

Health Information
Technology
Summit

eHealth Initiative
Washington
October 22, 2004

**The Transformation of
Clinical Research**

Integration of Policy and Process with
Information Technology

Charles Jaffe, MD, PhD
Director Medical Informatics, AstraZeneca

Transformation of Clinical Research

The Landscape

An Overview

- The US Healthcare System
- The Global Pharma & Biotech world
- Clinical Research today
- The state of Pharma IT
- Bird's eye view of the NHII
- Beyond CDISC
- Single Source
- Phoenix rising
- Making Integration pay off

Transformation
of
Clinical
Research

The Landscape

“There are two kinds of people. Those who finish what they start and so on.”

-Robert Byrne

Transformation of Clinical Research

Healthcare
Perspective

The US Healthcare System

- Accelerating portion of the GNP
- Disproportionate error rates in patient care
- Inequitable rewards for productivity not quality
- Failed experiments in payer system models
- Escalating costs driven by technology and innovation
- Unfavorable demographics with an aging population
- Challenging social consequences of un-insured and under-insured
- **Delay in the transfer of research findings into clinical practice**

Clinical
Research
Information
Infrastructure

Pharmaceutical
Perspective

The Global Pharma Dilemma

- Increasing cost of drug development
- Disproportionate decline in new molecules brought to market
- Escalating primary data sources and formats (genomics data)
- Insufficient and under-utilized data standards
- Incompatible data standards
- Competing Regulatory requirements
- Abbreviated life cycle for new compounds
- Challenging pricing models not based on value
- Delay in the transfer of best practices and inadequate knowledge management

Clinical Research Information Infrastructure

Pharmaceutical Perspective

The Pharma IT Conundrum

- “Pharma is in the Information business”
- World wide R&D Spend \$50B /year
- IT investment: 8% (\$4B /year)
- IT funds devoted to support, maintenance, connectivity: 90%
- IT funds devoted to innovation: 10%
- Which comes to \$400M /year
- **Ouch!**

Source: Bio-IT World 2003 Survey of Research IT Executives

Clinical
Research
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Infrastructure

Pharmaceutical
Perspective

The Pharma/Biotech IT Spend

- “IT is the number one factor for success.”
- How do you rate success factors for R&D?
 - Number 1: Quality of IT (81%)
 - Number 2: Quality of scientists (27%)
- Predicted growth for IT spending
 - 2003: 27%
 - 2013: 42%
- Realized growth for IT spending
 - 2003: 0% * Your actual milage may vary.

Source: BioIT World 2003 Survey of Research IT Executives

National
Health
Information
Infrastructure

National Perspective

Implementation of NHII

- Demonstration projects
- Establishment of architecture principles
- Resolution of patient identification issues
- Maturation of environment for scalable growth
- **Development of low barriers to entry**
- Incremental approach to adoption, with managed cost and risk
- Development of processes to align incentives for all stakeholders

National
Health
Information
Infrastructure

Pharmaceutical
Perspective

Integration with NHII: Next Steps

- Formation of action committees within individual pharmaceutical and biotech companies
- Meeting in Bio-Pharma stakeholders, with NHII leadership
- Coordination with global counterparts to investigate harmonization activities
- **Interaction with academic and government (NIH) research entities to explore opportunities**

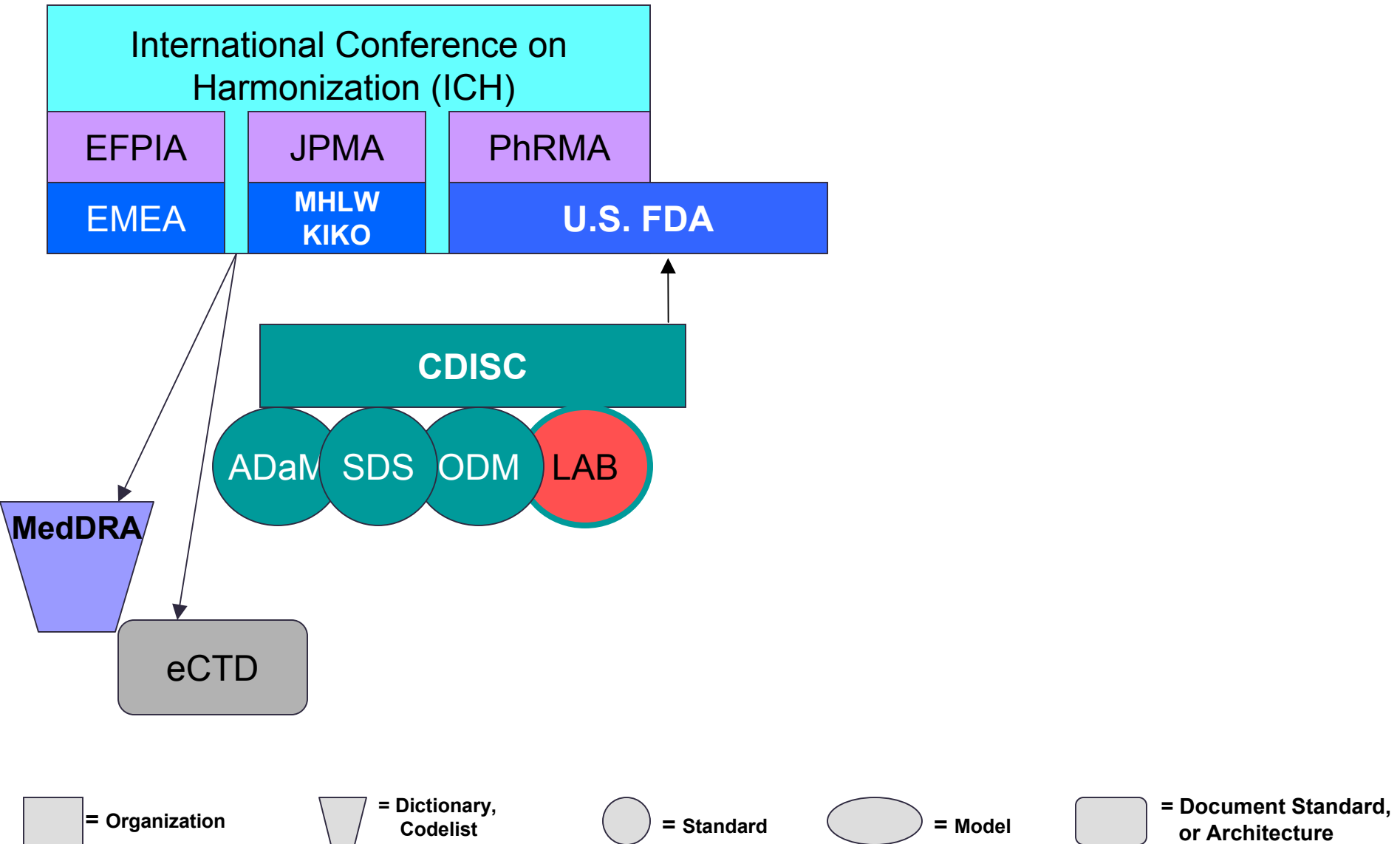
National
Health
Information
Infrastructure

Bio-Pharma
Perspective

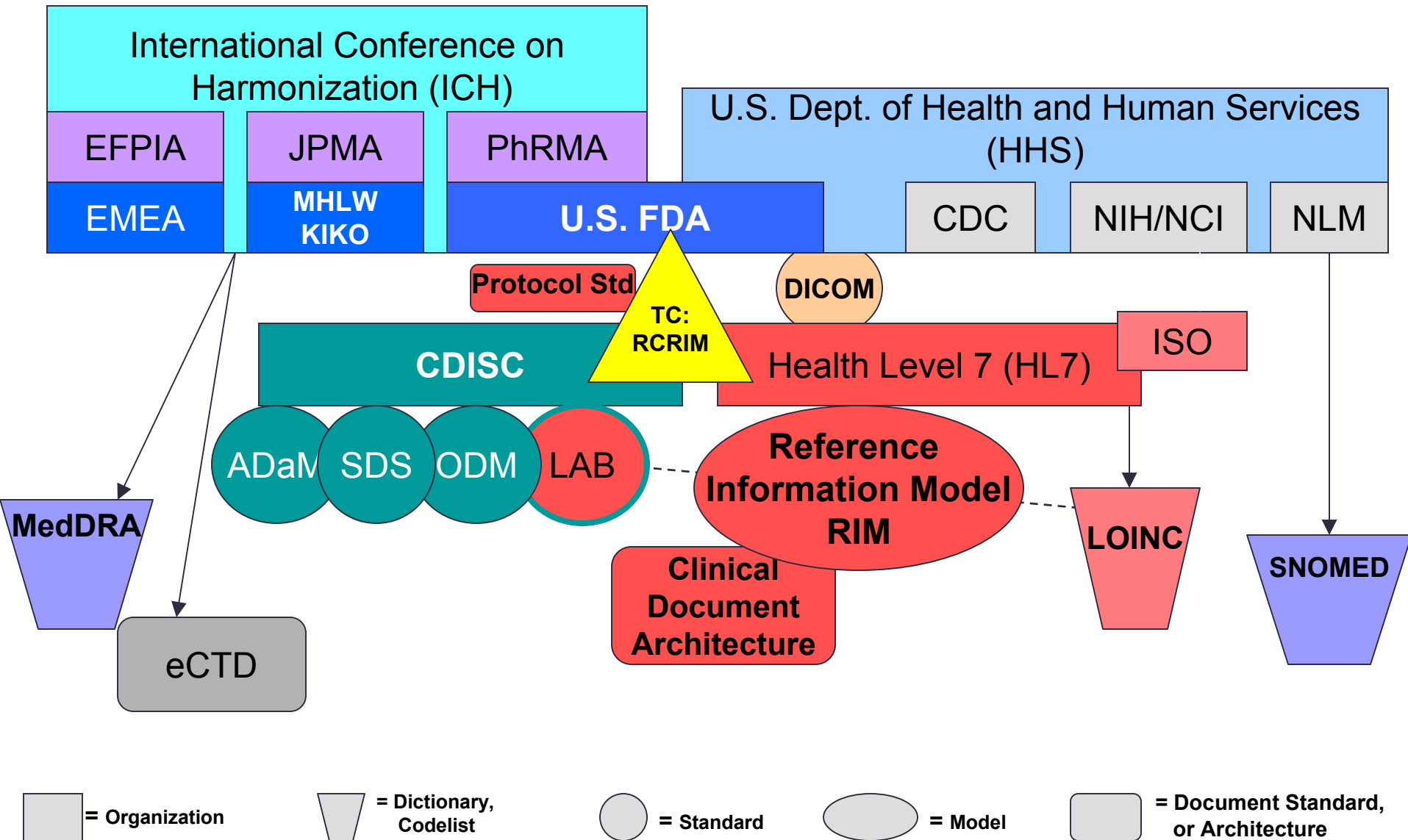
Implementation of NHII by Bio-Pharma

- Clinical Research Stakeholders group
- Bio-Pharma special interest group
- HL7 Outreach Committee on Clinical Research (OCCR)
- Secretary's Panel on Healthcare IT
- **Integration with IT standards**

Clinical Data *Interoperability* 2004

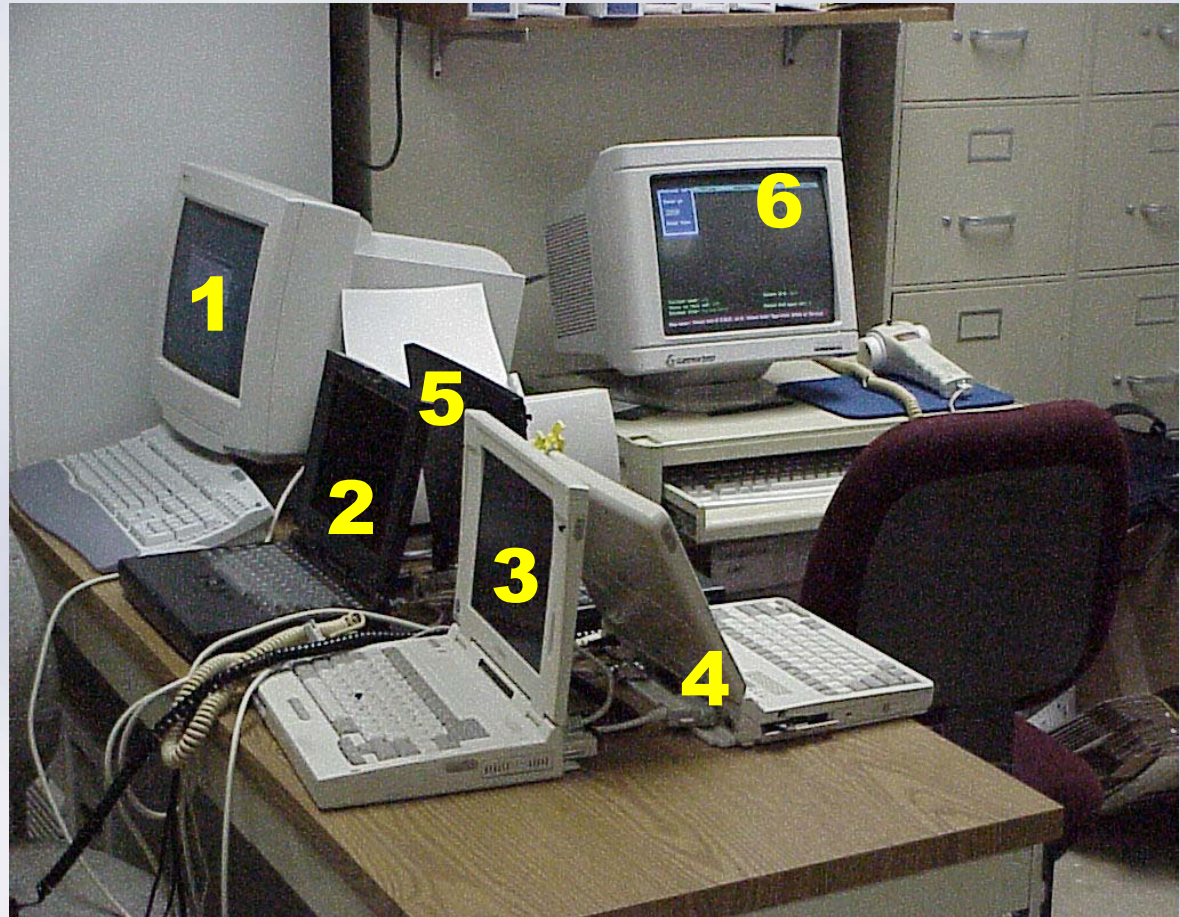


Clinical Data *Interoperability* 2004

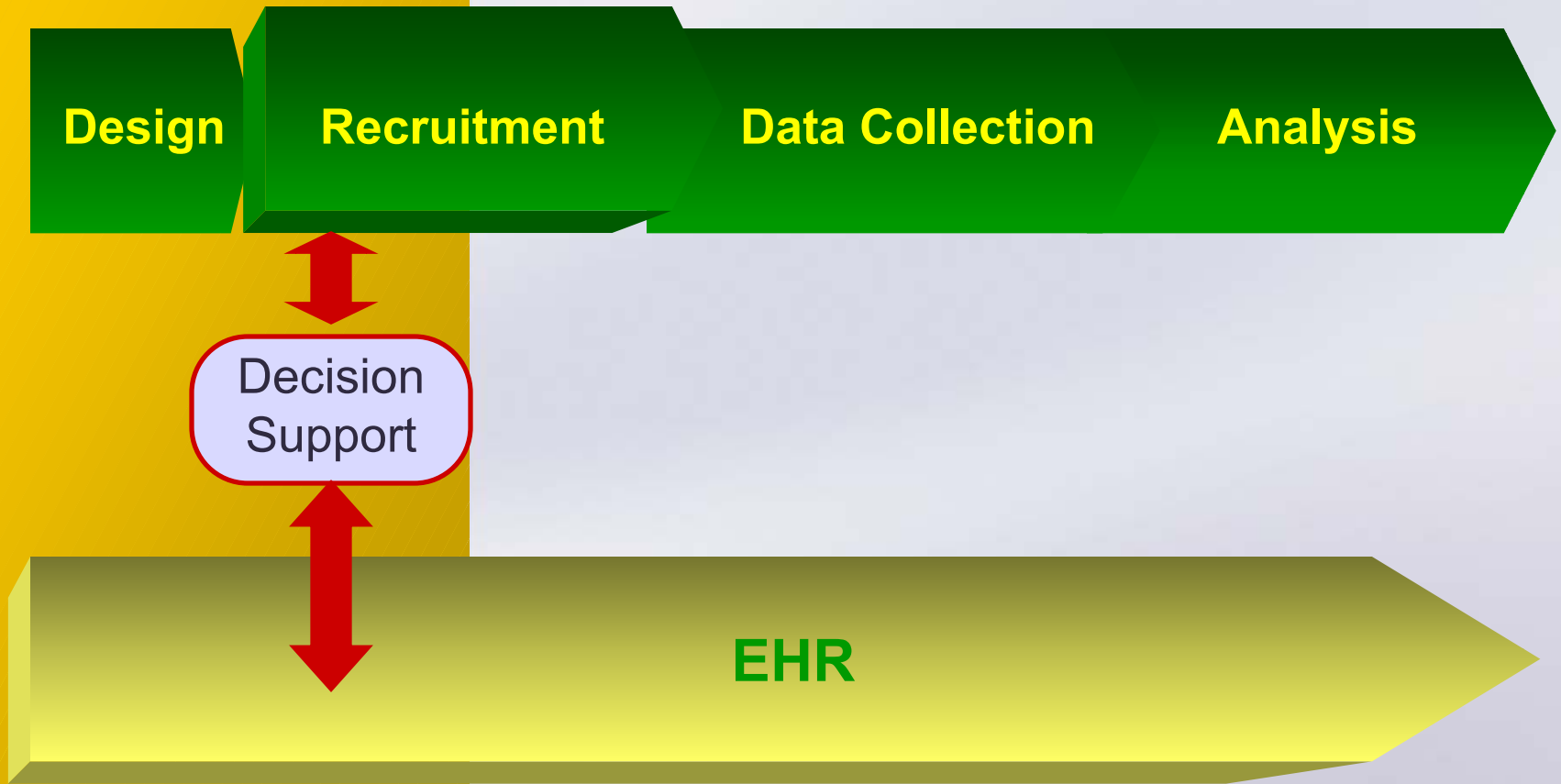


Principal Investigator's Office

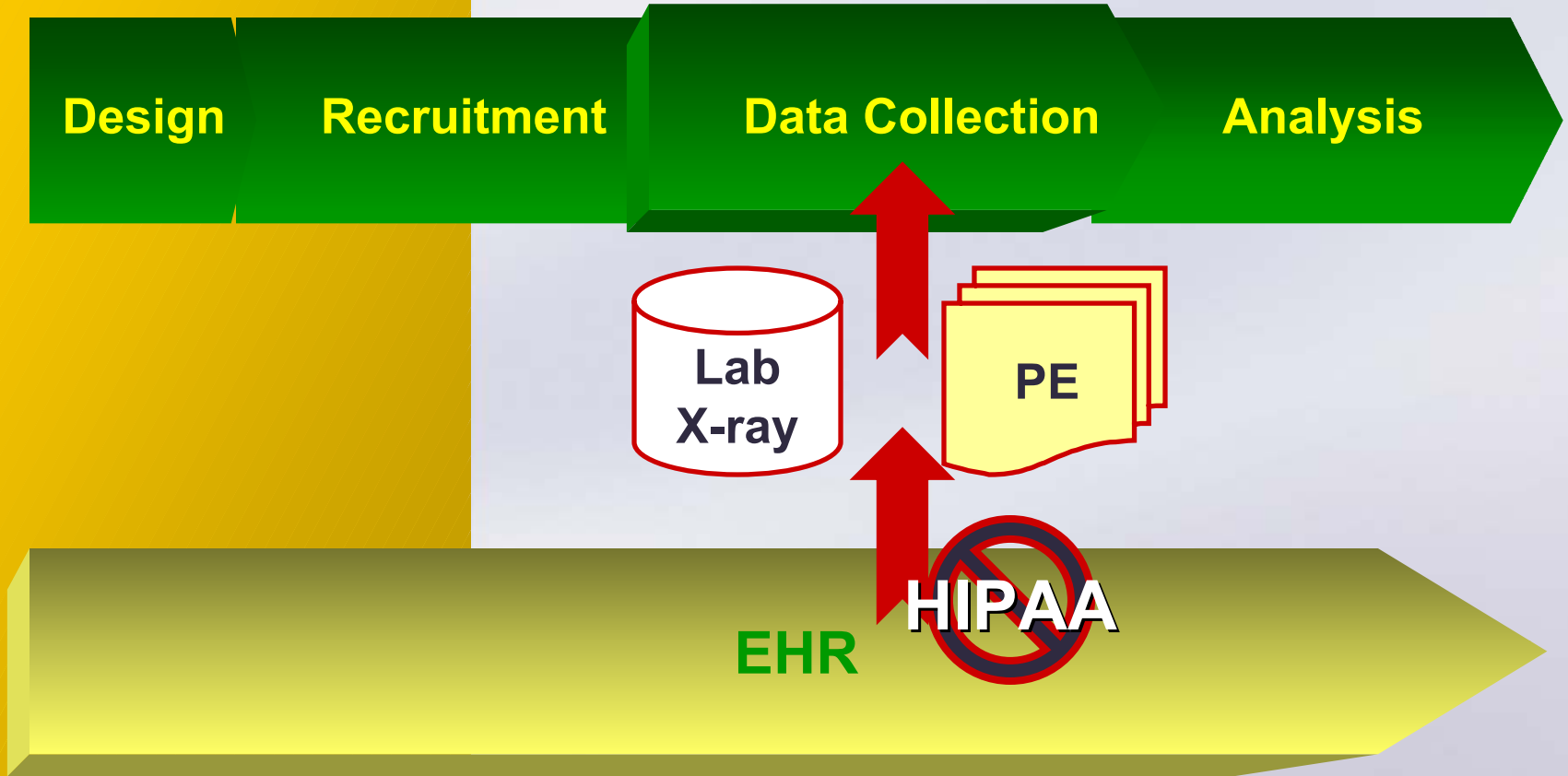
After the paper is gone



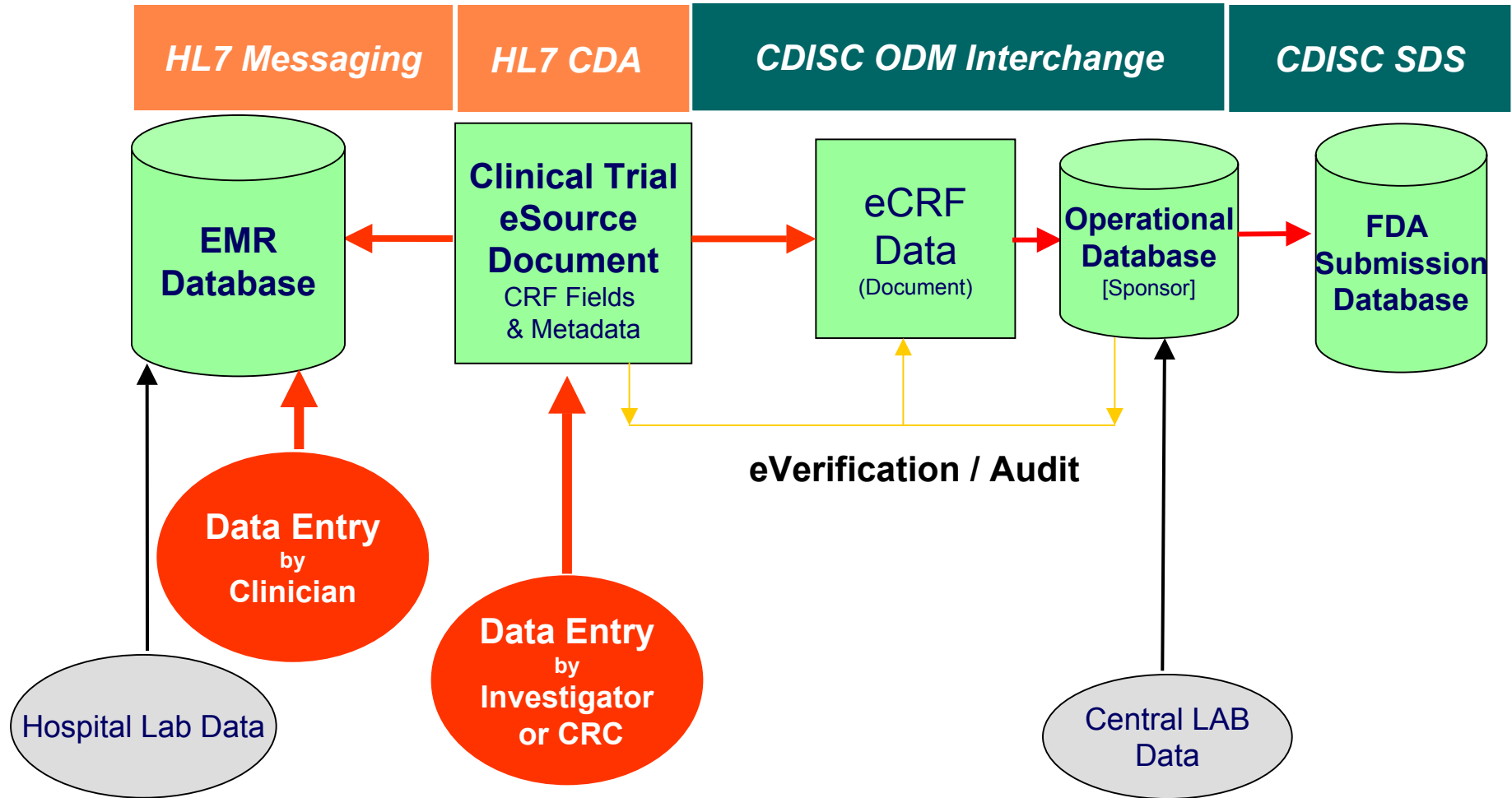
Integration with NHII: Subject Recruitment



Integration with NHII: Data Collection

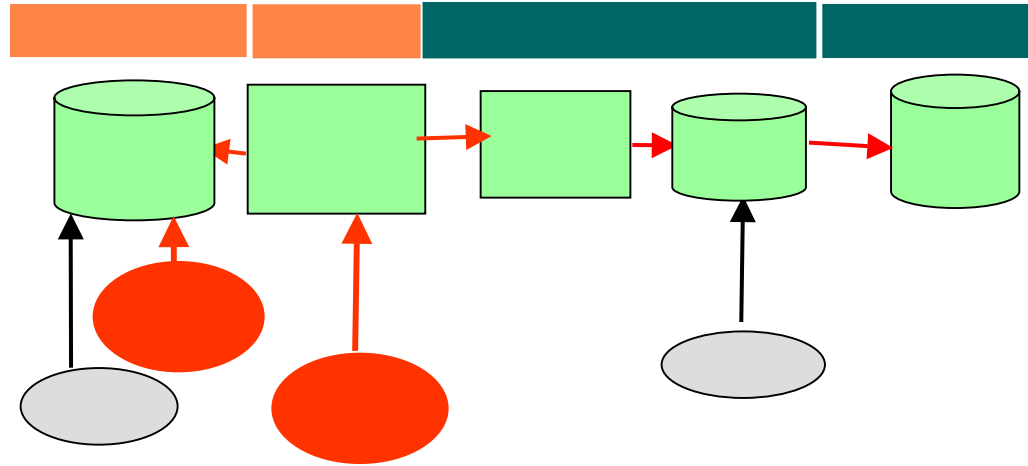


Single Source: Flow of Clinical Trial Data

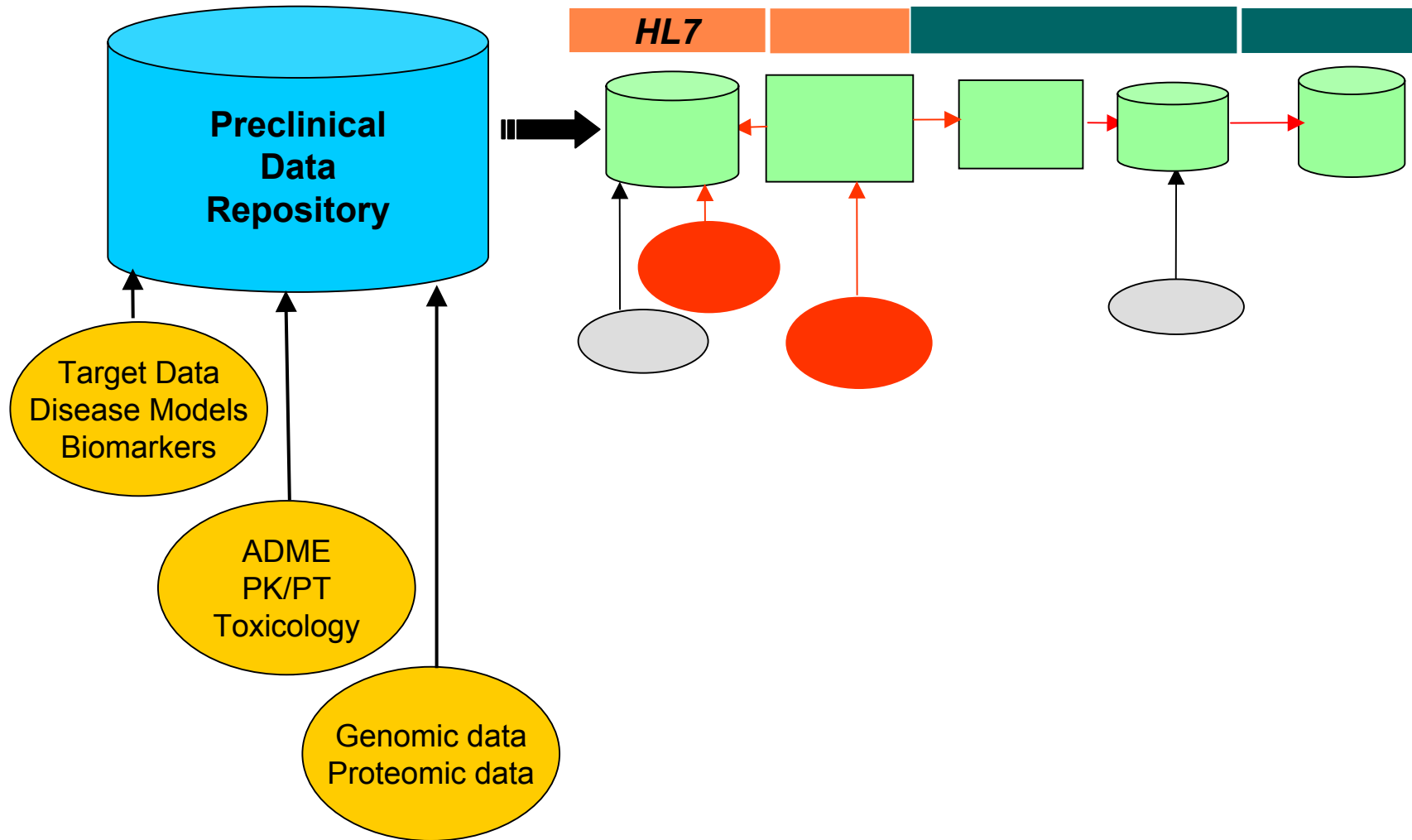


Clinical Trial – Clinical Care Data

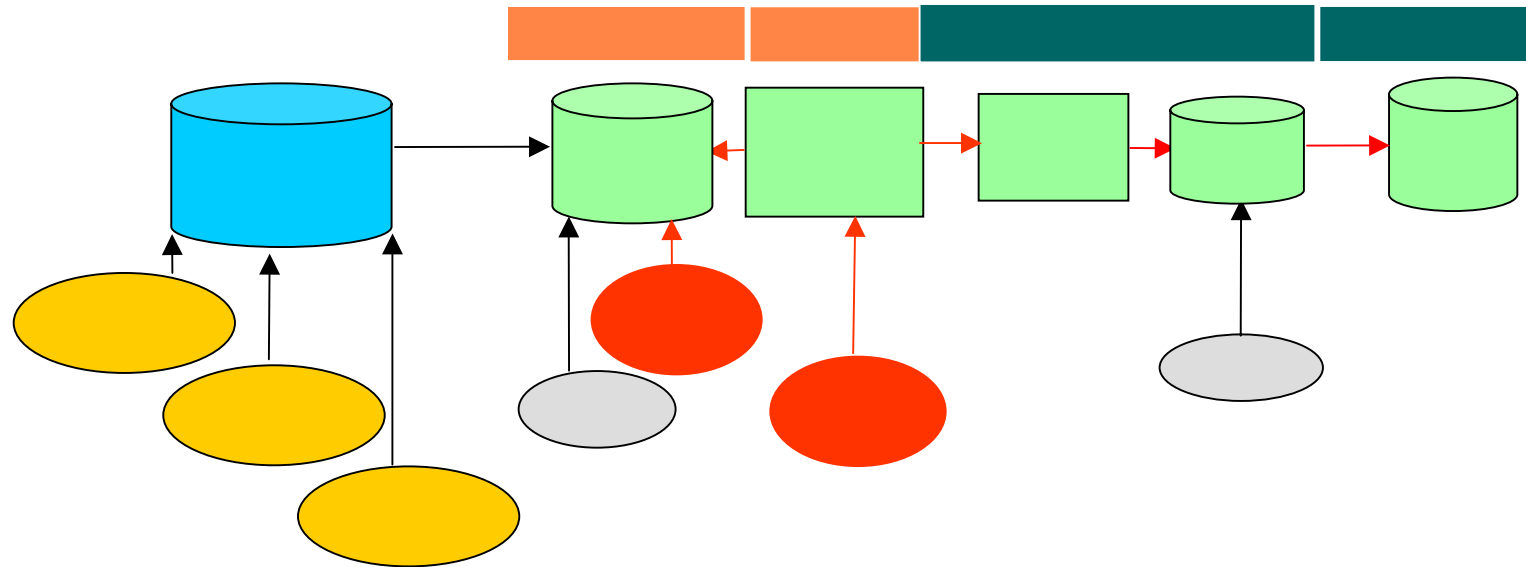
One Corner of the World



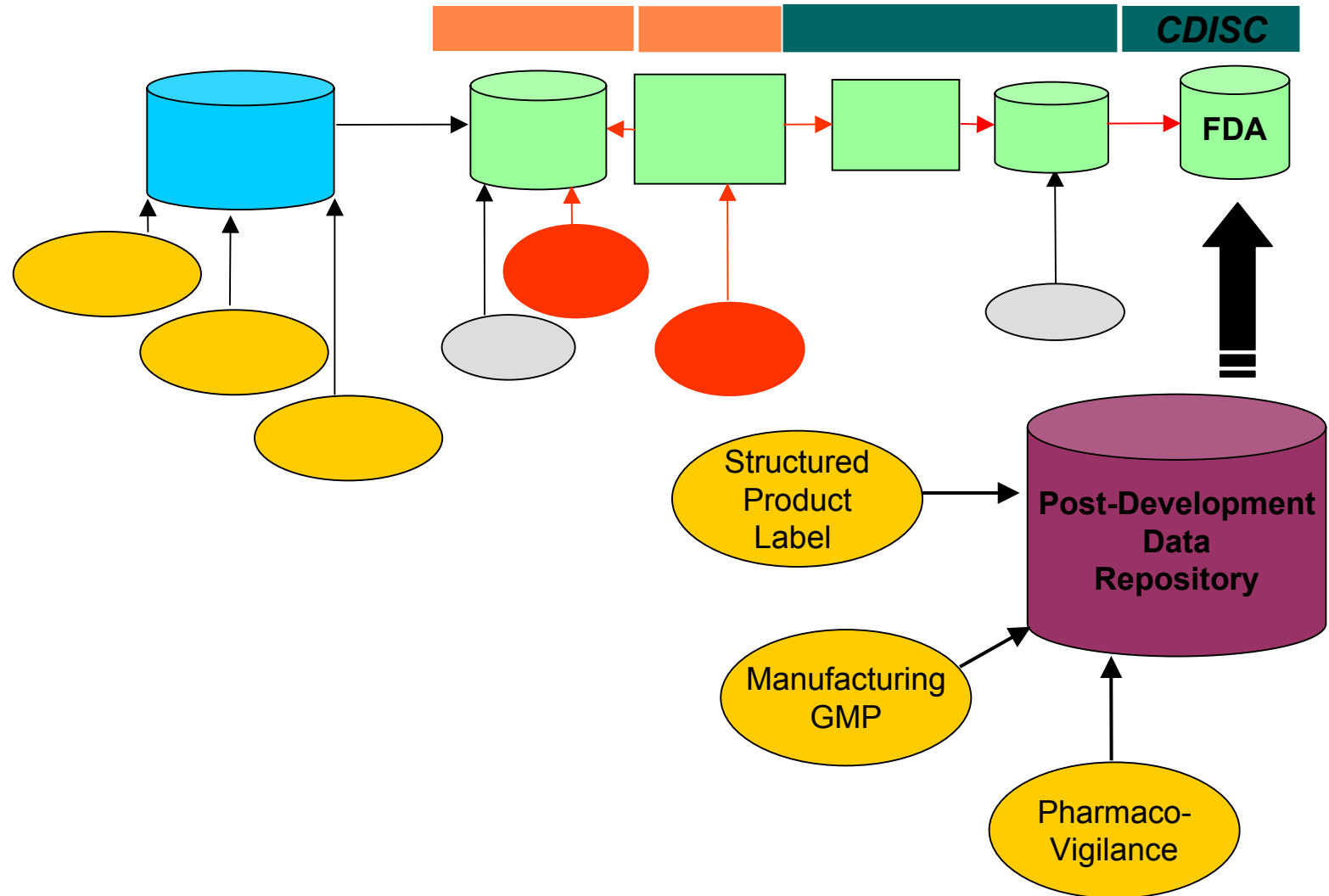
Preclinical & Clinical Data Integration



Preclinical & Clinical Data Integration Broadened Perspective



Preclinical & Clinical Data Integration



Mission Phoenix

Bio-Pharma
Government
Academic
Collaboration

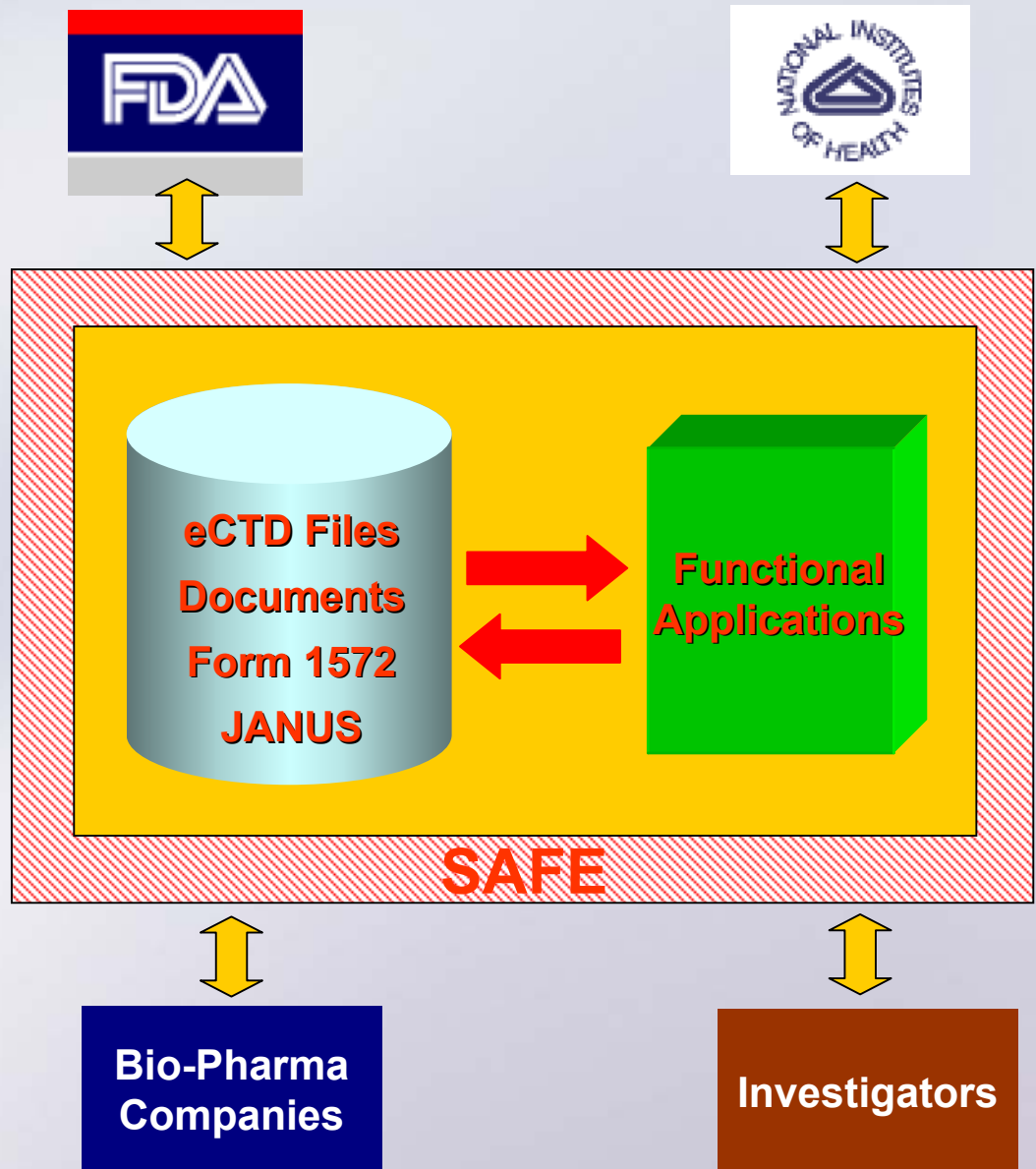
Mission Phoenix

- Collaborative project between industry, government, and academia to facilitate data interchange
- Cooperative effort between the NIH and the FDA spurred by the Inter-Agency Operational Task Force
- Developed with the experience of prior industry initiatives
 - SEBiX (Secure Electronic Biopharmaceutical Information Exchange)
 - SAFE (Secure Access for Everyone)

Mission Phoenix Model

Mission
Phoenix

Bio-Pharma
Government
Academic
Collaboration



National
Health
Information
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Pharmaceutical
Perspective

Integration with NHII:
Risks

- Regulatory barriers
- Incompatibility with global initiatives
- Infrastructure costs
- Insufficiencies of technical skill sets
- Political opposition
- Consumer apprehension
- Standards incompatibility
- **Change Management**

Transformation of Clinical Trials

Information

There are just *two* rules for success:

1. Never tell all you know.

-Roger H. Lincoln

For more information, please contact
charles.jaffe@astrazeneca.com