

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

Roadmap Office for Medical Research

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**NATIONAL INSTITUTES OF HEALTH**  
**Roadmap by Mechanism**  
(Dollars in thousands)

Mechanism	FY 2006 Actual (B.A.)		FY 2007 Estimate		FY 2008 President's Budget		Change	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
<u>Research Grants</u>								
<u>Research Projects</u>								
Noncompeting	79	\$42,192	74	\$36,935	152	\$67,991	78	\$31,056
Administrative Supplements	(8)	868	(4)	217	(4)	217	(0)	0
Competing	65	20,588	154	54,613	76	20,902	(78)	-33,711
Subtotal, RPGs	144	63,648	228	91,765	228	89,110	0	-2,655
SBIR/STTR	0	0	0	0	0	0	0	0
Subtotal, RPG	144	63,648	228	91,765	228	89,110	0	-2,655
<u>Research Centers</u>								
Specialized/Comprehensive	104	99,377	40	108,142	43	127,691	3	19,549
Clinical Research	4	40,090	7	73,654	9	94,393	2	20,739
Biotechnology	16	5,693	22	7,453	22	7,473	0	20
Comparative Medicine			0	0	0	0	0	0
Res. Centers in Minority Instit.			0	0	0	0	0	0
Subtotal, Centers	124	145,160	69	189,249	74	229,557	5	40,308
<u>Other Research</u>								
Research Careers	24	30,406	26	40,597	25	41,442	(1)	845
Cancer Education			0	0	0	0	0	0
Cooperative Clinical Research			0	0	0	0	0	0
Biomedical Research Support			0	0	0	0	0	0
Minority Biomed. Res. Support			0	0	0	0	0	0
Other	36	14,034	38	20,407	38	31,303	0	10,896
Subtotal, Other Research	60	44,440	64	61,004	63	72,745	(1)	11,741
Total Research Grants	328	253,248	361	342,018	365	391,412	4	49,394
<u>Training</u>								
Individual	FTTP	0	FTTP	0	FTTP	0	0	0
Institutional	416	17,521	522	20,271	533	20,612	11	341
Total Training	416	17,521	522	20,271	533	20,612	11	341
Research & Develop. Contracts (SBIR/STTR)	25	22,362	42	20,658	42	44,272	0	23,614
Intramural Research		26,204		19,586		19,448	0	-138
Res. Management & Support		13,255		11,610		10,409	0	-1,201
Cancer Prevention & Control		0		0		0	0	0
Construction		0		0		0	0	0
<b>TOTAL</b>		<b>332,590</b>		<b>414,143</b>		<b>486,153</b>		<b>72,010</b>

Numbers of grants identified in FY 2007 and FY 2008 are estimates, and WILL change as applications are received and selected for funding.

**NATIONAL INSTITUTES OF HEALTH**  
**NIH Roadmap by Initiative**  
(dollars in thousands)

Title of Initiative	Lead Administrative ICs	FY 2006 Actual (B.A.)	FY 2007 Continuing Resolution	FY 2008 President's Budget	Change
<b><u>New Pathways of Discovery</u></b>					
<b>Molecular Libraries and Imaging</b>					
Creation of NIH Bioactive Small Molecule Library & Screening Centers	NIMH, NHGRI	\$58,693	\$66,272	\$78,200	\$11,928
Cheminformatics	NHGRI, NLM	6,136	10,291	10,900	609
Technology Development	NIGMS, NINDS, NHGRI	23,004	25,931	30,572	4,641
Development of High-Specificity/High-Sensitivity Imaging Probes	NIGMS, NIBIB	5,109	5,178	5,541	363
Imaging Probe Database	NCI	610	700	1,400	700
Core Synthesis Facility to Produce Imaging Probes	NHLBI	3,400	3,000	3,000	0
<i>Subtotal, Molecular Libraries and Imaging</i>		<i>96,952</i>	<i>111,372</i>	<i>129,613</i>	<i>18,241</i>
<b>Building Blocks, Biological Pathways and Networks</b>					
National Technology Centers&Metabolomics Development	NCRR	15,990	15,681	16,819	1,138
Metabolomics Technology Development	NIDDK	13,514	3,950	3,950	0
Assessment of Critical Reagents for Proteomics	NHGRI	794	0	0	0
<i>Subtotal, Building Blocks, Biological Pathways and Networks</i>		<i>30,298</i>	<i>19,631</i>	<i>20,769</i>	<i>1,138</i>
<b>Structural Biology</b>					
Membrane Protein Production	NIGMS	9,869	9,637	9,892	255
<b>Bioinformatics and Computational Biology</b>					
National Centers for Biomedical Computing	NIGMS	23,885	22,994	23,070	76
<b>Nanomedicine</b>					
Nanomedicine Development Centers	NEI	10,388	14,000	24,733	10,733
<b><i>Subtotal, New Pathways of Discovery</i></b>		<b><i>171,392</i></b>	<b><i>177,634</i></b>	<b><i>208,077</i></b>	<b><i>30,443</i></b>
<b><u>Research Teams of the Future</u></b>					
<b>Interdisciplinary Research</b>					
Interdisciplinary Research Centers	NCRR	11,351	43,379	39,574	-3,805
Interdisciplinary Research Training Initiative	NIDDK, OBSSR, NIGMS	13,704	11,716	14,883	3,167
Innovation in Interdisciplinary Technology and Methods	OD/OBSSR, NIDA	254	3,050	2,968	-82
<i>Subtotal, Interdisciplinary Research</i>		<i>25,309</i>	<i>58,145</i>	<i>57,425</i>	<i>-720</i>
<b>High-risk Research</b>					
NIH Director's Pioneer Awards	NIGMS	20,266	26,885	24,459	-2,426
<b>Public-Private Partnerships</b>					
Designation of a Central Point of Contact	OD	248	450	574	124
High-Level Science Driven Partnership Meetings	OD	276	110	0	-110
<i>Subtotal, Public Private Partnerships</i>		<i>524</i>	<i>560</i>	<i>574</i>	<i>14</i>
<b><i>Subtotal, Research Teams of the Future</i></b>		<b><i>46,099</i></b>	<b><i>85,590</i></b>	<b><i>82,458</i></b>	<b><i>-3,132</i></b>
<b><u>Re-engineering the Clinical Research Enterprise</u></b>					
Clinical Research Policy Analysis and Coordination	OD/OSP	2,493	3,100	2,000	-1,100
Feasibility of Integrating and Expanding Clinical Research Networks	NHLBI, NCRR	10,144	10,000	10,000	0
Translational Research Core Services	NINDS, NCI	3,404	8,200	8,085	-115
Dynamic Assessment of Patient-Reported Chronic Disease Outcomes	NIAMS	6,198	6,236	6,235	-1
Enhance Clinical Research Training via the National Multi-disciplinary CR Career Development Program and CRTP and MSTP Expansions	NICHHD, OD/OIR, NCRR	31,070	33,539	8,417	-25,122
Create a National Clinical Research Associates Program	NICHHD	170	0	0	0
Clinical and Translational Science Awards	NCRR	61,105	89,844	130,881	41,037
<b><i>Subtotal, Re-engineering the Clinical Research Enterprise</i></b>		<b><i>114,584</i></b>	<b><i>150,919</i></b>	<b><i>165,618</i></b>	<b><i>14,699</i></b>
<b><i>Dedicated Roadmap Administration</i></b>		<b><i>515</i></b>			<b><i>0</i></b>
<b><i>Subtotal Roadmap</i></b>		<b><i>332,590</i></b>	<b><i>414,143</i></b>	<b><i>456,153</i></b>	<b><i>42,010</i></b>
<b><i>New Initiatives in Common Fund</i></b>				<b><i>30,000</i></b>	<b><i>30,000</i></b>
<b>Total Roadmap</b>		<b>332,590</b>	<b>414,143</b>	<b>486,153</b>	<b>72,010</b>

**NATIONAL INSTITUTES OF HEALTH**  
**Roadmap Contributions by Institute and Center**  
(Dollars in thousands)

Institutes and Centers	FY 2006 Actual (B.A.)	FY 2007 Estimate	FY 2008 President's Budget	Change
NCI	\$42,834	\$57,382	\$63,165	\$5,783
NHLBI	26,109	35,019	38,464	3,445
NIDCR	3,479	4,661	5,131	470
NIDDK	15,236	20,452	22,464	2,012
NINDS	13,715	18,406	20,204	1,798
NIAID	38,567	51,852	56,593	4,741
NIGMS	17,297	23,219	25,523	2,304
NICHD	11,302	15,179	16,682	1,503
NEI	5,958	7,983	8,785	802
NIEHS	5,729	7,693	8,428	735
NIA	9,353	12,552	13,783	1,231
NIAMS	4,539	6,090	6,686	596
NIDCD	3,516	4,727	5,175	448
NIMH	12,542	16,837	18,501	1,664
NIDA	8,937	12,009	13,170	1,161
NIAAA	3,896	5,231	5,745	514
NINR	1,227	1,648	1,808	160
NHGRI	4,343	5,830	6,400	570
NIBIB	2,652	3,559	3,937	378
NCRR	9,822	13,257	14,775	1,518
NCCAM	1,086	1,455	1,591	136
NCMHD	1,746	2,345	2,578	233
FIC	593	805	878	73
NLM	2,814	3,782	4,147	365
Subtotal ICs	247,292	331,973	364,613	32,640
OD DDF	85,298	82,170	121,540	39,370
Total Roadmap	332,590	414,143	486,153	72,010

Roadmap Initiatives are funded through a combination of funds appropriated to the Director's Discretionary Fund in the Office of the Director, and from contributions from the NIH Institutes and Centers (0.9% of their budgets in FY 2006, 1.2% of their budgets in FY 2007, and 1.3% in FY 2008).

**Justification**  
**Roadmap Office for Medical Research**

**OVERVIEW**

In September 2003, the new NIH Director, Dr. Elias Zerhouni, initiated the five-year NIH Roadmap for Medical Research. This wide-ranging and ambitious program addresses an emerging reality that today's scientific problems require new multidisciplinary approaches and collaborations; synergies between basic science, clinical research, and informatics as well as new training approaches for scientists. At the same time, the NIH must still emphasize the agencies core values of knowledge and discovery. The NIH Roadmap is a process of strategic coordination of research that cuts across the respective mission of the 27 NIH Institutes and Centers (ICs). The goal of the Roadmap is to focus a small percent of the NIH budget that has been contributed to a common fund for the purpose of supporting high priority, trans-NIH projects. The Roadmap is conceived as an "incubator" or venture capital mechanism to support innovative research projects. It supports research that is the responsibility of the entire NIH community. Rather than considering scientific research in the context of individual scientific sub-disciplines as has traditionally been the case, the Roadmap regards the different scientific sub-disciplines as part of one continuum. This is in effect the definition of translational science, basic science discoveries that are developed for medical purposes, such as therapeutic treatments or more accurate diagnostic treatments.

The NIH Roadmap funds research in three broad areas:

1. Research tools and/or methodologies that are of use to wide swaths of the scientific community.
2. Fundamental research that improves our understanding of biological systems and may result in new science paradigms.
3. Proposals and policy decisions that affect the culture and manner in which research is conducted.

The NIH Reform Act of 2006 will help NIH improve program coordination and operations as well as assess its structure and flexibility NIH is working to implement this new authorization.

Since Roadmap's inception, approximately 1 percent of the NIH budget has been pooled to support Roadmap projects. The funds are comprised of contributions from each of the ICs as well as the NIH Office of the Director (OD). The annual Roadmap budgets were originally projected based on the anticipated funds required to support the Roadmap initiatives over 5 years. In the first year of funding (2004), \$132 million was spent on Roadmap initiatives. By FY 2007 the Roadmap budget grew to \$414 million and in FY 2008 the projected funding level is \$486 million (1.3 percent of the NIH budget). In FY 2005, the NIH Director established the Office of Portfolio Analysis and Strategic Initiatives (OPASI) and institutionalized the concept of a "Common Fund" as a consistent pool of funds set aside by IC's and the Office of the Director to fund trans-NIH initiatives such as the Roadmap. The Roadmap budget serves as the basis for the Common Fund. As part of this structural reorganization, Roadmap coordination functions have been placed in the Operations Branch, Division of Strategic Coordination. Planning for other cohort of Roadmap initiatives to be funded through the Common Fund is underway (see inset).

## Major Changes in the Fiscal Year 2008 Budget Request

In FY 2008 there will be changes in funding for Roadmap and Common Fund programs in keeping with the \$72 million increase over the FY 2007 Roadmap budget.

Increases in Roadmap projects over FY 2007 levels will occur in the following areas:

Creating the NIH Bioactive Small Molecule Library and Screening Centers: (+\$12 million; total \$78 million)

Technology Development: (+\$5 million; total \$31million)

Nanomedicine Development Centers: (+\$11 million; total \$25 million)

Interdisciplinary Research Training Initiative: (+\$3 million; total \$15 million)

Clinical Research Training and Clinical & Translational Science Awards: (+\$41 million; total \$131 million)

Decreases will occur in:

Interdisciplinary Research Centers: (-\$4 million; total \$40 million)

Clinical Research Training via the National Multi-disciplinary Career Development Program: (-\$25 million; total \$8 million)

### **Portrait of a Program: New Roadmap Initiatives for FY 2008**

FY 2007 Level: \$0 million

FY 2008 Level: \$30 million

Change: +\$30 million

In FY 2008, the NIH Roadmap will spend \$30 million from within the Roadmap budget on the first year of funding for the second cohort of Roadmap initiatives. These will consist of approximately 5-8 new foci that will improve and accelerate biomedical research and its impact on the health of the Nation. Currently, the NIH is developing a new cohort of ideas that are in keeping with the Roadmap goals. The process for developing a broad consensus on the scientific themes to be addressed in the new initiatives is based on the process used in 2003 to develop the initial cohort of Roadmap initiatives. First, during the summer of 2006, Dr. Zerhouni convened a series of consultation meetings where outside scientific experts met to discuss research areas that should be addressed by the Roadmap. In the second phase, each of the ICs was asked to submit proposals for new initiatives. The consultants and ICs were asked to consider gaps in knowledge or tools that impede certain types of research from moving forward. These are tools that would allow researchers to overcome barriers in basic, translational, and clinical research. The outcomes of research performed in the new initiatives will improve the Nation's health and improve the synergy with which the NIH ICs fulfill their missions.

With a goal of increased transparency and participation, a third and final idea solicitation phase was conducted. In this phase, a Request for Information (RFI) inviting the public to comment on ideas put forth by the ICs and consultation meetings and to submit their own ideas was released in fall of 2006. All ideas will be judged as to whether or not they meet the outlined Roadmap criteria, then reviewed and prioritized by the NIH IC Directors and the NIH Director in consultation with the Advisory Council to the Director (ACD). The ideas that are given highest priority will be selected for Roadmap implementation.

## Highlights and Progress of the Three NIH Roadmap Areas

### New Pathways to Discovery

The complexity of biological systems and the need to understand individual molecular interactions in the context of multiple inter-connected biological processes requires an advanced set of tools in order to probe these processes. This theme enables such tools to be developed. In addition, New Pathways to Discovery supports the kind of multi-disciplinary research that is required to successfully utilize these new tools. There are five components within this theme.

#### *Molecular Libraries and Molecular Imaging*

Most drugs for the treatment of disease are small organic molecules that bind to one protein specifically which then modifies the behavior of that protein and its ability to interact with other cellular entities. In the pharmaceutical industry, a critical initial R&D step in drug development is to screen large libraries of small molecules in order to find one that binds to a protein of interest and has the desired properties for a suitable drug candidate. However, such extensive small molecule databases have historically not been readily available to researchers in the public sector. A publicly available repository of small molecules is important for understanding and developing cures for diseases that do not receive much attention by private pharmaceutical companies. Additionally, having a large, well-characterized database of small molecules will make it possible to understand cellular pathways with greater accuracy and precision.

The main thrust of *Molecular Libraries and Molecular Imaging* has been the pilot establishment of a national network of screening centers known as the Molecular Libraries Screening Network (MLSCN). These centers have focused on developing instrumentation for high throughput screening (HTS), an automated series of procedures for simultaneously analyzing many compounds. The public will have access to a repository containing the small molecules. Another major component of *Molecular Libraries and Molecular Imaging* is *PubChem* (<http://pubchem.ncbi.nlm.nih.gov/>), which is the free online database that contains the information on the small molecules including structural information and biological activity profiles. In addition, for each small molecule in *PubChem* there are links to related databases such as scientific literature (PubMed) and the 3D Structure Database, all of which have been developed and supported by NIH researchers. In FY 2008 the *Molecular Libraries and Molecular Imaging* pilot programs will use its increased funds to move beyond the pilot phase and establish a formal screening center network. \$66 million will be spent on Extramural Screening Centers and \$10 million will be spent on Assay Technology Development. New grant solicitations will take place to further develop the Small Molecule Repository.

#### *Building Blocks, Pathways, and Networks*

This implementation group of the NIH Roadmap focuses on the need to develop new technologies that are necessary to accelerate the process of scientific discovery and the understanding of biological pathways. For example, one of the project teams, the National Technology Centers for Networks and Pathways (administered by NCCR), develops tools that help researchers understand the dynamics of molecular interactions inside cells. The aim is to understand these processes both under normal conditions and in cases when they go awry, often

leading to disease states. Examples of these projects include: 1) efforts to understand how enzymes called proteases whose function is to cut other proteins in the cell, receive cellular instructions to carry out the cutting function, 2) to develop florescent probes that can be tagged to proteins which enables the protein's movement to be visualized inside the cell, and 3) to develop techniques to study groups of proteins that are temporarily bound as large complexes that facilitate the transmittal of cellular information and instructions. Future grant solicitations will fund research that leverages these tools to better understand cellular processes.

### *Bioinformatics and Computational Biology*

In an age where informatics and the ability to manage and organize large amounts of varied data is increasingly the underpinning of scientific research, the need for informatics tools is critical. These tools must be tailored to handle the large amount of scientific data that is generated and use engineering systems that are adapted for data analysis in the context of biological systems. The hallmark program in *Bioinformatics and Computational Biology* is the National Centers for Biomedical Computing (NCBCs). These programs are administered by the National Institute of General Medical Sciences (NIGMS). *Bioinformatics and Computational Biology* efforts support the development of an essential field that bridges biology, computer science, physics, and engineering.

### *Nanomedicine*

Nanotechnology, the study and manipulation of molecules less than 100 nanometers in size, holds tremendous promise for medical innovation. Molecules at this size have unique electronic and chemical properties that make them suitable for interacting with and reporting on physiological processes. Nanotechnology products are currently being developed to deliver drugs to specific locations in the body, for diagnostic purposes, as sensors to measure levels of cellular components, and for imaging purposes. In order to harness the potential of Nanomedicine, the Roadmap has established a network of 8 Nanomedicine Centers at academic institutions across the country. The Nanomedicine Centers have been administered by the National Eye Institute (NEI) using the Flexible Research Authority (FRA) mechanism.

### *Structural Biology*

One of the most important classes of proteins for maintaining cellular integrity and overall health is membrane proteins. These proteins are either partially or full embedded in the cell membrane. They control entry into the cell by molecules that can alter numerous cellular processes. They serve as the gateways through which most molecules exert their specific influence on the cell. They allow information to be transmitted that indicates the local molecular environment to entities inside the cell. Therefore, membrane proteins are the primary target of drug design efforts; most drugs affect disease by binding to and inhibiting the action of specific membrane proteins. However, understanding how these proteins behave has been limited by the availability of high-resolution views of the three-dimensional structures. In contrast, studying non-membrane proteins is not hampered by this limitation and the rate of solved structures of non-membrane proteins has grown exponentially in recent decades.

In order to better understand how membrane proteins function, one needs to produce sufficient quantities for study in a laboratory setting; this is very difficult and frequently the rate limiting step in any experiment using membrane proteins. The membrane surrounding the protein is



greasy and oily; removing a membrane protein from such an environment usually has deleterious and irreversible consequences for the protein's structure and function. The *Structural Biology* initiatives aim to formulate new methods and techniques for producing ample quantities of these proteins that are of a quality suitable for structural and functional studies. This is an area that has long stymied biologists and the ability to produce membrane proteins for further study would lead to major breakthroughs throughout the biological sciences. Indeed, most new structures of membrane proteins provide a major contribution to one or several biological realms. The first funds directed for the *Structural Biology* initiatives were used to establish Centers for Innovation in Membrane Protein Production. In FY 2007 the NIH Roadmap will award \$1.6 million in new grants towards solving membrane protein structures.

### **Research Teams of the Future**

This theme was created in recognition of the fact that scientific innovation requires novel modes of human interaction and communication in order to accelerate the pace of new discoveries that will lead to substantive medical improvements. Research Teams of the Future is sponsoring individual scientists whose research programs may involve a greater degree of risk compared to most NIH funded projects but have the potential to lead to high impact breakthroughs in their respective fields. Research Teams of the Future also encourages modification in existing organizational structures in order to fully address complex biological problems. Increasingly, research of this nature requires multidisciplinary collaborations that utilize numerous types of scientific expertise. It also requires that new working partnerships between the public and private sectors be established to capitalize on the unique strengths of public and private science enterprises. An example of a research project series that will be supported under this theme is a solicitation to develop programs to create technologies and methods for interdisciplinary integration of human social and behavioral science with other disciplines in order to advance a greater understanding of human health. This research addresses the growing recognition of the role of behavioral science in the complexity of medical ailments and conditions.

#### *Director's Pioneer Award*

The Director's Pioneer Award is a highly lauded and successful program to recognize visionary scientists. In FY 2008, the NIH will fund the fifth round of the Director's Pioneer Award. Traditionally, most NIH grants to individual investigators have been for specific research proposals. In contrast, these highly prestigious awards support specific researchers and are designed to allow the researcher to carry out extensive, high-risk, highly innovative research. These investigators perform research that is broad in its scope and may contribute to a transformation of new, fundamental principles within that research niche. These unique awards are for \$500,000 each year for a total of 5 years. To date 35 scientists have received this award. Since the Director's Pioneer Award was first given in FY 2004, the awardees have made strides in areas from understanding how viral DNA is released inside the cell to modeling neural networks. The Director's Pioneer Awards are administered by NIGMS. It is anticipated that in FY 2008 approximately 5-10 new awards will be made.

#### *Interdisciplinary Research Consortia*

A major focus of the NIH Roadmap is to foster new modes of conducting research. Today, the complexities of the biological problems being examined require a range of expertise. In the past,

scientists were trained in one type of technique or they focused on one type of biological system. Current biological problems and questions require that researchers bring to bear a range of techniques and expertise. This requires scientists to work with scientists whose area of expertise differs from their own. The *Interdisciplinary Research Consortia* seek to implement interdisciplinary collaborative, team approaches to problems that have been difficult and challenging to address using more conventional modes of inquiry. The issues that will be examined by the consortia must be considered highly significant for biomedical applications in that they will lead to new research approaches in addition to yielding improvements to human health. In FY 2007, the first year of the *Interdisciplinary Research Consortia*, the NIH Roadmap expects to spend roughly \$40 million to fund approximately eight consortia. This initiative is being administered by the National Center for Research Resources (NCRR). These consortia will foster team science, enable scientists to work across disciplines, and provide training opportunities to researchers to develop strategies for approaching scientific problems that have been resistant to conventional methods. Some examples of the types of problems that might be considered by the *Interdisciplinary Research Consortia* include understanding the role of genetics in disparate outcomes of cancer treatment, how intervention strategies can improve cancer survival rates in patients over 65, and the causes and risks of highly lethal types of cancer. The *Interdisciplinary Research Consortia* will support the use of the *Multiple Primary Investigator Model*. This is a new Roadmap policy initiative that bestows multiple individuals on a single grant with the status of Primary Investigator (PI). Since the number of grants that a scientist can claim to have been the PI on has direct consequences on tenure and department funding decisions, this will encourage more scientists to collaborate at the grant proposal stage.

### **Reengineering the Clinical Research Enterprise**

This theme of the NIH Roadmap seeks to enhance the efficiency and effectiveness of clinical research in order to ensure that NIH continues to be successful at preventing and treating illnesses in the future. The initiatives within Reengineering the Clinical Enterprise will strive to transform the entire system of clinical research in order to fulfill the potential of modern medicine. These initiatives will foster the creation of new partnerships and a higher level of institutional integration in order to improve working relationships among the numerous entities that are part of the clinical research process.

**Portrait of a Program: Clinical and Translational Science Awards (CTSA)**

FY 2007 Level: \$ 90 million  
FY 2008 Level: \$131 million  
Change: +\$41 million

The CTSA program is a unique and bold venture that meets the NIH Roadmap objective to restructure and improve the clinical research enterprise. As a prominent element in the Reengineering the Clinical Research Enterprise theme of the NIH Roadmap, the CTSA program will transform how clinical and translational research is conducted, ultimately enabling researchers to provide new treatments more efficiently and quickly to patients. To better address the needs of the clinical research community, the longstanding General Clinical Research Centers program, administered by NCRP, is being transitioned into the CTSA program. Currently, the CTSA program is administered and funded by both the NIH Roadmap and NCRP. As the program expands, its management and funding will transition solely to NCRP.

Through the CTSA, academic health centers (AHCs) will work as a national consortium. For many AHCs, the CTSA infrastructure will not only enhance the research capacity already developed through the General Clinical Research Center program, but will create an integrated home for clinical and translational science. CTSA will train and advance a cadre of multi- and inter-disciplinary investigators and collaborate to translate discoveries made in the laboratory into improved therapies for patients. Through these collaborations—with basic, translational, and clinical investigators—a new discipline of clinical and translational science will be formed. At the same time, CTSA researchers plan to expand their efforts with minority and medically underserved communities, and make broad connections across schools, institutions, and regions. Their strategic partnerships will also include the U.S. Department of Veterans Affairs, the Food and Drug Administration, and private health care organizations.

Twelve academic health centers received funding for CTSA in FY 2006, the first year that these awards were made. In addition, 52 academic institutions received planning grants to aid in their preparation for submitting CTSA proposals in future years. Additional CTSA awards are expected each year until the program is fully implemented in 2012, when the program is expected to support about 60 CTSA, linked together to energize the discipline of clinical and translational science. Funding for the CTSA program in FY 2008 will be provided by both the NIH Roadmap and NCRP. NCRP will continue to support the existing GCRCs that have not transitioned into a CTSA. The following table shows the sources of funding by Fiscal Year:

(\$ in thousands)

	<b>FY 2006</b>	<b>FY 2007</b>	<b>FY 2008</b>	<b>FY07-08 Change</b>
<b>CTSA/GCRC</b>				
Roadmap	\$61,105	\$89,844	\$130,881	\$41,037
NCRP	\$302,106	\$311,119	\$331,119	\$20,000
Total	\$363,212	\$400,963	\$462,000	\$61,037

Note: Since the CTSA Program is such an integral piece of both the NIH Roadmap and NCRP activities, it has been included in both the Roadmap and NCRP sections of this Congressional Justification.

*Patient-Reported Outcomes Measurement Information System (PROMIS)*

PROMIS is a revolutionary effort to enhance the precision of measures of patient-reported symptoms and function. The value of many treatments is best determined by asking patients themselves about their pain, fatigue, depression, physical functioning, social function and other important outcomes of medical care, but these parameters have often been difficult to measure reliably. PROMIS employs internet and other electronic media to gather patient input, and to report scores that are referenced to the US general population.

Modern statistical methods allow for more efficient assessment, tailored to the individual, by selecting the best questions from item banks that have been previously validated and calibrated.

Data from PROMIS will help to better inform clinical practice at the individual level, at lower cost, in a shorter time frame, with less patient burden and with greater precision, than any existing methods. In addition, short versions of PROMIS tests can be developed and standardized from available item banks to enable customized testing of specific patient groups with multiple co-morbid disorders, something which has previously been difficult to study systematically. PROMIS is comprised of 6 Primary Research Sites (PRS) which will develop survey questions and data compilation methods. These projects are 5 years in duration. Each PRS forges independent objectives but also comprises an essential integrated part of an integrated national effort. PROMIS Network data are managed by a Statistical Coordinating Center at Evanston Northwestern Healthcare and Northwestern University. The PROMIS initiative is administered by the National Institute of Arthritis and Musculoskeletal and Skin Disease (NIAMS). In FY 2008, investigators are scheduled to conduct the final testing of the software being developed for use in PROMIS, and feasibility studies of proposed PROMIS initiatives will also be undertaken.