DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

Common Fund/Roadmap

FY 2009 Budget | Page No.

NATIONAL INSTITUTES OF HEALTH

Common Fund/Roadmap

(Dollars in Thousands)

Budget Mechanism - Total

MECHANISM	FY 2007 Actual		FY 2008 Enacted		FY 2009 Estimate		Change	
Research Grants:	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Projects:								
Noncompeting	92	$53,001	167	$70,554	223	$83,517	56	$12,963
Administrative supplements	(0)	0	(0)	0	(0)	0	(0)	0
Competing:								
Renewal	0	0	0	0	0	0	0	0
New	208	120,493	254	116,669	260	125,075	6	8,406
Supplements	1	393	0	0	0	0	0	0
Subtotal, competing	209	120,886	254	116,669	260	125,075	6	8,406
Subtotal, RPGs	301	173,887	421	187,223	483	208,592	62	21,369
SBIR/STTR	0	0	0	0	0	0	0	0
Subtotal, RPGs	301	173,887	421	187,223	483	208,592	62	21,369
Research Centers:								
Specialized/comprehensive	80	112,575	42	113,931	42	114,580	0	649
Clinical research	10	58,703	5	62,543	4	53,054	(1)	-9,489
Biotechnology	22	7,978	22	7,807	18	7,442	(4)	-365
Comparative medicine	0	0	0	0	0	0	0	0
Research Centers in Minority Institutions	0	0	0	0	0	0	0	0
Subtotal, Centers	112	179,256	69	184,281	64	175,076	(5)	-9,205
Other Research:								
Research careers	20	31,523	18	29,301	10	24,125	(8)	-5,176
Cancer education	0	0	0	0	0	0	0	0
Cooperative clinical research	0	0	0	0	0	0	0	0
Biomedical research support	0	0	0	0	0	0	0	0
Minority biomedical research support	0	0	0	0	0	0	0	0
Other	51	17,583	36	28,975	19	27,014	(17)	-1,961
Subtotal, Other Research	71	49,106	54	58,276	29	51,139	(25)	-7,137
Total Research Grants	484	402,249	544	429,780	576	434,807	32	5,027
Research Training:	FTTPs		FTTPs		FTTPs			
Individual awards	0	0	0	0	0	0	0	0
Institutional awards	442	18,112	442	18,112	395	12,856	(47)	-5,256
Total, Training	442	18,112	442	18,112	395	12,856	(47)	-5,256
Research & development contracts	14	19,223	8	10,392	35	48,330	27	37,938
(SBIR/STTR)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	FTEs		FTEs		FTEs		FTEs	
Intramural research	0	25,899	0	19,544	0	19,837	0	293
Research management and support	0	17,517	0	17,780	0	18,047	0	267
Construction		0		0		0		0
Buildings and Facilities		0		0		0		0
Total, Common Fund/Roadmap	0	483,000	0	495,608	0	533,877	0	38,269

NATIONAL INSTITUTES OF HEALTH
Common Fund/Roadmap by Initiative
(Dollars in Thousands)

Title of Initiative	FY 2007 Actual (B.A.)	FY 2008 Enacted	FY 2009 Estimate	Change
New Pathways of Discovery				
Molecular Libraries and Imaging				
Creation of NIH Bioactive Small Molecule Library & Screening	$68,059	$79,200	$79,300	$100
Cheminformatics	5,938	3,900	4,100	200
Technology Development	26,612	27,300	23,300	-4,000
Development of High-Specificity/High-Sensitivity Imaging Probes	10,070	3,900	0	-3,900
Imaging Probe Database	700	1,200	700	-500
Core Synthesis Facility to Produce Imaging Probes	3,356	3,000	3,000	0
Subtotal, Molecular Libraries and Imaging	114,735	118,500	110,400	-8,100
Building Blocks, Biological Pathways and Networks				
National Technology Centers & Metabolomics Development	15,223	16,819	16,156	-663
Metabolomics Technology Development	3,883	3,950	0	-3,950
Subtotal, Building Blocks, Biological Pathways and Networks	19,106	20,769	16,156	-4,613
Structural Biology				
Membrane Protein Production	9,644	9,892	9,880	-12
Bioinformatics and Computational Biology				
National Centers for Biomedical Computing	30,273	23,070	22,970	-100
Nanomedicine				
Nanomedicine Development Centers	14,000	25,000	25,000	0
Human Microbiome				
Sequence a Reference Set of Genomes	8,200	0	13,840	13,840
Demonstration Projects	0	0	3,970	3,970
New Tools and Technologies for Metagenomic Analyses	0	4,222	7,000	2,778
Data Coordination	313	2,412	2,412	0
Resource Repository for Materials & Reagents	400	0	400	400
ELSI Studies Unique to HMP	0	603	603	0
HMP Workshops	61	693	693	0
Subtotal, Human Microbiome	8,973	7,930	28,918	20,988
Epigenomics				
Mapping Centers	1,000	12,060	12,060	0
Human Health and Disease	0	0	4,000	4,000
Data Management Center for the Mapping Centers	1,000	3,618	3,618	0
Technology Development in Epigenetics	0	4,221	4,221	0
NIH International Committee on Epigenomics (NICE)	1,000	0	0	0
Discovery of Novel Epigenetic Marks in Mammalian Cells	0	4,221	4,221	0
Subtotal, Epigenomics	3,000	24,120	28,120	4,000
Connectivity Map				
Workshops	0	250	0	-250
Pilot Project	0	0	1,000	1,000
Subtotal, Connectivity Map	0	250	1,000	750
Subtotal, New Pathways of Discovery	**199,731**	**229,531**	**242,444**	**12,913**
Research Teams of the Future				
Interdisciplinary Research				
Interdisciplinary Research Centers	41,428	39,574	39,563	-11
Interdisciplinary Research Training Initiative	10,497	14,883	6,242	-8,641
Innovation in Interdisciplinary Technology and Methods	3,151	2,968	2,968	0
Subtotal, Interdisciplinary Research	55,076	57,425	48,773	-8,652
High-risk Research				
NIH Director's Pioneer Awards	36,481	36,215	36,215	0
NIH Director's New Innovator Awards	64,119	56,174	56,174	0
Subtotal, High-Risk Research	100,600	92,389	92,389	0
Public-Private Partnerships				
Public-Private Partnerships	541	574	593	19
Subtotal, Research Teams of the Future	**156,216**	**150,388**	**141,755**	**-8,633**
Re-engineering the Clinical Research Enterprise				
Clinical Research Policy Analysis and Coordination	7,843	2,000	1,000	-1,000
Feasibility of Integrating and Expanding Clinical Research Networks	7,316	700	0	-700
Translational Research Core Services	1,330	8,085	8,085	0
Dynamic Assessment of Patient-Reported Chronic Disease Outcomes	8,931	6,235	7,580	1,345
Enhance Clinical Research Training via the National Multi-disciplinary CR Career Development Program and CRTP and MSTP Expansions	17,303	8,417	3,193	-5,224
Clinical and Translational Science Awards	84,122	90,252	83,224	-7,028
Subtotal, Re-engineering the Clinical Research Enterprise	**126,845**	**115,689**	**103,082**	**-12,607**
Future Common Fund/Roadmap Cohort Concept Development	208	0	200	200
Subtotal Common Fund/Roadmap	483,000	495,608	487,481	-8,127
New Initiatives in Common Fund/Roadmap			**46,396**	**46,396**
Total Common Fund/Roadmap	**483,000**	**495,608**	**533,877**	**38,269**

Office of the Director
Justification
Common Fund/Roadmap for Medical Research

Overview

In September 2003, the NIH Director, Dr. Elias Zerhouni, initiated the 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 agency's core values of knowledge and discovery. It is a process of strategic coordination of research that cuts across the respective mission of the 27 NIH Institutes and Centers (ICs). Since FY 2005, the Office of Portfolio Analysis and Strategic Initiatives (OPASI) has been managing trans-NIH, collaborative initiatives known as the Roadmap using the "Common Fund." The Common Fund receives a small percent of the NIH budget toward a common purpose in support of high priority, trans-NIH projects. It was conceived as a virtual "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, this program 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 methods.

The NIH Common Fund/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 to improve 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.

Since the Common Fund's inception, approximately 1 percent of the NIH budget has been pooled to support Roadmap projects. Initially, the funds were comprised of contributions from each IC as well as the NIH Office of the Director. Beginning in FY 2007, the Common Fund budget became a separate item in the Labor/HHS appropriations bills with funding included in the NIH Office of the Director. Since FY 2004, funding for Roadmap has increased from $132 million to $496 million in FY 2008. A total of $534 million is requested in the FY 2009 President's Budget, equal to 1.8 percent of the NIH budget. Roadmap coordination functions are managed by the OPASI Division of Strategic Coordination. Planning for a new cohort of Roadmap initiatives to be funded through the Common Fund began in FY 2007 and will become an annual process.

Major Changes in the Fiscal Year 2009 Budget Request

In FY 2009, there will be changes in funding for Common Fund/Roadmap programs in keeping with the $38 million net increase over the FY 2008 Roadmap budget.

Major increases in existing Common Fund/Roadmap projects over FY 2008 levels will occur in the following areas:

Sequencing a Reference Set of Genomes: (+$14 million; total $14 million)
Human Microbiome Demonstration Projects: (+$4 million; total $4 million)
Epigenomics in Human Health and Disease: (+$4 million; total $4 million)

Major decreases in existing Common Fund/Roadmap projects will occur in:

Technology Development: (-$4 million; total $27 million)
Interdisciplinary Research Training Initiative: (-$9 million; total $6 million)
Clinical Research Training: (-$5 million; total $3 million)
Clinical and Translational Science Awards: (-$7 million; total $83 million)

Portrait of a Program: New Common Fund/Roadmap Initiatives for FY 2009

FY 2008 level:	$ 0 million
FY 2009 level:	$46 million
Change:	+$46 million

In FY 2009, the NIH Common Fund/Roadmap will spend $46 million from the Common Fund on the first year of funding as it continues to roll out a third and new cohort of Common Fund/Roadmap initiatives. The development of new sets of ideas that respond to Common Fund/Roadmap goals began during the summer of 2006. At that time, the NIH launched an intensive, wide-ranging, and transparent planning process that solicited input from extramural researchers, NIH staff and scientists, and the broad stakeholder community and general public. More than 300 ideas for new initiatives were received and evaluated. Emphasis was given to ideas that addressed gaps in knowledge or would lead to the development of tools that would allow researchers to overcome barriers in basic, translational, or clinical research. Successful outcomes of new initiatives would enhance the ability of NIH as a whole to fulfill its mission to improve human health through research.

In addition, the process of solicitation, review, and prioritization of concept proposals that meet the criteria laid out for Common Fund support will be repeated each year. This open and cyclical planning process allows the NIH Common Fund/Roadmap to respond rapidly to emerging opportunities that have the potential to transform the research enterprise.

As an example of this planning process, two major programs were chosen to implement new initiatives with FY 2008 resources from the Common Fund/Roadmap. The new initiatives, within the Human Microbiome and the Epigenomics programs, expect to fund their first research awards in FY 2008.

Highlights and Progress of the NIH Common Fund/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 multidisciplinary research that is required to successfully utilize these new tools. There are nine components within this theme, including two that were launched in FY 2007—the Human Microbiome Project and Epigenomics, and one that is expected to start in FY 2008—Connectivity Map.

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 research and development 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 contribution of *Molecular Libraries and Molecular Imaging* has been the establishment of a national network of screening centers known as the Molecular Libraries Probe Production Center Network (MLPCN). In collaboration with the broad scientific community, these centers have focused on performing high throughput screens (HTS), an automated procedure for simultaneously analyzing many compounds. By submitting assays to the center, the public has access to a large and complex repository containing the small molecules. All data from these screens are deposited in the free, online database, *PubChem* (http://pubchem.ncbi.nlm.nih.gov/), which was designed and implemented by *Molecular Libraries and Molecular Imaging.* This public access database contains 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 2009 the *Molecular Libraries and Molecular Imaging* production phase will screen at least 200,000 different chemicals in at least 100 assays provided by the scientific community. About $70 million will be spent on Probe Production

Centers and $11 million will be spent on Assay Technology Development. New grants will be funded in FY 2009 to continue to increase the size and diversity of the Small Molecule Repository.

Building Blocks, Pathways, and Networks
This implementation group of the NIH Common Fund/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 (TCNP), 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 receive instructions to carry out their function of cutting other proteins 2) development of florescent probes that can be tagged to proteins which enables the movement of the protein movement to be visualized inside the cell, and 3) development of techniques to study groups of proteins that are temporarily bound as large complexes that facilitate the transmittal of cellular information and instructions.

Five TCNP centers have been funded for an initial period of 5 years. These centers work cooperatively to create new technologies for proteomics of dynamic systems with a high degree of quantitative, spatial, and temporal resolution. Each center brings unique expertise and resources to this problem. They integrate proteomics with cell biology, imaging, and modeling to study dynamic molecular systems. The centers are unique among NIH-supported proteomics programs because of their focus on the dynamics of protein interactions and emphasis on imaging and quantitative methods. The centers also serve as a resource for NIH-supported investigators, committing substantial resources to collaboration with and education of biomedical researchers, as well as the transfer of technologies to other laboratories. In FY 2009, the NIH anticipates extending funding for some of these active centers for another 5 years.

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 fully 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 2009, the NIH Common Fund/Roadmap expects to continue to support these Centers and other ongoing research projects aimed at finding new ways to determine the structure of membrane proteins.

Bioinformatics and Computational Biology
In an age where informatics and the ability to manage and organize large amounts of varied data increasingly underpins 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) which are administered by the National Institute of General Medical Sciences (NIGMS). A total of seven Centers were funded beginning in 2003-2004. The *Bioinformatics and Computational Biology* program underwent a midcourse review in 2007 that endorsed the importance of biomedical computing for NIH. The NCBC initiative was approved for additional Common Fund/Roadmap funding. After competitive review of the existing centers, the NIH Common Fund/Roadmap expects to renew the NCBC initiative for a second cycle of support in FY 2009.

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. To harness the potential of Nanomedicine, the Common Fund/Roadmap established a network of eight Nanomedicine Centers at academic institutions across the country. Funding for these Centers increased from $14 million in FY 2007 to $25 million in FY 2008 and FY 2009.

Human Microbiome Project
The number of microbial cells residing on or in the human body outnumbers the human cells by a factor of 100. Many of the microbes are beneficial whereas others cause disease. Bacteria have been implicated in conditions as diverse as asthma, cancer and obesity, yet the great majority of bacteria and viruses that reside on people are unidentified and uncharacterized. The new Common Fund/Roadmap Human Microbiome Project was launched to leverage advances in high throughput genomic technologies to identify and characterize approximately 600 new human microbes and to establish precedence for a definitive, causal link between certain bacteria and disease. It will also determine whether a core microbiome is shared by all people or whether each person has a unique spectrum of microbes by sampling microbes from several body sites from each of multiple people. In FY 2009, $14 million will support sequencing and cataloging efforts of these samples. In addition, $4 million will fund new grants designed to establish the link between the microbiome and disease.

Epigenomics
The completion of the Human Genome Project in 2003 provided a wealth of information about the sequence of the estimated 25,000 human genes that control normal physiology and that, if mutated, can cause disease. However, the sequence of DNA bases that line up in a gene is only one level of regulation of the genetic information. The human epigenome is the collection of all stable, “epigenetic,” modifications of the human genome structure that do not change the DNA sequence. Some human diseases are known to be associated with epigenetic changes, but little is known about the factors that cause these changes. Researchers need more sophisticated tools to efficiently detect epigenetic changes and correlate them with specific diseases or health conditions. The *Epigenomics* program has defined several initiatives that aim to map all common epigenetic changes in the human genome and to develop new technologies and data analysis tools for detecting and studying epigenetic modifications. Reference Epigenome Mapping Centers will develop reference epigenomes—a “map” of all epigenetic changes—in various cell types. The scientific community can use such maps to identify therapeutic targets and gain insights into normal biology as well as disease mechanisms. An Epigenomics Data Analysis and Coordination Center (EDACC) will analyze and coordinate data from the Mapping Centers and other epigenomics research efforts. The EDACC will create a database of standardized datasets that will be accessible to the public. Three initiatives will support individual investigator projects on the topics of the Epigenetics of Health and Disease, Technology Development in Epigenetics, and Discovery of Novel Epigenetic Markers. The Epigenomics program expects to award Centers and fund the first set of individual projects in FY 2008, with additional projects funded in FY 2009.

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 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. The New Innovator Award program was initiated in FY 2007 to foster highly innovative research and support exceptionally creative investigators.

Interdisciplinary Research Consortia

A major focus of the NIH Common Fund/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 access a range of techniques and expertise. This requires scientists to work with scientists whose area of expertise differs from their own. In FY 2007, the NIH awarded nine *Interdisciplinary Research Consortia*. These consortia will explore new ways to integrate different scientific disciplines to address critical health challenges.

Portrait of Program: Interdisciplinary Research Consortia

FY 2008 Level: $40 million (estimate)
FY 2009 Level: $40 million (estimate)
Change: $ 0 million

Interdisciplinary research integrates elements of a wide range of disciplines, often including basic research, clinical research, behavioral biology, and social sciences so that all of the scientists approach the problem in a new way. The members of interdisciplinary teams learn from each other to produce new approaches to a problem that would not be possible through any of the single disciplines. The Interdisciplinary Research Consortia will not only develop ways to think about challenging biomedical problems, but will provide a stimulus for academic research culture change such that interdisciplinary research becomes the norm. The consortia will define barriers to interdisciplinary research and develop strategies to overcome those barriers.

The missions of the individual consortia range broadly from deciphering the basis of neuropsychiatric disorders, to developing new approaches to drug discovery and targeted gene therapy, to preserving fertility in women with cancer, to understanding the fundamentals of the aging process, to a coordinated and systematic approach to regenerative medicine and obesity, to probing the relationship between self-control and addictive behavior, and to developing targeted molecular therapies for neurodegenerative disorders. These consortia are jointly administered by groups of Institutes and Centers, each of which manages one of several linked awards that form each consortium.

Director's Pioneer Award

The Director's Pioneer Award is a highly lauded and successful program to recognize visionary scientists. In FY 2009, the NIH will fund the sixth round of the Director's Pioneer Award. Traditionally, most NIH grants to individuals are awarded to individual investigators for specific research proposals. In contrast, the highly prestigious Pioneer

Awards support specific researchers and are designed to allow the researcher to conduct extensive, high-risk, highly innovative research. Awardees perform research that is broad in scope and may contribute to a transformation of new, fundamental principles within that research niche. These unique awards provide $500,000 each year in direct costs for a total of 5 years. To date, 47 scientists have received this award. Recent publications from awardees have demonstrated progress on topics as diverse as why stem cells in the muscles deteriorate as people age and understanding the function of sleep. The Director's Pioneer Awards are administered by NIGMS.

Director's New Innovator Award
The Director's New Innovator Award was launched in FY 2007 for the dual purposes of stimulating highly innovative research that has a potential to make a significant contribution to biomedical or behavioral research and supporting extraordinary new investigators. The New Innovator Awards provide up to $1.5 million in direct costs over 5 years. New investigators who have never held one of NIH's traditional investigator-initiated research project grants (often referred to as "R01s") or equivalent NIH grant are eligible to apply for this award. To date, New Innovator Awards have been given to 30 promising new investigators on the basis of their creativity and potential for innovation, funded through a combination of Common Fund/Roadmap and IC monies.

Public-Private Partnerships
Since its launch in 2005, the *Public-Private Partnerships* program has worked to develop resources and policies to facilitate NIH's ability to engage in partnerships with private organizations. A trans-NIH Public-Private Partnerships Coordination Committee, which has representation from all Institutes and Centers (ICs) and several offices from the Office of the Director, meets monthly to share best practices, partnership models and opportunities, and hear from outside speakers. Resources for the development of partnerships have been made available on the program's website. In 2007, an NIH Manual of Issuance chapter was released that describes policies and approaches to public-private partnerships. Another chapter describing the participation of outside entities in support of extramural funding activities was developed in concert with the Office of Extramural Research is in clearance. The *Public-Private Partnerships* program provides advice and guidance to both NIH ICs and outside parties seeking to develop and implement partnerships.

A major activity of the program has been the implementation of specific, large scale partnerships. Once activated, the ongoing management of such partnerships may transfer to the Foundation for the NIH (FNIH), and/or an IC or, alternatively, it may remain within the program. The Genetic Association Information Network is a large genome-wide association public-private partnership involving FNIH, a number of outside partners, and several NIH components such as NHGRI and NLM among others. Another example of a partnership established by the program is the Biomarkers Consortium, which is a very large partnership involving the NIH, FNIH, the Food and Drug Administration, the Centers for Medicare and Medicaid Services, the Pharmaceutical Research and Manufacturers of America, the Biotechnology Industry

Organization, as well as a number of companies, patient advocacy groups and professional societies. This Consortium is currently managed by the *Public-Private Partnerships* program.

Re-engineering the Clinical Research Enterprise

This theme of the NIH Common Fund/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 Re-engineering the Clinical Research Enterprise 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 the working relationships among the numerous entities that are part of the clinical research process.

Clinical and Translational Science Awards (CTSAs)
The CTSA program is a unique and bold venture that meets the NIH Common Fund/Roadmap objective to restructure and improve the clinical research enterprise. The CTSA program will transform how clinical and translational research is conducted, 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 NCRR, is being transitioned into the CTSA program. Currently, the CTSA program is administered and funded by both the NIH Common Fund/Roadmap and NCRR. As the program expands, its management and function will transition solely to NCRR.

Through the CTSAs, academic health centers (AHCs) will work as a national consortium. The CTSA infrastructure will enable institutions to enhance the research capacity developed through the General Clinical Research Center program, train a cadre of multi- and inter-disciplinary investigators, and collaborate to translate laboratory discoveries into improved therapies for patients. To date, 24 CTSAs have been funded at AHCs throughout the country. When fully implemented in 2012, about 60 CTSAs will be linked together to energize the discipline of clinical and translational science. Funding for the CTSA program in FY 2009 will continue to be provided by both the NIH Common Fund/Roadmap and NCRR. Approximately 12 new CTSAs will be awarded in FY 2009.

Patient-Reported Outcomes Measurements Information Systems (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 U.S. 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. In the first phase of the PROMIS initiative, seven Primary Research Sites (PRS) developed survey questions and data compilation methods. Each PRS pursued independent objectives but also comprises an essential part of an integrated national effort. The success of the first phase of PROMIS reinforces the high potential of this initiative to transform the conduct of clinical research in a way that is beyond what a single institute or center could have achieved independently. In FY 2009, the NIH Common Fund/Roadmap will launch the next phase of this initiative, PROMIS II. The goals of PROMIS II are to validate the PROMIS domains in the context of large scale clinical trials and to develop the PROMIS system to facilitate adoption by clinical researchers.