Evaluation Policy & Evaluation Practice for Large Scientific Research Initiatives
The Clinical and Translational Science Awards

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Challenges for Biomedical Research

“It takes an estimated average of 17 years for only 14% of new scientific discoveries to enter day-to-day clinical practice.”


“Studies suggest that it takes an average of 17 years for research evidence to reach clinical practice.”

“Of 101 very promising claims of new discoveries with clear clinical potential that were made in major basic science journals between 1979 and 1983, only five resulted in interventions with licensed clinical use by 2003 and only one had extensive clinical use.”

The NIH Response

• The **NIH Roadmap** is an innovative approach to accelerate fundamental discovery and translation of that knowledge into effective prevention strategies and new treatments.

• Through the NIH Roadmap, NIH aims to:
  – accelerate the pace of discovery
  – speed the application of new knowledge to the development of new prevention strategies, new diagnostics and new treatments
  – transfer these innovations to health care providers, and the public
Roadmap Initiatives

• New Pathways to Discovery
• Research Teams of the Future
• Re-engineering the Clinical Research Enterprise
  ➢ The Clinical and Translational Science Awards (CTSA)

http://nihroadmap.nih.gov/
The CTSA Initiative

- 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.
CTSA Funding

- Total dollars NIH spent on the CTSA initiative last project year (July, 2006 – June 2007) for the first 24 CTSAs
  - $243 million
- Total dollars NIH has budgeted for the current project year (38 CTSAs)
  - $370 million
- Total dollars NIH expects to spend annually once the initiative is fully funded (60 CTSAs)
  - $500 million
Building a National CTSA Consortium

Participating Institutions

- **New members 2008**
- **Members 2006 & 2007**
Building a National CTSA Consortium

**FY06 Grantees**
The Rockefeller University
University of Texas Health Sciences Center at Houston
University of California, Davis
University of Pittsburgh
University of California, San Francisco
University of Rochester School of Medicine and Dentistry
Duke University
University of Pennsylvania
Columbia University
Mayo Clinic
Oregon Health and Science University (partnering with Kaiser Permanente)
Yale University

**FY07 Grantees**
Emory University (partnering with Morehouse College)
Case Western University
Washington University
**Weill Cornell Medical College**
University Of Wisconsin Madison
Johns Hopkins
University Of Washington
University Of Michigan At Ann Arbor
University of Texas Southwestern Medical Center – Dallas
University Of Chicago
University Of Iowa
Vanderbilt University (partnering with Meharry Medical College)

**FY08 Grantees**
Albert Einstein College of Medicine
Boston University Medical Campus
Harvard University
Indiana University-Purdue University at Indianapolis
Northwestern University
Ohio State University
Scripps Research Institute
Stanford University
Tufts University Boston
University of Alabama at Birmingham
University of Colorado Denver/HSC Aurora
University of North Carolina Chapel Hill
University of Texas Health Science Center San Antonio
University of Utah
Weill Cornell CTSC Partner Institutions

- Hospital for Special Surgery
- Weill Cornell Medical College & Graduate School
- Memorial Sloan-Kettering
- Hunter College
- Cornell Cooperative Extension
- Hunter School of Nursing
CTSC Affiliated Hospitals in Underserved & Multi-Ethnic Areas

Concentrated Minority Group
- African-American
- Hispanic
- Asian
- Other
- No Concentrated Group

1 Lincoln Medical and Mental Health Center
2 CTSC Core Institutions
3 New York Downtown Hospital
4 New York Methodist Hospital
5 Brooklyn Hospital Center
6 Wyckoff Heights Medical Center
7 New York Hospital Medical Center of Queens
Organization of the CTSC

Dean
Weill Cornell Medical College
Cornell University

Operations Committee
- Director of CTSC
- Coordinating Program Directors
- Core Directors
- Administrative Director

Internal Advisory Board with Community Representative

Evaluation and Tracking

External Advisory Board

Research Education and Training
Technology Transfer
Translational Technologies and Resources
Community Engagement and Research
Clinical and Translational Resource Unit
Clinical and Translational and Collaborative Studies
Pilot and Collaborative Translational
Biomedical Informatics
Regulatory Knowledge and Support
Design, Biostatistics, and Clinical Research Ethics
Development of Novel Clinical and Translational Methodologies

Operations Committee
Evaluation Policy: Congress

“Each application under this part must include detailed information as to the following:

(f) Proposed methods for monitoring and evaluating individual activities and the overall center program;”

(PART 52a_NATIONAL INSTITUTES OF HEALTH CENTER GRANTS [Code of Federal Regulations][Title 42, Volume 1][Revised as of October 1, 2007]. From the U.S. Government Printing Office via GPO Access. [CITE: 42CFR52a.4][Page 200])
Call For Applications for the CTSAs

- The academic home may be a center/department/institute, as determined by institutional circumstances. Individual C/D/Is will:
  - conduct self-evaluation activities and participate in a national evaluation of the CTSA program

- Tracking and Evaluation Plan
  - The proposal should first include a detailed self-evaluation plan to assess implementation of the short-term and long-term CTSA goals, including implementing program activities and tracking trainees and scholars and their mentors, their pilot projects, and their involvement with multidisciplinary team research. For each proposed key function, the plan should include the objectives of the evaluation or tracking activities, the principal measures or indicators, and potential data sources. Applicants should describe procedures to obtain IRB approval and informed consent from trainees, scholars, and mentors in evaluation data collection efforts, if necessary. Listed below are examples of evaluation objectives for illustrative key functions:

Evaluation Policy: NIH/NCRR

Listed below are examples of evaluation objectives for illustrative key functions:

Assess the demand for, and effectiveness of, any novel clinical and translational methodologies, pilot and collaborative translational and clinical studies, community engagement and translational technologies and resources.

Biomedical Informatics
- assess informatics performance
- identify effective practices of intra- and inter-organizational sharing of data
- coordinate with NIH CTSA Informatics Steering Committee

Design, Biostatistics and Clinical Research Ethics
- assess support for clinical trial design and analysis and the tools and methods supplied
- assess the effectiveness of research topics prioritization
- assess the effectiveness of education in topics such as clinical research ethics

Regulatory Knowledge and Support
- assess demand, function and effectiveness

Participant and Clinical Interactions Resources
- track availability and use of resources
- assess needs of research community and integration with other resources
- assess studies to meet standards for quality of science
- address under-utilization and poor performance

Research Education, Research Training and Research Career Development
- assess curriculum development
- assess responsible research conduct training
- examine recruitment and retention of individuals from diverse backgrounds
- track T32 trainees and K12 scholars during their enrollment in the program
- document the role of mentors

Overall Operational Functions
- assess budget implementation, allocation of resources, and leveraging of additional resources to achieve program objectives
- assess effectiveness of resource sharing
- assess software dissemination plan

The evaluation plan should also describe how the applicant will participate in the national CTSA program evaluation established to:

- assess the entire range of clinical and translational research conducted by the CTSA consortium
- determine the effectiveness, flexibility, innovation, efficiency of the multidisciplinary team research approach
- assess the reduction of duplicative and/or redundant work processes
- track the short- and long-term career path of CTSA trainees, scholars, and mentors
- assess institutional change with respect to cooperation and collaboration of component functions, and changes in collaboration and cooperation of departments, schools, outside institutions in clinical and translational research
- assess processes of reorganization, such as how grantees and current program participants are able to move from the current model of institutional awards, such as K12, K30, and T32, to the inclusive CTSA model

To support this effort, the NIH will request that grantees participate in the planning, design, and conduct of the national evaluation and that grantees plan local evaluation activities that will provide data necessary for both their own evaluation and the national evaluation.

Evaluation Policy: CTSAs

- **Evaluation Steering Committee**
- **Steering Committee Workgroups**
  - Standardization and Operationalization
  - Social Network Analysis
  - Shared Resources
  - IRBs
- **Professional Capacity Building & Networking**
  - Social Network Analysis
  - AEA
Evaluation Policy: CTSC

• Evaluation Working Group
  – All Key Functions represented
  – Regular monthly meetings
  – Collaborative evaluation policy-making

• Topics/Issues
  – Defining “translational research”
  – Defining CTSA “members”
  – Identifying evaluation roles and responsibilities
    • Who collects what data
    • Who stores data and where
    • What is the consultative/support role of Evaluation KF

• Develop written evaluation policies
Evaluation Policy: CTSC Sample Policies

• EVALUATION WORKING GROUP
Each Key Function will make available a lead operational staff member to participate in regular meetings of an Evaluation Working Group that will provide advice and consultation on evaluation processes, methods, results and utilization.

• KEY FUNCTION MILESTONE DATA
Each key function will be responsible for maintaining up-to-date milestones for their work and data regarding accomplishments on these milestones.

• KEY FUNCTION DATA COLLECTION
Each key function will be responsible for collecting and delivering on a timely basis to the CTSC Evaluation Team the essential data needed for the evaluation of their key function.

• EVALUATION TEAM INTERNAL CONSULTING
The Evaluation Team is responsible for providing timely internal consulting to advise key function staff in the collection of data needed to evaluate their key function.
Conclusions

• CTSAs are “translational research laboratories”
• CTSAs are also “evaluation laboratories”
• *Evaluation* plays a critical role that addresses both NIH and Congressional policies
• CTSA RFA was one of the clearest statements of evaluation policy for large NIH center grants
• CTSA future directions in evaluation policy
  – National Steering Committee
  – National cross-center process evaluation
  – Collaboration among CTSA evaluation teams
• Moving towards a “*Science of Science Management*”
“Oh, if only it were so simple.”