



# **Health IT and Standards to Support Clinical Research: Combining clinical and genomics data**

**Secretary's Advisory Committee on Genetics,  
Health and Society**

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# Overview

- Health care and clinical research
- The ability of health IT to support clinical research
- A set of core clinical research elements
- Combining clinical data and genomics data

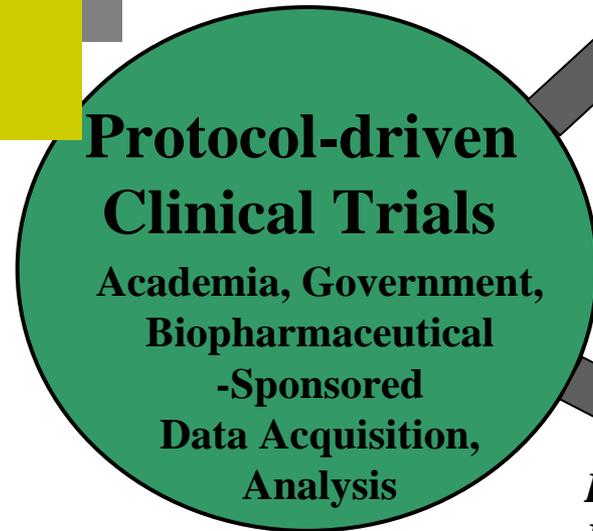
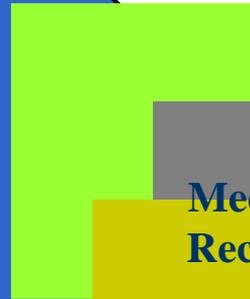
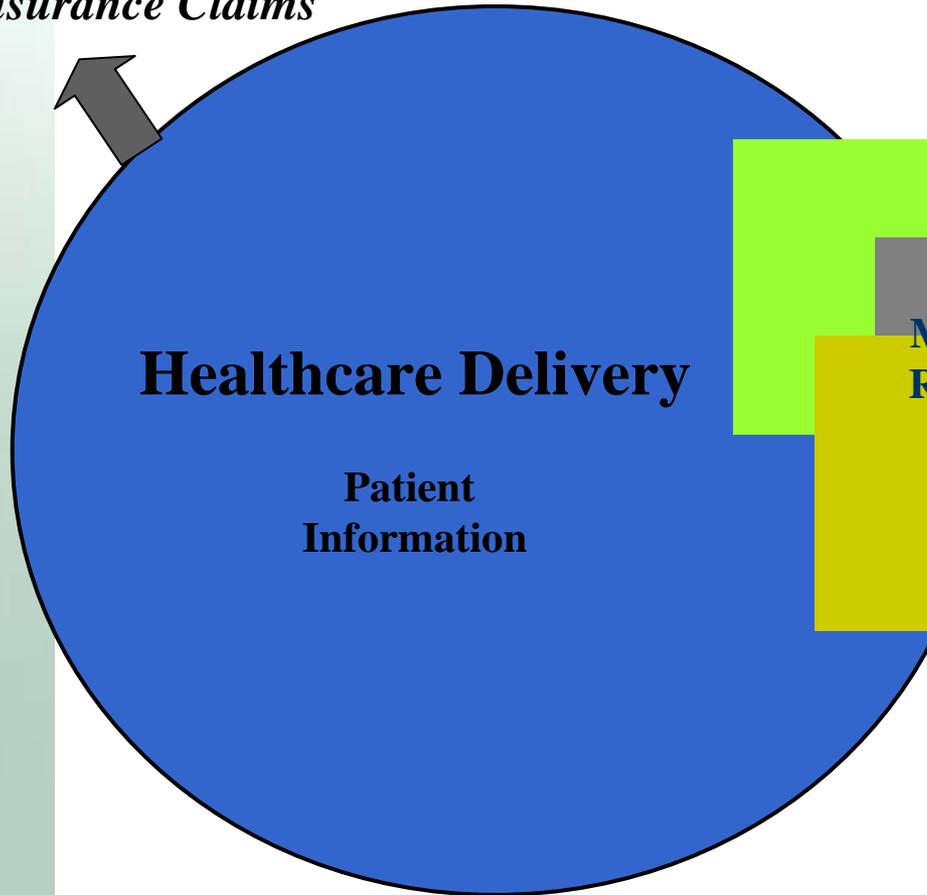
# Research informs health care decisions

## Medical Research

- **Approximately \$100B spent annually on medical research in the U.S.**
- **Data requirements for clinical research overlap substantially with clinical quality, safety and efficacy use cases.**
- **Health care and clinical research need to have consistent standards.**

## Clinical Care Decisions

*Insurance Claims*

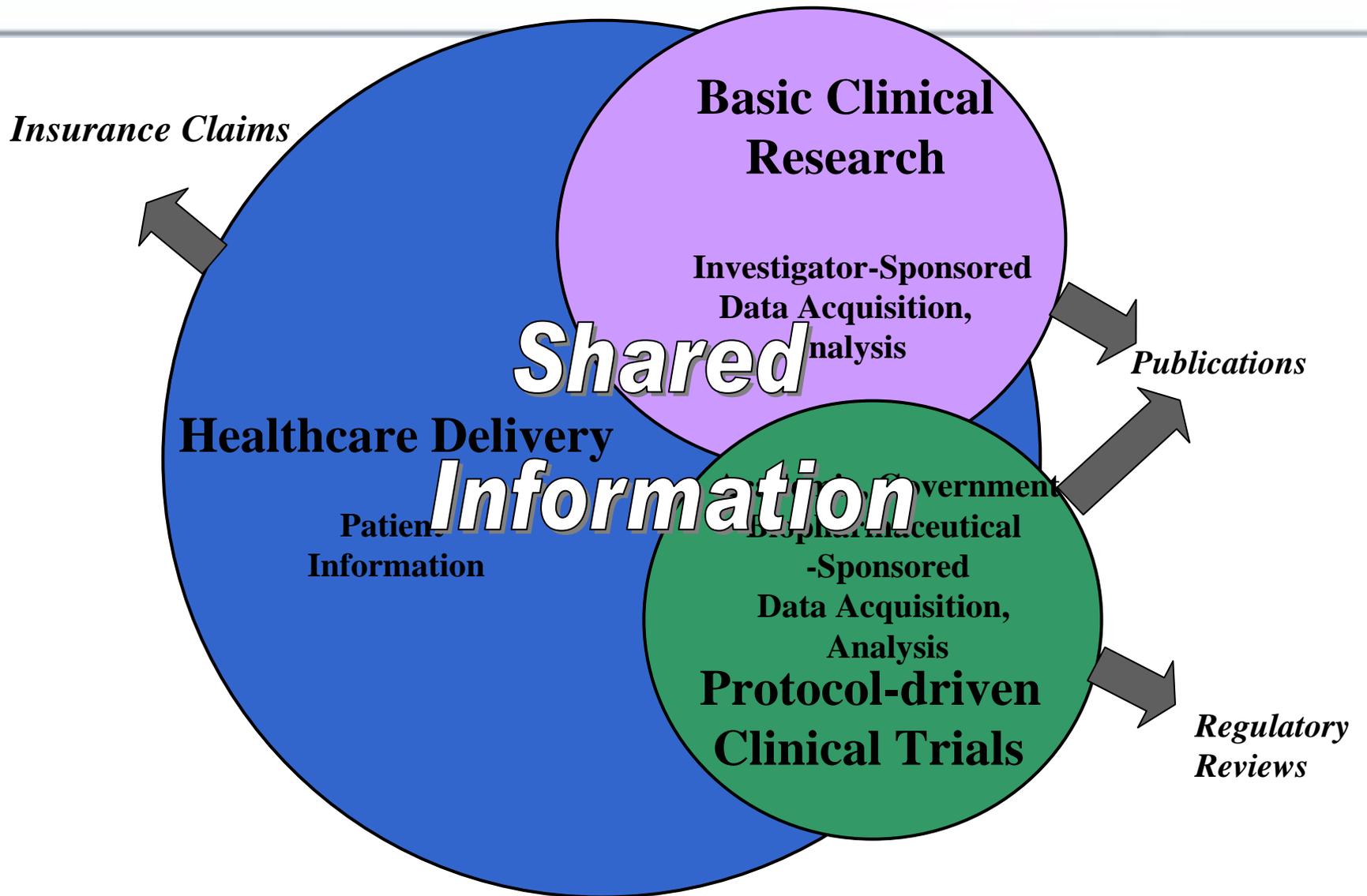


*Publications*

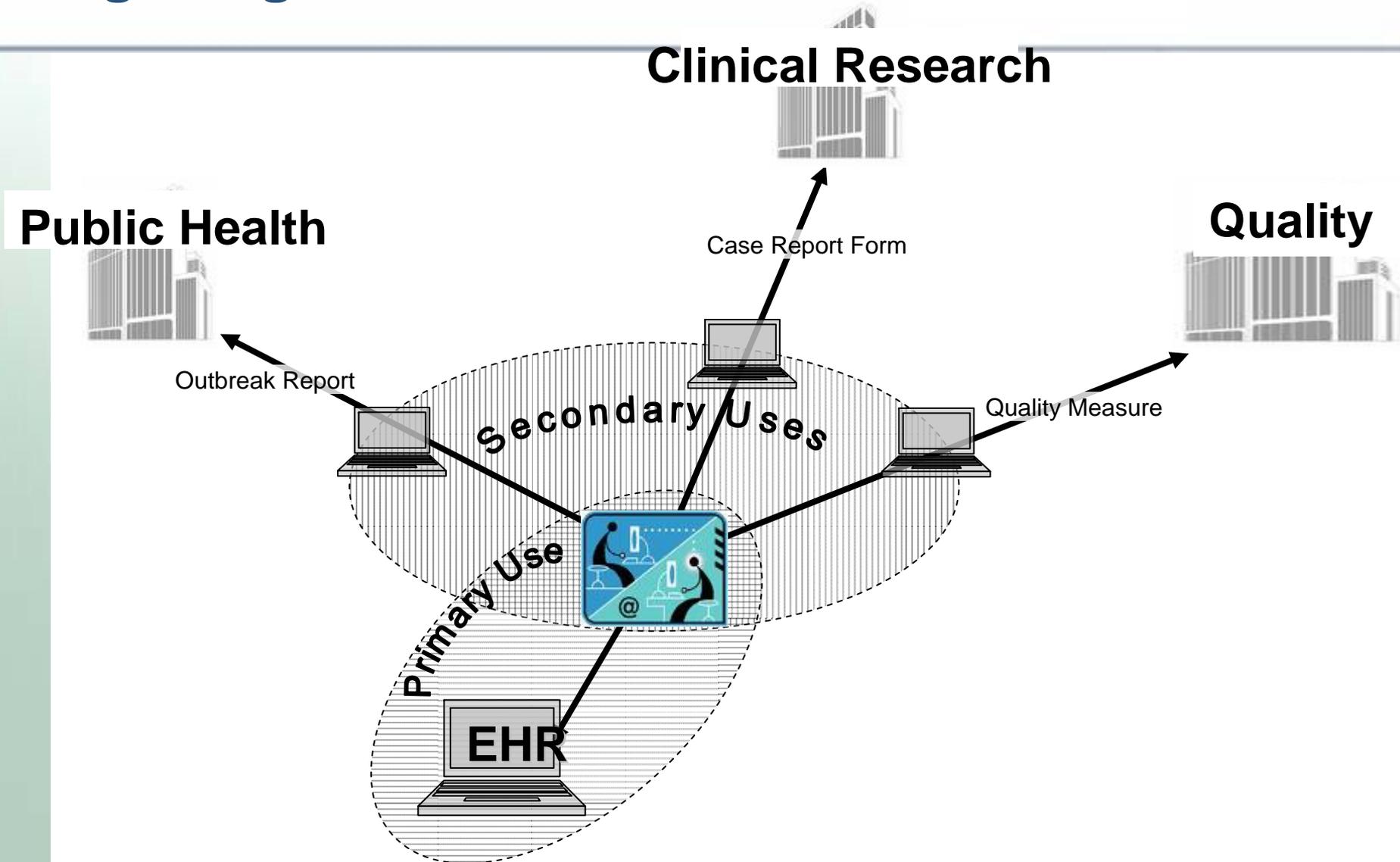
*Regulatory Reviews*

# The Current State of Clinical Information

- Healthcare information is found in:
  - paper medical records
  - disparate databases
  - hospital-based information systems
- Clinical research data exists in:
  - additional databases
  - research notebooks
- Clinical trial data collection;
  - 3-part NCR forms in ~60% of trials
  - multitude of electronic data capture applications
    - sites average 3 different applications



# Integrating Workflow: EHRs and Clinical Research



# EHR Clinical Research Workgroup

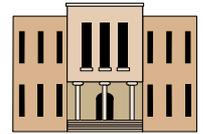
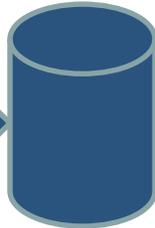
- ANSI has convened an EHR Clinical Research Workgroup for prioritization of clinical research use cases (the Workgroup is co-chaired by HHS and CDISC)
- Should leverage existing clinical/medical research standards
- **Initial Prioritized Value Case:** Identify a common set of data elements that can readily be exchanged between EHRs and clinical research systems
  - Anticipated to provide a foundation for potential future use cases including:
    - Patient participation in research (subject recruitment)
    - Pharmacovigilance
    - Clinical genomics and biomarkers
- **Long-term objective:** create an infrastructure through which healthcare advances clinical research and in turn informs clinical care

# Patient Value: Quality of Healthcare, Safety

Research informs healthcare more effectively and efficiently  
Build quality into process at beginning



De-identified Data



Regulatory Authority



Reviewers  
(e.g. Research Partner, Sponsor, Registry, Regulator, IRB, DSMB)

Research Site  
(Healthcare Location, Investigator, Site Personnel)

Study Sponsor  
(e.g. ARO, CRO, Vendor, Principal Investigator)



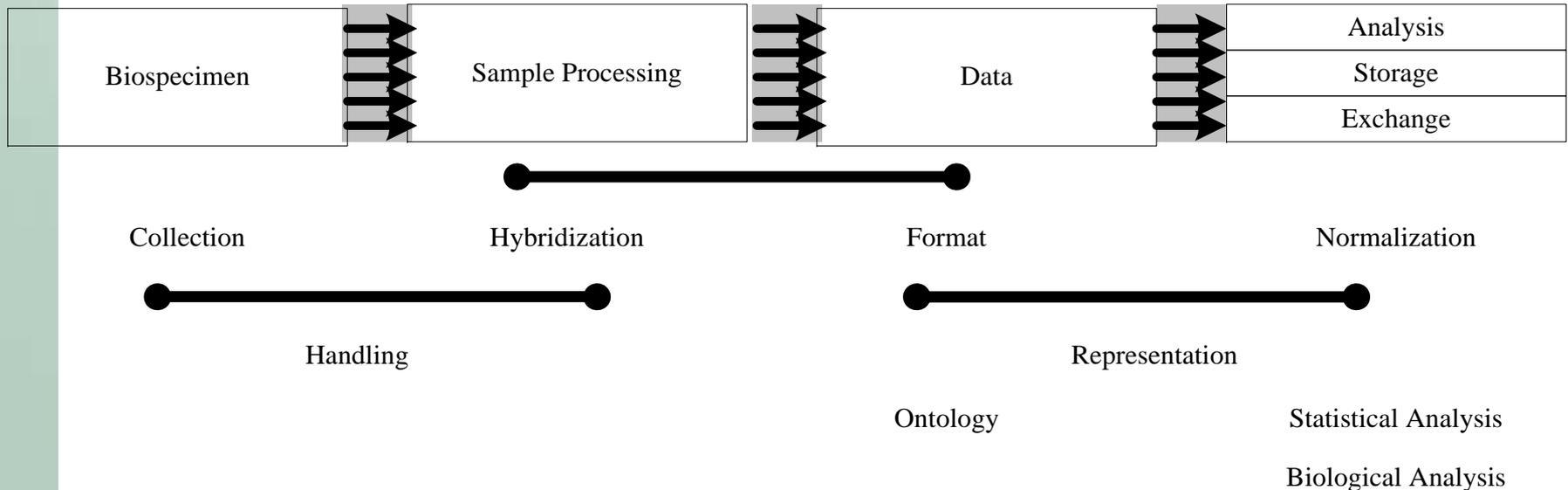
## Core Research Data Elements

- Reporting Requirements
  - Language
  - Informed Consents
  - Eligibility Verification
- Subject Demographics
- Prior and Concomitant Medications
- Medical History
- Physical Examination
- Substance Use (e.g. Habits)
- Vital Signs
- Laboratory Data
- Untoward Clinical Events (i.e., Adverse Events)

# Data Standards for Clinical Genomics

- Workgroup
  - Core Federal Workgroup Agencies: FDA, NCI
  - Expanding to both public and private stakeholders
- Standardized terminology and messages to record/report all phases of the production of genomics data

Genomics Data Information Flow



# Status of Clinical Genomics Standards

- HL7 current status of clinical genomics
  - Genetic Variation and Family History Models are available
  - Gene Expression under development
  - Genetic Testing Reports project proposal approved for development
- Innovative use in healthcare
  - Tailor screening based on familial risk factors
  - Customize treatment based on genetic profiling
- Innovative use in clinical research
  - Cohort identification for study trials
  - Drug metabolism
  - Initial use for bio-marker discovery
- Standards development
  - Joint effort by healthcare and research (CDISC and HL7)
  - Development of ontologies to support standardization of data exchange (e.g. HL7 messages)

# Current Barriers

- Research Barriers:
  - Lack of clear regulatory mandate for genomics data in studies
  - Lack of clearly defined process for bio-marker validation
  - Lack of global standard to facilitate data exchange.
    - Common standard needed to enable use of medical data in research.
    - Maintenance of multiple standards not sustainable
    - Many standards requires creation of cross-references
    - **Cost-effective** data management requires global standards that enable data use for multiple purposes (healthcare, research, epidemiology/public health, health-access policy).
- Healthcare Barriers:
  - Slow movement towards adoption of electronic healthcare records
  - Ontologies points above also apply to healthcare

**Note: Standards comments include both clinical genomics and medical data**

# Harmonized Information Exchange Standards for Clinical Research and Healthcare

## Harmonization essential:

- To aggregate information across stakeholders so that research findings lead to informed healthcare decisions
- For timely global safety surveillance
- To link biomarkers (including an individual's genetic markers) to population characteristics and outcomes
- To facilitate research for clinicians concurrent with clinical care

**Net Impact: Reduce time and costs of research and improve quality and effectiveness of healthcare**

## Information and Contacts

### EHR Clinical Research Value Case and Use Case

<http://publicaa.ansi.org/sites/apdl/EHR%20Clinical%20Research/Forms/AllItems.aspx>.

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# Contributors to HITSP EHR Clinical Research Initiative

- Abbott
- Accenture
- Biogen Idec
- Boehringer Ingelheim Pharmaceuticals, Inc.
- Cleveland Clinical and Translational Science Collaborative at Case Western Reserve University
  - Case Western Reserve University
  - Cleveland Clinic
  - MetroHealth System
  - University Hospitals
- Critical Path Institute
- CWR
- Digital Infuzion
- Duke University
  - Duke Comprehensive Cancer Center
  - Duke Clinical Research Institute
- Eli Lilly
- Genetic Alliance
- Genentech
- GlaxoSmithKline
- Greenway Medical Technologies
- HP
- Anonymous
- JSS Medical Research Inc.
- McDougall Scientific Ltd.
- Medidata Solutions Worldwide
- MedXview

## Contributors to HITSP EHR Clinical Research Initiative (2)

- Nextrials, Inc.
- Numoda Corporation
- Outcome
- Partners HealthCare
- Perceptive Informatics
- PharmaNet Development Group, Inc.
- Pfizer
- Phoenix Data Systems, a division of Bio-Imaging Technologies
- Quintiles
- Schering Plough Research Institute
- Target Health Inc.

### Government Agencies

- Eunice Kennedy Shriver National Institute of Child Health and Human Development
- National Cancer Institute
- National Center for Research Resources
- Office of the National Coordinator for Health Information Technology
- Department of Veterans Affairs,
- The Assistant Secretary of Planning and Evaluation, Department of Health and Human Services.