

Statewide Clinical Research Data Projects

Date: 4/02/2010

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Topics

IT Goals

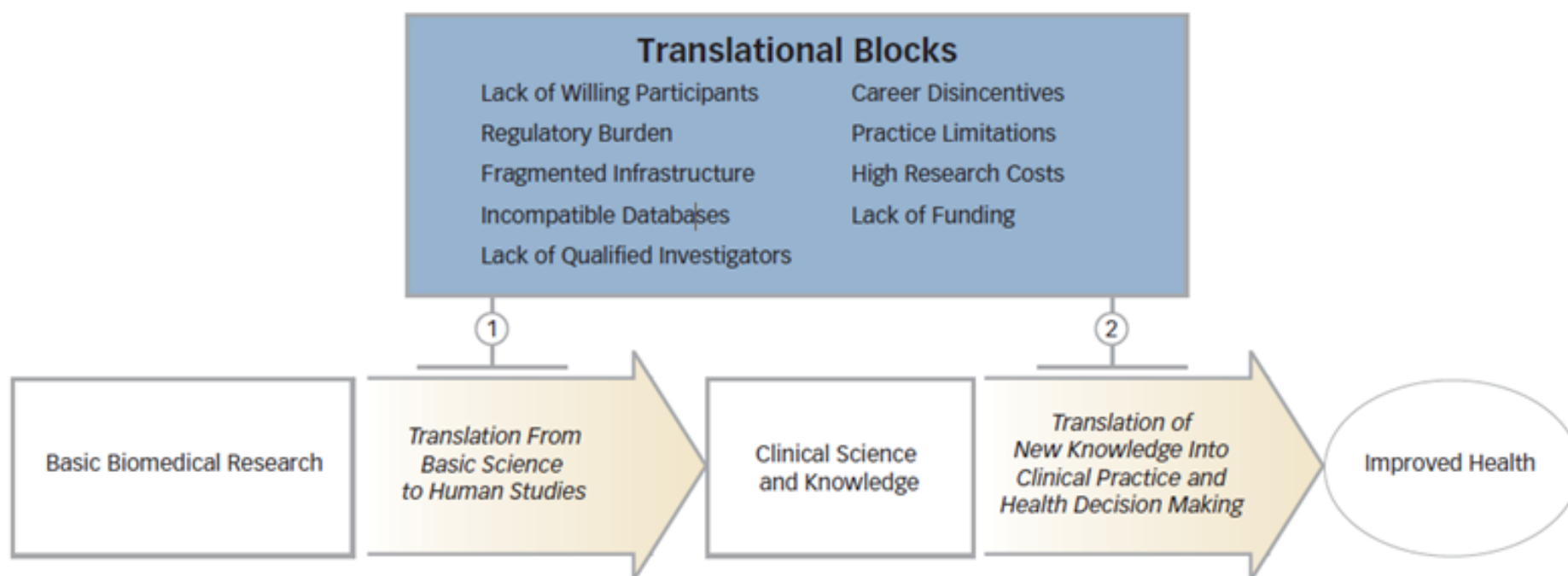
Concept of an Integrated Platform for Research

Current Status and Progress

Key Technologies – i2b2 and JavaCAPS

Other Informatics projects

Translational Research Overview



Source: "Central Challenges Facing the National Clinical Research Enterprise", Sung et al, JAMA, 3/12/2003 pp 1278-1287

HSSC's Informatics Goals

Provide Informatics Support for Statewide Clinical and Translational Research

- Significantly increase the number, efficiency and subject recruitment of multi-site clinical trials in SC. Enable SC to function as an integrated clinical trials network.
- Provide enabling tools for researchers - a “one-stop-shop”- that allows research participants to be seamlessly recruited from across SC.
- Allow clinical discovery projects by linking to biological specimens and omics data.

Alignment of Informatics Initiatives



**CTSA
Biomedical
Informatics**

Specific Aims:
Provide a catalog of
generic IT services
To support Translational
Research
In SC



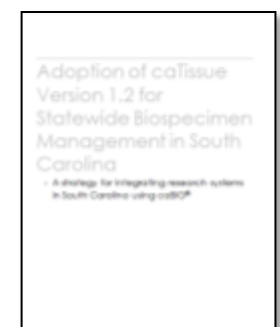
**HSSC's
IT
Business
Plan**

Specific Aims:
Build an integrated
Information system to
Impact wellness through
translational research in SC
(SCIPR)



**GO
Grant**

Specific Aims:
Create a Research
Permissions
Management System
for SC

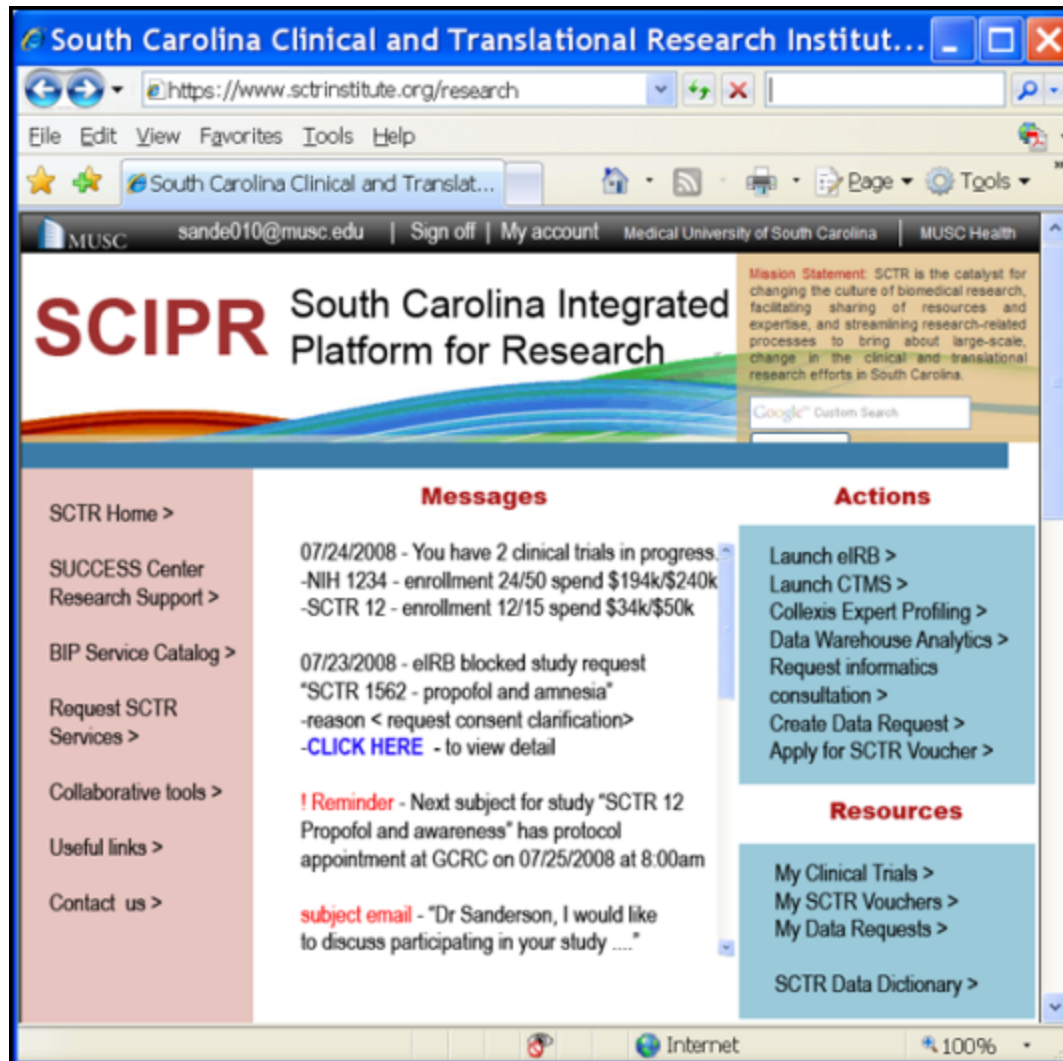


**? caBIG
Bio-
repository**

**Statewide support for translational
research through Informatics Solutions**



Concept of a Portal and “One-Stop-Shop” for Researchers.



What's Different about Research Informatics?

According to Vi Shaffer, Research Vice President and Global Industry Services director for healthcare at Gartner, SCIPR is an ACRIS (Advanced Clinical Research Information System):

Market penetration only 1% (as of 2008)*

“Academic medical centers that do not invest in ACRIS will have increased difficulty competing for research contracts and grants, and will face diminished stature and funding within a few years.”*

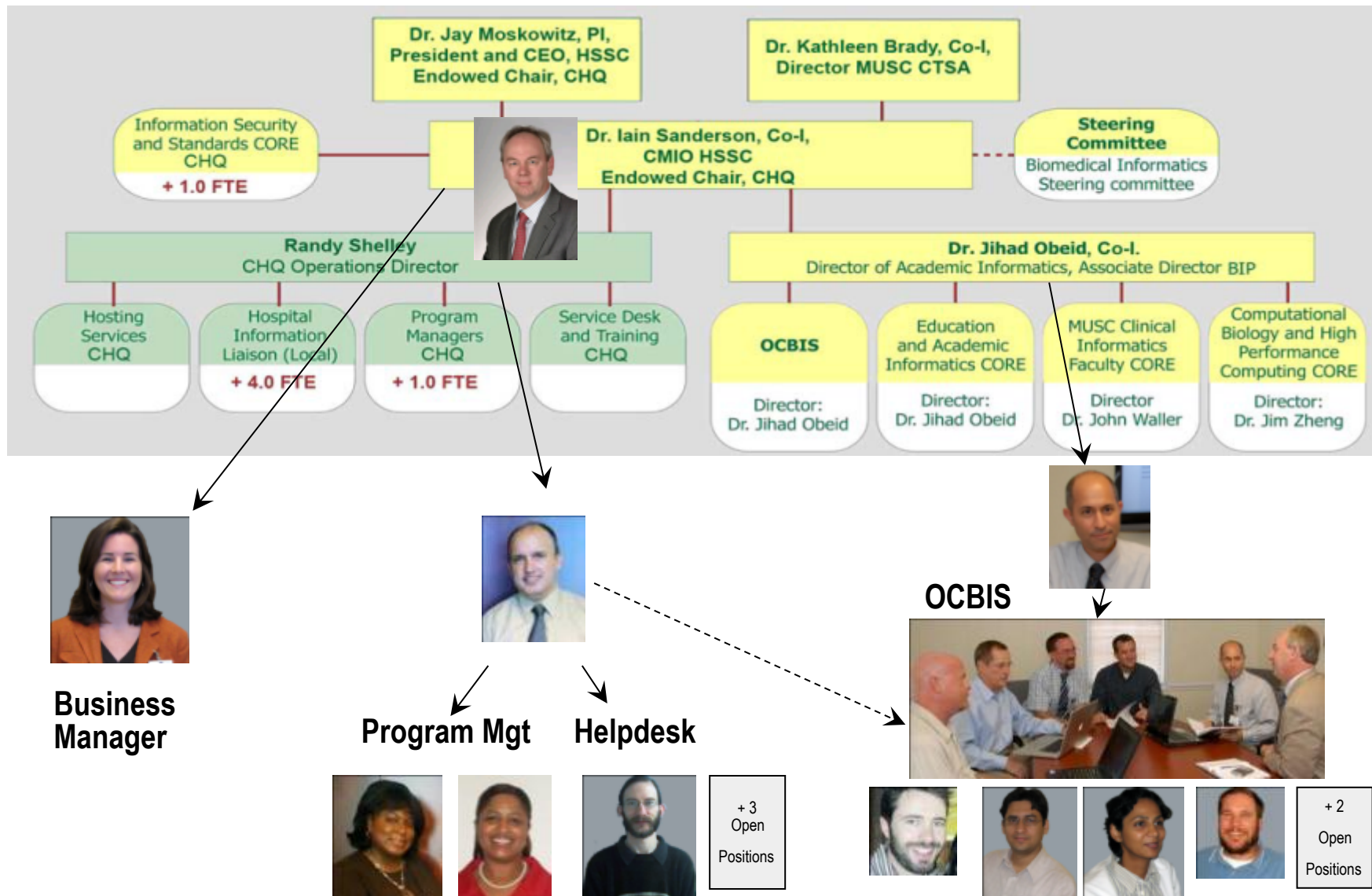
“Includes an enterprise data warehouse (EDW) able to bring in data from EHR systems and other clinical sources.”*

*Gartner Hype Cycle for Advanced Clinical Research Information Systems, June 2008, Vi Shaffer

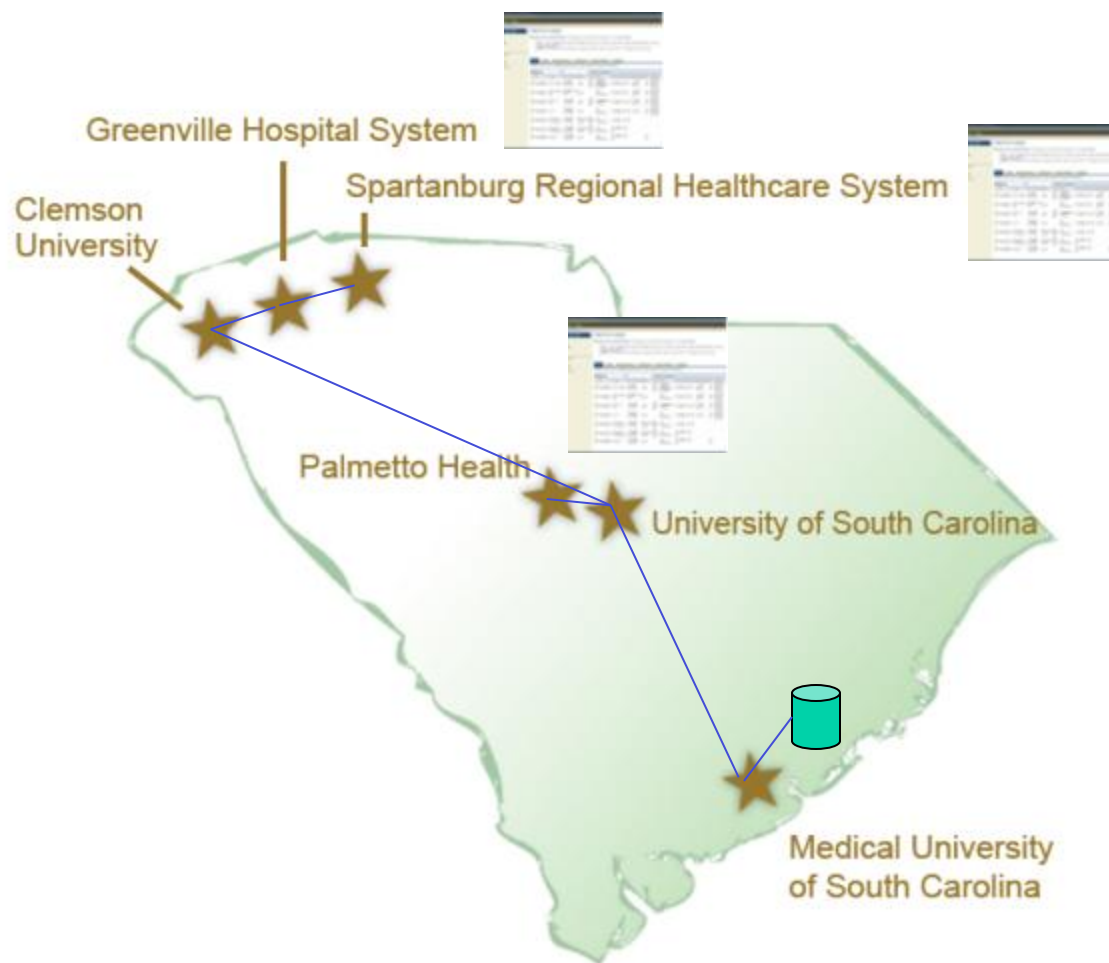


How?

Fund and Build an Organization...



Wins – a single Electronic IRB system (ClickCommerce)



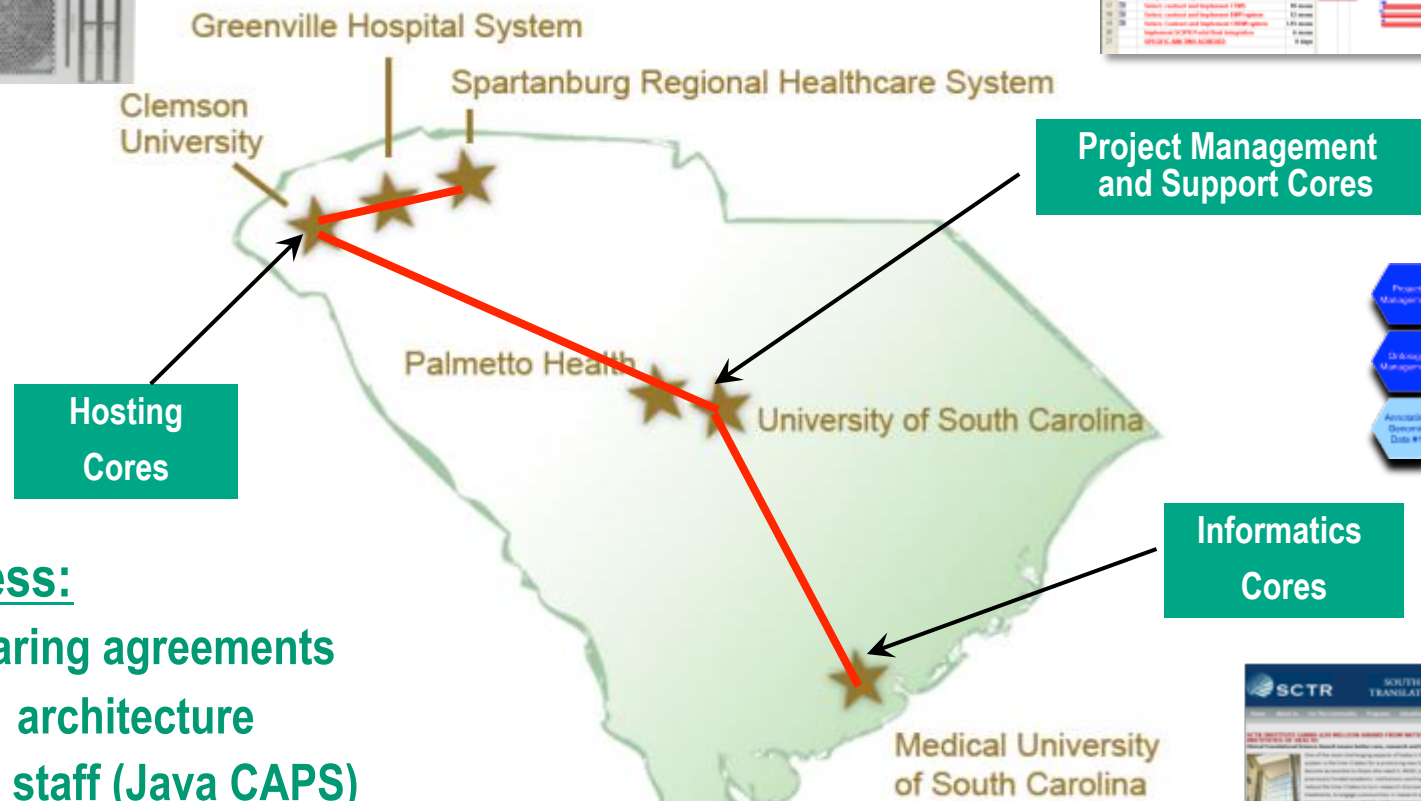
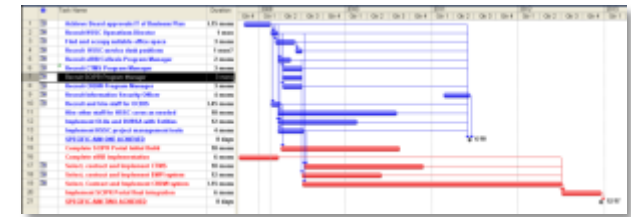
**New studies use
ClickCommerce
eIRB across
most HSSC.**

MUSC by Q2-2010

Wins – Shibboleth Authentication and Trust



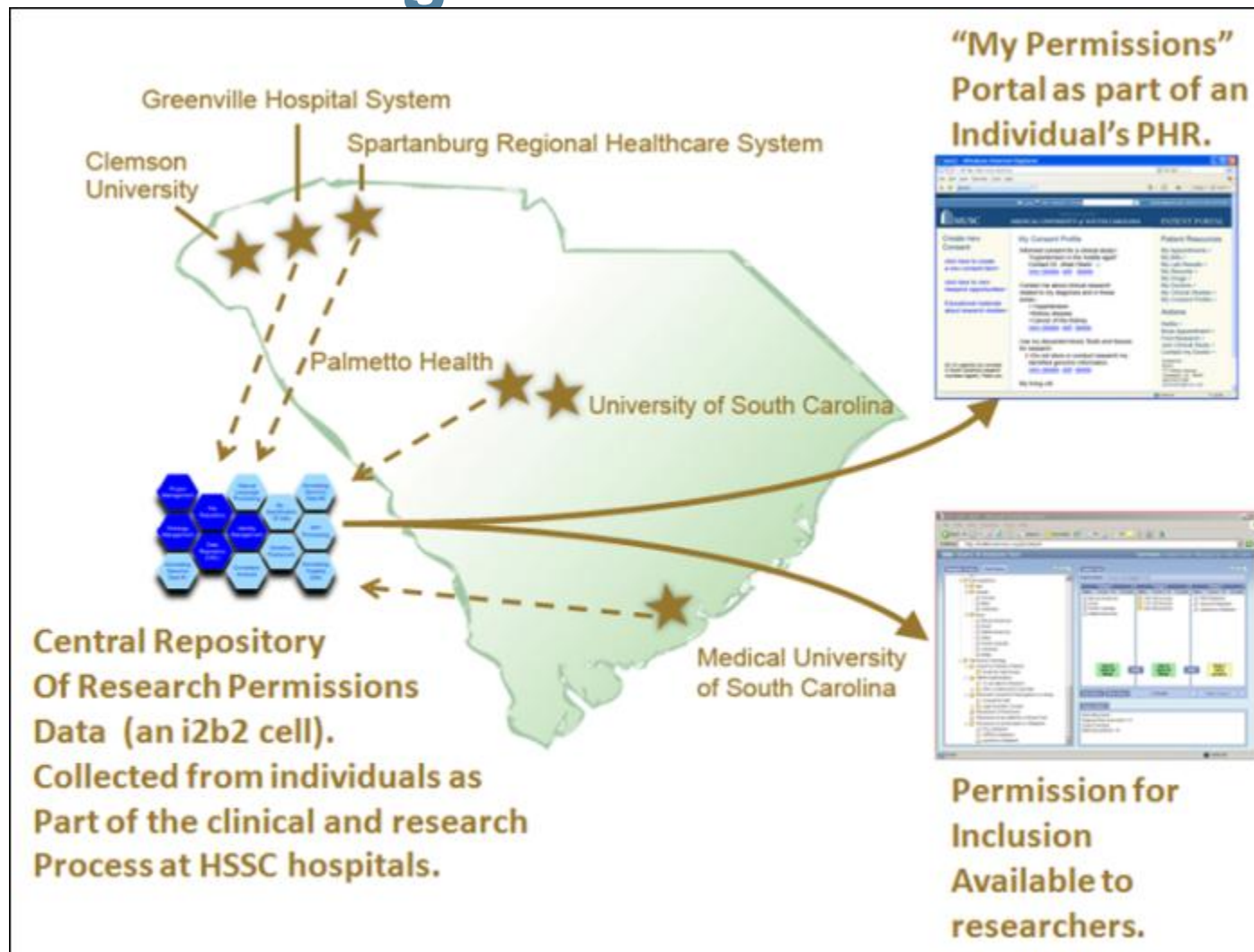
We Have Started Building the SCIPR Systems...



In Progress:

- Data sharing agreements
- Hosting architecture
- Training staff (Java CAPS)
- Building CTSA infrastructure at MUSC
- Collaborating with the South Carolina Health Information Exchange (SCHIEx)

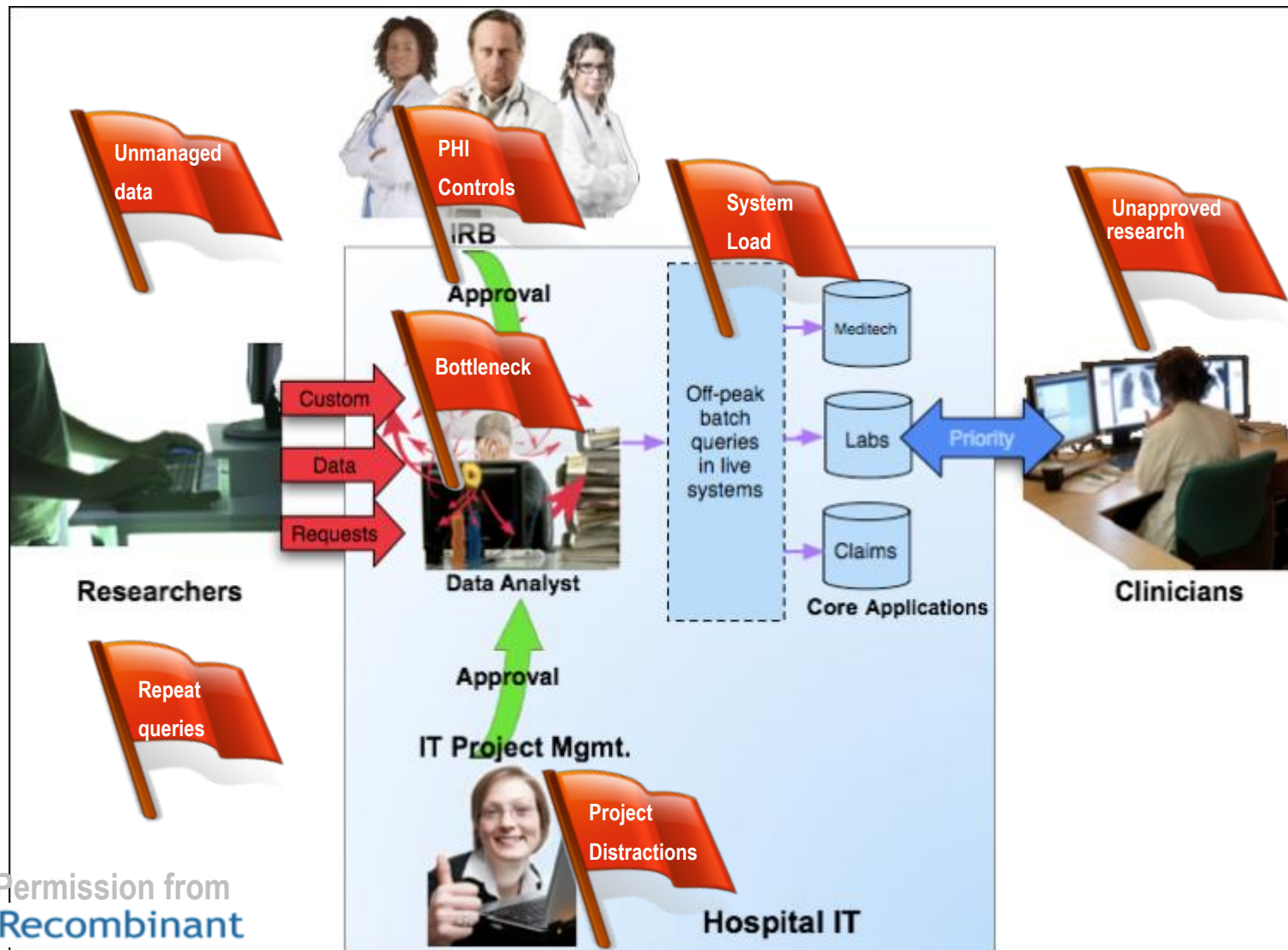
A Research Permission Management System – GO grant.



Key Technologies:

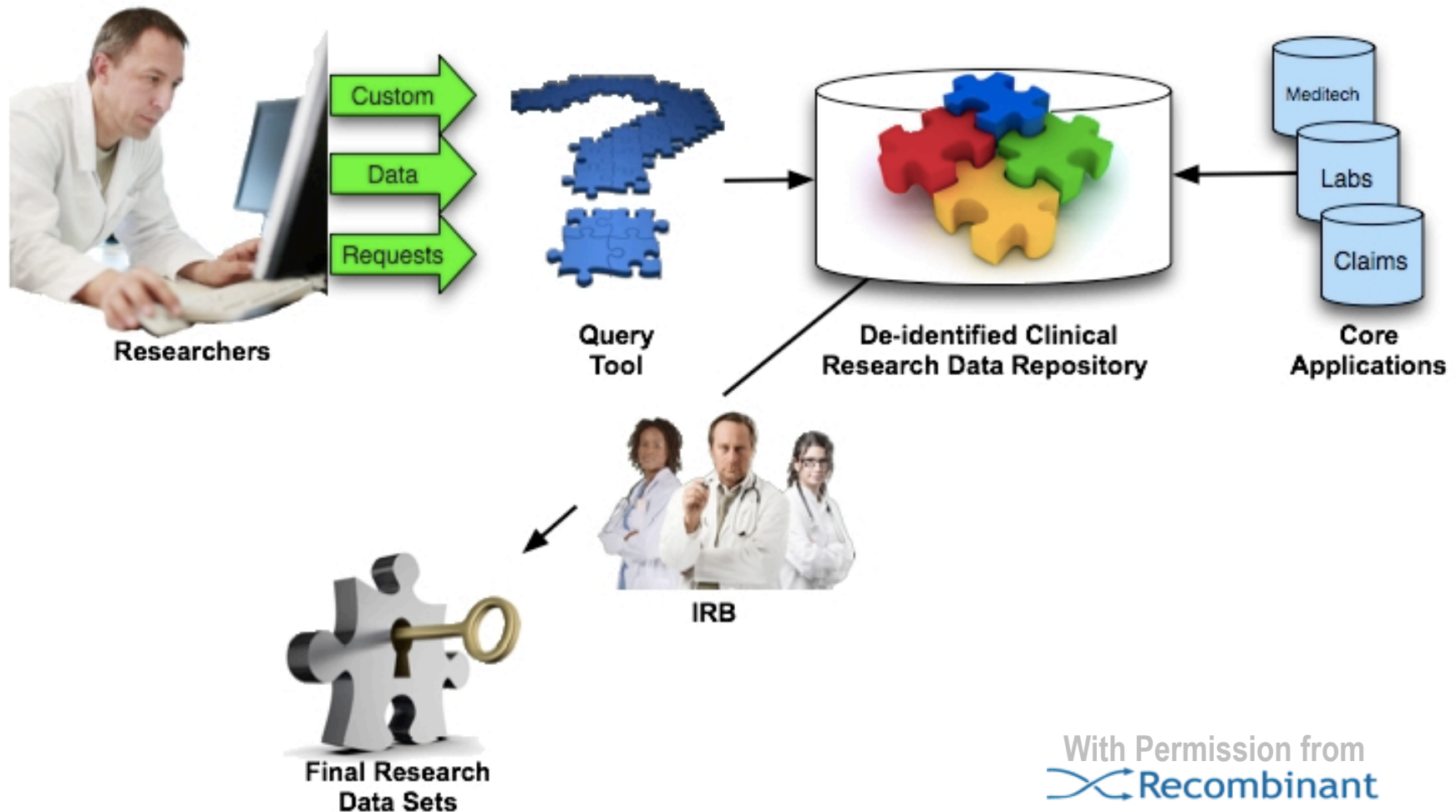
- i2b2 (Informatics for Integrating Biology and the Bedside
- JavaCaps (The Java Composite Application Product Suite)
- REDCap – Research Tools.

Research Data Access: Red flags!

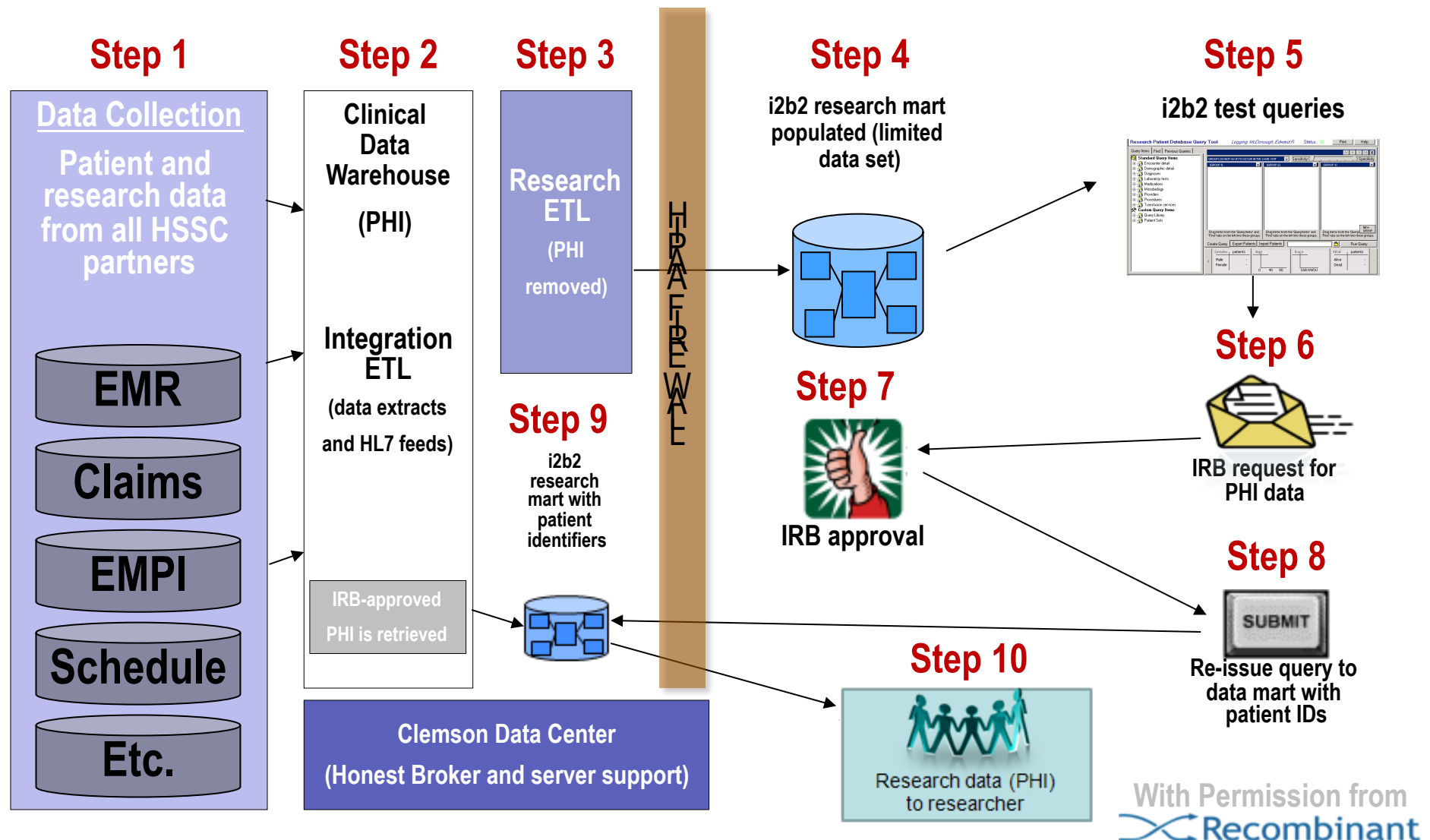


With Permission from
 Recombinant

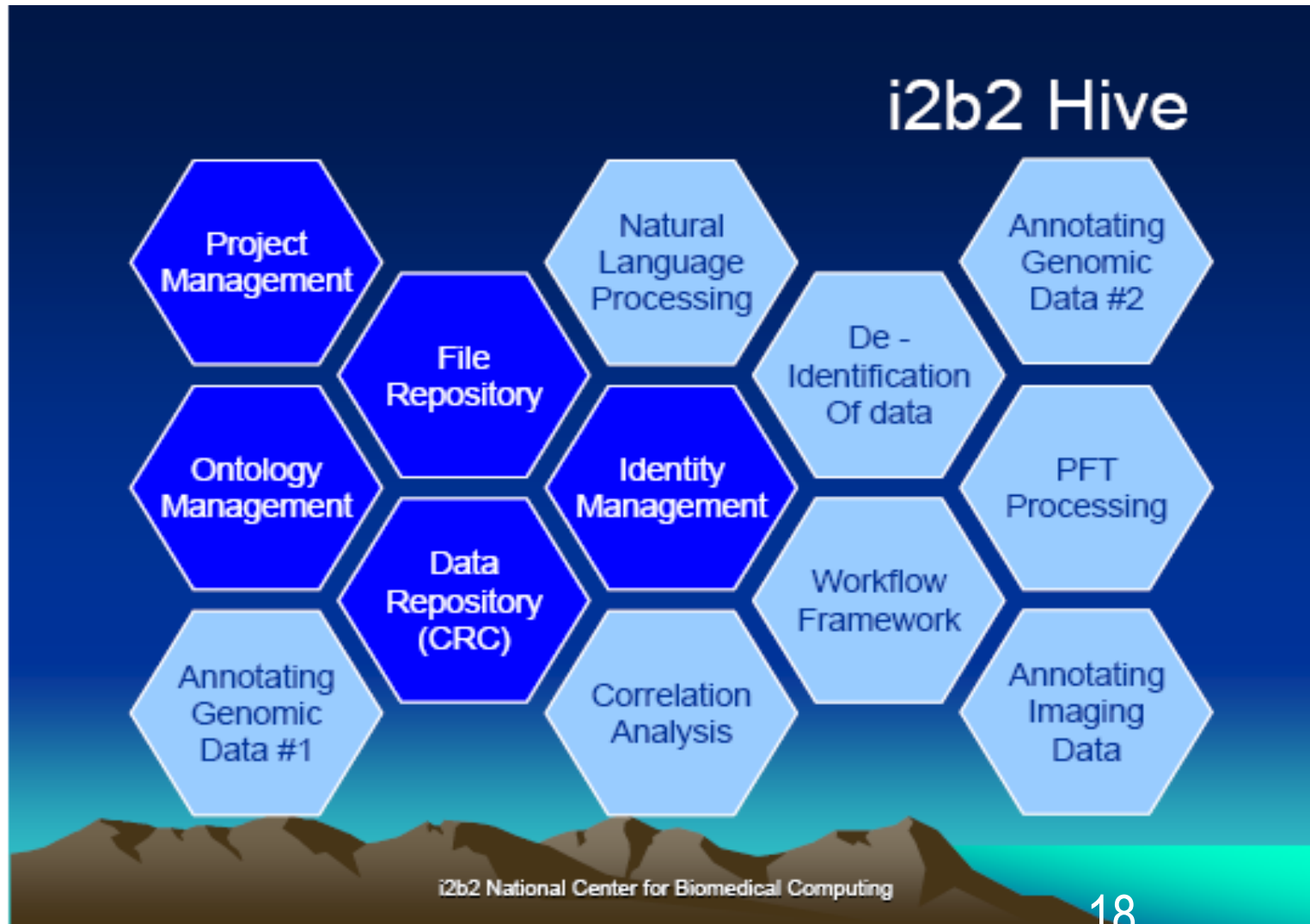
The Solution: Research Self-Service



Eventual i2b2 Research Flow



The i2b2 Hive – A Service Oriented Architecture



i2b2 Community

United States

- Beth Israel Deaconess Hospital, Boston, MA
- Boston University School of Medicine, Boston, MA
- Brigham and Women's Hospital, Boston, MA
- Children's Hospital, Boston, MA
- Denver Children's Hospital, Denver, CO
- Cincinnati Children's Hospital, Cincinnati, OH
- Cleveland Clinic, Cleveland, OH
- Weil Medical College of Cornell, NYC, NY
- Group Health Cooperative
- Harvard Medical School, Boston, MA
- Massachusetts General Hospital, Boston, MA
- Maine Medical Center, Portland, ME
- Marshfield Clinic, Wisconsin
- Morehouse School of Medicine, Atlanta, GA
- Oregon Health & Science University, Portland, OR
- Ohio State University Medical Center, Columbus, OH
- Philadelphia Children's Hospital, Philadelphia, PA
- Renaissance Computing Institute, Chapel Hill, NC
- Tufts New England Medical Center, Boston, MA
- University of California Davis, Davis, CA
- University of California San Francisco, SF, CA

United States (continued)

- University of Massachusetts Medical School, Worcester, MA
- University of Michigan Medical Center, Ann Arbor, MI
- University of Pennsylvania School of Medicine, Philadelphia, PA
- University of Rochester Medical Center, Rochester, NY
- University of Texas Health Sciences Center Houston, Houston, TX
- University of Texas Health Sciences Center San Antonio, SA, TX
- University of Texas Health Sciences Center Southwestern,
- Utah Health Science Center, Salt Lake City, UT
- University of Washington, Seattle, WA

International

- Georges Pompidou Hospital, Paris, France
- University of Goettingen, Goettingen, Germany
- University of Pavia, Pavia, Italy
- University of Seoul, Seoul, Korea

Pharmaceutical

- Johnson and Johnson

i2b2 Query & Analysis Tool

Find Patients | Analysis Tools | Message Log | Help | Logout

Navigate Terms

Find Terms

- Demographics
 - Age
 - Gender
 - Female
 - Male
 - Unknown
 - Race
 - African-American
 - Asian
 - Native-American
 - Other
 - Pacific-Islander
 - Unknown
 - White
- Permission Ontology
 - Assent for Pediatric Patients
 - Assent by Age Groups
 - HIPAA Authorization
 - To use data for Research
 - Who is Authorized to See Data
 - Informed Consent for Participation in a Study
 - Consent for Self
 - Legal Guardian Consent
 - Mechanism of Permission
 - Permission to be called for a Clinical Trial
 - Permission to be Included in a Databank
 - DNA Databank
 - Genome Databank
 - Lipidomics Databank

Query Tool

Query Name: African-180-209@20:11:56

Group 1			Group 2			Group 3		
Dates	Occurs > 0x	Exclude	Dates	Occurs > 0x	Exclude	Dates	Occurs > 0x	Exclude
African-American			180-209 pounds			DNA Databank		
Asian			210-239 pounds			Genome Databank		
Pacific-Islander			240-269 pounds			Lipidomics Databank		
Native-American								

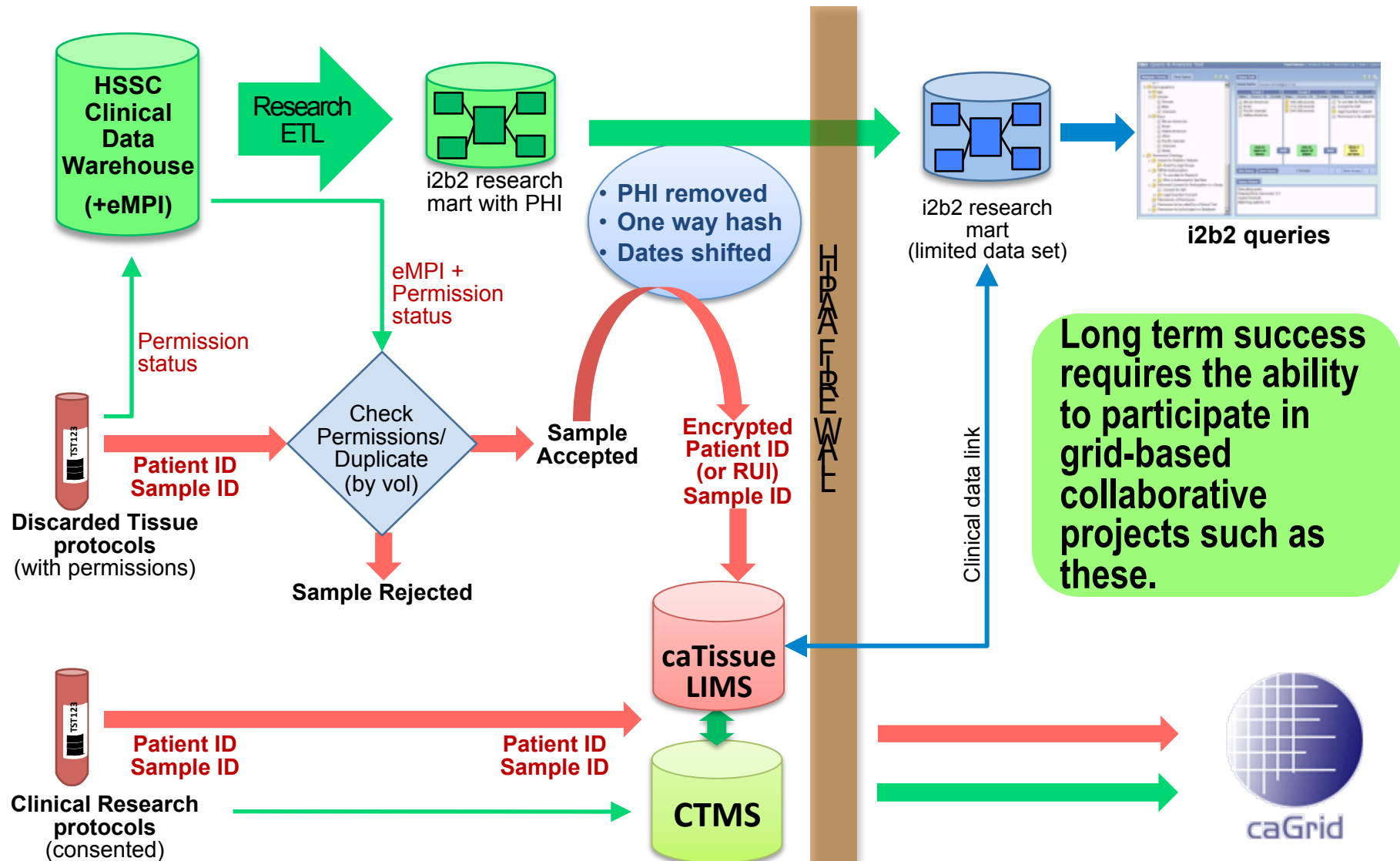
one or more of these
AND
one or more of these
AND
drop a term on here

Run Query New Query 2 Groups New Group

Query Status

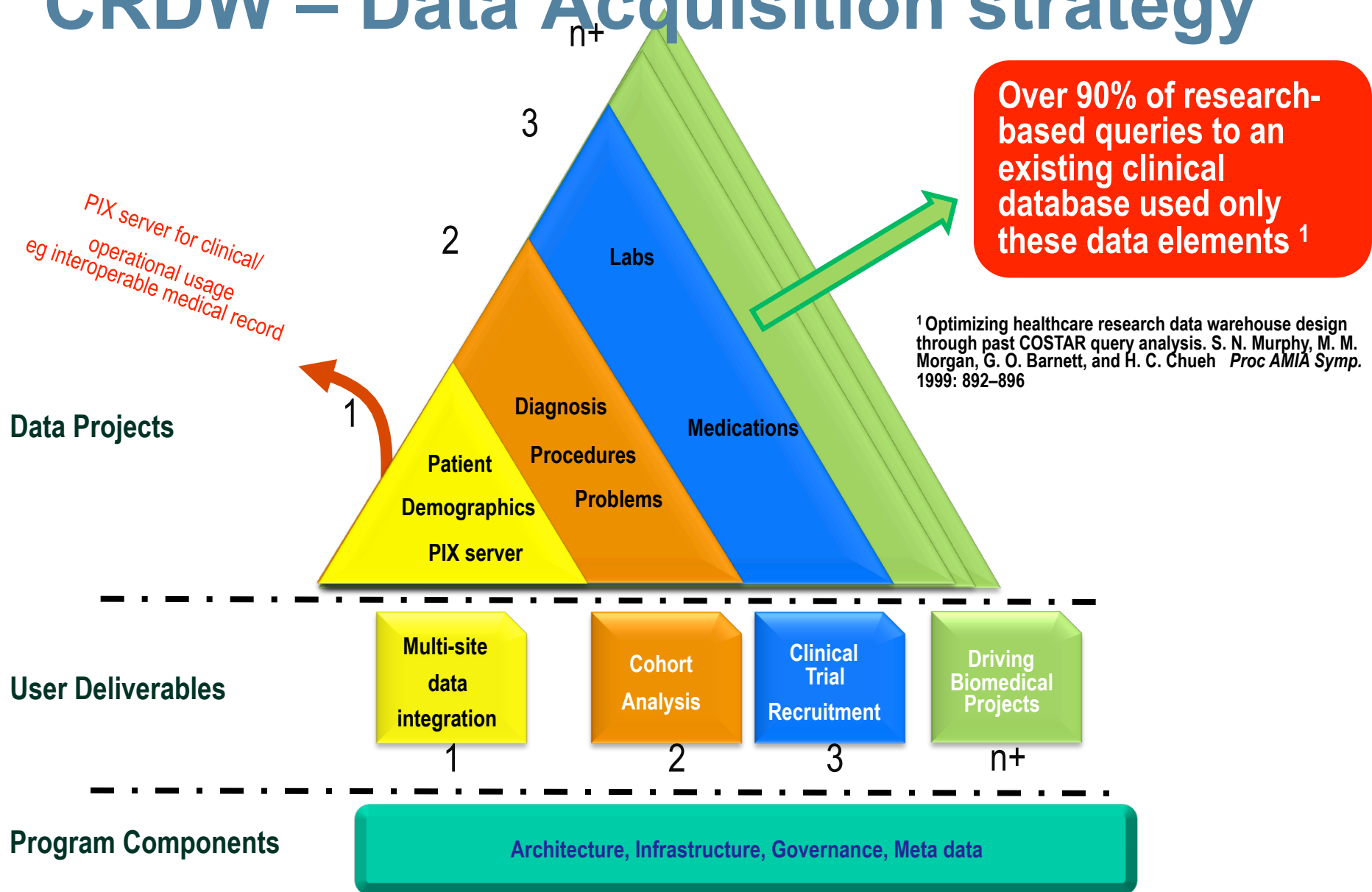
Executing query...
 Elapsed time (seconds): 5.3
 Query Finished...
 Matching patients: 35

i2b2 and caBIG components

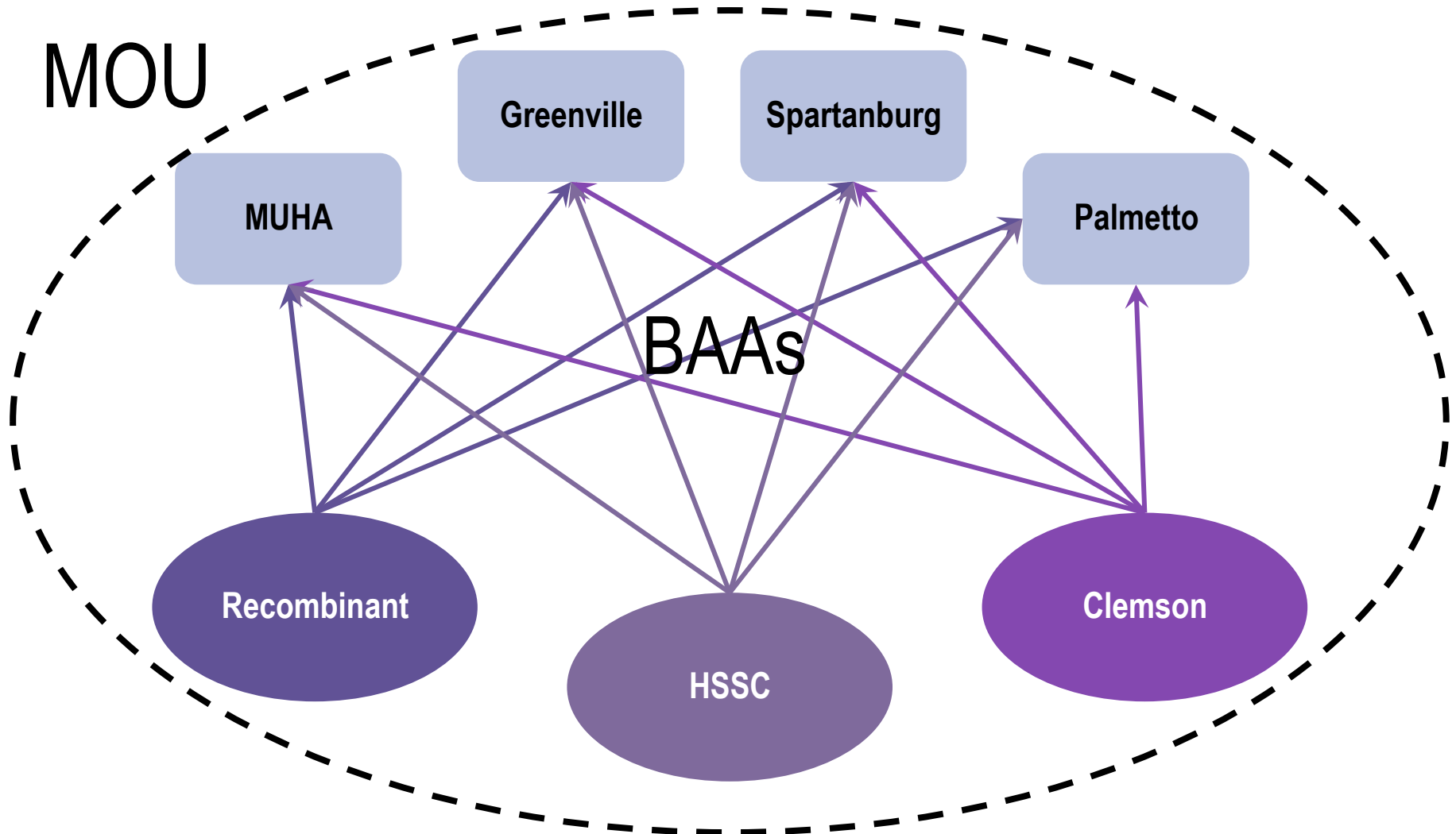


SCIPR Data Management Overview

CRDW – Data Acquisition strategy



Legal Agreements



Key Technologies

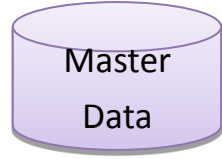
JavaCAPS

HSSC will create a data “Trust”

Data Sources



- Clinical notes
- Diagnoses
- Procedures
- Medications



- Demographics
- Provider master
- Code sets
- Locations



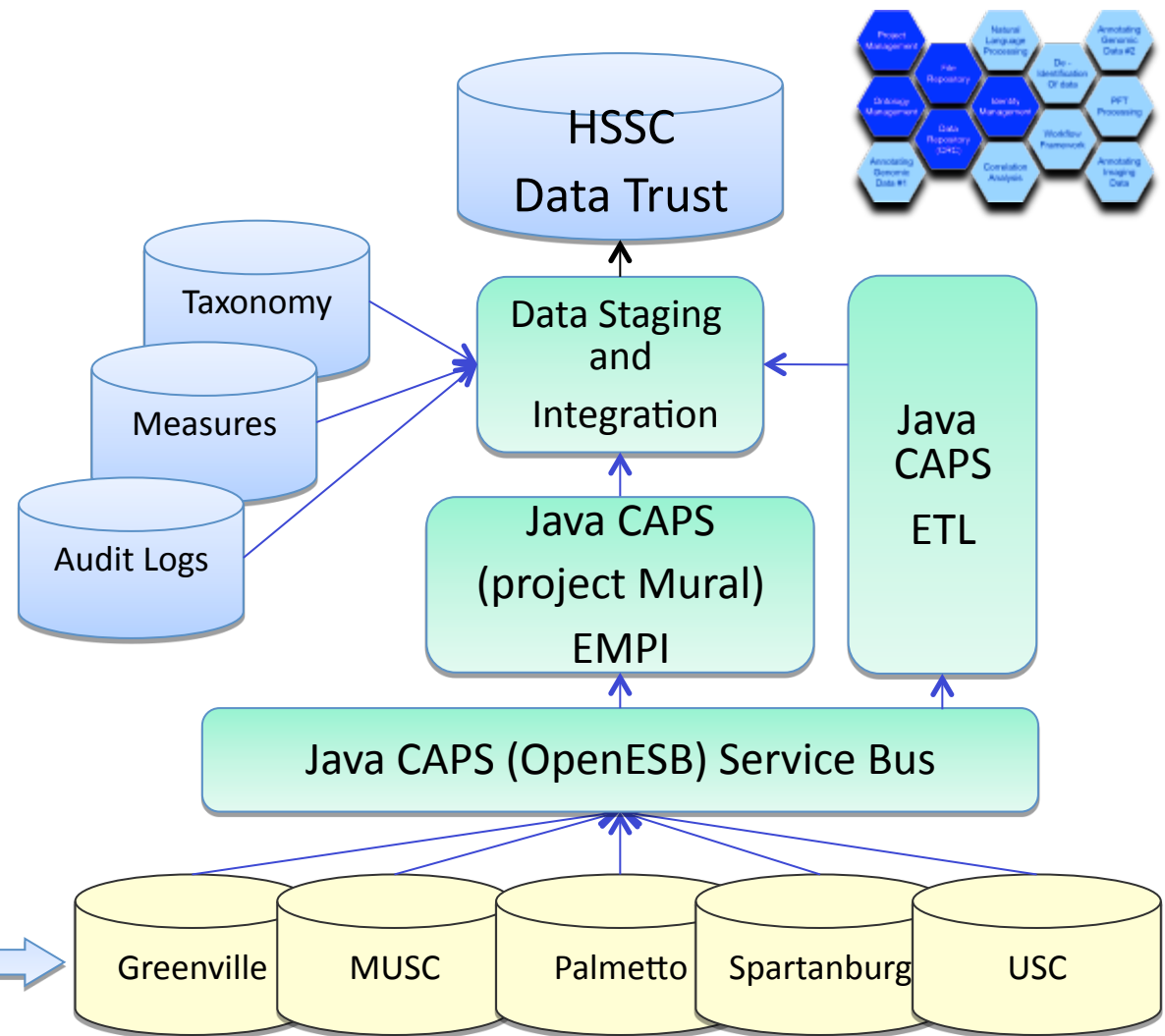
- Claims
- Billing



- Pathology
- Radiology
- Genomics



- Specialty databases
- Research databases
- CTMS

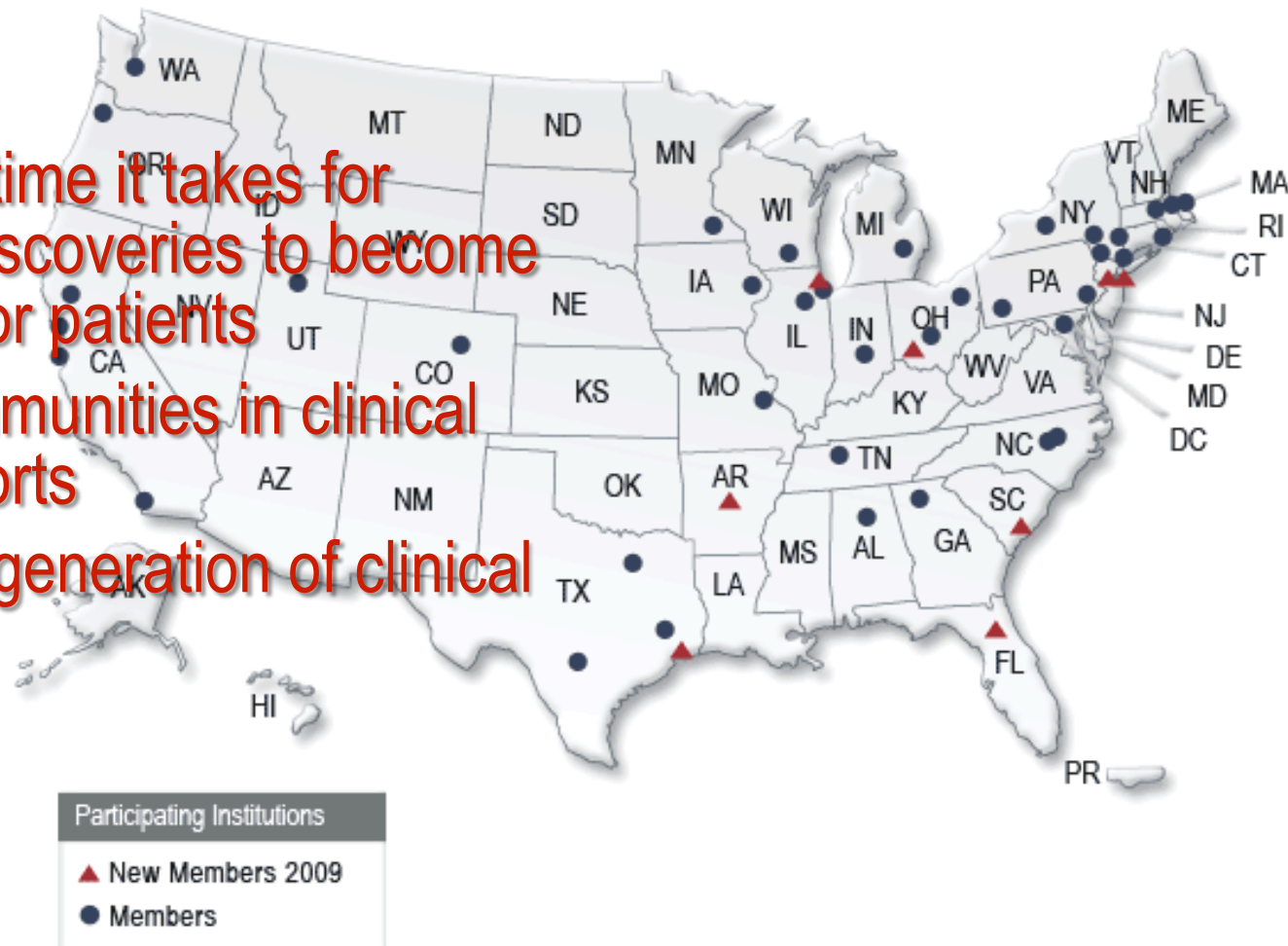


Other Projects

- SCTR/CTSA
- REDCap Consortium
- CTSA-COBRE collaboration

CTSA Consortium: supported by NCRRT

- Reduce the time it takes for laboratory discoveries to become treatments for patients
- Engage communities in clinical research efforts
- Train a new generation of clinical researchers.



Infrastructural Projects



SCTR home Website

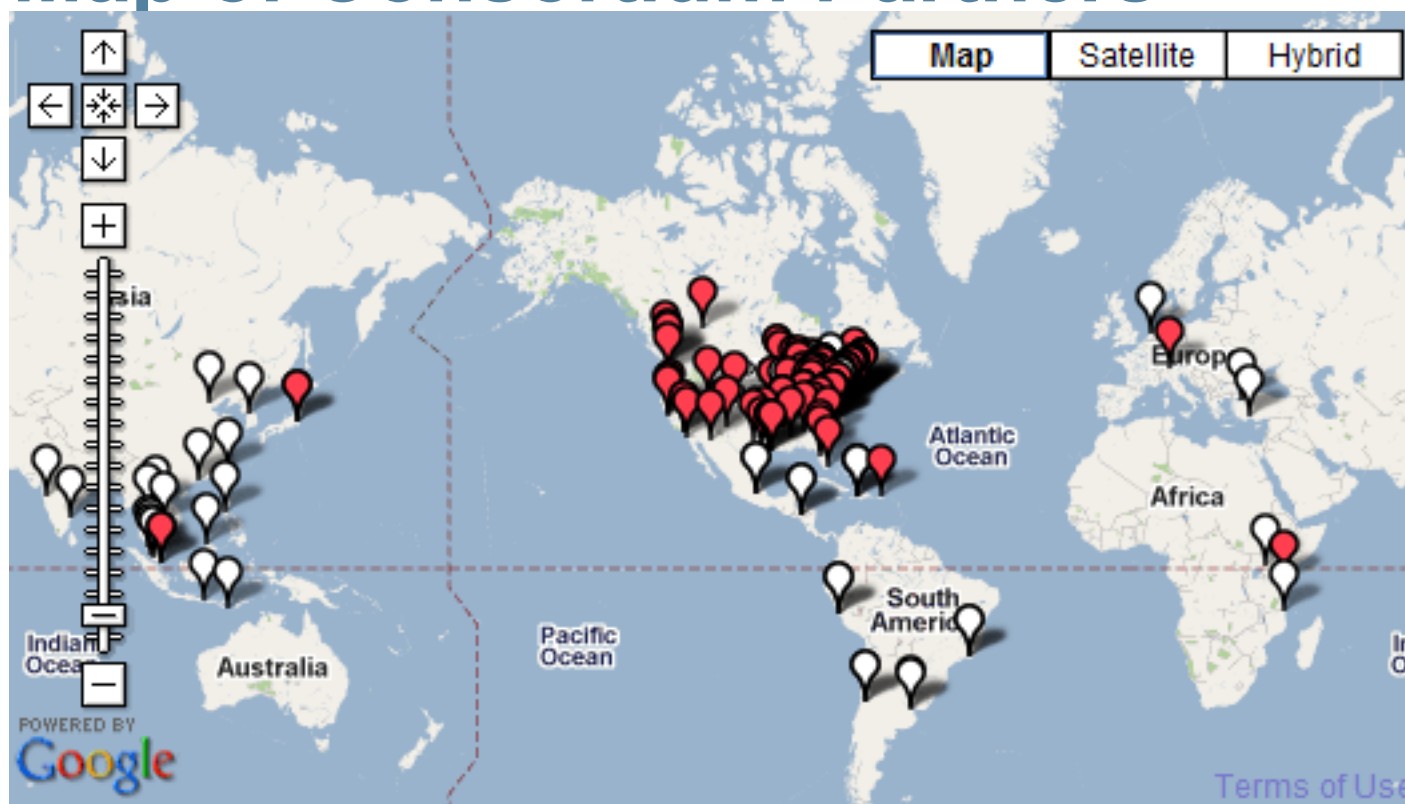
Research Toolkit

MAP-R (research application)

Service Request



Map of Consortium Partners



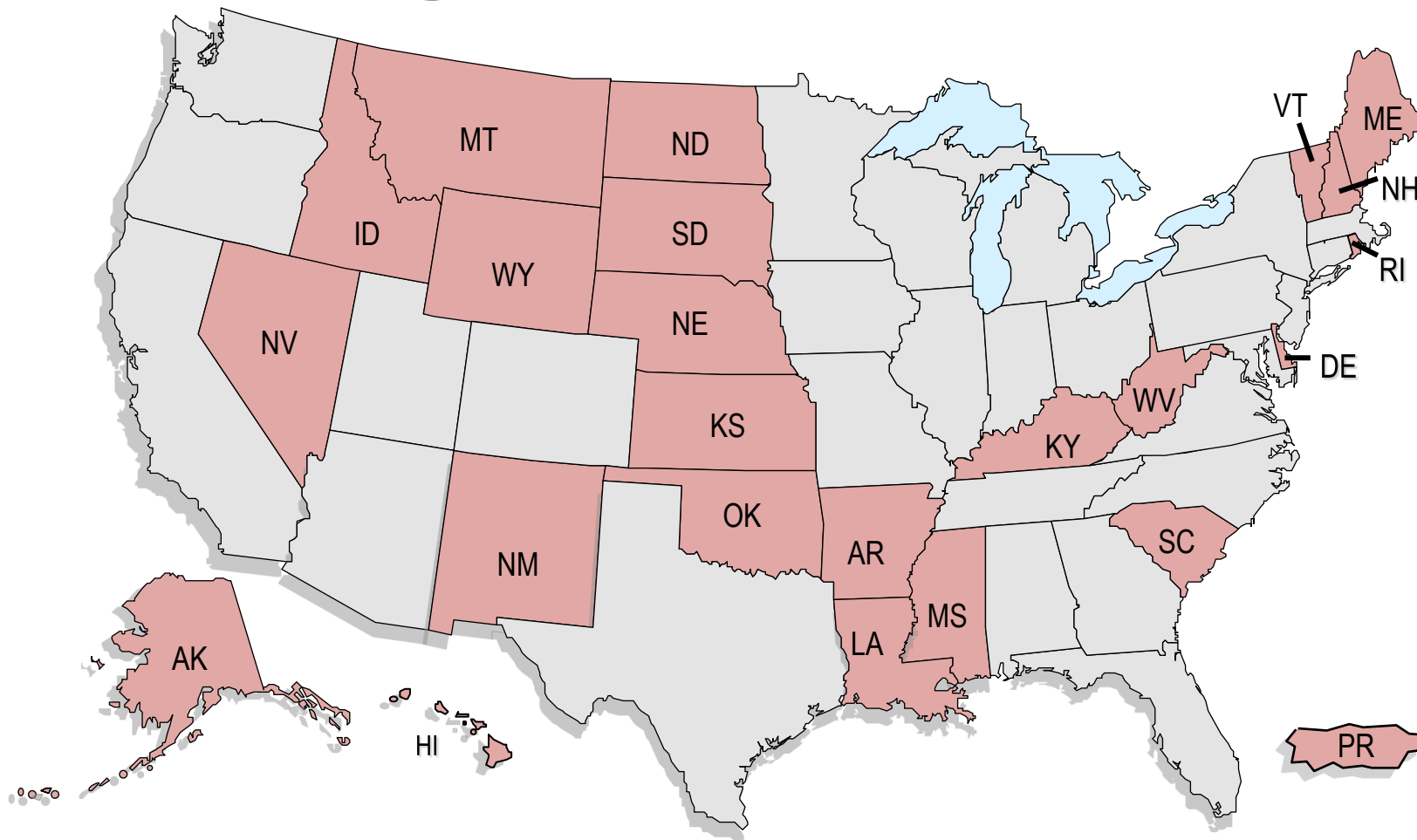
Consortium Partners Multi-Center Partners

▶ For more information see <http://project-redcap.org/>

REDCap Tools

- ▶ **Development:** initiated at Vanderbilt and includes >90 active institutional partners (including MUSC)
- ▶ **What are the tools?**
 - ▶ A secure, web-based application designed exclusively to support data capture for research studies
 - ▶ Intuitive interface for data entry (with data validation)
 - ▶ Includes an advanced survey tool
 - ▶ Export procedures for common statistical packages (SPSS, SAS, Stata, R)
 - ▶ Other features include branching logic, calculated fields and data de-identification
 - ▶ Graphical data representation

IDeA Program

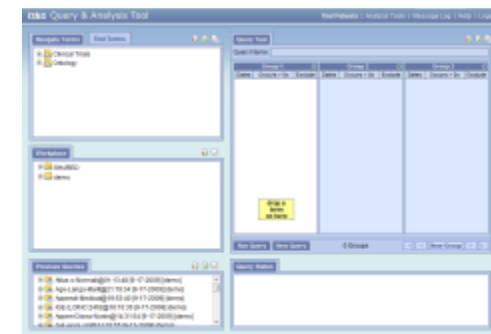
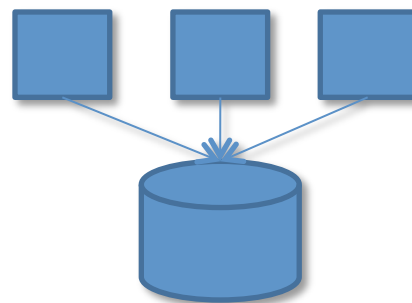


INBRE: 23 statewide networks (1 in SC)

COBRE: 83 thematic research centers (4 in SC)

COBRE in Lipidomics Portal Administrative Supplement

- Capitalizes on Informatics team infrastructure
- Interfaces with CTSA
- Provides access to state of the art Bioinformatics tools



Acknowledgements

