

PUBLIC POLICY COUNCIL'S 22ND ANNUAL LEGISLATIVE BREAKFAST



**National Center for
Research Resources**

CTSA Clinical & Translational
Science Awards

The CTSA's and Pediatric Research: Challenges and Opportunities

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Organized by the Public Policy Council (APS/SPR/AMSPDC) for the Public Policy



Myron Genel, M.D.

Has documented that he/she has no relevant financial relationships to disclose or COIs to resolve.

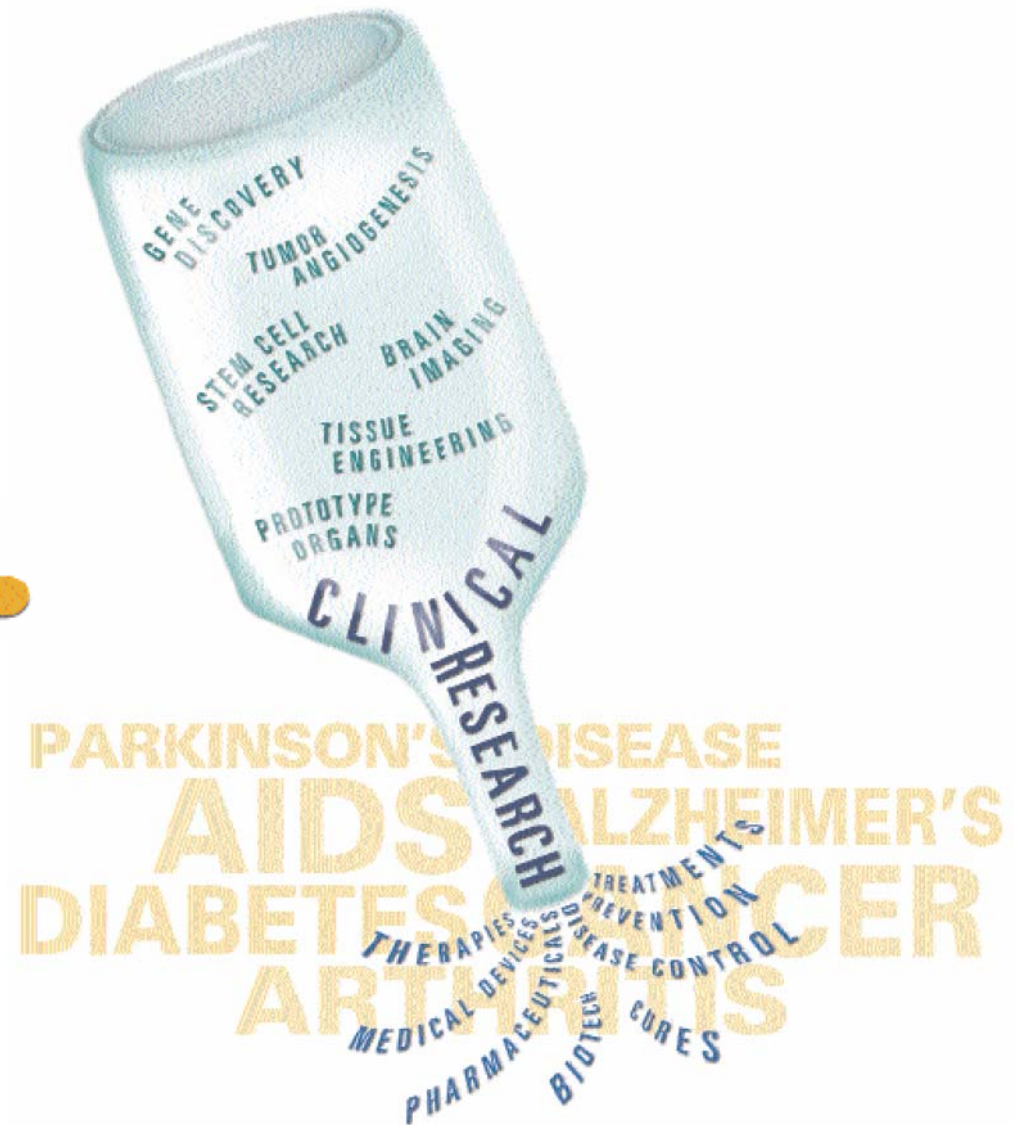


BREAKING THE SCIENTIFIC BOTTLENECK

NOVEMBER 1999

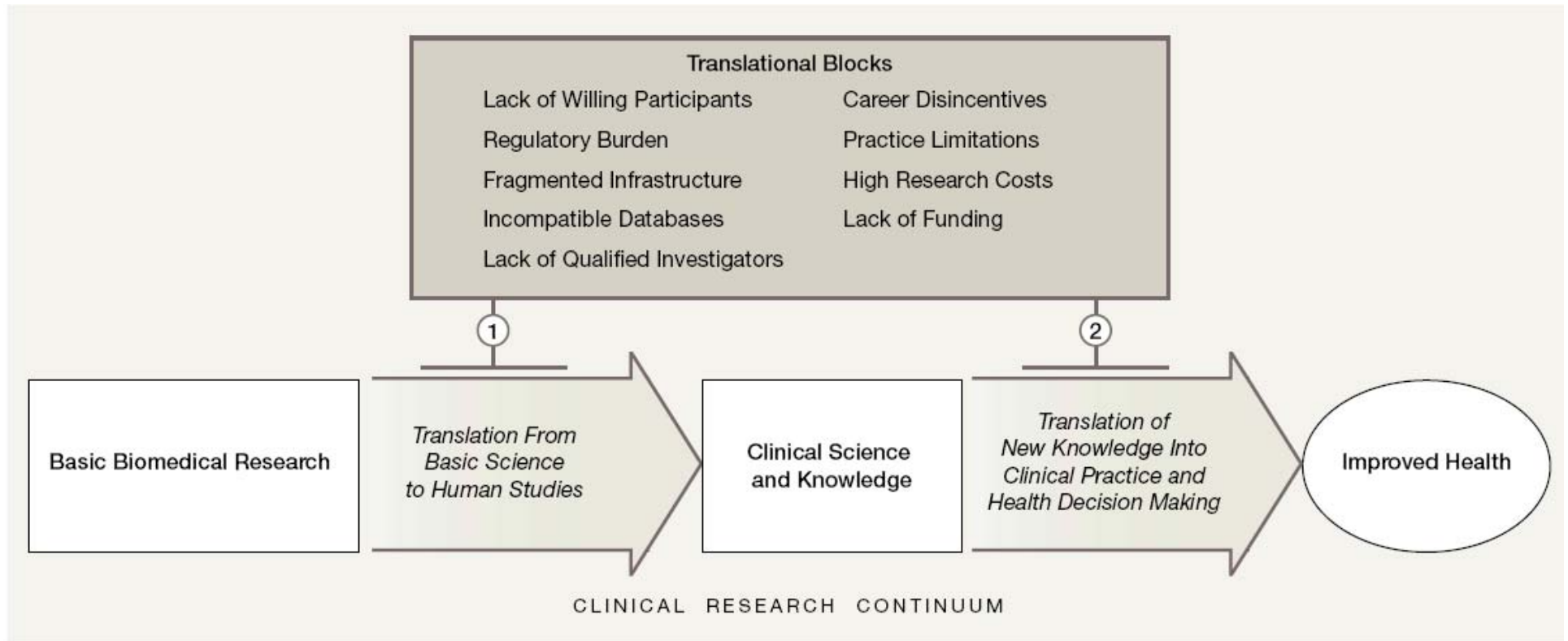
BREAKING THE SCIENTIFIC BOTTLENECK

CLINICAL RESEARCH: A NATIONAL CALL TO ACTION



Central Challenges Facing the National Clinical Research Enterprise

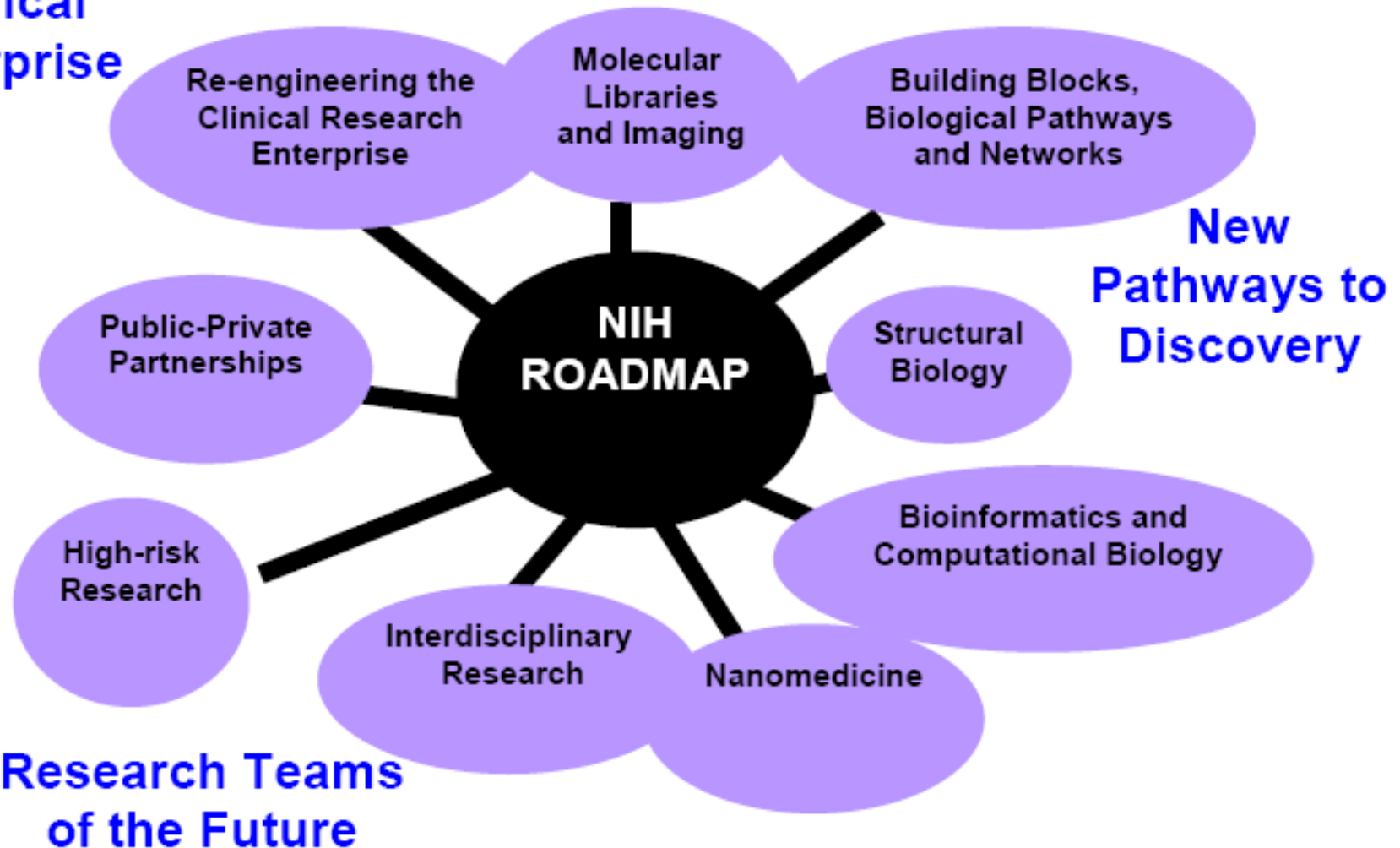
The 2 Translational Blocks in the Clinical Research Continuum



Sung, N. S., Crowley, W.F., Genel, M. et al. JAMA 2003;289:1278-1287.

NIH Roadmap for Medical Research

**Clinical
Enterprise**



**Research Teams
of the Future**



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CTSA Clinical & Translational
Science Awards

Fact Sheet: NIH Clinical and Translational Science Awards (CTSA)

FOR IMMEDIATE RELEASE: Wednesday, October 12, 2005

Joyce McDonald/Ann Puderbaugh, NCRR

Need for Change

Clinical and translational research is critical to improving human health. Finding cures and treatments for diabetes, Parkinson's and Alzheimer's diseases, AIDS, cardiovascular disease, inherited disorders, and hundreds of other diseases and conditions will rely on the work of clinical and translational researchers. However, the ability to conduct this research has become increasingly difficult.

In an attempt to address the concerns the research community has raised about clinical and translational research, the NIH has funded facilities, resources, or both to bolster clinical and translational research, such as General Clinical Research Centers, grants for individual or institutional training and mentoring, support for disease-specific centers, clinical trial networks, and training of generations of translational scientists. However, concerns persisted in the research community that clinical and translational research needed greater attention.

NIH Response: Institutional CTSA

To address the need for better integrated and focused clinical and translational research support, NIH is announcing a Request for Applications (RFA) to launch a novel program that will fund Institutional Clinical and Translational Science Awards (CTSAs.) Through these awards, academic health centers may propose transformative efforts appropriate to their own institutions. The RFA was formulated after soliciting input from the research community through meetings and other forums.

The CTSA will provide a "home" for clinical and translational research science within the academic health centers. This home, which can be a center, department, or institute (C/D/I), is expected to include faculty able to conduct original research, develop graduate and postgraduate training curricula and lead programs that integrate clinical and translational science across multiple departments, schools, clinical and research institutes and hospitals.

In addition to the CTSA RFA, NIH is also issuing a one-time solicitation for planning grants to allow institutions more time to prepare a CTSA application in the future.

Vision for the CTSA Program



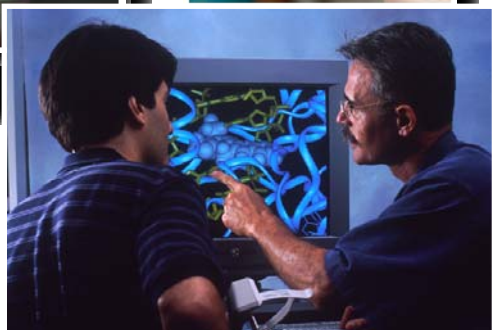
Strengthen Clinical Research as an academic discipline by creating a 'home' and a career structure.

Support the clinical and translational researcher through provision of resources that are most needed.

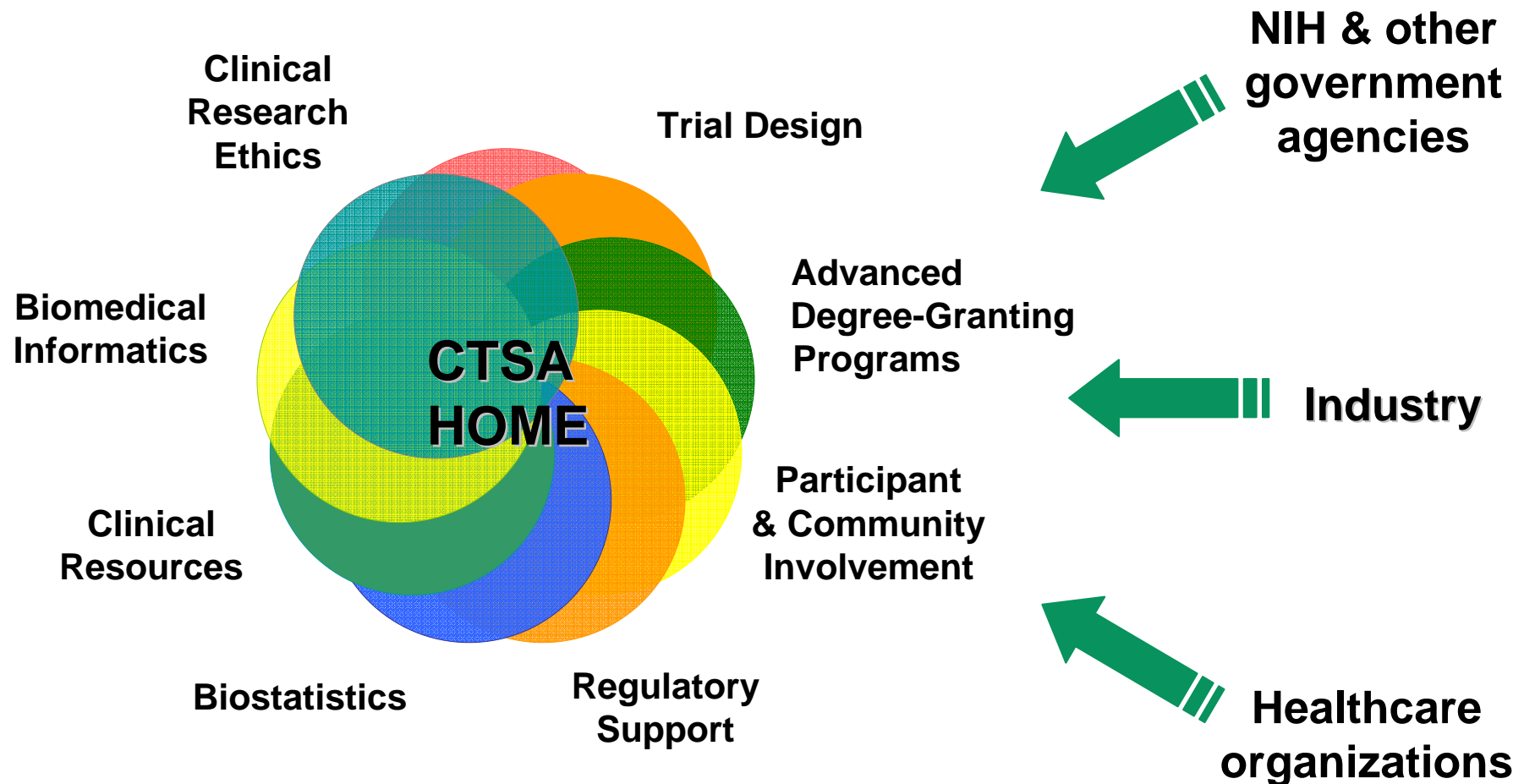


Speed clinical and translational research through resource and data sharing.

Advance the safety and quality of research through adoption of good clinical practices and effective use of informatics.



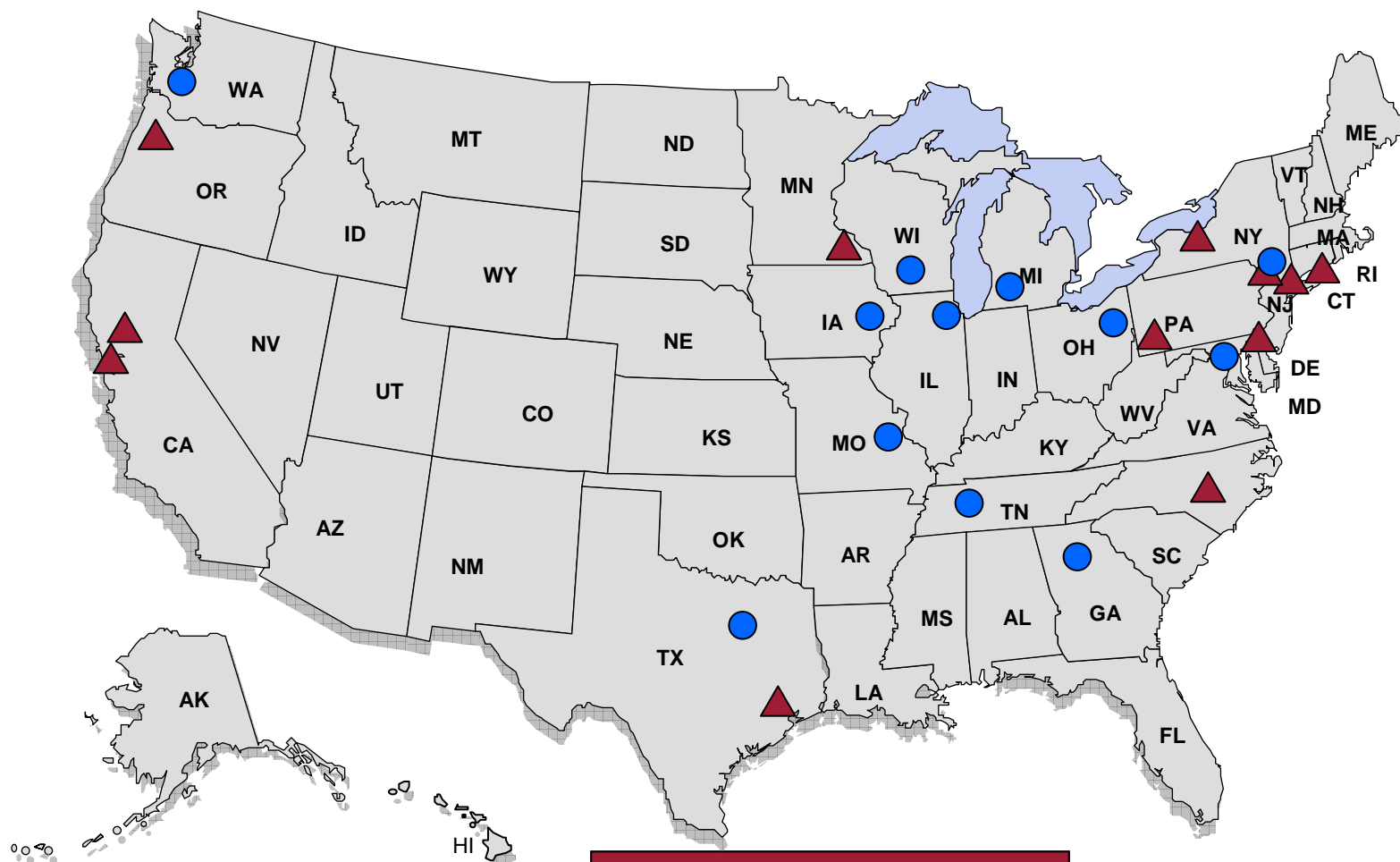
Each academic health center will create a home for clinical and translational science



Courtesy of Anthony Hayward, MD, Ph.D, NIH/NCRR

CTSA Clinical & Translational
Science Awards

Building a National CTSA Consortium



Participating Institutions

- ▲ Since 2006
- Since 2007

Courtesy of Anthony Hayward, MD, Ph.D, NIH/NCRR

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Science Awards

PL 109-482

SEC. 106. <<NOTE: 42 USC 284 note.>>

ENHANCING THE CLINICAL AND TRANSLATIONAL SCIENCE AWARD.

(a) In General.--In administering the Clinical and Translational Science Award, the Director of NIH shall establish a mechanism to preserve independent funding and infrastructure for pediatric clinical research centers by--

(1) allowing the appointment of a secondary principal investigator under a single Clinical and Translational Science Award, such that a pediatric principal investigator may be appointed with direct authority over a separate budget and infrastructure for pediatric clinical research; or

(2) otherwise securing institutional independence of pediatric clinical research centers with respect to finances, infrastructure, resources, and research agenda.

(b) Report.--As part of the biennial report under section 403 of the Public Health Service Act, the Director of NIH shall provide an evaluation and comparison of outcomes and effectiveness of training programs under subsection (a).

(c) Definition.--For purposes of this section, the term "Director of NIH" has the meaning given such term in section 401 of the Public Health Service Act.