



The Roadmap for Re-engineering Clinical Research: Where are We Going?

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Public Health Challenges



Acute to chronic conditions



Aging Population



Health Disparities



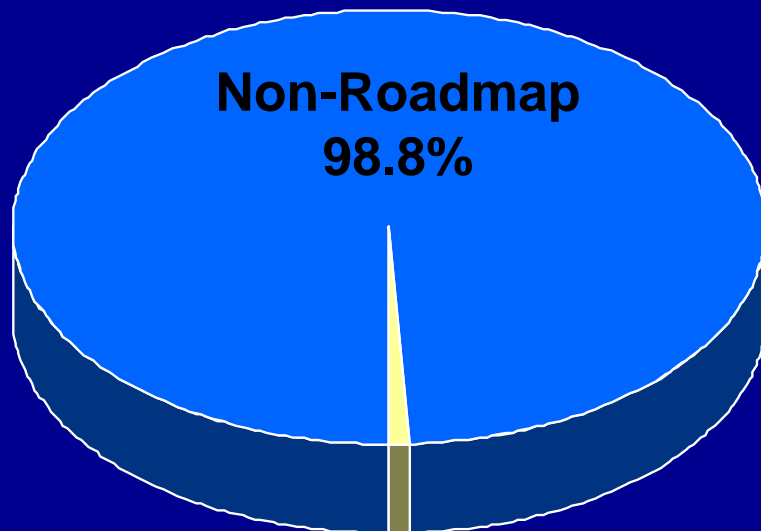
Emerging Diseases



Biodefense

NIH Roadmap is Not Shifting Funds Away from Grant Pool

FY2006 Budget = \$28.6 B

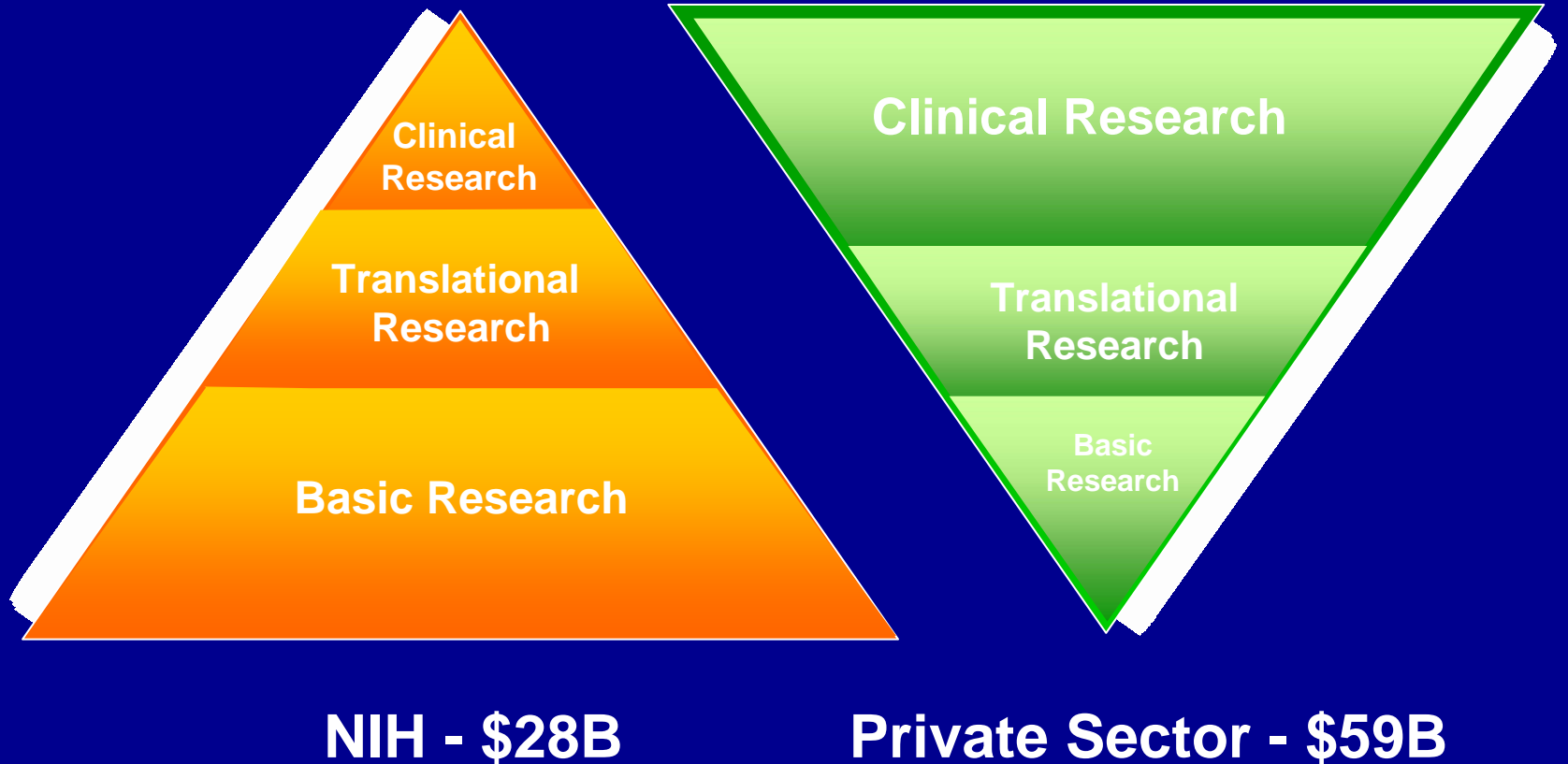


**Roadmap
1.2%**



- Developed to increase synergy across NIH
- Not a single initiative but over 345 individual awards in FY 2005, 133 institutions, 33 states

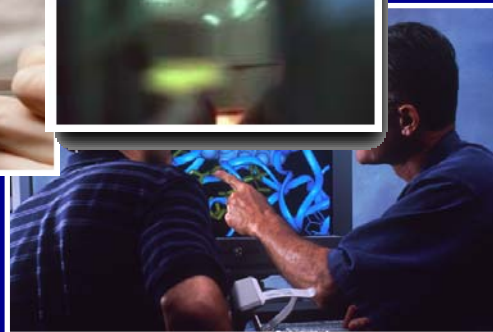
Balanced National Biomedical Research Portfolio



Clinical and Translational Science Awards



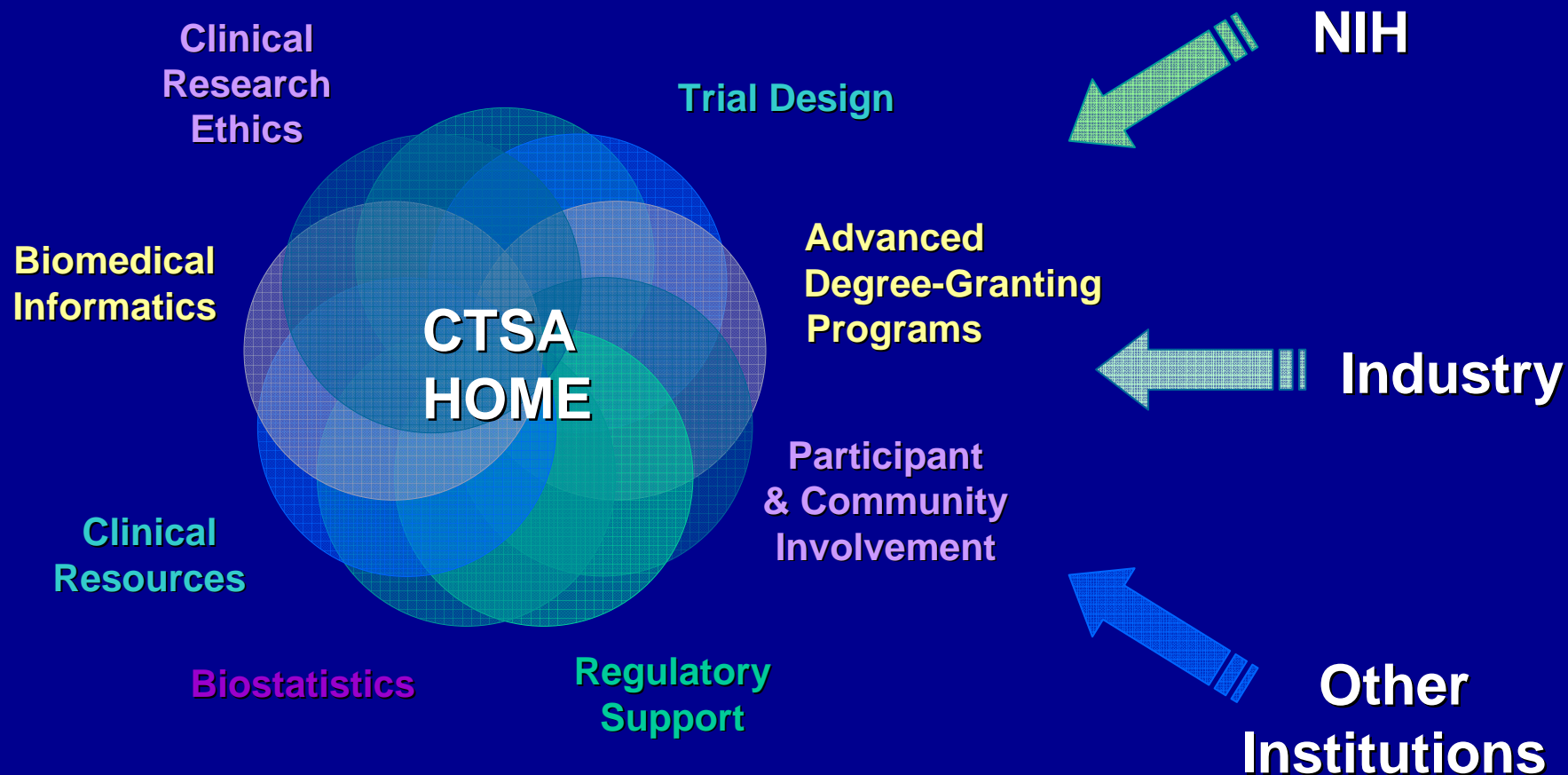
- ❑ Implementing biomedical discoveries made in the last 10 years demands an evolution of clinical science
- ❑ New prevention strategies and treatments must be developed, tested, and brought into medical practice more rapidly
- ❑ CTSA awards will lower barriers between disciplines, and encourage creative, innovative approaches to solve complex medical problems
- ❑ These clinical and translational science awards will catalyze change -- breaking silos, breaking barriers, and breaking conventions



Definitions

- ▣ *Clinical Research* covers all studies of diseases and trials of treatments that take place in human subjects.
- ▣ *Translational Research* describes the steps between a fundamental discovery and its application in clinical medicine.

NIH CTSA Award: A Home for Clinical and Translational Science



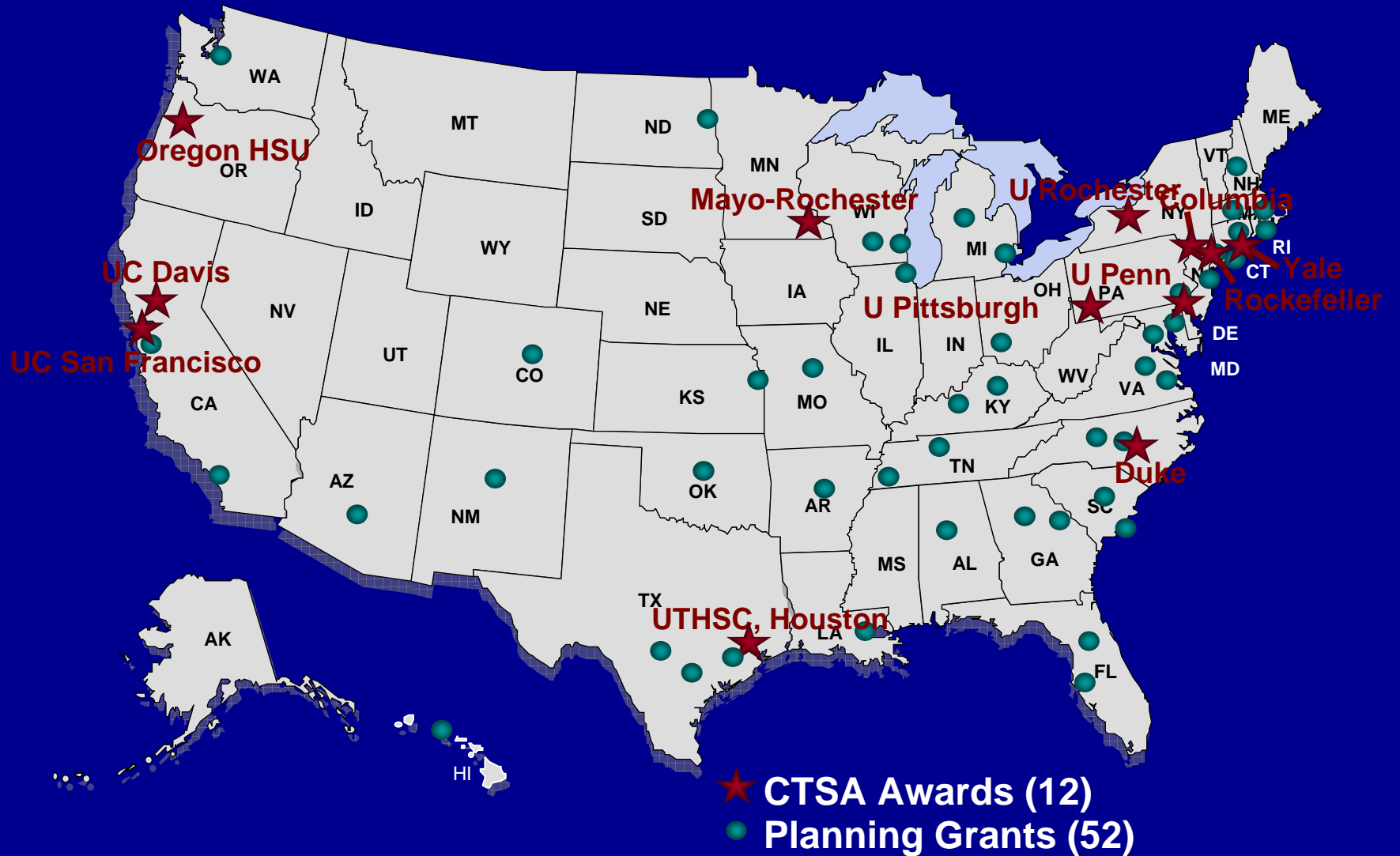
First CTSA Awards Announced October 3

- 12 Academic Health Centers (AHCs) nationwide
- 52 AHC planning grants to prepare applications to join consortium
- In 2012, ~60 institutions will be linked to energize clinical and translational science



Building A National CTSA Consortium

FY 2006 CTSA Awards & Planning Grants



Examples of CTSA Activities

Duke University

- Translate bench-bedside findings to populations using advanced informatics and health services delivery methods

University of California, San Francisco

- Pursue new opportunities with the San Francisco VA and Kaiser Permanente
- Create new community research centers to expand efforts in minority and medically underserved populations

Oregon Health Sciences University

- Developing informatics capabilities to partner with Kaiser Permanente NW Center for Health Research, Oregon Rural Practice Research Network, Portland VA Medical Center for intervention research

Opportunities for Best Practices

CTSA Examples

Rockefeller University

- ❑ Establish national research nursing standards
- ❑ Share research pharmacy best practices
- ❑ Collaborate with NIH Clinical Center to measure the experience of clinical research participants

University of Pennsylvania

- ❑ Involve industry scientists in teaching and in training
- ❑ Bridge the pediatric/adult interface

University of California, Davis

- ❑ Partner with schools of veterinary medicine, biological sciences, engineering, environmental sciences, and the state health care system in cross-disciplinary efforts
- ❑ Provide clinical consultations through novel telecommunications

Partnerships

- FDA
- CMS (data analysis, clinical trials)
- VA (informatics, clinical trials)
- Industry (developing better approaches for IP, cofunding large initiatives through the Foundation for the NIH)

Informatics

- ❑ Interconnected, interoperable informatics network
- ❑ Standardization while reducing impediments
- ❑ Interlinking AHC with clinical trial networks
- ❑ Allow system-to-system application, monitoring, reporting

Use the Same Standards

- The **same** standards should be used by biomedical researchers and clinicians to the extent possible
- Standards being developed by biomedical researchers need to be integrated with clinical data and the EHR as new technologies mature
 - **Imaging standards** evolving for MRI annotation
 - **Standards for new tests** like DNA microarrays and proteomics need to be developed and incorporated before these tools move into the clinic
 - **PHR** standards, to capture patient-provided information in a structured form

Informatics Challenges

- **The challenges to the informatics community are to:**
 - Adopt standards that can structure data, syntactically and semantically, from devices into the EHR and then into the longitudinal record
 - Harmonize clinical informatics standards with research standards
 - CDISC, SNOMED, genomics, etc.
 - Work with research community to provide interactive clinical and research records.
 - Ensure that ongoing informatics activities in BIRN, caBIG, and LARIAT are fully leveraged in the CTSAs

Role of Clinical Research Informatics

- ❑ Extract data for clinical research use from EHRs of consenting patients
- ❑ Improve communication between clinical researchers and patients to create opportunities for participation
- ❑ Bring news and updates about trials to participants during and after studies
- ❑ Facilitate patients' ability to follow up with investigators

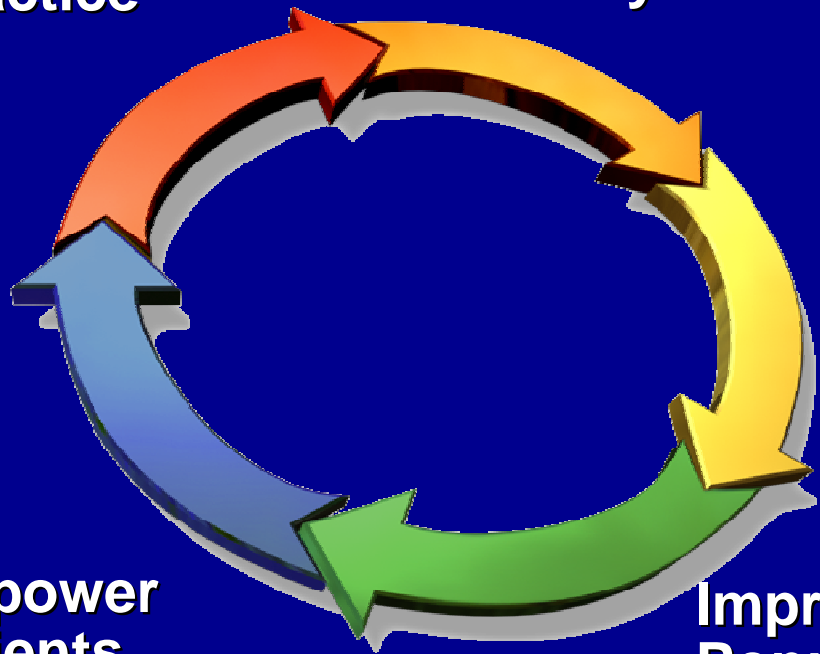
NIH and the President's Health Information Technology Strategic Plan

**Transform
Clinical
Practice**

**Connect
Physicians**

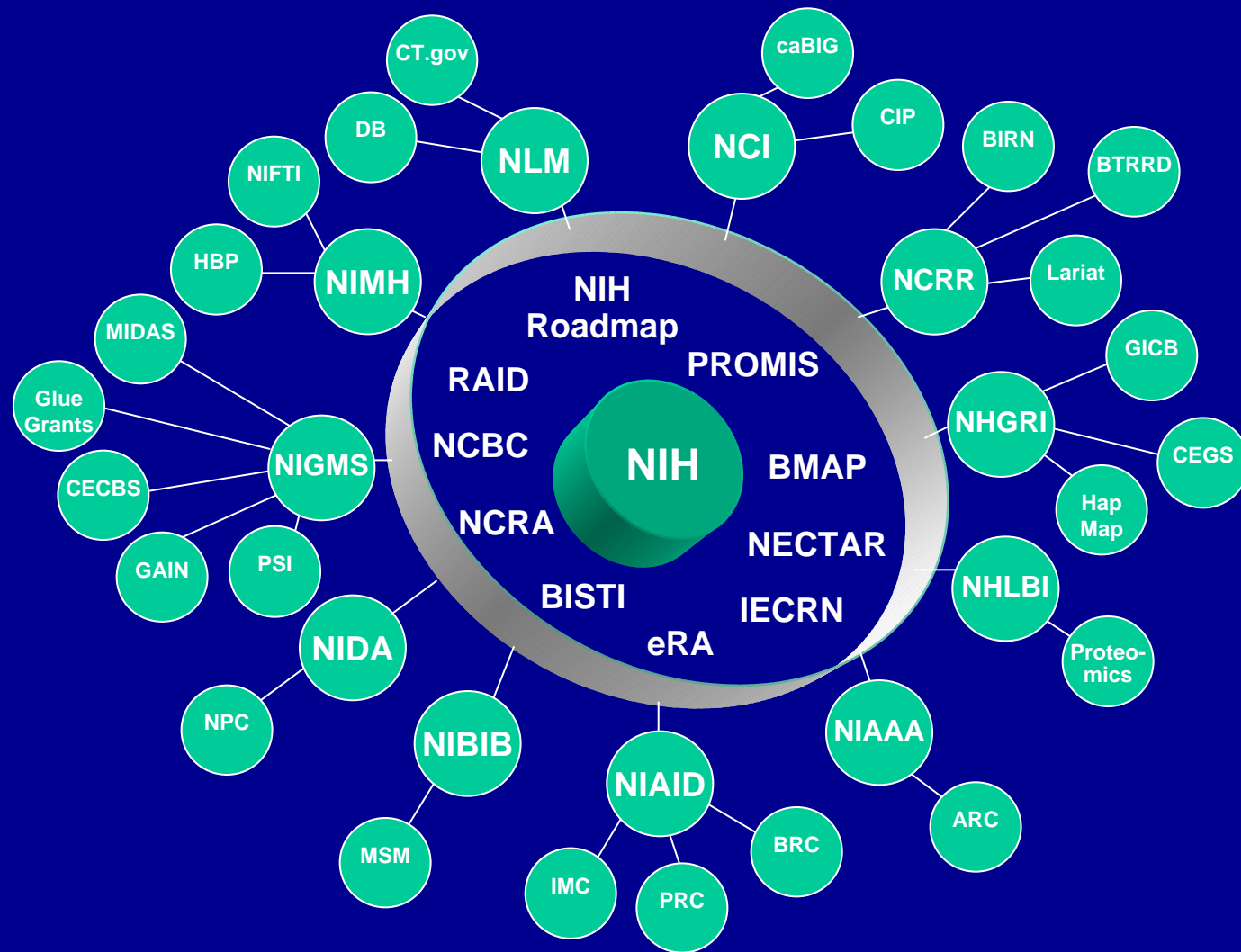
**Empower
Patients**

**Improve
Population
Health**

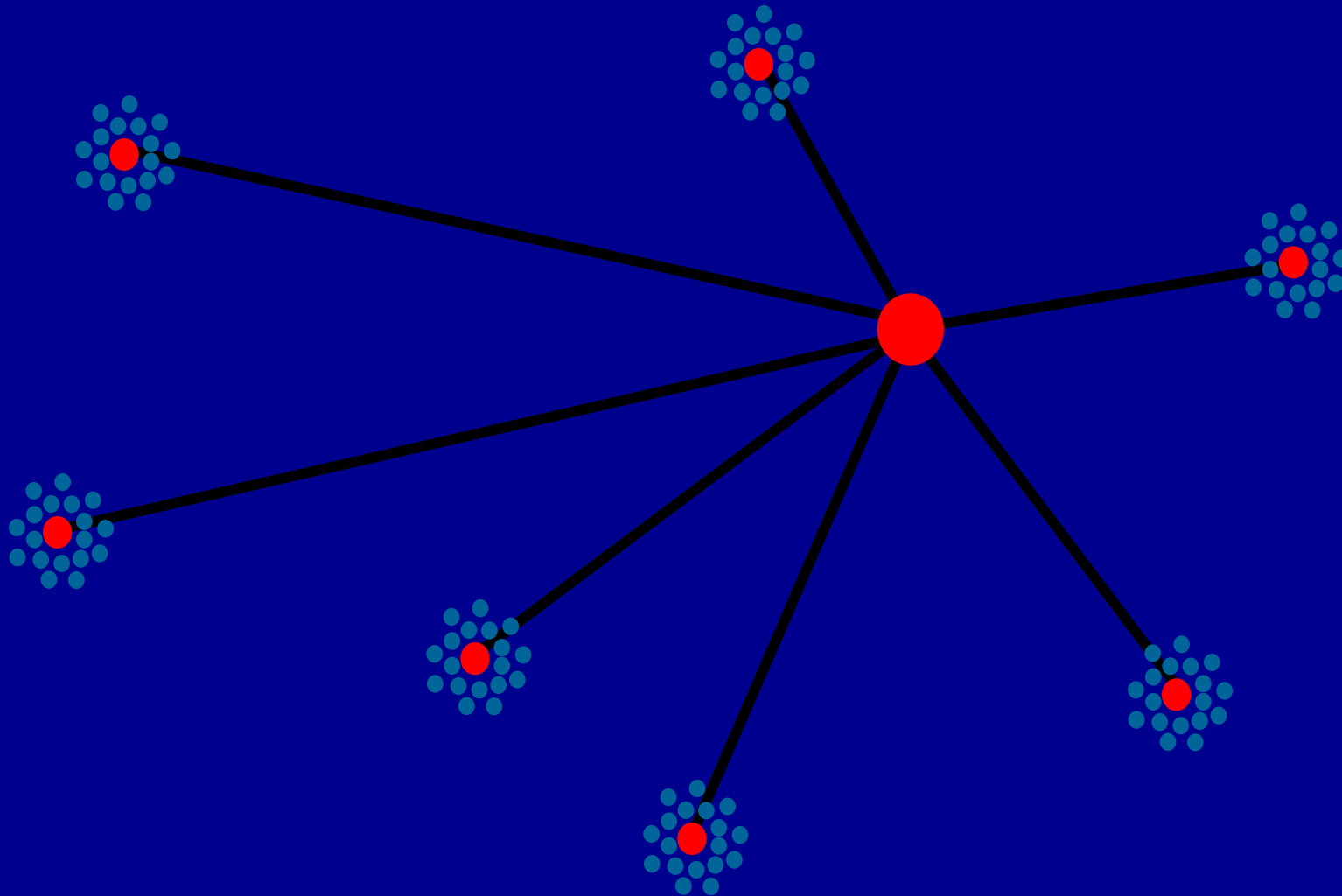


- **Optimize Efficiency and Productivity of Biomedical Research**
- **Basic exploration**
 - **Bioinformatics and computational biology**
- **Accelerate research translation**
 - **CTSAs**
- **Research IT systems**
 - **caBIG**
 - **Vocabularies**
 - **Standards**

NIH Informatics Activities



Typical NIH Network Academic Health Center Sites & Data Coordinating Center



Integrating Clinical Research Networks

- Link existing networks so clinical studies and trials can be conducted more effectively
- Ensure that patients, physicians, and scientists form true “Communities of Research”
- National Electronic Clinical Trials and Research (NECTAR) Network



Examples of caBIG Activities at CTSA Institutions

Mayo Clinic and University of Pennsylvania

- ▣ Involved in caBIG architecture, data sharing and intellectual capital, strategic planning, tissue banks and pathology tools, and training

University of Pennsylvania

Involved in caBIG imaging initiative and clinical trial management systems

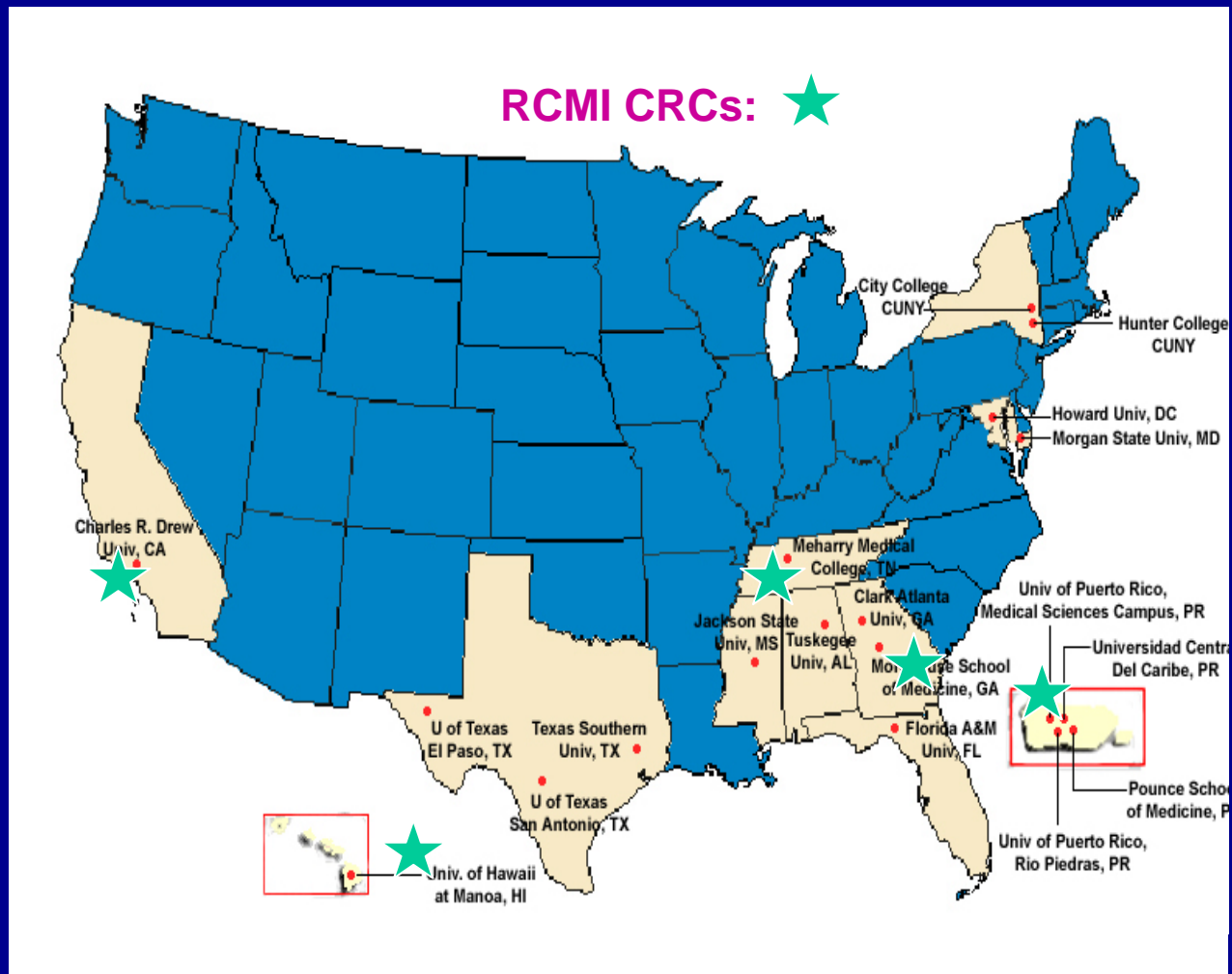
Mayo Clinic

Involved in caBIG vocabularies and common data elements

Beyond the CTSA Consortium – Opportunities for Interaction with Diverse Communities

- CTSAAs can develop partnerships with grantees at Research Centers in Minority Institutions (RCMIs) and in Institutional Development Award (IDeA) states
 - **Developing states and institutions offer geographically and ethnically diverse representation**
 - **IDeA and RCMI grantees have track record in training and mentoring**

Research Centers in Minority Institutions: Clinical Research Centers

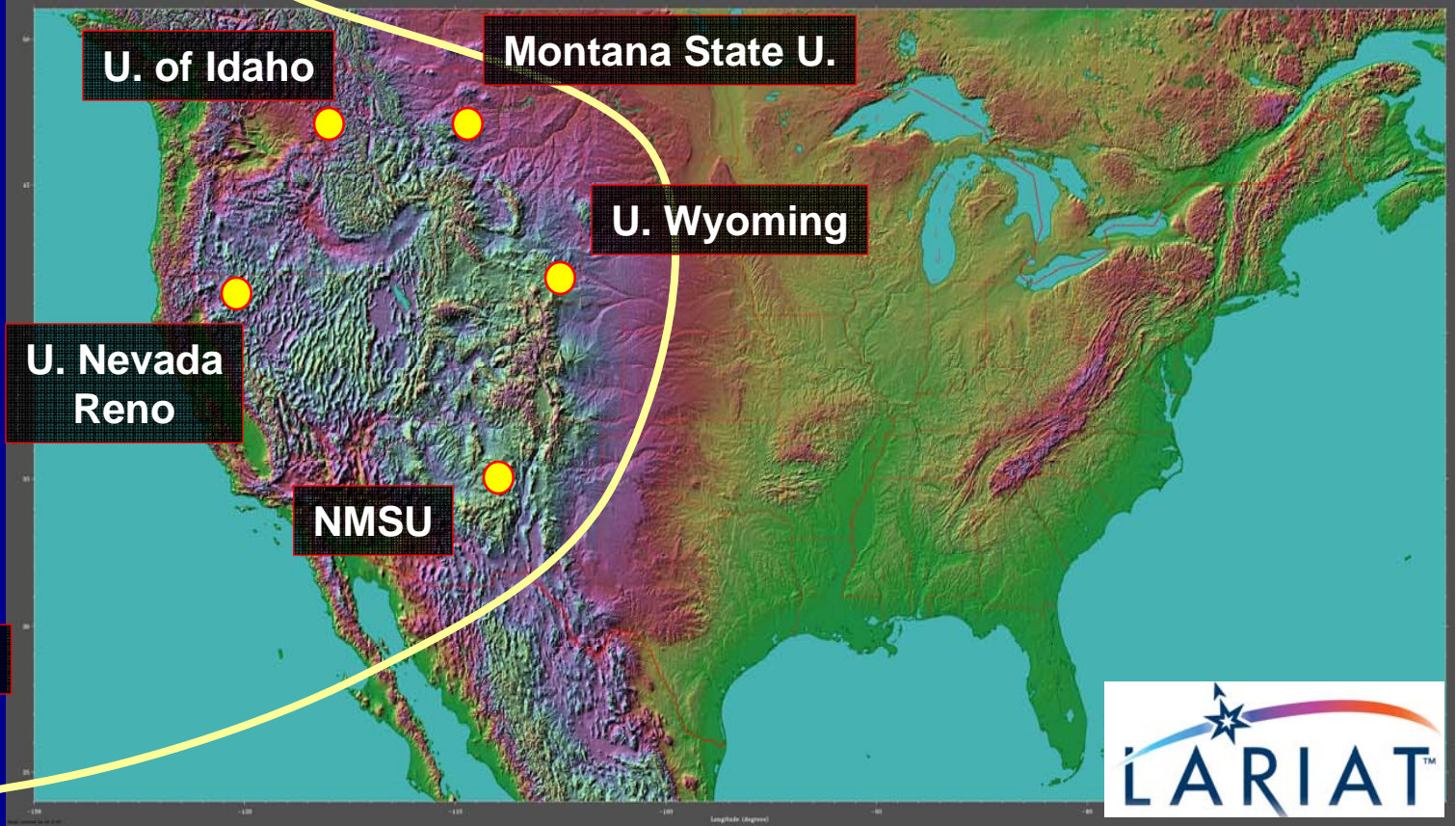
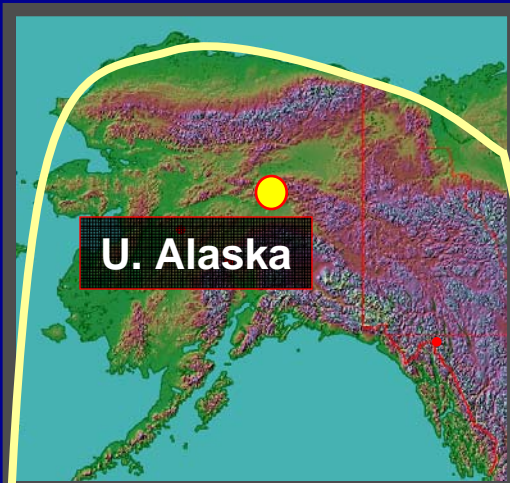


IDeA States - 23 States and Puerto Rico



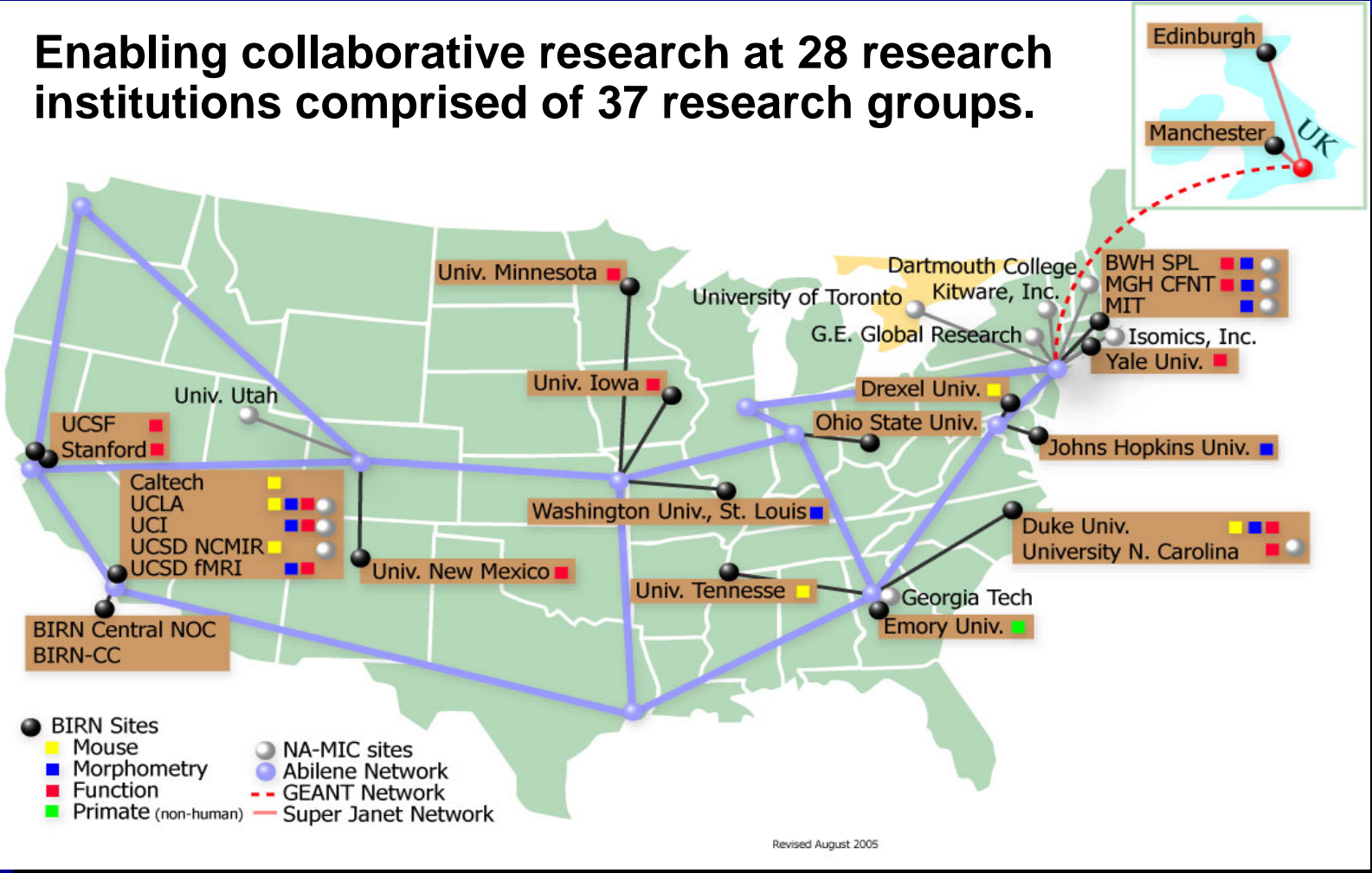
IDeANET

Lariat: Connecting universities and researchers in the rural west to advanced national cyberinfrastructure for access to e-science opportunities and informatics resources.



Biomedical Informatics Research Network (BIRN) –funded by NCRR

Enabling collaborative research at 28 research institutions comprised of 37 research groups.



Congressional Interest

House & Senate Appropriations Committee Report Requests:

- **Support of Clinical Investigators (Due 3/1/2007)**
 - Extent to which CTSA awards support pilot studies.

- **Clinical and Translational Research (Due 4/1/2007)**
 - Detail NIH's progress in implementing the CTSA model across multiple ICs and identify potential barriers to widespread implementation of CTSA program.

- **GCRCs/CTSAs (Due 7/1/2007)**
 - Status of implementing CTSA program, details on portion of budget going to GCRCs and CTSAs, status of evaluation, and how clinical research community recommendations will be addressed in next RFA.

The Future

- ❑ **The CTSA consortium offers an unparalleled opportunity to disseminate standards and best practices that will guide both translational and clinical research and health care delivery**
- ❑ **The success of the CTSA consortium will be measured in part by the acceptance of its standards**
- ❑ **CTSAs will partner with geographically and ethnically diverse institutions that broaden their impact**
- ❑ **The ultimate goal: continuous improvement in the health of populations and individuals throughout the nation**