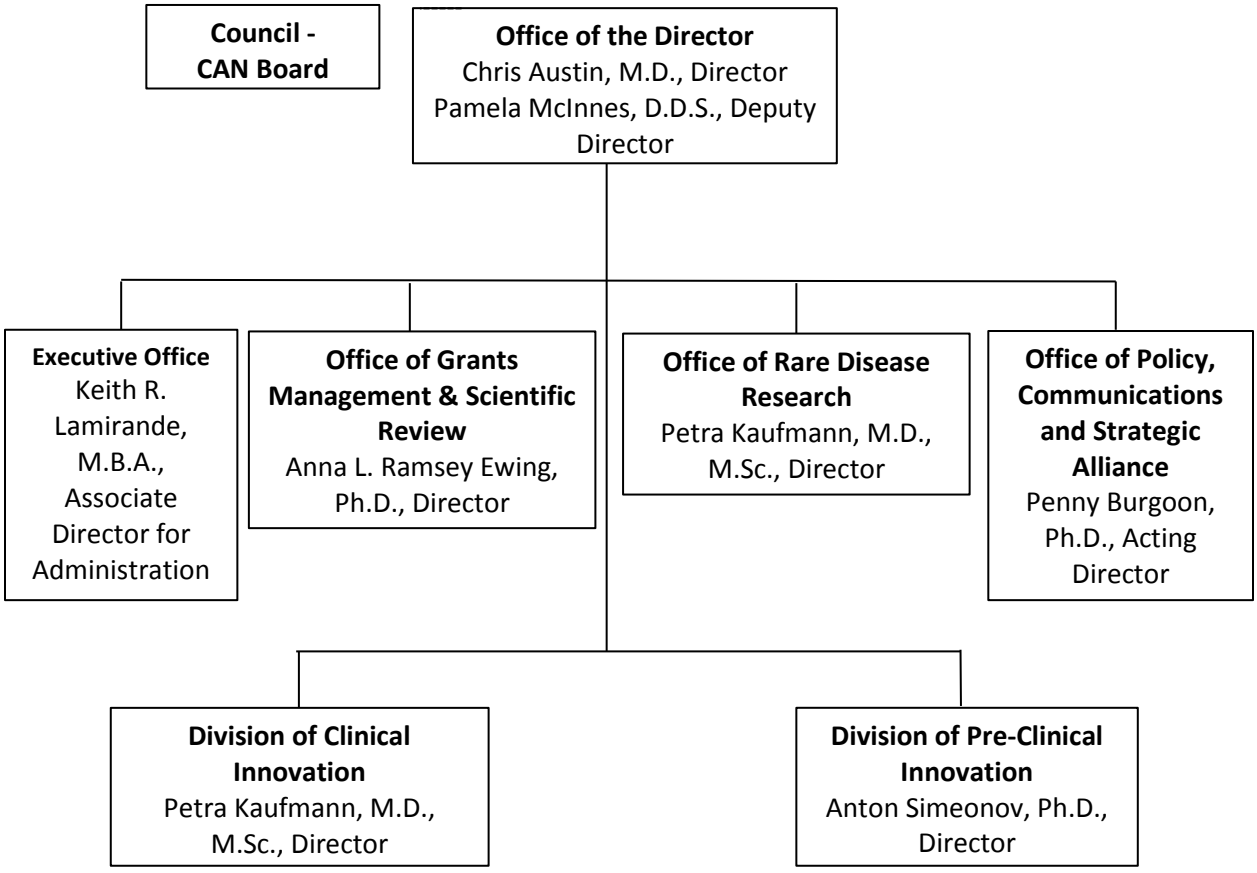
DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

National Center for Advancing Translational Sciences (NCATS)

FY 2017 Budget — Page No.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For carrying out section 301 and title IV of the PHS Act with respect to translational sciences, [$685,417,000]*$660,131,000*: Provided, That up to $25,835,000 shall be available to implement section 480 of the PHS Act, relating to the Cures Acceleration Network [Provided further, That at least $500,000,000 is provided to the Clinical and Translational Sciences Awards program].

Amounts Available for Obligation[1]

(Dollars in Thousands)

Source of Funding	FY 2015 Actual	FY 2016 Enacted	FY 2017 President's Budget
Appropriation	$635,230	$685,417	$685,417
Mandatory Appropriation: (non-add)			
Type 1 Diabetes	*(0)*	*(0)*	*(0)*
Other Mandatory financing	*(0)*	*(0)*	*(25,286)*
Rescission	0	0	0
Sequestration	0	0	0
FY 2015 First Secretary's Transfer	0	0	0
FY 2015 Second Secretary's Transfer	0	0	0
Subtotal, adjusted appropriation	$635,230	$685,417	$685,417
OAR HIV/AIDS Transfers	-2,520	0	0
National Children's Study Transfers	0	0	0
Subtotal, adjusted budget authority	$632,710	$685,417	$685,417
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	$632,710	$685,417	$685,417
Unobligated balance lapsing	-81	0	0
Total obligations	$632,629	$685,417	$685,417

[1] Excludes the following amounts for reimbursable activities carried out by this account:
FY 2015 - $22,144 FY 2016 - $25,000 FY 2017 - $25,000

NATIONAL INSTITUTES OF HEALTH
National Center for Advancing Translational Sciences

Budget Mechanism - Total[1]

(Dollars in Thousands)

MECHANISM	FY 2015 Actual		FY 2016 Enacted		FY 2017 President's Budget[3]		FY 2017 +/- FY 2016	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Projects:								
Noncompeting	4	$17,758	8	$21,530	31	$26,871	23	$5,341
Administrative Supplements	*(7)*	1,861	*(7)*	2,269		310	*(-7)*	-1,959
Competing:								
Renewal								
New	4	2,998	38	17,682	48	22,775	10	5,093
Supplements								
Subtotal, Competing	4	$2,998	38	$17,682	48	$22,775	10	$5,093
Subtotal, RPGs	8	$22,616	46	$41,481	79	$49,956	33	$8,475
SBIR/STTR	28	13,781	33	16,157	35	17,047	2	890
Research Project Grants	36	$36,398	79	$57,638	114	$67,003	35	$9,365
Research Centers:								
Specialized/Comprehensive	3	$20,081	3	$19,733	3	$18,101		-$1,632
Clinical Research	58	399,835	59	408,500	57	397,159	-2	-11,341
Biotechnology								
Comparative Medicine		198		198		198		
Research Centers in Minority Institutions								
Research Centers	61	$420,115	62	$428,431	60	$415,458	-2	-$12,973
Other Research:								
Research Careers	61	$48,018	61	$50,000	61	$48,400		-$1,600
Cancer Education								
Cooperative Clinical Research								
Biomedical Research Support								
Minority Biomedical Research Support								
Other	6	867	16	5,410	16	5,410		
Other Research	67	$48,885	77	$55,410	77	$53,810		-$1,600
Total Research Grants	164	$505,398	218	$541,479	251	$536,270	33	-$5,208
Ruth L Kirchstein Training Awards:	FTTPs		FTTPs		FTTPs		FTTPs	
Individual Awards								
Institutional Awards	341	13,416	346	15,000	330	14,500	-16	-500
Total Research Training	341	$13,416	346	$15,000	330	$14,500	-16	-$500
Research & Develop. Contracts	104	$27,021	101	$31,795	101	$35,456		$3,661
(SBIR/STTR) (non-add)[2]	*(15)*	*(4,740)*	*(9)*	*(3,900)*	*(9)*	*(4,114)*		*(214)*
Intramural Research	34	$54,190	35	$61,273	35	$61,886		$613
Res. Management & Support	95	32,685	95	35,870	95	37,305		1,434
Res. Management & Support (SBIR Admin) (non-add)[2]		*(253)*		*(294)*		*(310)*		*(16)*
Office of the Director - Appropriation[2]								
Office of the Director - Other								
ORIP/SEPA (non-add)[2]								
Common Fund (non-add)[2]								
Buildings and Facilities								
Appropriation								
Type 1 Diabetes								
Program Evaluation Financing								
Cancer Initiative Mandatory Financing								
Other Mandatory Financing						-25,286		-25,286
Subtotal, Labor/HHS Budget Authority		**$632,710**		**$685,417**		**$660,131**		**-$25,286**
Interior Appropriation for Superfund Res.								
Total, NIH Discretionary B.A.		**$632,710**		**$685,417**		**$660,131**		**-$25,286**
Type 1 Diabetes								
Proposed Law Funding								
Cancer Initiative Mandatory Financing								
Other Mandatory Financing						25,286		25,286
Total, NIH Budget Authority		**$632,710**		**$685,417**		**$685,417**		
Program Evaluation Financing								
Total, Program Level		**$632,710**		**$685,417**		**$685,417**		

[1] All Subtotal and Total numbers may not add due to rounding.
[2] All numbers in italics and brackets are non-add.
[3] Includes mandatory financing.

Major Changes in the Fiscal Year 2017 President's Budget Request

Note that there may be overlap between activity detail and budget mechanism. The items highlighted refer to budget activity changes greater than $1 million and will not sum to the total change of zero for the FY 2017 budget request for NCATS.

Reengineering Translational Sciences: (+$1.716 million; total $67.451 million): In FY 2017, NCATS will increase support for its SBIR grant and contract program by $1.1 million, and will increase funding by $0.6 million for NCATS' intramural research program to offset the increased payroll and other mandatory cost increases.

Rare Disease Research and Therapeutics: (-$2.153 million; total $41.596 million): In FY 2017, NCATS plans to reduce funding for a research center award and for administrative supplements.

NATIONAL INSTITUTES OF HEALTH
National Center for Advancing Translational Sciences

Summary of Changes

(Dollars in Thousands)

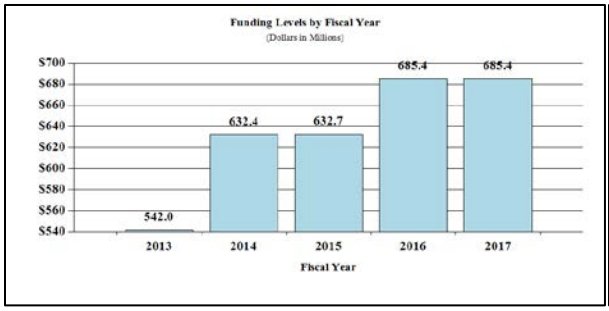
FY 2016 Enacted	$685,417
FY 2017 President's Budget	$685,417
Net change	$0

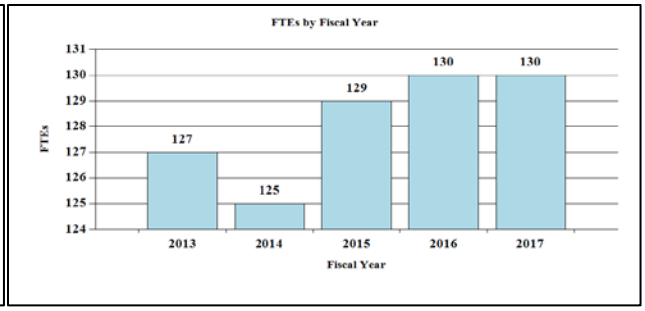
CHANGES	FY 2017 President's Budget[1] FTEs	FY 2017 President's Budget[1] Budget Authority	Change from FY 2016 FTEs	Change from FY 2016 Budget Authority
A. Built-in:				
1. Intramural Research:				
a. Annualization of January 2016 pay increase & benefits		$6,541		$24
b. January FY 2017 pay increase & benefits		6,541		94
c. Two less days of pay		6,541		-50
d. Differences attributable to change in FTE		6,541		0
e. Payment for centrally furnished services		3,551		13
f. Increased cost of laboratory supplies, materials, other expenses, and non-recurring costs		51,793		997
Subtotal				$1,078
2. Research Management and Support:				
a. Annualization of January 2016 pay increase & benefits		$13,814		$49
b. January FY 2017 pay increase & benefits		13,814		195
c. Two less days of pay		13,814		-104
d. Differences attributable to change in FTE		13,814		0
e. Payment for centrally furnished services		566		14
f. Increased cost of laboratory supplies, materials, other expenses, and non-recurring costs		22,925		430
Subtotal				$583
Subtotal, Built-in				$1,661

CHANGES	FY 2017 President's Budget[1] No.	FY 2017 President's Budget[1] Amount	Change from FY 2016 No.	Change from FY 2016 Amount
B. Program:				
1. Research Project Grants:				
a. Noncompeting	31	$27,181	23	$3,382
b. Competing	48	22,775	10	5,093
c. SBIR/STTR	35	17,047	2	890
Subtotal, RPGs	114	$67,003	35	$9,365
2. Research Centers	60	$415,458	-2	-$12,973
3. Other Research	77	53,810	0	-1,600
4. Research Training	330	14,500	-16	-500
5. Research and development contracts	101	35,456	0	3,661
Subtotal, Extramural		$586,226		-$2,047
	FTEs		FTEs	
6. Intramural Research	35	$61,886	0	-$465
7. Research Management and Support	95	37,305	0	851
8. Construction		0		0
9. Buildings and Facilities		0		0
Subtotal, Program	130	$685,417	0	-$1,661
Total changes				$0

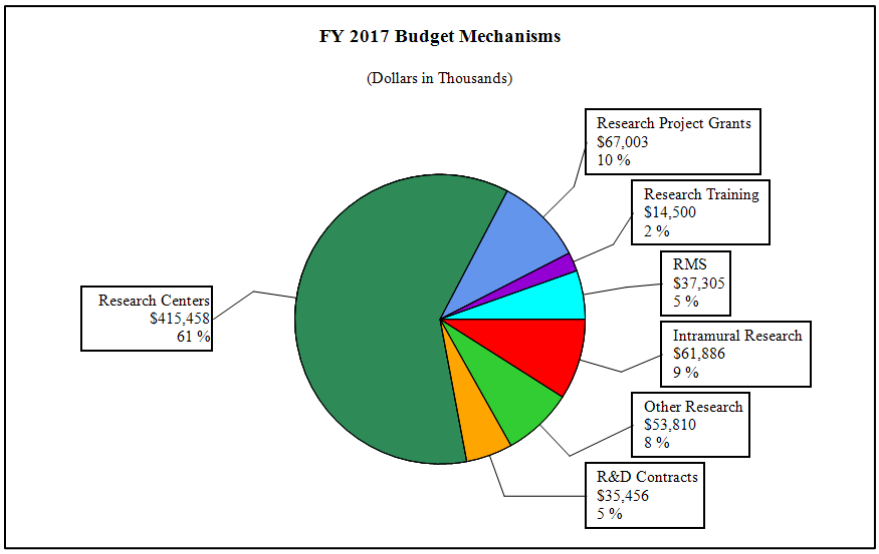
[1] Includes mandatory financing.

History of Budget Authority and FTEs:

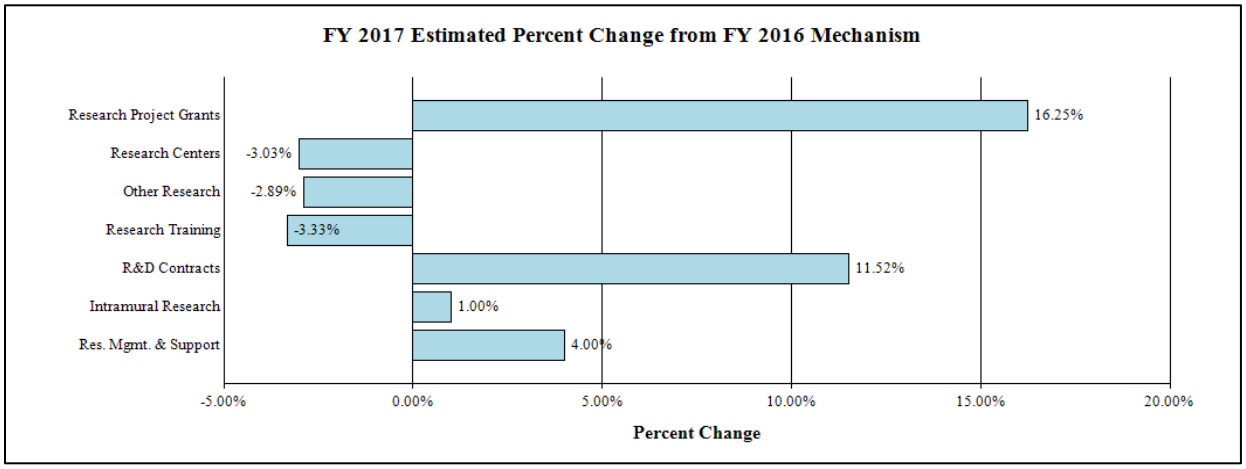




Distribution by Mechanism:



Change by Selected Mechanism:



Budget Authority by Activity[1]

(Dollars in Thousands)

	FY 2015 Actual		FY 2016 Enacted		FY 2017 President's Budget[2]		FY 2017 +/- FY 2016	
Research	**FTE**	**Amount**	**FTE**	**Amount**	**FTE**	**Amount**	**FTE**	**Amount**
Detail								
Clinical and Translational Science Activities		$472,226		$500,000		$500,000		$0
Program Leadership and Oversight (non-add)[3]				*(4,500)*		*(5,200)*		*(700)*
Rare Disease Research and Therapeutics		45,372		43,749		41,596		-2,153
Reengineering Translational Sciences		55,441		65,735		67,451		1,716
Cures Acceleration Network		9,834		25,835		25,835		0
Program Leadership and Oversight (non-add)[3]				*(440)*		*(500)*		*(60)*
Translational Research Resources		17,151		19,168		18,930		-238
Subtotal, Research		**$600,025**		**$654,487**		**$653,812**		**-$674**
Intramural Research (non-add)[3]	**34**	***($54,190)***	**34**	***($61,273)***	**34**	***($61,886)***	**0**	***($613)***
Research Management & Support[4]	**95**	**$32,685**	**96**	**$30,930**	**96**	**$31,605**	**0**	**$674**
TOTAL	**129**	**$632,710**	**130**	**$685,417**	**130**	**$685,417**	**0**	**$0**

[1] Includes FTEs whose payroll obligations are supported by the NIH Common Fund.
[2] Includes mandatory financing.
[3] All items in italics and brackets are non-add entries.
[4] Research Management & Support excludes $4.94 million in FY 2016 and $5.70 million in FY 2017 for CTSA and CAN Program Leadership and Oversight .

Authorizing Legislation

	PHS Act/ Other Citation	U.S. Code Citation	2016 Amount Authorized	FY 2016 Enacted	2017 Amount Authorized	FY 2017 President's Budget[1]
Research and Investigation	Section 301	42§241	Indefinite	$685,417,000	Indefinite	$660,131,000
National Center for Advancing Translational Sciences	Section 401(a)	42§281	Indefinite		Indefinite	
Total, Budget Authority				$685,417,000		$660,131,000

[1]Excludes mandatory financing.

Appropriations History

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
2007				
Rescission				$0
2008				
Rescission				$0
2009				
Rescission				$0
2010				
Rescission				$0
2011				
Rescission				$0
2012	$721,601,000		$582,326,000	$576,456,000
Rescission				$1,089,502
2013	$639,033,000		$631,346,000	$575,366,498
Rescission				$1,150,733
Sequestration				($28,879,442)
2014	$665,688,000		$661,264,000	$633,267,000
Rescission				$0
2015	$657,471,000			$635,230,000
Rescission				$0
2016	$660,131,000	$643,111,000	$699,319,000	$685,417,000
Rescission				$0
2017[1]	$685,417,000			

[1] Includes mandatory financing.

NATIONAL INSTITUTES OF HEALTH
National Center for Advancing Translational Sciences

Justification of Budget Request

Authorizing Legislation: Section 301 and title IV of the Public Health Service Act, as amended and Section 480 of the PHS Act, relating to the Cures Acceleration Network.

Budget Authority (BA):

	FY 2015 Actual	FY 2016 Enacted	FY 2017 President's Budget	FY 2017 +/- FY 2016
BA	$632,710,000	$685,417,000	$685,417,000	0
FTE	129	130	130	

Program funds are allocated as follows: Competitive Grants/Cooperative Agreements; Contracts; Direct Federal/Intramural and Other.

Director's Overview

The National Center for Advancing Translational Sciences (NCATS) is about getting more treatments to more patients more quickly. NCATS develops, demonstrates, and disseminates innovations that reduce, remove, or bypass system-wide bottlenecks in the translational science process. NCATS defines translation as the process of turning observations in the laboratory and clinic into interventions that improve the health of individuals and the public – from diagnostics and therapeutics to medical procedures and behavioral changes. Translational science is the field of investigation focused on understanding the scientific and operational principles underlying each step of the translational process.

Rather than targeting a particular disease, NCATS focuses on what is common across diseases and the translational process. The central challenge that NCATS and the translational science field face is that the development of new medical interventions takes too long, costs too much, and too often ends in failure. It can take on average 14 years and $1 billion to $2 billion to develop a new drug, with a failure rate exceeding 95 percent. Additionally, of the thousands of diseases that affect humans, only about 500 have any FDA-approved treatment.

NCATS programs and initiatives span the translational science spectrum, which covers each stage of research. These stages include basic research, pre-clinical research, clinical research, clinical implementation, and public health. The translational process is multidirectional; starting at any stage and potentially going directly to any other stage.[1] NCATS scientists typically do not conduct basic research. However, insights gained from the Center's studies can inform basic research. In one recent example, NCATS scientists and collaborators tested combinations of known and newly identified drugs to treat malaria. The analyses not only led to identification of new potential treatments (moving from the pre-clinical to clinical stage) but also shed light on the underlying biology of malaria (moving from the pre-clinical to basic research stage).

[1] https://ncats.nih.gov/translation/spectrum

One way to streamline drug development is through repurposing, which is finding new uses for drugs that already have been approved or that have cleared several steps along the development pathway. Several of NCATS' repurposing programs provided important advances in FY 2015. Screens of the NCATS Pharmaceutical Collection (NPC), a library of approved and investigational drugs, identified compounds that may treat additional diseases including multiple sclerosis, hepatitis C, and Ebola virus infection. Through NCATS' Discovering New Therapeutic Uses for Existing Molecules program, researchers are demonstrating success in finding new indications for previously shelved compounds, including a potential new treatment for Alzheimer's disease.

A major bottleneck in drug development is the ability to predict toxicity of experimental drug candidates. NCATS is tackling this problem in several ways, including the Tissue Chip for Drug Screening Program, developed in collaboration with DARPA and the FDA. Researchers have developed microchip platforms that support human cells and tissues, thereby serving as miniature models of living organs such as the lung, liver, and heart. In the second phase of the program, scientists are working together to connect organ systems to function with one another. This integration enables real-time measurement of drug activity within and across various organs and tissues. For example, a team of scientists has created a tissue chip that includes female reproductive tissues that interact with each other over periods of a month or more much like they do in the human body. The device, called "EVATAR™," will be used in drug development and to study the basic female reproductive biology. Looking to the future, it likely will be possible to create a human body on a chip for specific individuals, which could be used as a precision medicine testing system to identify drug responders and non-responders, and individuals prone to adverse drug reactions.

Another challenge in translational science is the conduct of clinical trials and how interventions are tested for safety and efficacy. NCATS' Clinical and Translational Science Awards Program (CTSA) is therefore focused on transforming the way clinical research is conducted, creating a national network for translational medicine that will be more efficient and effective. CTSA investigators and NCATS staff worked together in FY 2015 to pilot a number of initiatives to jumpstart progress in these areas. These included CTSA Accrual to Clinical Trials, a nationwide network of sites that share electronic health record data to identify and enroll participants in clinical studies; IRBrely, a national Institutional Review Board (IRB) reliance agreement to streamline the clinical trial review and approval process; and a collaboration between CTSA and I-Corps at NIH, an innovation training program designed to train biomedical researchers in how to overcome key obstacles towards commercialization.

In FY 2016, NCATS will begin integrating CTSA institutional hubs with new CTSA Recruitment Innovation Centers (RICs, improving research participant recruitment) and Trial Innovation Centers (TICs, network capacity for multisite clinical studies). In addition, new CTSA Collaborative Innovation Awards will provide opportunities for CTSA hubs to work together to share expertise and collaboratively solve common translational roadblocks. Through these and other diverse efforts, CTSA will address system-wide bottlenecks to make clinical and translational research more efficient.

Rare diseases research remains a NCATS priority. New discoveries about the molecular basis of rare diseases offer unprecedented opportunities to improve the diagnosis and treatment of the thousands of diseases that currently have no treatments. New scientific insights, from genomics and experimental therapeutics are increasingly identifying other diseases, both rare and common, that share biochemical pathways, allowing rapid application of the insights gained from the study of one disease to the treatment of others. To ensure that NCATS clinical and translational research activities are optimally aligned, the NCATS Office of Rare Diseases Research (ORDR) and the Division of Clinical Innovation (including CTSA) were brought under common leadership in FY 2015. This enables NCATS leadership to leverage the strengths of the ORDR and DCI programs to advance clinical translational science. This is timely as NCATS' national networks – the Rare Diseases Clinical Research Network (RDCRN) and the CTSA Program – are ideally suited for advancing precision medicine given their scale, access to diverse populations, and efforts to make translation more effective and efficient. Combined, NCATS activities are streamlining all parts of the translational science spectrum, thus enabling full realization of the promise of our growing understanding of human biology to revolutionize the way we treat human disease and improve public health.

Program Descriptions and Accomplishments

Clinical and Translational Science Activities: CTSA is designed to develop innovative solutions that will improve the efficiency, quality, and process for turning observations in the laboratory, clinic, and community into public health interventions. To achieve this goal, and in line with the recommendations of the 2013 Institute of Medicine (IOM) report that evaluated CTSA, NCATS is evolving the program into an innovative national network of clinical and translational research institutions (hubs), which soon will be integrated with new Recruitment Innovation Centers (RICs) and Trial Innovation Centers (TICs). As described below, the hubs, RICs, and TICs, along with continuing opportunities to strengthen network collaboration through CTSA Collaborative Innovation Awards (CCIAs), will focus on addressing system-wide bottlenecks in the clinical and translational research process to make clinical and translational research more efficient for the nation.

- **Clinical and Translational Science Award Program hubs:** testing and implementing solutions for clinical and translational research. In the fall of 2015, NCATS announced new funding for 18 CTSA hubs. The CTSA hubs are the awarded institutions, charged with working with NCATS leadership to develop, demonstrate, and disseminate innovative solutions that address system-wide scientific and operational problems in clinical and translational research that no one organization can overcome. The program portrait below highlights some of the current activities and issues that NCATS leadership and the hub investigators have been tackling together. With the continuous development of CTSA, the program now adheres to regular NIH application cycles, which include multiple standard receipt dates per year. This provides potential applicants with additional flexibility in planning submission of their applications.
- **CTSA Program RICs:** improving patient recruitment for clinical and translational research studies, particularly in traditionally underrepresented groups. In May 2015, NCATS issued a funding opportunity announcement (FOA) for CTSA RICs, which will utilize big data and electronic health records to improve research participant recruitment

in the planning and implementation phase of clinical trials. In the planning phase of a clinical trial, the RICs will rapidly provide investigators and funders with estimates of the availability of candidate participants who meet the study's entry criteria. Such estimates will be based on de-identified, aggregate data derived from the electronic health records at individual sites and across the CTSA network. In the implementation phase of a clinical trial, the RICs will support investigators through innovative strategies for enrolling research participants in a timely manner. CTSA RIC awards will be issued in FY 2016.

- **CTSA Program TICs:** streamlining and harmonization efforts for multisite studies. In June 2015, NCATS issued a FOA for CTSA TICs, which are intended to transform the CTSA network's ability to implement multisite studies by adding innovative network capacity to the existing strengths at the program hubs. TICs will have the capacity to identify and coordinate a cadre of specialist investigators from across the CTSA network to implement studies efficiently in response to a broad range of disease-specific opportunities. Additionally, select TICs will have particular expertise to conduct multisite studies with special populations, such as pediatric or geriatric subjects. CTSA TIC awards will be issued in FY 2016.
- **CCIAs:** enhancing collaborations to strengthen the CTSA network. In April 2015, NCATS released FOAs for the CCIAs, which are meant to stimulate and strengthen team-based research across the CTSA network by supporting collaborations among investigators from a minimum of three CTSA hubs. These awards encourage all program hubs to collaboratively conceptualize, develop, and implement multisite innovative experimental approaches that overcome translational barriers in science, operations, and training. The first cohort of CCIA awards will be issued in FY 2016.

In building and optimizing these clinical translational trial components and interfacing them with the CTSA hubs for implementation, all clinical researchers will be able to "plug into" the program network to conduct their clinical studies more effectively, without having to rebuild costly and time-consuming clinical trial components for each study.

Finally, for NCATS to be able to fully evolve into a national network in line with the strategic goals set forth in the 2013 IOM report, and in particular the specific recommendation to "Strengthen NCATS leadership of CTSA," the NCATS scientific team that leads and oversees the program must have the quality and depth of expertise of the program itself. This demands collective expertise in a broad range of disciplines, including biomedical informatics, epidemiology, and knowledge of the multiple facets of clinical research. Therefore, it is imperative that NCATS have the ability to recruit staff that have the expertise that matches the CTSA program's research objectives.

Through the efforts described above, NCATS leadership is addressing all of the IOM report recommendations to advance CTSA goals. Awards made through the hub, CCIA, RIC, and TIC initiatives will serve to strengthen CTSA as a unique and valuable resource. The infusion of new, innovative ideas will transform clinical and translational research, making it more efficient and even more accessible to all involved in clinical and translational research — scientists, clinicians, patients, and the community.

Program Portrait: CTSA Program - Transforming Clinical Trials in the United States

FY 2016 Level: $500.0 million
FY 2017 Level: $500.0 million
Change: $0.0 million

NCATS has made progress over the past year in implementing the new direction of CTSA described in the previous budget request. CTSA investigators, together with NCATS staff, have piloted the projects described below to address common problems that plague clinical trials. As a next step, NCATS staff and the program investigators will work together to incorporate successful efforts into the operations of CTSA.

- **Accrual to Clinical Trials (ACT):** data sharing. The aim of CTSA ACT is to develop a nationwide network of sites that share electronic health record data to identify and enroll participants who meet criteria for a given clinical study. The ACT investigators are building on existing informatics platforms and operating models to create a network with common standards, data terminology, and shared resources. The team has created standard categories and terminology for demographic and clinical visit data, as well as for medications and laboratory results.
- **IRBrely:** streamlining oversight of clinical trials. For multisite studies, the IRB review and approval process can be complex and lengthy, often discouraging researchers from initiating important trials. Several CTSA investigators have achieved significant progress in overcoming this roadblock using a concept called IRB reliance. IRBrely is a national CTSA IRB reliance agreement that builds upon the expertise of existing regional IRB models. With this model, institutions develop networks in which each of the institutions in a multisite study agrees to rely on a single IRB of record for initial approval and continuing review of the trial.
- **Good Clinical Practice (GCP) initiative:** standardizing research training. Before investigators enroll participants and launch a trial, study personnel must be qualified and acquire necessary competencies to conduct safe and efficient research. The GCP initiative is a process that incorporates established ethical and scientific quality standards for the design, conduct, recording, and reporting of clinical research involving human participants. The goals of the CTSA initiative are to streamline and standardize GCP training for clinical study personnel across the program consortium, eliminate redundant training requirements, and measure the impact of the changes.
- **Workforce training:** CTSA has interfaced with the I-Corps at NIH, a pilot of the National Science Foundation Innovation Corps program, which is tailored to train biomedical researchers and entrepreneurs on how to overcome key obstacles along the path of commercialization. Investigators from 10 CTSA Program hubs will receive I-Corps training to become I-Corps educators, who in turn can provide entrepreneurship training for other translational scientists. I-Corps implemented through CTSA will prepare participants to identify and develop valuable commercial opportunities that emerge from the research setting, with the intent of moving discoveries more quickly into treatments and cures.

Budget Policy:
The FY 2017 President's Budget request is $500.000 million, the same as the FY 2016 Enacted level. These resources will be used to continue development of the CTSA program in-line with the 2013 Institute of Medicine (IOM) recommendations.

Rare Diseases Research and Therapeutics: Rare diseases research remains very important to NCATS. Rather than focusing on a single type of condition or biological system, NCATS looks for what is common among diseases. This systematic approach is especially important when investigating rare diseases, which number in the thousands with only a few hundred having any FDA-approved treatment. Though rare diseases by definition affect relatively small numbers of people (usually defined as fewer than 200,000 in the United States), together, these diseases affect an estimated 25 million Americans and are the source of enormous suffering, premature death, and lost economic activity. Most rare diseases are caused by mutations in single genes, but they typically affect many different organ systems simultaneously. The large number of

currently untreatable rare diseases, and the fact that they each affect multiple organs, make the typical one-disease-at-a-time, one-organ-at-a-time translational model untenable.

NCATS supports rare diseases research with multiple initiatives in both its intramural and extramural programs focused on therapeutics development, clinical research, patient engagement, and access to and dissemination of rare diseases information. Some of these initiatives are described below:

- **Therapeutics for Rare and Neglected Diseases (TRND) program.** The intramural TRND program supports therapeutics development through research collaborations among NIH investigators, academic university scientists, nonprofit organizations, and pharmaceutical and biotechnology companies working on rare and neglected diseases. The program provides expertise and resources, working with research partners to move therapeutics through pre-clinical testing, including plans for clinical trials and submission of an investigational new drug (IND) application to FDA. These efforts effectively "de-risk" therapeutic candidates and make them attractive for adoption by outside business partners for their continued development as treatments. Two TRND projects targeting Niemann-Pick disease type C1 (a rare pediatric neurodegenerative disease) and GNE myopathy (a rare genetic disorder characterized by progressive muscle weakness and severe incapacitation) recently yielded candidate treatments that have now been licensed by companies that are conducting human clinical trial studies.

- **NCATS Office of Rare Diseases Research (ORDR).** This office supports and coordinates rare diseases research, responds to research opportunities for rare diseases, and provides information on rare diseases. Using a combination of research initiatives and information exchanges, ORDR attends to the needs of rare diseases patient communities seeking treatment and information on any of the thousands of these diseases known today. Through programs such as the Genetic and Rare Diseases Information Center (GARD) and the Rare Diseases Clinical Research Network (RDCRN), ORDR coordinates and fosters relationships with a variety of stakeholders, from patient advocacy groups to academic institutions, and with other NIH ICs.

- **GARD.** NCATS' emphasis on patient engagement extends to making a difference in the lives of patients and families through GARD, which provides accurate information about thousands of genetic and rare conditions to patients, their families, health care providers, researchers, and the public. Through the GARD website, e-mail, telephone, and traditional mail, NCATS disseminates research findings – a key part of the translational process – around the world.

  Over the past 13 years, GARD information specialists have responded to questions regarding more than 4,000 different rare or genetic diseases. Each month, the GARD website receives approximately 200,000 unique visitors, and specialists respond to an average of 563 inquiries. These numbers increase each year, reflecting expanded awareness and growing demand for GARD's resources. GARD responds to Spanish-language inquiries and launched disease pages in Spanish on its website in March 2014.

- **RDCRN.** RDCRN advances medical research on rare diseases by facilitating collaboration, study enrollment, and data sharing. Through the network of 22 participating consortia and a Data Management and Coordinating Center, multidisciplinary teams at hundreds of clinical sites around the world work together with representatives of more than 130 patient advocacy groups to study more than 280 rare diseases. NCATS collaborates with 10 NIH ICs to fund the RDCRN consortia, each of which focuses on a group of three related rare diseases.

  RDCRN facilitates clinical research in rare diseases through support for: 1) collaborative activities, including longitudinal studies of individuals with rare diseases, clinical studies, and clinical trials; 2) training of clinical investigators in rare diseases research; 3) pilot and demonstration projects; 4) uniform data collection protocols; 5) cost-sharing infrastructure; and 6) access to information about rare diseases for basic and clinical researchers, academic and practicing physicians, patients, and the public.

  Since its inception in 2003, RDCRN has enrolled 40,000 participants in multisite clinical research studies. RDCRN currently supports natural history studies (see program portrait below), clinical trials, and other clinical studies on more than 280 rare diseases at more than 250 clinical centers across the United States and in other countries. Twenty-five of the participating clinical centers are located outside of the United States. Ninety-one studies are currently underway.

Program Portrait: RDCRN Coalition of Patient Advocacy Groups (CPAG) - Patients as research partners

FY 2016 Level: $17.3 million
FY 2017 Level: $15.0 million
Change: -$2.3 million

Previous experience has demonstrated that RDCRN consortia that both engage with and integrate patient advocacy groups into their research programs achieve greater success in study enrollment. CPAG, a collective representation of patient groups affiliated with the RDCRN, participates as full research partners with their RDCRN consortium. In fact, inclusion of patient groups is required for any consortia to apply for RDCRN funding.

In one example, a patient advisory group called the PCD Foundation helped build knowledge about a genetic disorder called primary ciliary dyskinesia (PCD), which leads to frequent infections of the lungs, ears, throat, and sinuses and can result in serious and permanent damage. The PCD Foundation worked with the RDCRN Genetic Disorders of Mucociliary Clearance Consortium (GDMCC) to expand on the natural history research that GDMCC had conducted. This collaboration has fueled an explosion of research activity that has significantly contributed to scientists' understanding of the disease, defining the clinical features of PCD, identifying 32 genes linked to PCD, establishing diagnostic standards, and leading to the creation of PCD medical centers.

Budget Policy:
The FY 2017 President's Budget request is $41.596 million, a decrease of $2.153 million or 4.9 percent compared to the FY 2016 Enacted level.

Re-engineering Translational Sciences: NCATS develops novel approaches to improve the process of moving basic science discoveries into initial testing of therapies in humans. NCATS' efforts include creating and testing innovative methods to improve and accelerate the drug development process; discovering new uses for approved drugs to provide the quickest possible

transition from bench to bedside; developing better model systems for drug and toxicity testing; and using state-of-the-art resources to enable the ongoing operation of all NCATS translational research activities. Some examples of NCATS' programs in this area include:

- **NCATS Pharmaceutical Collection (NPC).** Large-scale screening of compound libraries supports rapid identification of therapeutic leads. To enable early-stage re-purposing on a broad scale, researchers can tap the NCATS Pharmaceutical Collection, housed in the NCATS intramural program. NPC is a comprehensive database and compound screening library of drugs and investigational medicines approved for clinical use by regulatory authorities in the United States, Europe, Canada, and Japan. NPC is available in two forms: as a free electronic resource that lists the drugs and their regulatory status, and as a compound library used for collaborative high-throughput screening projects at the NCATS Chemical Genomics Center.
- **Bridging Interventional Development Gaps (BrIDGs).** The NCATS intramural BrIDGs program supports late-stage therapeutics development by preparing therapeutic leads for clinical testing and evaluation. Through this program, NCATS makes available, on a competitive basis, resources that investigators need to develop new therapeutic agents for both common and rare diseases, including small-molecule drugs, biologics, and gene therapy. Successful applicants receive access to NCATS scientific expertise and contract resources to conduct the crucial pre-clinical studies necessary for regulatory approval for first-in-human trials. These resources include compound synthesis, formulation, pharmacokinetic studies, and toxicology studies in support of investigator-held IND applications to FDA.
- **Discovering New Therapeutic Uses for Existing Molecules (New Therapeutic Uses).** Launched in 2012, NCATS' New Therapeutic Uses extramural program is a collaborative effort between pharmaceutical companies and the biomedical research community to partner in advancing therapeutics development. This innovative program uses a crowdsourcing method to match pharmaceutical companies and their experimental drugs or biologics that have cleared many key steps in the drug development process, with academic investigators who have new ideas for disease indications in which the drugs could be tested.

NCATS streamlined the legal and administrative processes for research collaboration across organizations through template partnership agreements, which are freely available on the NCATS public website.[2] These agreements have significantly reduced the time to establish collaborations between industry and academia. In addition to being used by the partners in the New Therapeutic Uses program, these template agreements have been downloaded from the NCATS website more than 200 times, suggesting that they may be proving useful for other biopharmaceutical companies and academic researchers that are establishing similar collaborations.

[2] https://ncats.nih.gov/ntu

Program Portrait: NCATS Drug Repurposing Efforts

FY 2016 Level: $11.0 million
FY 2017 Level: $11.0 million
Change: $0.0 million

One way to shorten the process of developing new treatments and cures for disease is to find new uses for drugs that already have been approved or that have cleared several key steps along the development pathway; this is called drug repurposing. NCATS drug repurposing efforts continue to generate encouraging results on new indications for existing compounds at both the early and late stages of pre-clinical therapeutics development. Screens of NPC have identified several compounds that have potential indications as treatments for other diseases. The New Therapeutics Uses program continues to demonstrate success at finding new indications for previously shelved experimental compounds.

- **Alzheimer's Disease:** In March 2015, NCATS celebrated an advance made possible through the New Therapeutic Uses program. Scientists at Yale University School of Medicine partnered with biopharmaceutical company AstraZeneca to test whether an experimental compound originally developed as a cancer therapy potentially could be used to treat Alzheimer's disease. The compound successfully reversed brain defects in mouse models of the condition, and now the researchers are testing it in humans.
- **Ebola Virus:** The search for effective treatments for Ebola virus infection has become a high priority due to the recent epidemic. Prior therapeutic development had lagged because of limited supplies of antibody-based therapies, a lack of clinical trials, and the sheer amount of time needed to develop, test, and deploy treatments such as vaccines. Time and money-saving efforts become critical in such public health crises, and drug repurposing is a viable option that offers great potential. A team of researchers from NCATS and the Icahn School of Medicine at Mount Sinai developed a miniaturized assay for high-throughput screening to find compounds that block the ability of Ebola virus-like particles (VLPs) to enter and infect cells. A screen using 2,816 compounds from the NPC identified 53 drugs with entry-blocking activity against Ebola VLPs. Although further testing is needed before any of these drugs could be used to treat Ebola, the findings can jumpstart the development of such treatments.
- **Multiple Sclerosis:** Utilizing NCATS' NPC and with funding from the National Institute of Neurological Disorders and Stroke, scientists at Case Western Reserve University School of Medicine found that two drugs – the active ingredient in an antifungal cream and a steroid currently used to treat eczema – may hold promise as therapies for multiple sclerosis. The drugs appear to activate stem cells in the brain to repair damage caused by the disease.

- **Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Programs.** NCATS SBIR/STTR programs provide resources for small businesses to further expand upon NCATS' goal to bring more treatments to more patients more quickly. Since the main objective of the SBIR/STTR programs is to assist small businesses in developing and commercializing novel technologies and products, NCATS has developed various funding opportunities and specialized SBIR contract topics that address the development of innovative tools, technologies, and intervention platforms that would support the creation of novel therapeutics and/or diagnostics.

  An outstanding example is a project with IonField Systems, Inc. (Moorestown, NJ) to scale up and commercialize an innovation that resulted from an NCATS intramural initiative. NCATS' high-throughput robots help researchers produce screening results in one week that would take a scientist 12 years to do manually. Until recently, the cost-effectiveness of the system was limited by the need to purchase the thousands of plastic 1,536-well plates used for screening tests. Used plates were thrown-out (to a landfill or incinerator) and created substantial biohazard and plastic waste. An NCATS team devised a better process: wash and reuse the plates. So far, this method has saved the Center almost half a million dollars and kept nearly 50,000 plastic plates from being

discarded. The solution also has saved staff an estimated four weeks of loading and unloading plates.

Realizing the success of developing the washing process and demonstrating that it could be integrated into a high-throughput system, NCATS utilized its SBIR program to solicit and secure a contract with IonField Systems to further refine the cleaning process using a plasma washing method. Ultimately, the method can be scaled up and sold to other academic and industry screening facilities so that all high-throughput facilities may realize cost-savings and waste minimization from this innovation. On May 6, 2015, the NCATS team involved received the U.S. Department of Health and Human Services' Green Champions Award, which honors outstanding sustainability projects by HHS employees.

- **Toxicology in the 21st Century (Tox21).** The Tox21 program, a Federal collaboration involving the NIH National Institute of Environmental Health Sciences (NIEHS) National Toxicology Program, the Environmental Protection Agency (EPA), and FDA, is developing more efficient and effective methods to assess the potential toxicity of drugs and environmental chemicals. The Tox21 consortium leverages its partners' resources and expertise to predict how a collection of 10,000 compounds composed of environmental chemicals and approved drugs will affect human health and the environment. NCATS scientists use a high-throughput, automated robotic screening system to test the compounds in cellular and biochemical assays for their potential to disrupt biological pathways that may result in toxicity. This system provides unparalleled speed, reliability, and high quality reproducible data. The millions of data points generated from this screening process are transformed into in vitro chemical signatures that may be used to study the mechanism of action of compounds, predict toxicity, and minimize traditional animal toxicity testing. All data from the Tox21 program are made freely available to the public.

Budget Policy:
The FY 2017 President's Budget request is $67.451million, an increase of $1.716 million or 2.6 percent compard to the FY 2016 Enacted level. The increase reflects the increased proportion of research funding that is statutorily a set-aside for Small Business Innovation Research, as well as increased funding for intramural programs focused on collaborative research.

Cures Acceleration Network (CAN): CAN was authorized to advance the development of "high-need cures" and reduce significant barriers between research discovery and clinical trials. To achieve these objectives, CAN provides NCATS with new flexibilities in its funding authorities. Under CAN, NCATS may award large grants of up to $15 million per fiscal year, partnership awards that require 1:3 matching funds, and award 20 percent of the CAN funds as flexible research awards – also known as Other Transactions Authority (OTA) awards – that enable projects to be actively and aggressively managed by using mechanisms similar to those used by the Defense Advanced Research Projects Agency (DARPA). NCATS will continue to ensure robust leadership and oversight of the CAN program.

- **Tissue Chip for Drug Screening Program (Tissue Chip).** NCATS, DARPA, and the FDA collaborate on the Tissue Chip for Drug Screening program, an initiative revolutionizing the process for predicting drug safety. Researchers developed microchip platforms that support human cells and tissues, thereby serving as miniature models of living organs, such as the lung, liver, and heart. A key catalyst in this effort is the dissemination of resources to the scientific community. Through the Tissue Chip, NCATS has a partnership with pharmaceutical companies GlaxoSmithKline and Pfizer, Inc., which have made compounds available for Tissue Chip-funded researchers to perform pre-clinical functionality tests on their device platforms.

  Now in the second phase of the program, teams of scientists are working together to connect organ systems that were developed separately to function with one another. This integration enables real-time measurement of drug activity within and across various organs and tissues, such as the liver and digestive system. It also will enable monitoring of drug effectiveness in the target organ, such as the kidney or heart.

  As one example, a team of scientists from Northwestern University, Charles Stark Draper Laboratory and the University of Illinois at Chicago (UIC) designed a tissue chip for use in drug testing and to study the basic biology of female reproduction (EVATAR™). The device they created enables the female reproductive tissues to interact over periods of a month or more, much like they do in the human body. This advance solved a major technical challenge in the field: enabling organ models to communicate with each other via secreted factors, including hormones, to more closely resemble human physiology. Miniaturized pumps and tubes carry liquids and hormones through each of the tissues on the chip. The hormone fluctuations and behavior of the cells are designed to mimic a woman's 28-day reproductive cycle. The group plans to use EVATAR™ to better understand the basic hormonal and cellular functioning of the reproductive tract. Scientists also eventually could use it to predict whether a candidate drug, vaccine, or biologic agent is safe or toxic in humans in a faster and more cost-effective way than is possible with current methods.

The FY 2016 budget provided CAN with $25.8 million, a major increase from the FY 2015 level of $9.8 million. CAN investments are guided by the NCATS CAN Review Board, which has recommended seven initiatives for potential support under CAN. NCATS is exploring how to implement these under the increased CAN budget in FY 2016 and the requested budget for FY 2017. One of the approved initiatives is the creation of Tissue Chip Testing Centers, which will validate the microphysiological systems created by Tissue Chip for Drug Screening Program. These centers will test a select group of compounds using predefined assays according to FDA and pharmaceutical standards.

Budget Policy:
The FY 2017 President's Budget request is $25.835 million, the same as the FY 2016 Enacted level.

Translational Research Resources: The Translational Research Resources (TRR) program funds specialized programs and initiatives that provide support to NIH researchers.

Budget Policy:
The FY 2017 President's Budget request is $18.930 million, a decrease of $0.238 million or 1.2 percent compared to the FY 2016 Enacted level.

Intramural Research Program (IRP): All NCATS intramural programs operate via collaborations with outside partners. These include scientists at other NIH ICs as well as collaborators from academia, industry, and patient organizations. Because pre-clinical translation requires highly specialized but disease-agnostic expertise, NCATS intramural research IRP consists of a series of programs, several of which were described in more detail in the previous sections. Each program addresses a different roadblock in the pre-clinical translational process; generally programs operate via competitive access to extramural investigators. Successful access to an IRP results in pairing of the collaborator with IRP scientists on a joint project team. An individualized, milestone-driven implementation plan is developed to advance the collaborator's translational goals while also providing generalizable information to benefit all translational research efforts.

NCATS programs such as TRND, and the NCATS Chemical Genomics Center (which houses the NPC), match NCATS' unique intramural scientific expertise and technology resources with the research priorities of NIH IC-supported extramural or intramural, patient organization, or biopharmaceutical investigators to advance their translational goals. NCATS provides highly specialized scientific, technological and operational resources, including generation of novel pharmacological tools, large public datasets for target validation and toxicity assessment, leads for drug development, de-risking of drug development projects for rare diseases, creation of novel partnership structures, and provision of contract services, and project management for generation of data needed for regulatory approval.

The NCATS intramural programs therefore serve as a collaborative bridge between the research efforts of the private sector and those of the NIH ICs or academic investigators. These collaborations frequently involve co-funding and in-kind contributions from the other ICs and biopharmaceutical companies, and the programs all have formal processes for project selection, milestone establishment, progress assessment, and reporting.

Budget Policy:
The FY 2017 President's Budget request is $61.886 million, an increase of $0.613 million or 1.0 percent compared to the FY 2016 Enacted level. These resources will be used to support the above research activities.

Research Management and Support (RMS):
The RMS budget supports the scientific, administrative management, communication, and information technology activities associated with NCATS' operations. These activities support the review, award, and monitoring of research grants, training awards, and research and development contracts.

Budget Policy:
The FY 2017 President's Budget request is $37.305 million, an increase of $1.434 million or 4.0 percent compard to the FY 2016 Enacted level. This increase in resources will be used to help strengthen NCATS' scientific and administrative management capacity.

Budget Authority by Object Class[1]
(Dollars in Thousands)

		FY 2016 Enacted	FY 2017 President's Budget[2]	FY 2017 +/- FY 2016
Total compensable workyears:				
	Full-time employment	130	130	0
	Full-time equivalent of overtime and holiday hours	0	0	0
	Average ES salary	$169	$172	$3
	Average GM/GS grade	12.8	12.8	0.0
	Average GM/GS salary	$112	$113	$2
	Average salary, grade established by act of July 1, 1944 (42 U.S.C. 207)	$138	$139	$1
	Average salary of ungraded positions	$161	$162	$1
	OBJECT CLASSES	**FY 2016 Enacted**	**FY 2017 President's Budget[2]**	**FY 2017 +/- FY 2016**
	Personnel Compensation			
11.1	Full-Time Permanent	$9,300	$9,371	$71
11.3	Other Than Full-Time Permanent	5,161	5,200	39
11.5	Other Personnel Compensation	314	317	2
11.7	Military Personnel	170	171	1
11.8	Special Personnel Services Payments	731	736	6
11.9	**Subtotal Personnel Compensation**	**$15,676**	**$15,795**	**$119**
12.1	Civilian Personnel Benefits	$4,334	$4,419	$86
12.2	Military Personnel Benefits	140	141	1
13.0	Benefits to Former Personnel	0	0	0
	Subtotal Pay Costs	**$20,149**	**$20,355**	**$206**
21.0	Travel & Transportation of Persons	$384	$391	$7
22.0	Transportation of Things	69	71	1
23.1	Rental Payments to GSA	0	0	0
23.2	Rental Payments to Others	0	0	0
23.3	Communications, Utilities & Misc. Charges	303	308	5
24.0	Printing & Reproduction	7	7	0
25.1	Consulting Services	$1,680	$1,710	$30
25.2	Other Services	26,783	27,267	484
25.3	Purchase of goods and services from government accounts	41,257	45,523	4,266
25.4	Operation & Maintenance of Facilities	$429	$437	$8
25.5	R&D Contracts	20,722	21,095	373
25.6	Medical Care	2,045	2,100	55
25.7	Operation & Maintenance of Equipment	1,510	1,537	27
25.8	Subsistence & Support of Persons	0	0	0
25.0	**Subtotal Other Contractual Services**	**$94,427**	**$99,670**	**$5,244**
26.0	Supplies & Materials	$7,993	$8,137	$144
31.0	Equipment	5,605	5,706	101
32.0	Land and Structures	0	0	0
33.0	Investments & Loans	0	0	0
41.0	Grants, Subsidies & Contributions	556,479	550,770	-5,708
42.0	Insurance Claims & Indemnities	0	0	0
43.0	Interest & Dividends	1	1	0
44.0	Refunds	0	0	0
	Subtotal Non-Pay Costs	**$665,268**	**$665,062**	**-$206**
	Total Budget Authority by Object Class	**$685,417**	**$685,417**	**$0**

[1] Includes FTEs whose payroll obligations are supported by the NIH Common Fund.
[2] Includes mandatory financing.

Salaries and Expenses

(Dollars in Thousands)

OBJECT CLASSES	FY 2016 Enacted	FY 2017 President's Budget	FY 2017 +/- FY 2016
Personnel Compensation			
Full-Time Permanent (11.1)	$9,300	$9,371	$71
Other Than Full-Time Permanent (11.3)	5,161	5,200	39
Other Personnel Compensation (11.5)	314	317	2
Military Personnel (11.7)	170	171	1
Special Personnel Services Payments (11.8)	731	736	6
Subtotal Personnel Compensation (11.9)	**$15,676**	**$15,795**	**$119**
Civilian Personnel Benefits (12.1)	$4,334	$4,419	$86
Military Personnel Benefits (12.2)	140	141	1
Benefits to Former Personnel (13.0)	0	0	0
Subtotal Pay Costs	**$20,149**	**$20,355**	**$206**
Travel & Transportation of Persons (21.0)	$384	$391	$7
Transportation of Things (22.0)	69	71	1
Rental Payments to Others (23.2)	0	0	0
Communications, Utilities & Misc. Charges (23.3)	303	308	5
Printing & Reproduction (24.0)	7	7	0
Other Contractual Services:			
Consultant Services (25.1)	1,630	1,659	29
Other Services (25.2)	26,783	27,267	484
Purchases from government accounts (25.3)	23,405	23,883	477
Operation & Maintenance of Facilities (25.4)	429	437	8
Operation & Maintenance of Equipment (25.7)	1,510	1,537	27
Subsistence & Support of Persons (25.8)	0	0	0
Subtotal Other Contractual Services	**$53,758**	**$54,783**	**$1,026**
Supplies & Materials (26.0)	$7,993	$8,137	$144
Subtotal Non-Pay Costs	**$62,514**	**$63,698**	**$1,183**
Total Administrative Costs	**$82,663**	**$84,053**	**$1,390**

Detail of Full-Time Equivalent Employment (FTE)

OFFICE/DIVISION	FY 2015 Actual			FY 2016 Est.			FY 2017 Est.		
	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Division of Clinical Innovation									
Direct:	12	1	13	13	1	14	13	1	14
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	12	1	13	13	1	14	13	1	14
Division of Pre-Clinical Innovation									
Direct:	19	-	19	19	-	19	19	-	19
Reimbursable:	6	-	6	6	-	6	6	-	6
Total:	25	-	25	25	-	25	25	-	25
Executive Office									
Direct:	31	-	31	31	-	31	31	-	31
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	31	-	31	31	-	31	31	-	31
Office of Grants Management and Scientific Review									
Direct:	20	-	20	20	-	20	20	-	20
Reimbursable:	10		10	10		10	10		10
Total:	30	-	30	30	-	30	30	-	30
Office of Policy, Communications, and Strategic Alliances									
Direct:	15	-	15	15	-	15	15	-	15
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	15	-	15	15	-	15	15	-	15
Office of Rare Diseases Research									
Direct:	6	-	6	6	-	6	6	-	6
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	6	-	6	6	-	6	6	-	6
Office of the Director									
Direct:	8	-	8	8	-	8	8	-	8
Reimbursable:	1		1	1		1	1		1
Total:	9	-	9	9	-	9	9	-	9
Total	128	1	129	129	1	130	129	1	130
Includes FTEs whose payroll obligations are supported by the NIH Common Fund.									
FTEs supported by funds from Cooperative Research and Development Agreements.	0	0	0	0	0	0	0	0	0

FISCAL YEAR	Average GS Grade
2013	12.8
2014	12.6
2015	12.8
2016	12.8
2017	12.8

Detail of Positions[1]

GRADE	FY 2015 Actual	FY 2016 Enacted	FY 2017 President's Budget
Total, ES Positions	1	1	1
Total, ES Salary	166,526	169,074	171,661
GM/GS-15	16	16	16
GM/GS-14	24	24	24
GM/GS-13	29	30	30
GS-12	11	11	11
GS-11	7	7	7
GS-10	1	1	1
GS-9	4	4	4
GS-8	3	3	3
GS-7	1	1	1
GS-6	0	0	0
GS-5	1	1	1
GS-4	0	0	0
GS-3	0	0	0
GS-2	0	0	0
GS-1	0	0	0
Subtotal	97	98	98
Grades established by Act of July 1, 1944 (42 U.S.C. 207)	0	0	0
Assistant Surgeon General	0	0	0
Director Grade	1	1	1
Senior Grade	0	0	0
Full Grade	0	0	0
Senior Assistant Grade	0	0	0
Assistant Grade	0	0	0
Subtotal	1	1	1
Ungraded	34	34	34
Total permanent positions	99	100	100
Total positions, end of year	134	135	135
Total full-time equivalent (FTE) employment, end of year	129	130	130
Average ES salary	166,526	169,074	171,661
Average GM/GS grade	12.8	12.8	12.8
Average GM/GS salary	109,890	111,571	113,278

[1] Includes FTEs whose payroll obligations are supported by the NIH Common Fund.