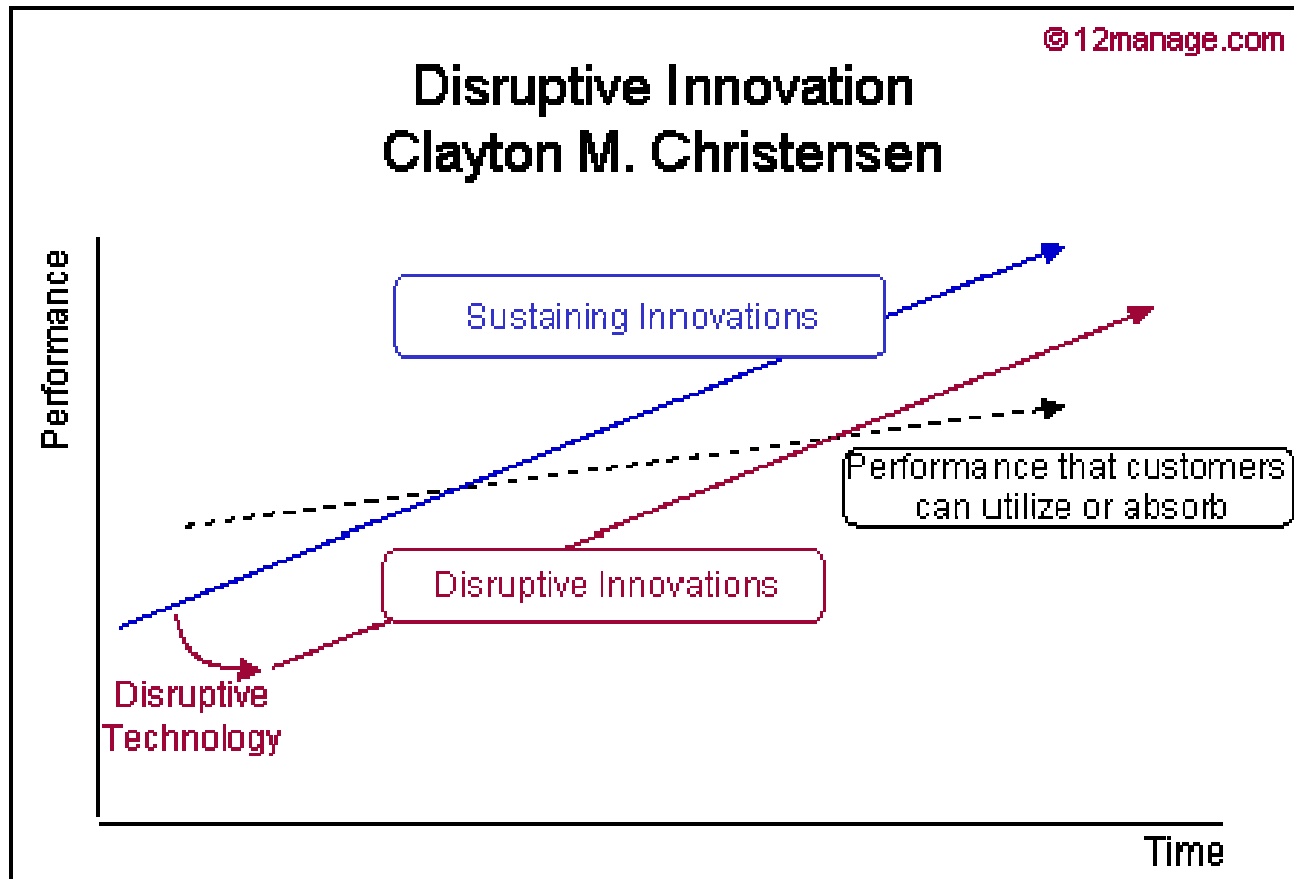


AP / Damian Dovarganes

**2/3 of sites have more than one data capture system.
17% have 5 or more!**



“Two paradigmatic trajectories of progress interact.”



CDISC and IHE

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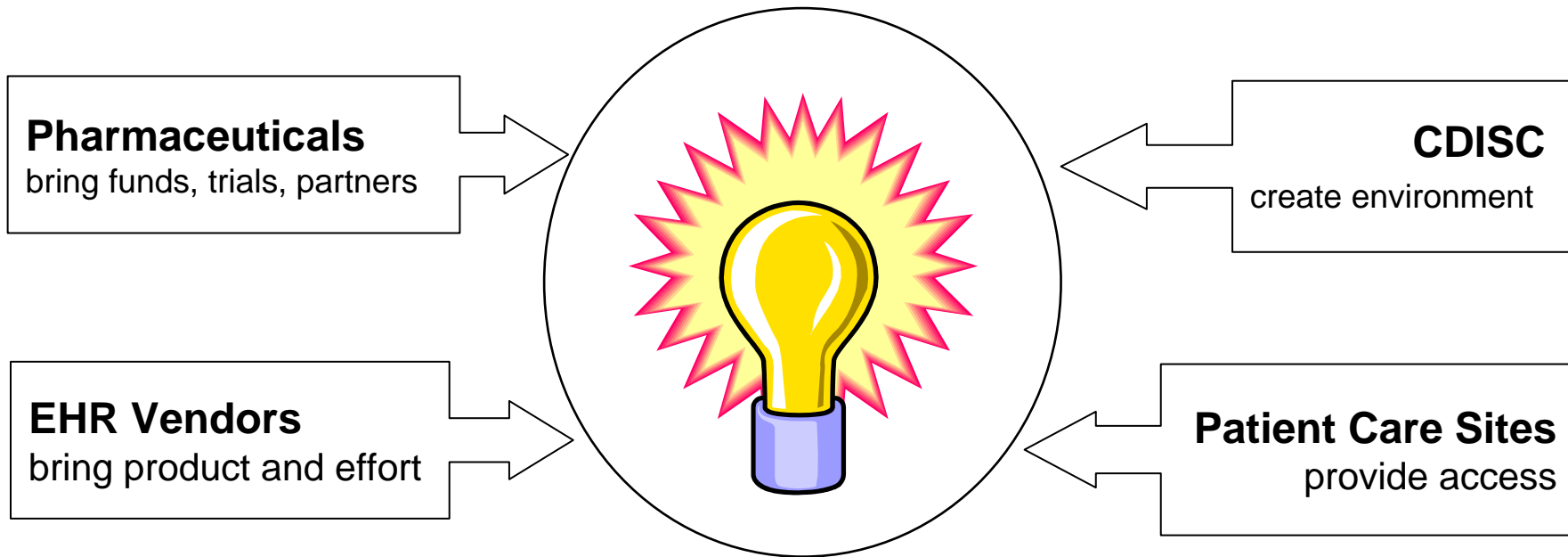


**Bio-
Surveillance**

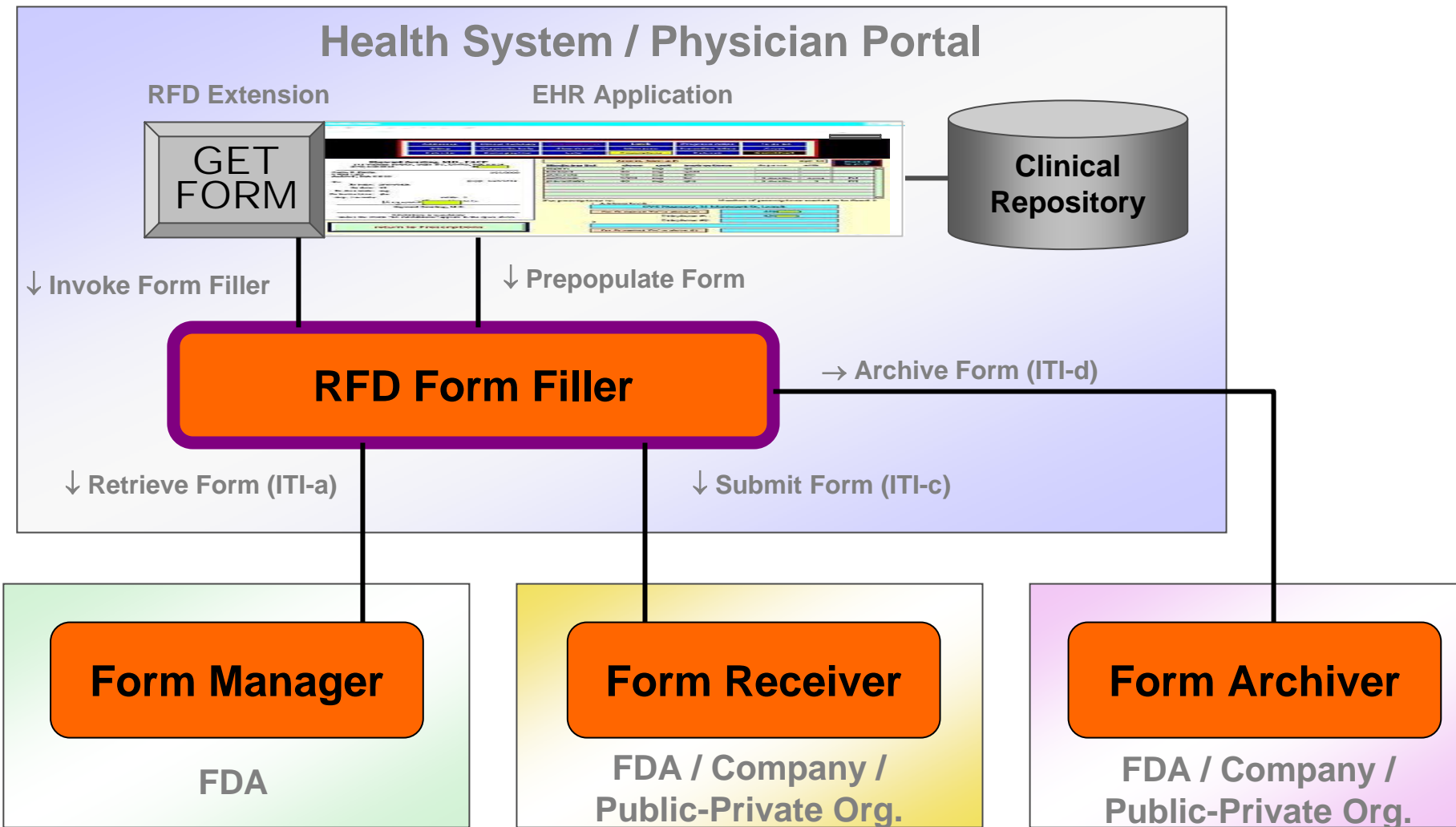
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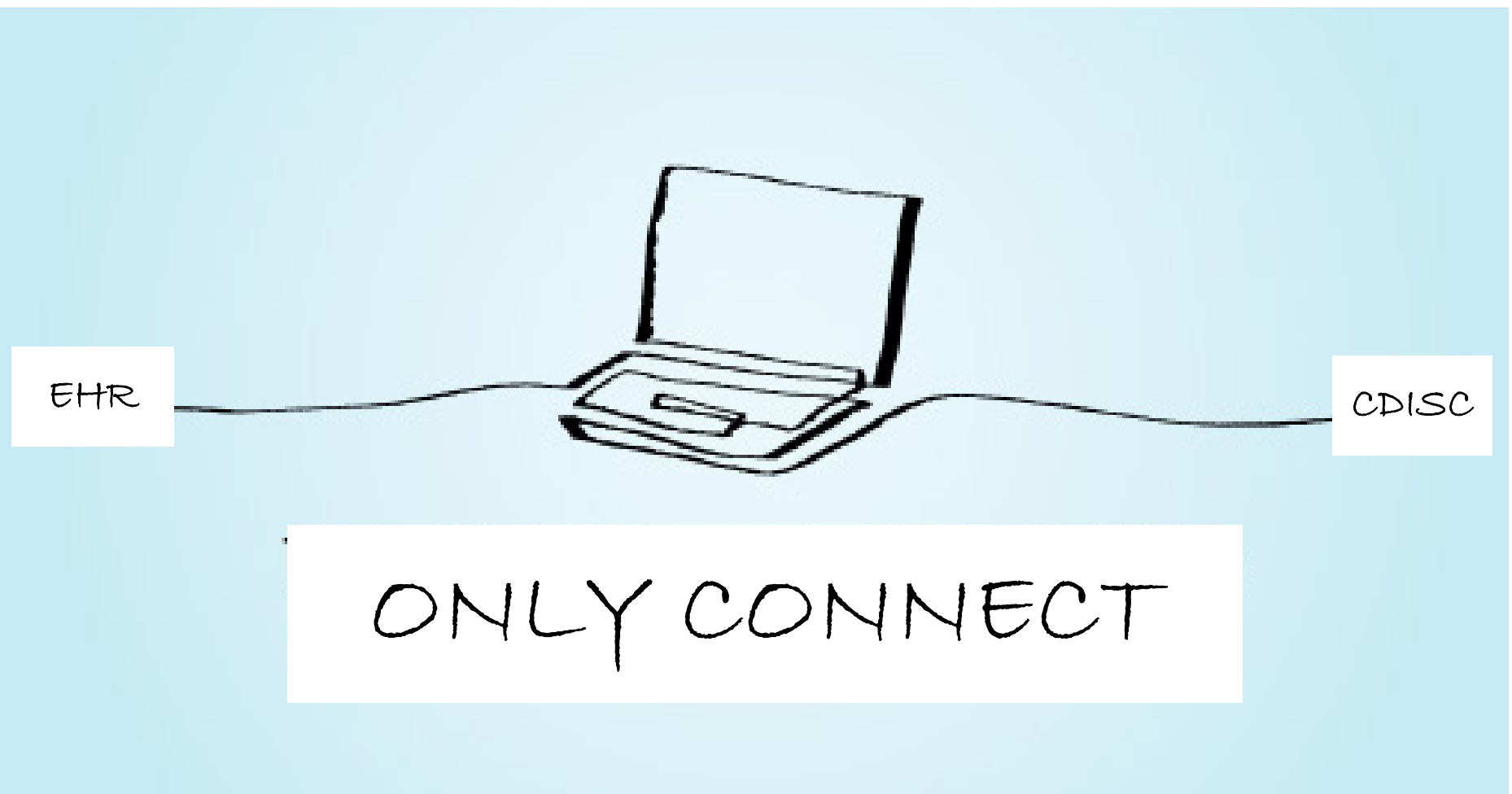


- Goals: auto-population of form, data clarification.
- Infrastructure work (ITI)
 - Add data clarification transaction
 - Beef up security
 - Formally test @ Connectathon
- Content work (PCC)
 - PV: ICSR, BAER
 - CDASH will define data elements for electronic case report forms.
 - CDISC's Terminology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



- EHR offers two assets to PV:
 - Existing data;
 - Eyeballs.
- A tension exists between these assets: “A wealth of information creates a poverty of attention.”
- The scarce asset to be used wisely is the clinical staff’s attention.





lbain@cdisc.org