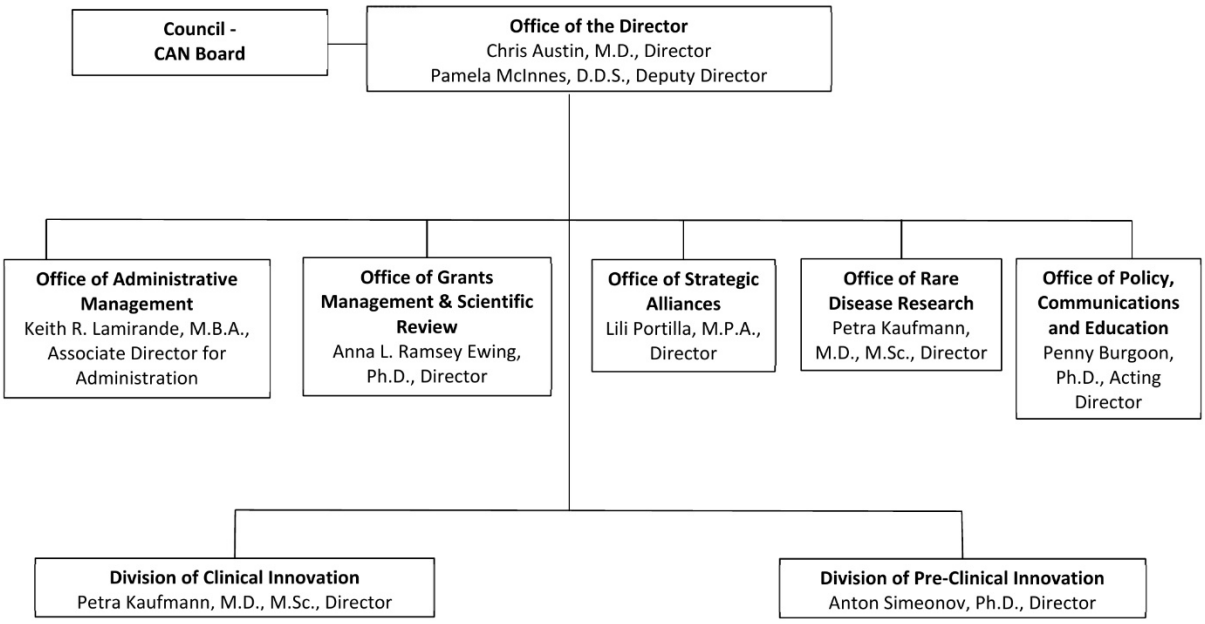
DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

National Center for Advancing Translational Sciences (NCATS)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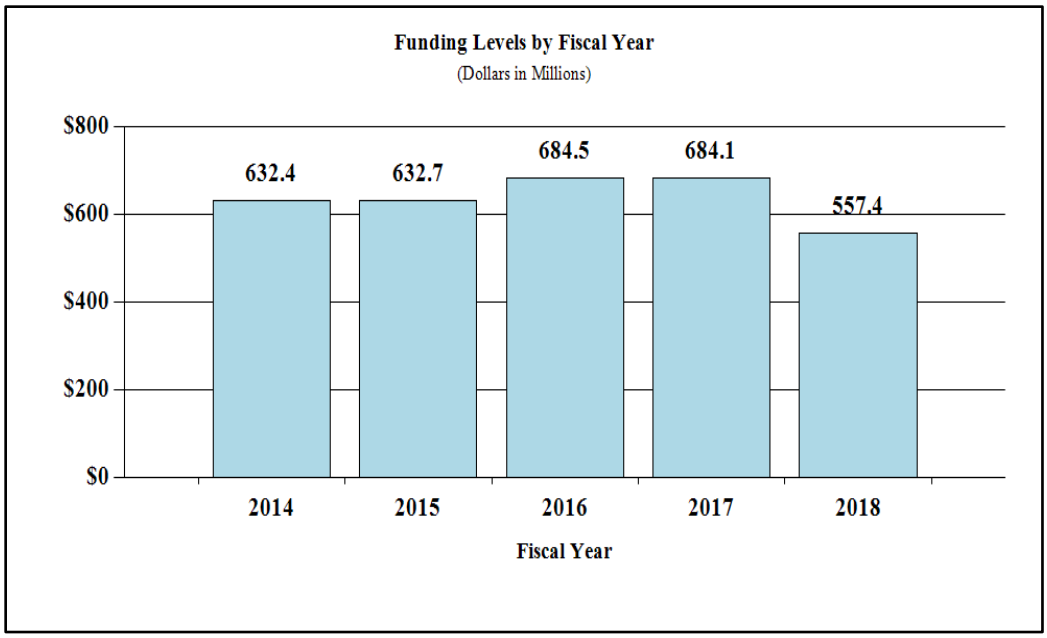
For carrying out section 301 and title IV of the PHS Act with respect to translational sciences, $557,373,000: Provided, That up to $24,496,593 shall be available to implement section 480 of the PHS Act, relating to the Cures Acceleration Network.

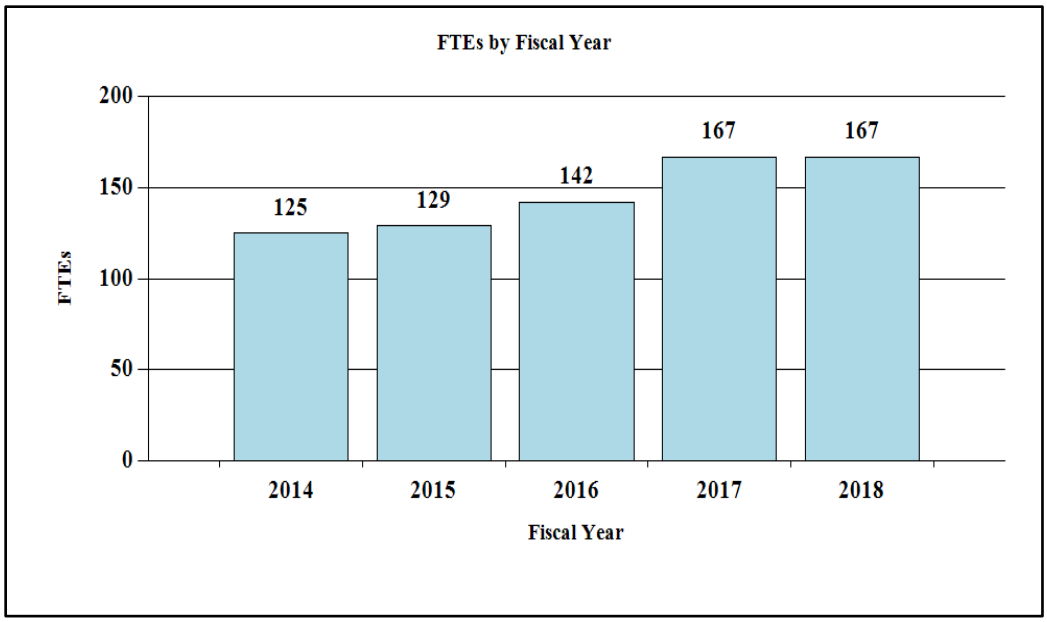
Amounts Available for Obligation[1]
(Dollars in Thousands)

Source of Funding	FY 2016 Final	FY 2017 Annualized CR	FY 2018 President's Budget
Appropriation	$685,417	$685,417	$557,373
Mandatory Appropriation: (non-add) *Other Mandatory financing*	*(0)*	*(0)*	*(0)*
Rescission	0	-1,303	0
Zika Intra-NIH Transfer	-949	0	0
Subtotal, adjusted appropriation	$684,468	$684,114	$557,373
OAR HIV/AIDS Transfers	0	0	0
Subtotal, adjusted budget authority	$684,468	$684,114	$557,373
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	$684,468	$684,114	$557,373
Unobligated balance lapsing	-103	0	0
Total obligations	$684,366	$684,114	$557,373

[1] Excludes the following amounts for reimbursable activities carried out by this account:
FY 2016 - $17,873 FY 2017 - $25,010 FY 2018 - $19,695

History of Budget Authority and FTEs:





Authorizing Legislation

	PHS Act/ Other Citation	U.S. Code Citation	2017 Amount Authorized	FY 2017 Annualized CR	2018 Amount Authorized	FY 2018 President's Budget
Research and Investigation	Section 301	42§241	Indefinite	$684,114,022	Indefinite	$557,373,000
National Center for Advancing Translational Sciences	Section 401(a)	42§281	Indefinite		Indefinite	
Total, Budget Authority				$684,114,022		$557,373,000

Appropriations History

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
2008 Rescission				$0
2009 Rescission				$0
2010 Rescission				$0
2011 Rescission				$0
2012 Rescission	$721,601,000		$582,326,000	$576,456,000 $1,089,502
2013 Rescission Sequestration	$639,033,000		$631,346,000	$575,366,498 $1,150,733 ($28,879,442)
2014 Rescission	$665,688,000		$661,264,000	$633,267,000 $0
2015 Rescission	$657,471,000			$635,230,000 $0
2016 Rescission	$660,131,000	$643,111,000	$699,319,000	$685,417,000 $0
2017[1] Rescission	$685,417,000	$707,335,000	$713,849,000	$685,417,000 $1,303,000
2018	$557,373,000			

[1] Budget Estimate to Congress includes mandatory financing.

[2] NCATS was authorized in Fiscal Year 2012

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 2016 Final	FY 2017 Enacted	FY 2018 President's Budget	FY 2018 +/- FY 2017
BA	$684,468,351	$684,114,022	$557,373,000	-$126,741,022
FTE	142	167	167	0

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 transforming the translational science process so that more new treatments and cures for disease can reach more patients faster. Currently, a new drug can take about 14 years and more than one billion dollars to develop, with a failure rate exceeding 95 percent.[1] NCATS was established in FY 2012 to develop, demonstrate, and disseminate innovations that reduce, remove, or bypass costly, time-consuming, system-wide bottlenecks in the translational research process. Rather than targeting particular diseases or fundamental science, NCATS focuses on what is common across diseases and the translational process.

NCATS defines translation as the process of turning observations in the laboratory, clinic, and community 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. NCATS studies translation on a system-wide level as a scientific and operational problem.

NCATS recently released its new Strategic Plan that articulates the Center's bold vision for translational science. To accomplish the overarching goal of bringing more treatments to more patients more quickly, the Center strives to apply the following principles to all of its programs and initiatives: catalytic (enabling others to perform more efficient and effective translation); generalizable principles (uncovering fundamental principles shared among diseases and translational processes); innovative (establishing fundamentally new ways of doing translation); collaborative (requiring the expertise of multiple people and groups, as research is carried across

[1] B. Munos, Lessons from 60 years of pharmaceutical innovation. Nat. Rev. Drug Discov. 8, 959–968 (2009)

different phases of translational science); patient-focused (committed to patients and their communities).

The application of innovation to translational science also benefits fundamental, or basic research. NCATS recently launched its Biomedical Data Translator program (Translator), which is supported through the Center's Cures Acceleration Network. The intent is to create a ground-breaking, publicly available resource that integrates the full spectrum of medical and scientific data types, from signs and symptoms to molecules and drugs. Translator will enable the identification of new therapeutic targets for diseases, advance basic understanding of disease biology, and open up new opportunities for both basic and translational research by integrating existing data sets. Crucial to the success of this program are the flexibilities provided by NCATS' other transaction authority (OTA), which enables the Center to nimbly assemble and redirect the scientific and technological expertise, tools, technologies, and approaches needed to meet program objectives.

Collaborative research with a broad array of stakeholders enables NCATS to develop treatments more efficiently and effectively. As an example, research conducted by scientists at NIH's National Institute of Mental Health (NIMH) demonstrated that the drug ketamine can rapidly bring relief to patients suffering from depression; however, the drug has addictive properties, making it a potential drug of abuse. In partnership with NIMH, NIH's National Institute on Aging (NIA), and investigators at the University of Maryland and the University of North Carolina, NCATS medicinal chemists identified a by-product of ketamine that has the antidepressant effects of ketamine without its addictive characteristics. The team is now performing the studies needed to initiate an NIMH clinical trial of this potential breakthrough treatment for depression.

Drug repurposing, which utilizes a drug developed for one disease to treat an entirely different disease, is a promising approach to speeding therapeutics development and is being used in various NCATS programs and initiatives. NCATS has developed a flexible platform for drug repurposing that has been applied to emerging public health emergencies. Investigators from Johns Hopkins University and Florida State University collaborated with NCATS experts on drug repurposing and high throughput screening to identify rapidly two classes of existing compounds that potentially can be used to fight Zika. These compounds were effective either in inhibiting the replication of Zika virus or in preventing the virus from killing brain cells. All data on the effects of the several thousand drugs screened were made available immediately in public databases, allowing these compounds to be further studied by the broader research community to help combat the Zika public health crisis. NCATS drug repurposing platform and expertise has also been applied to address Ebola and Hepatitis C.

NCATS supports innovation in clinical research and promotes good stewardship of taxpayer funds by working closely with academic research centers across the nation to make the conduct and management of clinical studies more efficient and effective. Through NCATS' Clinical and Translational Science Awards (CTSA) Program, academic investigators have worked closely with NCATS staff to develop a single institutional review board (IRB) reliance platform for multisite clinical studies: the NCATS Streamlined, Multisite, Accelerated Resources for Trials (SMART) IRB Reliance Platform. This model platform addresses a long-standing impediment

to multisite clinical studies, the time-consuming process of ethical review and approval of study conduct by each participating site's IRB. The NCATS SMART IRB Reliance Platform helps streamline the IRB review process by having participating sites agree to rely on the review and approval from a single IRB, with the intent of making the review more efficient and study conduct more consistent. In addition, NCATS' Trial Innovation Network is a new CTSA Program initiative featuring two new Trial Innovation Centers and a Recruitment Innovation Center, through which investigators will collaborate with CTSA Program hub researchers to develop innovative ideas in the conduct of clinical trials. These and other CTSA Program efforts build on the strengths of the CTSA Program hubs to make clinical research more efficient and effective.

Engaging patients and their communities is a bedrock of NCATS' operating principle. As the intended beneficiaries of translational research efforts, the inclusion of patients on research teams is central to the Center's work of improving health through smarter science. Patients provide insights, focus, urgency, and connectivity that can be instrumental in making the development, testing, and deployment of new interventions more efficient and effective. NCATS views the science of patient and community engagement as a key area for exploration and innovation.

Overall Budget Policy:
The FY 2018 President's Budget request is $557.373 million, a decrease of $126.741 million compared with the FY 2017 Annualized CR level. These reductions are distributed across all programmatic areas, although high priority Cures Acceleration Network research has been reduced less.

Program Descriptions and Accomplishments

Clinical and Translational Science Activities: Through its Clinical and Translational Science Awards (CTSA) Program, NCATS is tackling system-wide issues that limit efficiency in clinical and translational science. NCATS has built this program on the strength of more than 50 unique CTSA Program-supported academic medical centers (called "hubs") nationwide. NCATS relies on the individual strengths of the CTSA Program hubs and partners with them to develop and implement innovative, collaborative solutions intended to transform clinical and translational research. Together, they address common areas of need that call for collaborative solutions, including:

- Training and cultivating the translational science workforce;
- Engaging patients and communities in every phase of the translational process;
- Promoting the integration of special and underserved populations in translational research across the human lifespan;
- Innovating methods and processes to increase the quality and efficiency of translational research, particularly of multisite trials; and
- Advancing the use of cutting-edge informatics.

Several CTSA Program initiatives are underway to address specifically these areas of need:

- **CTSA Program Collaborative Innovation Awards (CCIA)**: CCIA projects are intended to foster research collaboration by encouraging teams from three or more CTSA Program hubs to work together to develop, demonstrate, and disseminate innovative, experimental approaches to overcoming translational science roadblocks. In response to the Institute of Medicine's report recommendation to establish an innovation fund to promote collaboration, NCATS funded in FY 2016 a set of CCIA awards designed to stimulate team-based research across the program network.

- **Streamlined, Multisite, Accelerated Resources for Trials (SMART) IRB Reliance Platform:** The process of obtaining ethical approval for a multisite clinical trial by multiple institutional review boards (IRBs) is a longstanding challenge to clinical research. It leads to significant delays in study activation and can result in inconsistent review of study conduct across sites. One way to provide more consistent, high-quality IRB review is by having all participating sites in a multisite clinical study rely on a single IRB, an approach referred to as an "IRB reliance" model. The NCATS SMART IRB Reliance Platform is based on successful CTSA Program-supported demonstration projects of IRB reliance. SMART IRB Reliance is designed to be a flexible platform that will enable harmonization and streamlining of processes, and also will be a key component of NCATS' Trial Innovation Network. NCATS has worked closely with the broader NIH community on ways this platform can serve as a roadmap to help clinical researchers nationwide to implement NIH's single IRB policy for multisite clinical research.

- **Good Clinical Practice (GCP) Training**: Through GCP training, NCATS promotes and standardizes good clinical practices by developing and enhancing a competency-based education curriculum for research teams across the CTSA Program network. GCP is a process that incorporates established ethical and scientific quality standards for the design, conduct, recording, and reporting of clinical research involving the participation of human subjects. These standards are intended to equip the workforce with the competencies to execute clinical trials effectively, efficiently, and safely.

- **NCATS Trial Innovation Network**: This network is a new CTSA Program collaborative initiative composed of three key organizational partners: Trial Innovation Centers (TICs), a Recruitment Innovation Center (RIC), and the CTSA Program hubs. Through the Trial Innovation Network, NCATS is supporting innovations to address critical roadblocks in the conduct of clinical trials to accelerate ultimately the translation of novel interventions into new treatments. The network is focused on operational innovation, operational excellence, and collaboration, and is leveraging the expertise, diversity, and broad reach of the CTSA Program. The network features the NCATS SMART IRB Reliance Platform mentioned above, master contracting agreements, quality-by-design approaches, and a focus on evidence-based strategies for study recruitment and patient engagement. The goal is to execute trials better, faster, and more cost-efficiently, and to serve as a national laboratory to study, understand, and improve the process of conducting clinical trials.

Program Portrait: Pulmonary alveolar proteinosis (PAP): Moving a promising treatment through the translational science spectrum

Pulmonary alveolar proteinosis (PAP) is a rare, potentially fatal, autoimmune disease during which the lungs become dysfunctional, resulting in clogged airways. The current treatment for severe PAP is whole lung lavage, a procedure whereby both lungs are repeatedly filled and washed with a salt solution, an invasive, risky, and uncomfortable medical procedure. NCATS has supported translational research efforts on this rare disease, providing support through the translational science spectrum from fundamental research, to pre-clinical research, and to early phase clinical trials.

As part of NCATS' Rare Disease Clinical Research Network (RDCRN), Bruce Trapnell, M.D., of the Cincinnati Children's Hospital, had been studying the potential of using protein granulocyte-macrophage colony-stimulating factor (GM-CSF) as a treatment for PAP. Animal and human studies suggested that GM-CSF could stimulate a patient's own immune system to clear the lungs. To develop further GM-CSF as an inhaled treatment for PAP, Trapnell entered into a successful collaboration with NCATS through its Therapeutics for Rare and Neglected Diseases (TRND) program and the Genzyme Corporation, which owns GM-CSF. NCATS' TRND researchers conducted pre-clinical toxicology studies and drug formulation development, the results of which enabled the team to earn Investigational New Drug (IND) designation from the FDA. Through its CTSA Program, NCATS now is providing support to carry out an early phase clinical study of inhaled GM-CSF at two CTSA Program hubs, the Cincinnati Children's Hospital and the University of California, Los Angeles. The multisite collaboration also will feature the NCATS SMART IRB Reliance Platform to facilitate the implementation of the study.

Rare Diseases Research and Therapeutics: In the United States, a disease is considered to be rare if it affects fewer than 200,000 Americans.[2] There are about 7,000 rare diseases affecting approximately 25 million Americans and their families.[3] Rare diseases can be progressive, chronic illnesses that result in disability and often lead to premature death; many are genetic and affect infants and children. Though research progress has been made, few drug companies develop treatments for rare diseases since it is difficult to recover the costs of developing treatments for small, geographically dispersed populations. More than 95 percent of rare diseases have no or inadequate treatment.[4] NCATS supports a number of translational science programs and activities to address the translational research needs of rare diseases patients and their families.

- **Therapeutics for Rare and Neglected Diseases (TRND)**: Through its TRND program, NCATS supports pre-clinical development of therapeutic candidates intended to treat rare or neglected disorders, with the goal of submitting a successful Investigational New Drug (IND) application to the Food and Drug Administration (FDA). Therapeutics development research is stimulated through collaborations with NIH's other Institutes and Centers (ICs), academic scientists, nonprofit organizations, and pharmaceutical and biotechnology companies working on rare and neglected illnesses. NCATS provides expertise and resources, and works with research partners to move therapeutics through pre-clinical testing, including plan development for clinical trials and submission of an IND application. These efforts effectively "de-risk" therapeutic candidates and make them more attractive for adoption by outside business partners. Through this process, NCATS is able to create successful approaches to addressing other translational problems. NCATS' TRND investigators use the

[2] Orphan Drug Act of 1983 (P.L. 97-414), as amended
[3] Rare Diseases Act of 2002 (P.L. 107-280), as amended
[4] FDA Office of Orphan Products Development

Center's high-throughput screening (HTS) facility and access thousands of clinically approved drugs to expeditiously find and test compounds that can be "repurposed" as potential treatments for other diseases.

Program Portrait: Potential Treatments for Zika

NCATS' TRND researchers recently identified compounds that have the potential to inhibit Zika virus replication and reduce the virus' ability to kill brain cells. This translational science effort was based on initial research by Johns Hopkins University and Florida State University scientists, who discovered that the Zika virus infects brain cells early in development. A common symptom of Zika virus infection is fetal microcephaly, an abnormally small head resulting from an underdeveloped and/or damaged brain. NCATS researchers led a drug repurposing screen to test three strains of Zika. The scientists first developed an assay (test) using caspase 3, a protein that causes brain cell death when infected by the virus. The next step was screening 6,000 FDA-approved and investigational compounds, including NCATS Pharmaceutical Collection, which resulted in the identification of more than 100 promising compounds. The team then evaluated the protective effect of these compounds in brain cells after Zika virus infection. Three lead compounds — emiracsan, niclosamide, and an inhibitor known as PHA-690509 — were identified as reducing neuronal cell death caused by Zika virus infection. These compounds now can be studied by the broader research community to help combat the Zika public health crisis. In addition to Johns Hopkins University and Florida State University, NCATS also collaborated with Emory University, the Maryland Stem Cell Research Fund, the National Institute of Neurological Disorders and Stroke, and the National Institute of Allergy and Infectious Diseases.

- **Rare Diseases Clinical Research Network (RDCRN):** NCATS' RDCRN is designed to advance medical research on rare diseases by providing support for clinical studies and facilitating collaboration, study enrollment, and data sharing. Through the RDCRN consortia, physician scientists and their multidisciplinary teams work together with patient advocacy groups to study more than 200 rare diseases at sites across the nation. Recently, investigators from the Nephrotic Syndrome Rare Disease Clinical Research Network (also known as NEPTUNE) identified a urine protein called urinary epidermal growth factor that is linked to chronic kidney disease (CKD), a condition which can progress to kidney failure and is treatable only by dialysis and kidney transplants. The identification of this protein as a biomarker for CKD presents an easily accessible, non-invasive way to monitor patients at risk for progression of kidney disease. NEPTUNE brings together physician scientists at 23 sites in the United States and Canada, along with patient advocacy groups.

Genetic and Rare Diseases Information Center (GARD): Through GARD, NCATS directly serves the public as a resource that provides comprehensive information about rare and genetic diseases to patients, their families, health care providers, researchers, and the public at large. The GARD website[5] provides accurate, up-to-date information about ongoing research, symptoms, treatment options, and other details. GARD information specialists are available to discuss questions by phone. GARD provides information on more than 6,000 diseases on its website in English and nearly 200 diseases in Spanish. In FY 2016, the GARD website received a monthly average of 245,000 visitors and 460 public inquiries.

[5] https://ncats.nih.gov/gard

Re-engineering Translational Sciences: NCATS also improves health through smarter science via its programs to make translational science more efficient and effective for the early and late pre-clinical stages of therapeutics development.

- **Bridging Interventional Development Gaps (BrIDGs):** NCATS' BrIDGs program enables researchers to advance candidate therapeutics for both common and rare diseases into clinical testing. Through this program, selected researchers partner with NCATS experts to generate pre-clinical data and clinical-grade material through government contracts for use in IND applications to a regulatory authority such as the Food and Drug Administration. In general, through BrIDGs, NCATS provides synthesis, formulation, pharmacokinetic, and toxicology expertise and resources to collaborators. Current projects are focused on therapeutics development as potential treatments for diseases such as pancreatic cancer, multiple sclerosis, and Alzheimer's disease.

- **NCATS Pharmaceutical Collection (NPC):** The NPC is a comprehensive, publicly accessible collection of approved and investigational molecular entities for high-throughput screening that provides a valuable resource for both validating new models of disease and better understanding the molecular basis of diseases and interventions. Nearly 2,750 small molecular entities have been approved for clinical use by U.S., European Union, Japanese, and Canadian authorities and also are suitable for high-throughput screening. Of these, NCATS currently has 2,500, along with about 1,000 additional investigational compounds, as part of its screening collection. The NPC has proven a valuable resource, as NCATS investigators utilized this collection to screen for and identify potential compounds that may be repurposed for their potential inhibitory properties for fighting Zika virus infections (see Program Portrait). NCATS scientists regularly host training workshops designed to share best practices and advice on robust assay design and development methodologies for researchers involved in the drug discovery process, thereby helping them better identify promising compounds for molecular probes or drug discovery.

- **Discovering New Therapeutic Uses for Existing Molecules (New Therapeutic Uses):** NCATS developed its New Therapeutic Uses program in recognition that high therapeutic development failure rates meant there were many existing, partially developed therapeutic candidates that might be repurposed for use in a new disease indication. In FY 2016, NCATS announced a new Bench-to-Clinic Repurposing initiative through this program to support pre-clinical studies to test the effectiveness of an independent crowdsourcing effort, computational algorithm, or big dataset from patient records to predict new uses for a drug or biologic. The aim is to identify systematic approaches for predicting which existing drug or biologic might be effective in treating a disease or condition.

Cures Acceleration Network (CAN): NCATS' Cures Acceleration Network (CAN) was created to advance the development of high-need cures and reduce significant barriers between research discovery and clinical trials. To achieve these objectives, the Public Health Service Act authorizes CAN to . make large grant awards of up to $15 million per fiscal year, partnership awards that require 1:3 matching funds, and flexible research awards using the special

authorization called other transaction authority (OTA), when grants, contracts and cooperative agreements may not adequately address scientific needs. NCATS staff utilizes OTA to support high risk-high reward research, using this authority to attract non-traditional government partners and to expand, modify and, if needed, discontinue activities to meet the program's needs. CAN investments are guided by an advisory body, the CAN Review Board.

Based on available funds each fiscal year, CAN enables a variety of initiatives designed to address scientific and technical challenges that can bottleneck transitional research. CAN currently is supporting projects through NCATS' Tissue Chip for Drug Screening, Biomedical Data Translator, and Three-dimensional Bioprinting programs.

- **Tissue Chip for Drug Screening:** NCATS, the Defense Advanced Research Projects Agency (DARPA), and the FDA collaborate on the Tissue Chip for Drug Screening program, an initiative designed to revolutionize 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. Teams of scientists have joined forces to connect the individual chips into organ systems that mimic the complex interactions and diseases of the human body. Ultimately, the goal is to create an integrated body-on-a-chip that accurately models and improves the predictability of a drug or compound's safety and toxicity, a common cause of drug development failure. New "tissue chip" initiatives for FY 2017 expand on the promise of tissue chip development for modeling human diseases and for examining the biology of human tissue in the gravity-free space environment.

    - **Tissue Chip Testing Centers:** Building on the success and the translational potential of this Tissue program, NCATS awarded support for three Tissue Chip Testing Centers to "test drive" the chips and determine if they perform as intended. The intent of the testing centers is for scientists to work independently to validate completed chips platforms as reproducible models that can be translated for use in all areas of research and to establish standardized methods for the preclinical testing of any drug or biologic. The testing centers will: provide the means for scientists funded by NCATS' Tissue Chip program to test and validate tissue chip platforms independently; ensure wide-ranging availability of tissue chip technology, particularly for regulatory agencies and pharmaceutical companies; and promote the adoption of this technology by the broad research community.

    - **Tissue Chips for Disease Modeling and Efficacy Testing:** NCATS supports the scientific expansion of the Tissue Chip program to support further development of tissue chip models of human disease that mimic the pathology in major human organs and tissues. These FY 2017 awards will: support studies to develop disease models using primary tissue or induced pluripotent stem cell (iPSC)-derived patient cell sources on tissues/organs-on-chips platforms; determine disease relevance of these models by preliminary testing of key experimental features; and test the effectiveness of candidate drugs. A number of NIH Institutes, Centers, and Offices recognize the potential of this initiative for developing new models of human disease for therapeutics testing and have signed on as participating partners.

- **Tissue Chips in Space:** NCATS and the Center for the Advancement of Science in Space (CASIS) are partnering to refine tissue chip technology for translational research at the International Space Station U.S. National Laboratory (ISS-NL). Translational research at the ISS-NL provides unprecedented opportunities to study the effects of a microgravity environment (diminished or close to zero gravity compared to Earth) on the human body. For example, it is now widely known that symptoms of accelerated aging occur after prolonged exposure to microgravity. Health concerns that resemble aging — such as muscle deterioration, osteoporosis (bone loss), reduced cardiopulmonary function, and immune deficiency — when in space have been documented, and it also has been observed that these conditions are reversible when astronauts return to Earth. Tissue chip translational science at the ISS-NL will enable the study of organs at the cell and tissue levels under reduced gravity, will contribute to our understanding of the process of aging, and could reveal molecular targets that can slow that process. NCATS will issue awards in FY 2017 to develop these models to facilitate the assessment of biomarkers, bioavailability, efficacy, and toxicity of therapeutic agents for testing at the ISS-NL.

Program Portrait: NCATS Biomedical Data Translator (Translator)

As a result of recent scientific advances, there is a tremendous amount of biomedical research data and data available from disease classifications, health records, clinical trials, and adverse event reports that could be useful for understanding health and disease and for developing and identifying treatments for diseases. Ideally, these data would be mined collectively to provide insights into the relationship between molecular and cellular processes (the targets of drug design) and the signs and symptoms of diseases. Currently, these very rich yet different data sources are housed in various locations, often in forms that are not compatible or interoperable with each other.

To address these problems, NCATS launched its Biomedical Data Translator program, called "Translator" for short. This multiyear, iterative effort will culminate in the development of a comprehensive, relational, multi-dimensional Biomedical Data Translator that integrates multiple types of existing data sources, including objective signs and symptoms of disease, drug effects, and intervening types of biological data relevant to understanding pathophysiology. The Translator will be broader in scope than existing catalogues, revealing potential relationships across the spectrum of data types, from signs and symptoms to molecules and drugs. The goal is to identify and design innovative tools to integrate and leverage the vast amounts of medical research data currently available — all of which could bring about rapid, high-impact change that could revolutionize translational research and the translational science process.

In FY 2016, NCATS issued awards to form a project team of experts from 11 leading universities and other research institutions. Through a series of feasibility assessments, this team will examine components and test solutions for specific aspects of the Translator. Their work will help define the infrastructure requirements needed to support diverse data types and demonstrate the potential impact of new analytical tools that promote the discovery of relationships for the research community. NCATS is funding the Translator through its Cures Acceleration Network (CAN) using Other Transaction authority (OTA), which permits NCATS to make research awards that are not grants, contracts, or cooperative agreements. OTA provides NCATS with the flexibility to aggregate the necessary scientific and technological expertise needed to design, build, and test the Translator. NCATS staff will work closely with the newly awarded experts to expand and modify — and if needed, discontinue — activities based on program needs.

- **Three-dimensional Bioprinting (3-D Bioprinting):** The ability to reproduce, repeatedly and rapidly, biological models of human tissues that faithfully characterize native human tissue will provide clinically relevant data to make the drug discovery process more predictable and efficient. Bioprinting of defined and biologically relevant human live tissues is emerging as a key technology for drug discovery. 3-D bioprinting of human tissues has the potential to accelerate the drug discovery process, enabling treatments to be developed faster and at a lower cost by bridging the gap between lab tests and animal tests for positive clinical outcomes. The newly established NCATS 3-D Bioprinting laboratory is focused on the generation of live, human tissues that can be reliably reproduced in format for drug screening. Reproducible and robust methodologies will be developed, optimized, and validated. The program is currently working on bioprinting eye, skin, blood vessel, and tumor tissues.

Translational Research Resources: Translational Research Resources (TRR) activity funds scientific conference grants, often in collaboration with other NIH organizations. This budget activity also funds trans-NIH supported research programs and initiatives.

Intramural Research Program (IRP): Using intramural research funds, NCATS' Division of Pre-Clinical Innovation (DPI) plans, conducts, and advances research in a highly and uniquely collaborative manner across the pre-clinical phases of the translational science spectrum. Specifically, this division:

- Plans, conducts, and collaborates on research to develop new methods and technologies to enhance pre-clinical processes.
- Plans, conducts, and collaborates on research to evaluate existing and developing approaches, technologies, and processes in the pre-clinical spectrum.
- Supports training programs relevant to pre-clinical phases of translational science.
- Collaborates with other NIH ICs and the scientists they support.
- Consults with stakeholders, including patients, industry representatives, and regulators.

NCATS matches its intramural scientific expertise and technology resources with NIH IC-supported extramural investigators or NIH IC intramural investigators to advance the scientific goals of a project. The Center provides innovative technological and operational expertise and resources, including generation of and access to unique pharmacological tools, establishment of partnership agreements, regulatory support, and access to contract services. As a result, successful collaborations through these programs benefit from NCATS' efforts to improve diagnostics and therapeutics development, and make translational science more efficient, less expensive, and less risky.

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

Detail of Full-Time Equivalent Employment (FTE)

OFFICE/DIVISION	FY 2016 Final			FY 2017 Annualized CR			FY 2018 President's Budget		
	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Division of Clinical Innovation	-	-	-	-	-	-	-	-	-
Direct:	18	1	19	23	1	24	23	1	24
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	18	1	19	23	1	24	23	1	24
Division of Pre-Clinical Innovation	-	-	-	-	-	-	-	-	-
Direct:	31	-	31	39	-	39	39	-	39
Reimbursable:	6	-	6	6	-	6	6	-	6
Total:	37	-	37	45	-	45	45	-	45
Office of Administrative Management	-	-	-	-	-	-	-	-	-
Direct:	30	-	30	32	-	32	32	-	32
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	30	-	30	32	-	32	32	-	32
Office of Grants Management and Scientific Review	-	-	-	-	-	-	-	-	-
Direct:	14	-	14	17	-	17	17	-	17
Reimbursable:	10	-	10	10	-	10	10	-	10
Total:	24	-	24	27	-	27	27	-	27
Office of Policy, Communications, and Education	-	-	-	-	-	-	-	-	-
Direct:	11	-	11	11	-	11	11	-	11
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	11	-	11	11	-	11	11	-	11
Office of Rare Diseases Research	-	-	-	-	-	-	-	-	-
Direct:	6	-	6	6	-	6	6	-	6
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	6	-	6	6	-	6	6	-	6
Office of Strategic Alliances	-	-	-	-	-	-	-	-	-
Direct:	5	-	5	6	-	6	6	-	6
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	5	-	5	6	-	6	6	-	6
Office of the Director	-	-	-	-	-	-	-	-	-
Direct:	9	-	9	15	-	15	15	-	15
Reimbursable:	1	-	1	1	-	1	1	-	1
Total:	10	-	10	16	-	16	16	-	16
	-	-	-	-	-	-	-	-	-
Total	141	1	142	166	1	167	166	1	167
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
2014	12.6
2015	12.8
2016	12.8
2017	12.7
2018	12.7

Detail of Positions[1]

GRADE	FY 2016 Final	FY 2017 Annualized CR	FY 2018 President's Budget
Total, ES Positions	1	1	1
Total, ES Salary	174,852	181,846	185,301
GM/GS-15	18	21	21
GM/GS-14	32	29	29
GM/GS-13	45	48	48
GS-12	5	9	9
GS-11	10	6	6
GS-10	1	1	1
GS-9	5	12	12
GS-8	3	4	4
GS-7	2	1	1
GS-6	1	1	1
GS-5	1	0	0
GS-4	0	0	0
GS-3	0	0	0
GS-2	0	0	0
GS-1	0	0	0
Subtotal	123	132	132
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	40	39	39
Total permanent positions	125	134	134
Total positions, end of year	165	173	173
Total full-time equivalent (FTE) employment, end of year	142	167	167
Average ES salary	174,852	181,846	185,301
Average GM/GS grade	12.8	12.7	12.7
Average GM/GS salary	109,956	112,045	114,174

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