The Transformation of Clinical Research
Integration of Policy and Process with Information Technology

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<th>Transformation of Clinical Research</th>
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- 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
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<th>Transformation of Clinical Research</th>
<th>“There are two kinds of people. Those who finish what they start and so on.”</th>
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<td>The Landscape</td>
<td>-Robert Byrne</td>
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### 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
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
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
### 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
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
### 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

International Conference on Harmonization (ICH)

- EFPIA
- JPMA
- PhRMA
- EMEA
- MHLW KIKO
- U.S. FDA

CDISC
- ADaM
- SDS
- ODM
- LAB

MedDRA

eCTD

= Organization  
= Dictionary, Codelist  
= Standard  
= Model  
= Document Standard, or Architecture
Clinical Data *Interoperability* 2004

- **International Conference on Harmonization (ICH)**
  - EFPIA
  - JPMA
  - PhRMA
  - EMEA
  - MHLW KIKO

- **U.S. Dept. of Health and Human Services (HHS)**
  - CDC
  - NIH/NCI
  - NLM

- **U.S. FDA**

- **CDISC**
  - ADaM
  - SDS
  - ODM
  - LAB

- **Protocol Std**
  - TC: RCRIM

- **DICOM**

- **Health Level 7 (HL7)**
  - ISO

- **Reference Information Model (RIM)**
  - Clinical Document Architecture

- **LOINC**

- **SNOMED**

- **MedDRA**

- **eCTD**

**Legend**:
- **Organization**
- **Dictionary, Codelist**
- **Standard**
- **Model**
- **Document Standard, or Architecture**
Principal Investigator’s Office

After the paper is gone
Integration with NHII: Subject Recruitment

- Design
- Recruitment
- Data Collection
- Analysis

Decision Support

EHR
Integration with NHII: Data Collection

- Design
- Recruitment
- Data Collection
- Analysis

- Lab
- X-ray
- PE
- EHR
- HIPAA
Single Source: Flow of Clinical Trial Data

EMR Database

Clinical Trial eSource Document
CRF Fields & Metadata

eCRF Data (Document)

Operational Database [Sponsor]

FDA Submission Database

Data Entry by Clinician

Data Entry by Investigator or CRC

Hospital Lab Data

Central LAB Data

eVerification / Audit
Clinical Trial – Clinical Care Data
One Corner of the World
Preclinical & Clinical Data Integration

Preclinical Data Repository

Target Data
Disease Models
Biomarkers

ADME
PK/PT
Toxicology

Genomic data
Proteomic data

HL7
Preclinical & Clinical Data Integration
Broadened Perspective
Preclinical & Clinical Data Integration

CDISC

FD

Structured Product Label

Manufacturing GMP

Pharmacovigilance

Post-Development Data Repository

Preclinical & Clinical Data Integration
| 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

Bio-Pharma Companies
Investigators

SAFE

FDA
National Institutes of Health

eCTD Files
Documents
Form 1572
JANUS

Functional Applications
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
There are just *two* rules for success:
1. Never tell all you know.

-Roger H. Lincoln

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