

FDA Sentinel Network Hearing
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***Incorporating postmarket medical product
safety data collection into the clinical practice
workflow at the point-of-care***

**The Retrieve Form for Data Capture profile in
Pharmacovigilance**



Michael A. Ibara
Head of Pharmacovigilance Information Management
Safety and Risk Management

RFD and product safety: Initial Work



- ◆ Demonstrate the technical feasibility of providing a seamless way for physicians to submit high-quality adverse event reports
- ◆ Demonstrate the use of the EHR as a primary data source
- ◆ Stimulate additional thought / work in this area

RFD Pharmacovigilance Demonstration (HIMSS)



◆ Scenario

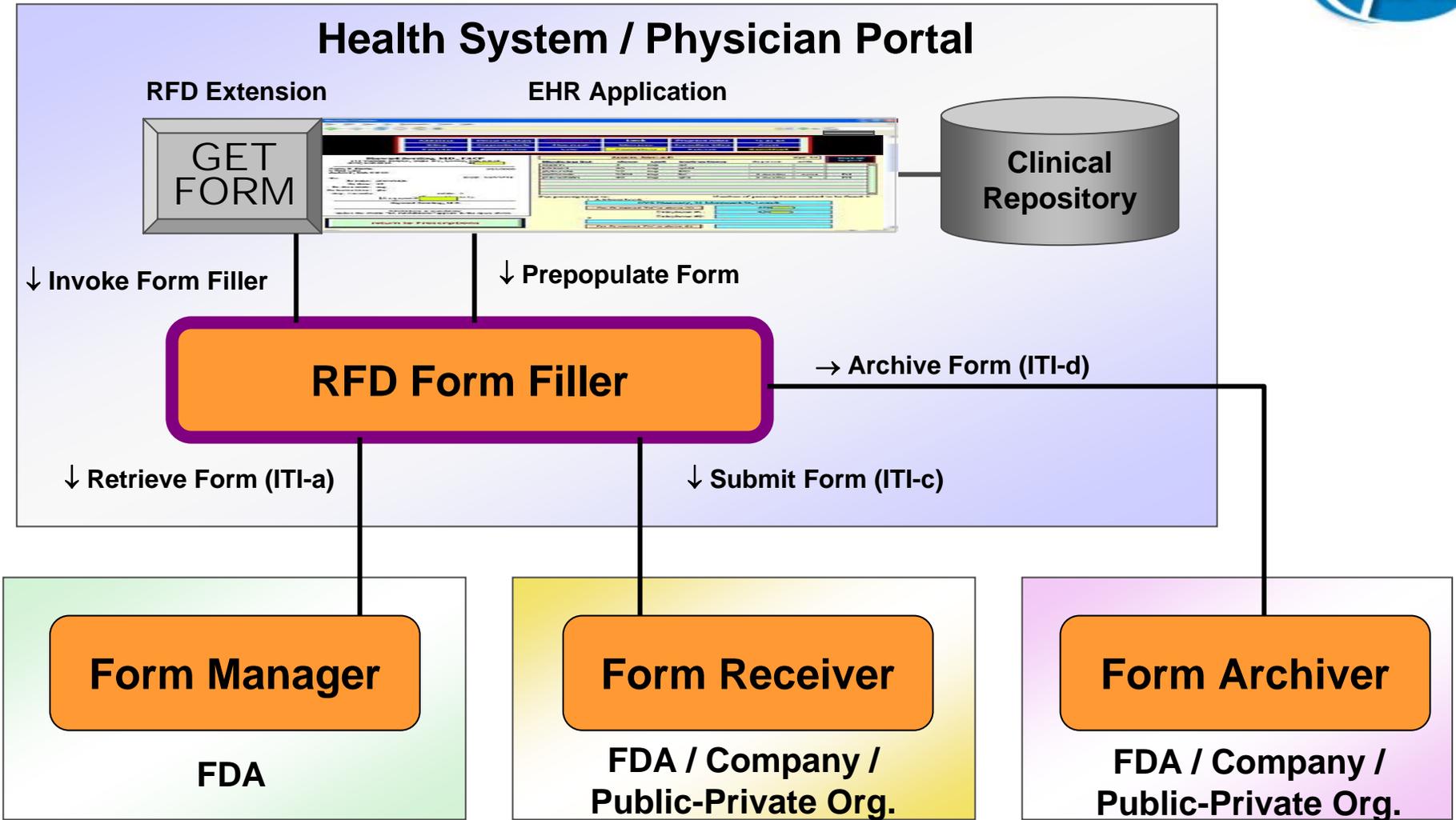
- Physician/investigator, using an EHR, discovers a suspected adverse drug event and summons a data-capture form; provides information on the event; submits form electronically to the manufacturer and Regulator(s)

◆ Team: Pfizer, Sentrx, Allscripts, Relsys

◆ Standards: XForm, CDISC ODM, HL7 ICSR / E2B(M/R3)

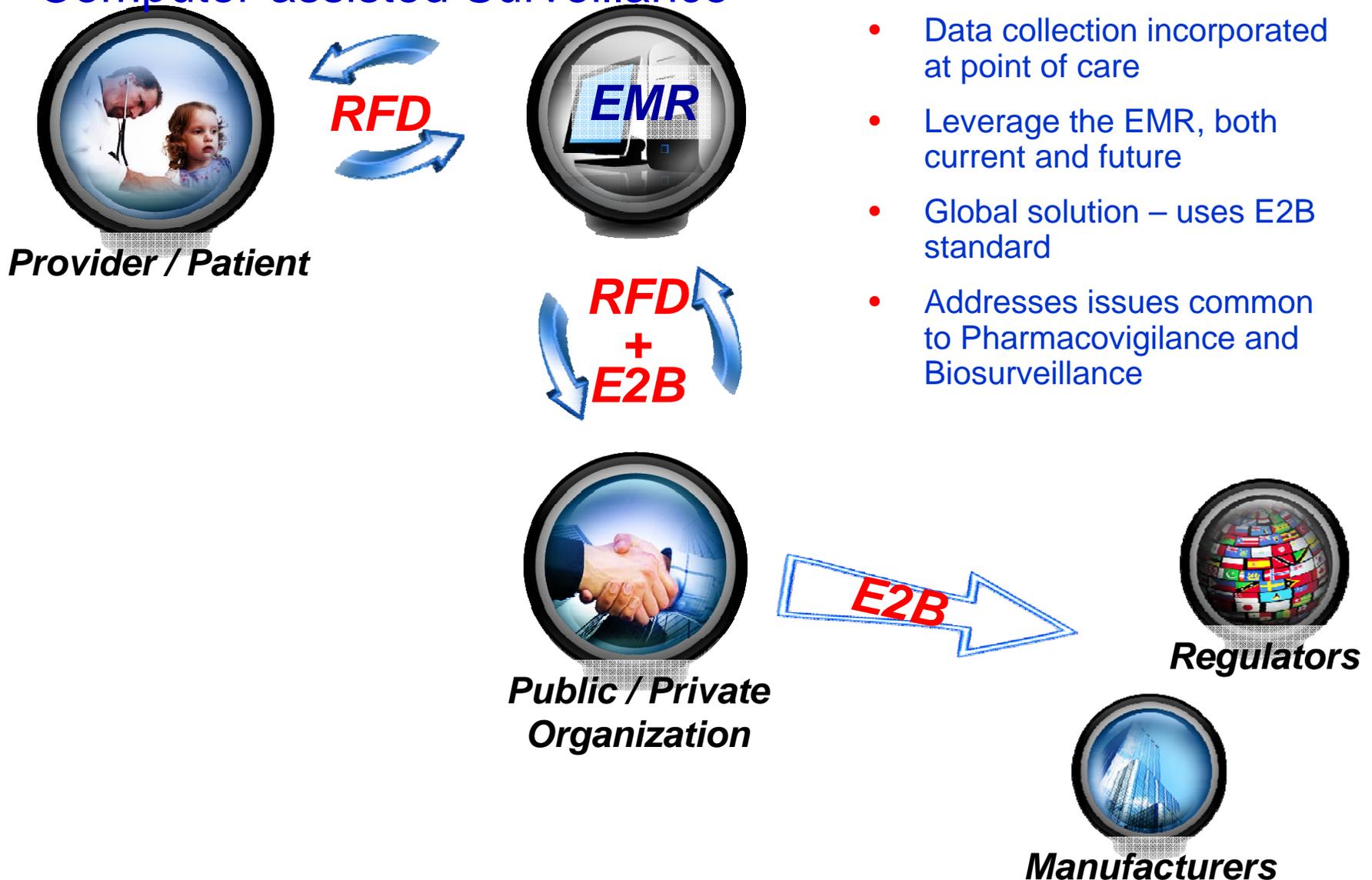
- Mapped CDISC Operational Data Model (ODM) to the ICH E2B format
- *Enables seamless transmission of safety event from collection to reporting*

RFD's flexibility



Vision: RFD as Part of a Sentinel Network

Computer-assisted Surveillance



Next Steps



- ◆ Real world experience
- ◆ Development of user interface, prepopulation of complete clinical data
- ◆ Study of actual burden, reporting rates, report data quality, etc.

To be effective...



“A [system] design...suitable to a world in which the scarce factor is information may be exactly the wrong one for a world in which the scarce factor is attention” (H.Simon)

◆ Successful system design will require...

1. A deep understanding of the medical product safety domain - an ontology which describes safety concepts, roles, and definitions
2. A willingness to precede technological change with the organizational change which will be required to make it truly effective

Thank you

