National Center for Advancing Translational Sciences

CONGRESSIONAL JUSTIFICATION
FY 2023

Department of Health and Human Services
National Institutes of Health

NIH National Center for Advancing Translational Sciences

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

National Center for Advancing Translational Sciences (NCATS)

FY 2023 Budget Table of Contents

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Director's Overview

Joni L. Rutter, Ph.D.,
Acting Director, NCATS

The theme for NIH's fiscal year (FY) 2023 President's Budget Request is "NIH In a Changing World: Science to Enhance Human Health," a theme that has been the very definition of the National Center for Advancing Translational Sciences (NCATS) since its inception a decade ago.

NCATS is a critical part of the NIH ecosystem, with a unique mission of addressing scientific and operational challenges that accelerate the development of treatments and cures for disease. By engaging with public and private sectors, NCATS continues to mount a vigorous research response against COVID-19, continues to drive new pre-clinical innovations in the opioid epidemic, and is poised to disrupt the rare disease treatment development space through the Bespoke Gene Therapy Consortium, a cross-sector public-private partnership with the Foundation for the National Institutes of Health (FNIH), NIH, and the United States Food and Drug Administration (FDA) as part of the Accelerating Medicines Partnership program. The NCATS FY 2023 Congressional Justification outlines a vision for how NCATS research capitalizes on new opportunities for scientific exploration and addresses new challenges for human health in this ever-changing landscape.

NCATS' mission is to turn promising research discoveries into health solutions by removing the crimps in the translational research pipeline to accelerate access to knowledge and therapy development. The Center studies translation as a science and combines foundational investments with a willingness to de-risk ambitious projects, all while keeping an eye on revolutionary innovations to advance its portfolio, with the driving goal of getting more treatments to all people more quickly.

NCATS is always questioning what, where, when, and how to apply innovation, technology, and collaborative, strategic approaches to enable and accelerate scientific advances to benefit patients and the public. What have been the urgent needs during the COVID-19 pandemic where NCATS could readily leverage its resources and expertise to make needed information and knowledge readily accessible? **Where** are the opportunities to partner and test therapeutic strategies in the rare disease space in a manner that could be applicable for all diseases? **When** should we take risks in investing in unproven and unexplored areas of research? **How** can we apply the science of translation to address the public health needs of *all* Americans?

In NCATS' ten years of existence, we have learned that efficiencies are gained by establishing collaborations, promoting partnerships, and thinking of new ways to support innovative science. Platform approaches require both innovative technology and ingenuity to be fast, scalable, and adaptable.

At the ready for the pandemic response

NCATS' foundational investments in improving clinical research and clinical trials through its Clinical and Translational Science Awards (CTSA) program have paid dividends as many of these trial-ready institutions and the CTSA Trial Innovation Network have been efficiently coordinating multiple clinical trials during the pandemic, capitalizing on the program's expansive reach. In partnership with the NIH Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) efforts, CTSA-supported institutions are conducting trials testing therapeutic options for COVID-19, including the use of immunomodulators and convalescent plasma, and repurposing existing drugs already approved for other uses. The Center for Data to Health (CD2H) within the CTSA Program was testing an approach to create harmonized electronic health record (EHR) data when the pandemic reached the United States. By September 2020, the National COVID Cohort Collaborative (N3C) was established at NCATS in collaboration with the CTSA Program as a first-of-its-kind, rich resource for COVID-19 research.): As of March 2022, this secure data enclave contained over 14 billion rows of health data representative of over 12 million patients from across the United States, with over 4.5 million COVID-19 positive cases. Clinical research teams are already sharing knowledge learned from the N3C including (1) that in the largest U.S. cohort of COVID-19 positive solid organ transplant recipients, 42.9 percent required hospital admission and 40.9 percent experienced a major adverse kidney or cardiac event, and (2) that COVID-19 was twice as likely to be fatal for people with chronic obstructive pulmonary disease (COPD) than for those without COPD.[1] This resource is also important to NIH's efforts to understand the long-term impacts of COVID-19 as participating health care institutions refresh the data they provide to the N3C on a near monthly basis.

One potential idea for fighting SARS-CoV-2, the virus responsible for COVID-19, is to use old drugs in new ways. NCATS supports drug repurposing work and is uniquely suited to deploy this strategy for COVID-19. As soon as the SARS-CoV-2 virus was characterized, scientists in NCATS' Division of Preclinical Innovation used their expertise to rapidly screen over 10,000 compounds, including approximately 3,000 FDA-approved drugs and compounds in the NCATS Pharmaceutical Collection (NPC), as potential therapeutic candidates against the SARS-CoV-2 virus. NCATS also built the OpenData Portal to share COVID-19-related drug repurposing data and experiments openly and quickly. The data, which include positive and negative results, can be viewed, sorted, searched, and exported from the public web portal. The scientific community can use the data for a variety of drug repurposing activities, allowing them to formulate and test hypotheses, prioritize research opportunities, and speed the search for effective therapies against the virus and the disease it causes. NCATS' demonstrated capabilities in addressing the COVID-19 pandemic also led to collaborations on new initiatives on COVID-19 and pandemic preparedness. As a partner in the Antiviral Program for Pandemics (APP) and ACTIV Tracking Resistance and Coronavirus Evolution (TRACE), NCATS continues to meet the changing needs of science and public health during this ever-evolving pandemic. As part of the NIH ACTIV public-private-partnership, NCATS is leading the ACTIV-6 clinical trial to test currently approved medications for their effectiveness in helping people manage COVID-19 symptoms at home.

[1] pubmed.ncbi.nlm.nih.gov/34646938/

NCATS' work on the pandemic did not stop there, though. To address the pandemic's impacts on patients with rare diseases, NCATS supported the Survey on Impacts of COVID-19 on the Rare Disease Community as part of the work of the Rare Diseases Clinical Research Network (RDCRN). Close partnerships with patient groups enabled RDCRN researchers and clinicians to recognize that many people with rare diseases faced new challenges from the COVID-19 pandemic, from reduced access to needed medical care to possible heightened anxiety and stress. The RDCRN online survey sought community input on how the COVID-19 pandemic is impacting individuals with rare diseases, their families, and their caregivers. Forthcoming results will help researchers shed light on the needs of people with rare diseases during the pandemic and other potential health crises, in addition to informing future research efforts.

Helping rare disease patients by focusing on more than one disease at a time

NCATS' attention to supporting rare disease research originates from the recognition that rare diseases, collectively, are not rare. A recent NCATS-supported study indicates that total national spending on medical costs for rare disease patients is $400 billion per year, which is similar to annual direct medical costs for cancer, heart failure, and Alzheimer's disease.[2] With approximately 1 in 10 people affected by a rare disease, these patients will benefit from translational science approaches and innovations which can inform the understanding and treatment of many diseases at once. NCATS' guiding principle of "many diseases at a time" also highlights potential paths for understanding and treating more common diseases as well. To grow its footprint in rare disease research, NCATS intends to elevate its Office of Rare Diseases Research to Division-level representation within the Center.

NCATS currently supports several initiatives to provide and share information on all rare diseases. Data science, information technology, and informatics-centered approaches are important to leverage in understanding diseases which do not affect many individuals. The Genetics and Rare Diseases Information Center (GARD) provides a public information "clearinghouse" for understandable and clear information about rare diseases. The Rare Disease Informatics Platform (RDIP) aims to create a knowledge center to collect, integrate, and analyze rare diseases data from diverse sources. By incorporating data on rare disease prevalence, disease course, and research activities, RDIP can provide centralized data to inform rare disease research needs. These, and many other rare disease research initiatives at NCATS, will leverage forward-thinking data science, information technology approaches, and informatics capabilities embedded across the Center.

While the number of gene therapy clinical trials is increasing, all gene therapy programs face common barriers, such as manufacturing bottlenecks that cause multiyear delays and drive up costs. In the case of gene therapy for rare diseases, the current model of therapeutic development for a single disease is expensive and difficult to incentivize for small population sizes. Two NCATS efforts aim to significantly increase the efficiency of gene therapy trial startup, which is especially important for rare disease patients, but also can generate scientific knowledge to be applied to all diseases. The Platform Vector Gene Therapy (PaVe-GT) program is supported by the NCATS Cures Acceleration Network (CAN), which is mandated to address high-need cures. PaVe-GT is testing a standardized process using the same gene-delivery vehicle (vector) and

[2] ojrd.biomedcentral.com/articles/10.1186/s13023-021-02061-3

methods and applying this to four different rare diseases to optimize gene therapy efficacy and efficiency.

In a related effort, NCATS is taking a leading role in the newly launched Bespoke Gene Therapy Consortium (BGTC), part of the NIH Accelerating Medicines Partnership® (AMP®) program. With project coordination supported in part through the NCATS CAN, the BGTC is a partnership between NIH, the FDA, pharmaceutical companies, and non-profit organizations, and it aims to optimize and streamline the gene therapy development process to help fill the unmet medical needs of people with rare diseases, in particular those diseases that are too rare to be of commercial interest. This demonstrates how the NCATS approach to innovation, which began with its focus on helping patients across several rare disease groups, now stands to have even broader benefits for patients with other conditions which can be addressed by gene-directed therapies.

Cures Acceleration Network builds platforms and capabilities to deliver high need cures

The CAN was authorized to accelerate the development of high-need cures and reduce significant barriers between research discovery and clinical trials. To achieve these objectives, CAN authorities enable flexible funding approaches. Funding for CAN is provided through the NCATS appropriation, with a current overall ceiling of $60.0 million. NCATS proposes increasing the overall ceiling to $90.0 million in FY 2023..

Some of the ways that NCATS has implemented the CAN objectives include:

- Tackling bold challenges requiring platform approaches at scale
- Engaging needed allies for cross-sector coordination
- Creating new capabilities, while future-proofing the resources (e.g., technologies, data resources, disease models)
- Initiating high-risk approaches that hold promise for establishing entirely new paradigms for health advances
- De-risking problems to overcome market voids or failures

A key part of addressing human health needs in a changing world is looking for opportunities to maximize research investments for broad impact. Platform-based approaches – bringing together diverse disciplines and research partners and creating innovations with the potential for scaling up – are some of the most impactful programs within the NCATS portfolio. Moving tissue chips, 3D tissue biofabrication, and therapies based on patient cells into clinical development can help overcome certain translational research roadblocks and support the 3Rs (Replacement, Reduction, and Refinement) of using animal models in research. Data science-intensive projects, such as the Biomedical Data Translator and the N3C, fill a necessary niche by taking vast quantities of extant data and distilling them into tools that can themselves create new research insights, or be used to complement and inform new or ongoing research initiatives.

Focusing on the patient to address health disparities

The health of our nation is only as strong as the biomedical research that advances discoveries to meet the treatment needs of *all* Americans. The CTSA program and its community engagement

efforts provide an avenue for rapidly initiating work with trusted community partners to address COVID-19 health disparities. Both the NIH Rapid Acceleration of Diagnostics (RADx®) program and the Community Engagement Alliance (CEAL) Against COVID-19 Disparities program are engaging CTSA institutions as partners in addressing the pandemic impacts on medically underserved populations. This is critical given that research utilizing data from the NCATS N3C indicates that rural Americans have higher COVID-19 hospitalization rates and mortality.[3] A CTSA program attendee-driven "Un-Meeting"[4] in May 2021 explored how community hospitals can be better included in research in order to increase research participant diversity and inclusion through productive connections between community-focused clinical settings and academic research activities.

To address the unique needs of patients in rural communities, the CTSA program includes institutions in several states with significant representation and reach into rural areas. The CTSA Trial Innovation Network tests new technologies to further increase engagement and follow-up with research participants in rural areas. The CTSA program's work is furthered by partnerships with National Institute of General Medical Sciences (NIGMS)-funded institutions with Institutional Development Award Program Infrastructure for Clinical and Translational Research (IDeA-CTR) awards, boosting research capacity in states which historically have had low levels of NIH funding.

[3] www.medrxiv.org/content/10.1101/2021.10.05.21264543v1

[4] An Un-Meeting is an event without the rules and structure of a traditional conference. Attendees create and drive the agenda and discussions, based on a common theme. This format provides a unique approach for attendees to discuss their experiences and identify areas of potential research, innovation, and collaboration, with the ultimate goal of developing multidisciplinary, collaborative partnerships.

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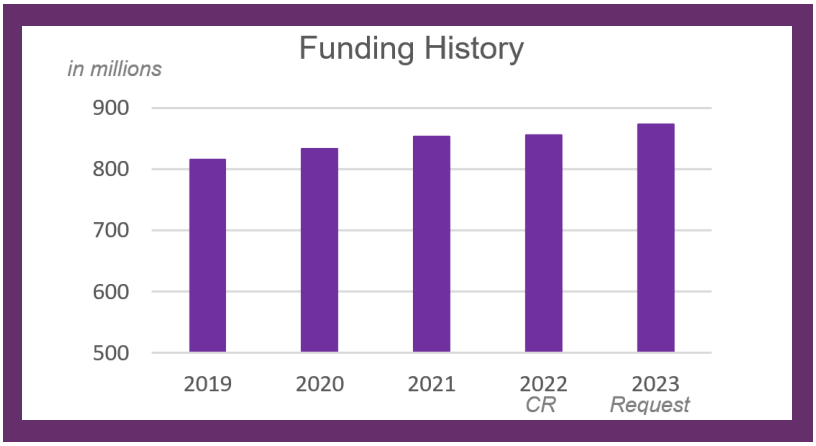
NCATS: A "Unique" Mission

Since its establishment in Fiscal Year 2012, NCATS focuses on **shortening the journey from scientific observation to clinical intervention, so that more treatments and cures can reach more patients more quickly.** NCATS supports development of innovative research tools, technologies, and strategies that can quickly pivot to address emerging needs or unaddressed, long-standing problems. NCATS undertakes research projects which cut through scientific and operational roadblocks. These robust yet nimble approaches are leveraged to address rare diseases, clinical trials, and public health emergencies, including the opioid crisis and COVID-19 pandemic, among other research areas.



Research Highlights

- Leveraging expertise in forming collaborative teams, engaging the academic community, and building partnerships with private sector experts to benefit all diseases, including rare diseases
- Platform-based approaches to address translational research needs, such as gene-targeted therapies which can be used for many genetic and rare diseases
- Addressing COVID-19 needs and future pandemic preparedness through drug repurposing and screening
- Active involvement in four COVID-19 clinical trials: expansion of two convalescent plasma trials, immune system modulation therapy trials, and trials to test several existing drugs for mild-to-moderate COVID-19
- Home to a centralized national data enclave and analytics platform to systematically collect clinical data on COVID-19-tested patients for research

Joni L. Rutter, Ph.D., became the NCATS Acting Director in April 2021. She is recognized internationally for her work in basic and clinical research in human genetics.

Facts and Figures:

- ~ 3,000 drugs and compounds in the NCATS Pharmaceutical Collection (NPC) for drug screening
- 61 Clinical and Translational Science Awards (CTSA) hubs
- 12 million+ individuals represented by data derived from electronic health records (EHRs) in the NCATS National COVID Cohort Collaborative (N3C) research enclave
- RDCRN: 20 consortia studying 200 rare diseases
- 146 intramural projects
- 28 patents licensed
- (CY 2018-2021)
- 14 INDs (CY2018-2021) from NCATS intramural advances

10 YEARS of NCATS
COLLABORATE. INNOVATE. ACCELERATE.

March 2022

National Center for Advancing Translational Sciences

MORE TREATMENTS, MORE QUICKLY. That's the goal of translational science.

Focusing on Rare Diseases and Harnessing Cross-cutting Research Approaches and Collaborations

The concept of "further together" is demonstrated through the concept of platform-based approaches to rare diseases research. With the myriad of rare diseases in need for cures and treatments, only cross-cutting approaches will result in the dramatic impacts to enhance the livelihood of people affected by rare diseases. Through the Bespoke Gene Therapy Consortium (BGTC) and the Platform Vector Gene Therapy (PaVe-GT) program, NCATS is actively leading highly collaborative efforts to more-readily advance gene-directed therapies for rare disease treatment needs, as well as demonstrate the potential of gene therapies for broader use. NCATS is also leveraging informatics capabilities and approaches to harness data to understand rare diseases in new ways.

Catalyzing the Community for Rapid Implementation of Clinical Trials

NCATS' CTSA Program is a national network of clinical trial-ready institutions, capable of addressing complex clinical research needs. NCATS and the CTSA Program have deployed the resources and expertise to rapidly engage in clinical trials for a variety of interventions. Most recently, NCATS oversees a large clinical trial to test up to seven over-the-counter and repurposed drugs for self-administered home treatment of mild-to-moderate COVID-19. NCATS takes an active involvement in patient recruitment for these efforts.

Making Data Accessible to Support Research

For example, NCATS' National COVID Cohort Collaborative (N3C) enables COVID-19 studies on a nation-wide harmonized data set derived from electronic health records (EHRs) from over 12 million COVID-19 tested patients, with demographic representation similar to that of the American population.

Identifying and Testing Potential Therapies Faster

Many NCATS efforts support the repurposing of existing drugs and molecules as a path towards discovering new treatments for disease and identifying ways to overcome technical and operational barriers. Advanced technological approaches and team science approaches allow NCATS' scientists to rapidly test over 10,000 compounds and identify their biological interactions with the COVID-19 virus. NCATS built the OpenData Portal to openly and quickly share data from these COVID-19-related drug repurposing experiments. Through participation in the Antiviral Program for Pandemics (APP), they will continue using rapid screening and dissemination models, and collaboration with academic scientists and the private sector, to advance drug discovery and development in preparedness for future infectious disease needs.

NCATS

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Major Changes in the Fiscal Year 2023 President's Budget Request

The budget request for NCATS of $873.7 million represents a $18.2 million or 2.1 percent increase from the FY 2022 Continuing Resolution (CR) level. NCATS will support priority research programs. NCATS will pay non-competing grant awards at their committed levels and fund high priority new awards.

Research Project Grants (+$109.3 million; total $159.2 million):
Beginning in FY 2023 the primary funding mechanism for the Clinical and Translational Science Awards (CTSA) Program will transition from Clinical Research Centers to Research Project Grants. NCATS will continue to fund a total of 61 hub awards between the Research Project Grants and Clinical Research Centers mechanisms. This is the same number funded as in both FY 2021 and FY 2022.

Research Centers (-$106.4 million; total $311.6 million):
Divided between the Research Project Grants and Clinical Research Centers funding mechanism, NCATS will fund a total of 61 hub awards under the Clinical and Translational Science Awards (CTSA) Program in FY 2023, the same number funded as in both FY 2020 and FY 2021.

Research and Development Contracts (+$11.1 million; total $84.2 million):
NCATS will increase support to the National COVID-19 Cohort Collaborative (N3C) and Genetic and Rare Diseases Information Center (GARD) in FY 2023 as well as support additional meritorious SBIR research and development contracts.

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Budget Mechanism *

(Dollars in Thousands)

Mechanism	FY 2021 Final		FY 2022 CR		FY 2023 President's Budget		FY 2023 +/- FY 2022	
	Number	Amount	Number	Amount	Number	Amount	Number	Amount
Research Projects:								
Noncompeting	61	$43,698	48	$35,905	52	$26,023	4	-$9,882
Administrative Supplements	*(17)*	$1,467	*(4)*	$475	*(4)*	$500	0	$25
Competing:								
Renewal	0	$0	0	$0	0	$0	0	$0
New	19	$8,589	35	$13,470	56	$132,648	21	$119,178
Supplements	0	$0	0	$0	0	$0	0	$0
Subtotal, Competing	**19**	**$8,589**	**35**	**$13,470**	**56**	**$132,648**	**21**	**$119,178**
Subtotal, RPGs	80	$53,754	83	$49,849	108	$159,171	25	$109,321
SBIR/STTR	34	$21,398	37	$23,341	33	$20,556	-4	-$2,785
Research Project Grants	114	$75,152	120	$73,190	141	$179,727	21	$106,536
Research Centers								
Specialized/Comprehensive	0	$10,441	0	$10,745	0	$10,291	0	-$454
Clinical Research	61	$404,309	61	$407,256	45	$301,312	-16	-$105,945
Biotechnology	0	$0	0	$0	0	$0	0	$0
Comparative Medicine	0	$0	0	$0	0	$0	0	$0
Research Centers in Minority Institutions	0	$0	0	$0	0	$0	0	$0
Research Centers	**61**	**$414,751**	**61**	**$418,001**	**45**	**$311,603**	**-16**	**-$106,399**
Other Research:								
Research Careers	61	$59,859	61	$63,083	61	$63,957	0	$874
Cancer Education	0	$0	0	$0	0	$0	0	$0
Cooperative Clinical Research	0	$0	0	$0	0	$0	0	$0
Biomedical Research Support	0	$0	0	$0	0	$0	0	$0
Minority Biomedical Research Support	0	$0	0	$0	0	$0	0	$0
Other	39	$41,366	41	$38,266	41	$37,327	0	-$939
Other Research	**100**	**$101,224**	**102**	**$101,349**	**102**	**$101,284**	**0**	**-$65**
Total Research Grants	275	$591,127	283	$592,541	288	$592,613	5	$73
Ruth L Kirschstein Training Awards:	FTTPs		FTTPs		FTTPs		FTTPs	
Individual Awards	0	$0	0	$0	0	$0	0	$0
Institutional Awards	461	$27,227	461	$27,608	484	$29,711	23	$2,103
Total Research Training	**461**	**$27,227**	**461**	**$27,608**	**484**	**$29,711**	**23**	**$2,103**
Research & Develop. Contracts	119	$75,377	117	$73,051	120	$84,190	3	$11,138
SBIR/STTR (non-add)	*(7)*	*($3,539)*	*(6)*	*($1,561)*	*(6)*	*($4,911)*	*(0)*	*($3,350)*
Intramural Research	80	$98,217	105	$99,059	115	$100,964	10	$1,904
Res. Management & Support	157	$60,904	172	$63,161	183	$66,176	11	$3,015
SBIR Admin. (non-add)	*(0)*	*($0)*	*(0)*	*($0)*	*(0)*	*($380)*	*(0)*	*($380)*
Construction		$0		$0		$0		$0
Buildings and Facilities		$0		$0		$0		$0
Total, NCATS	**237**	**$852,853**	**277**	**$855,421**	**298**	**$873,654**	**21**	**$18,233**

* All items in italics and brackets are non-add entries.

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NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES

For carrying out section 301 and title IV of the PHS Act with respect to translational sciences, $873,654,000: Provided, That up to $90,000,000 shall be available to implement section 480 of the PHS Act, relating to the Cures Acceleration Network: Provided further, That at least $599,349,000 is provided to the Clinical and Translational Sciences Awards program.

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Summary of Changes
(Dollars in Thousands)

FY 2022 CR	$855,421
FY 2023 President's Budget	$873,654
Net change	$18,233

CHANGES	FY 2022 CR FTEs	FY 2022 CR Budget Authority	FY 2023 President's Budget FTEs	FY 2023 President's Budget Budget Authority	Built-In Change from FY 2022 CR FTEs	Built-In Change from FY 2022 CR Budget Authority
A. Built-in:						
1. Intramural Research:						
a. Annualization of January 2022 pay increase & benefits		$22,628		$25,407		$150
b. January FY 2023 pay increase & benefits		$22,628		$25,407		$766
c. Paid days adjustment		$22,628		$25,407		-$86
d. Differences attributable to change in FTE		$22,628		$25,407		$2,263
e. Payment for centrally furnished services		$3,331		$3,398		$67
f. Cost of laboratory supplies, materials, other expenses, and non-recurring costs		$73,100		$72,159		$1,620
Subtotal						$4,780
2. Research Management and Support:						
a. Annualization of January 2022 pay increase & benefits		$31,816		$34,988		$211
b. January FY 2023 pay increase & benefits		$31,816		$34,988		$1,076
c. Paid days adjustment		$31,816		$34,988		-$121
d. Differences attributable to change in FTE		$31,816		$34,988		$2,071
e. Payment for centrally furnished services		$209		$213		$4
f. Cost of laboratory supplies, materials, other expenses, and non-recurring costs		$31,136		$30,975		$664
Subtotal						$3,905
Subtotal, Built-in						$8,685

CHANGES	FY 2022 CR No.	FY 2022 CR Amount	FY 2023 President's Budget No.	FY 2023 President's Budget Amount	Program Change from FY 2022 CR No.	Program Change from FY 2022 CR Amount
B. Program:						
1. Research Project Grants:						
a. Noncompeting	48	$36,380	52	$26,523	4	-$9,857
b. Competing	35	$13,470	56	$132,648	21	$119,178
c. SBIR/STTR	37	$23,341	33	$20,556	-4	-$2,785
Subtotal, RPGs	120	$73,190	141	$179,727	21	$106,536
2. Research Centers	61	$418,001	45	$311,603	-16	-$106,399
3. Other Research	102	$101,349	102	$101,284	0	-$65
4. Research Training	461	$27,608	484	$29,711	23	$2,103
5. Research and development contracts	117	$73,051	120	$84,190	3	$11,138
Subtotal, Extramural		$693,201		$706,515		$13,314
6. Intramural Research	105	$99,059	115	$100,964	10	-$2,875
7. Research Management and Support	172	$63,161	183	$66,176	11	-$890
8. Construction		$0		$0		$0
9. Buildings and Facilities		$0		$0		$0
Subtotal, Program	277	$855,421	298	$873,654	21	$9,548
Total built-in and program changes						$18,233

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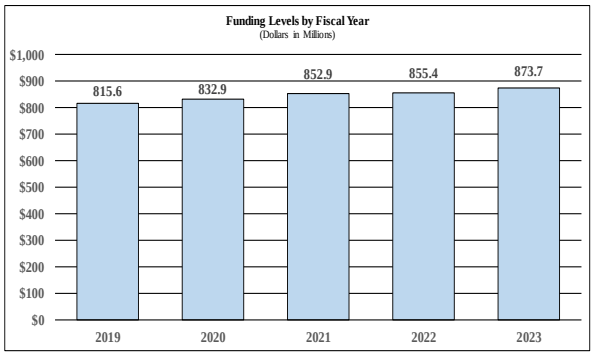
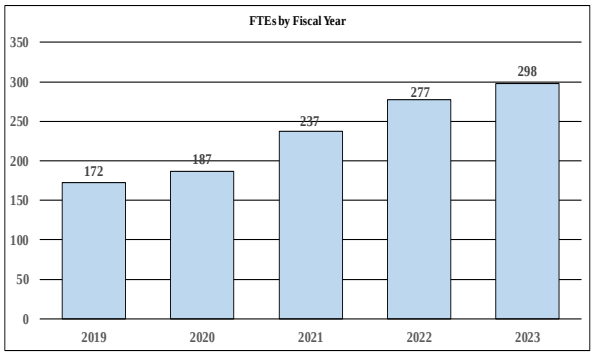
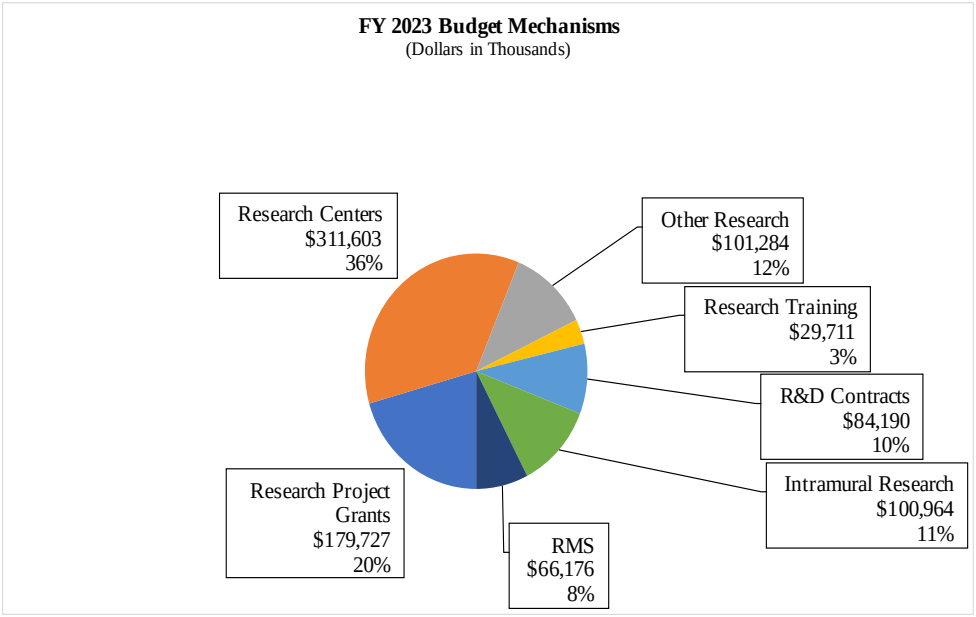
History of Budget Authority and FTEs:

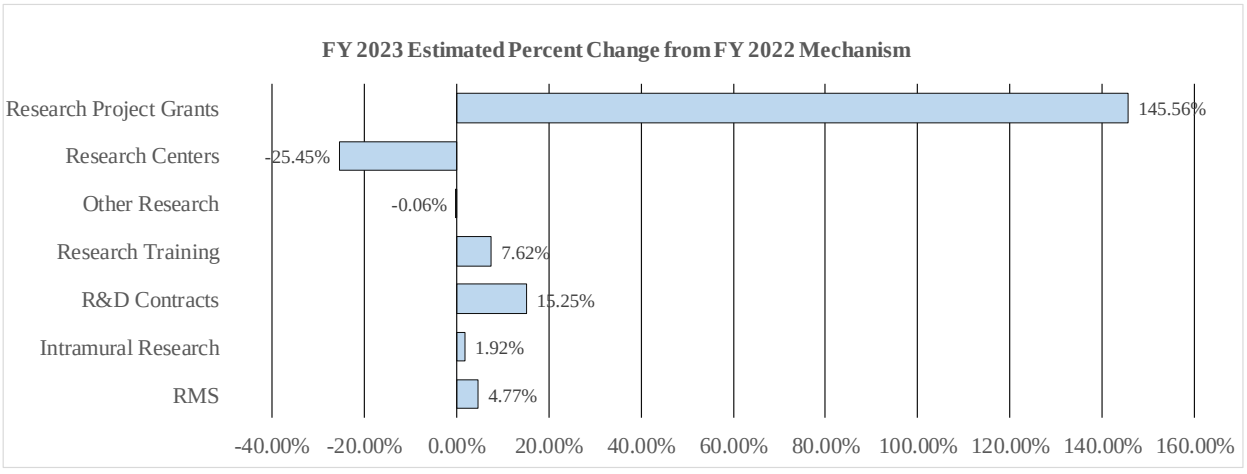




Distribution by Mechanism:



Changes by Selected Mechanism:



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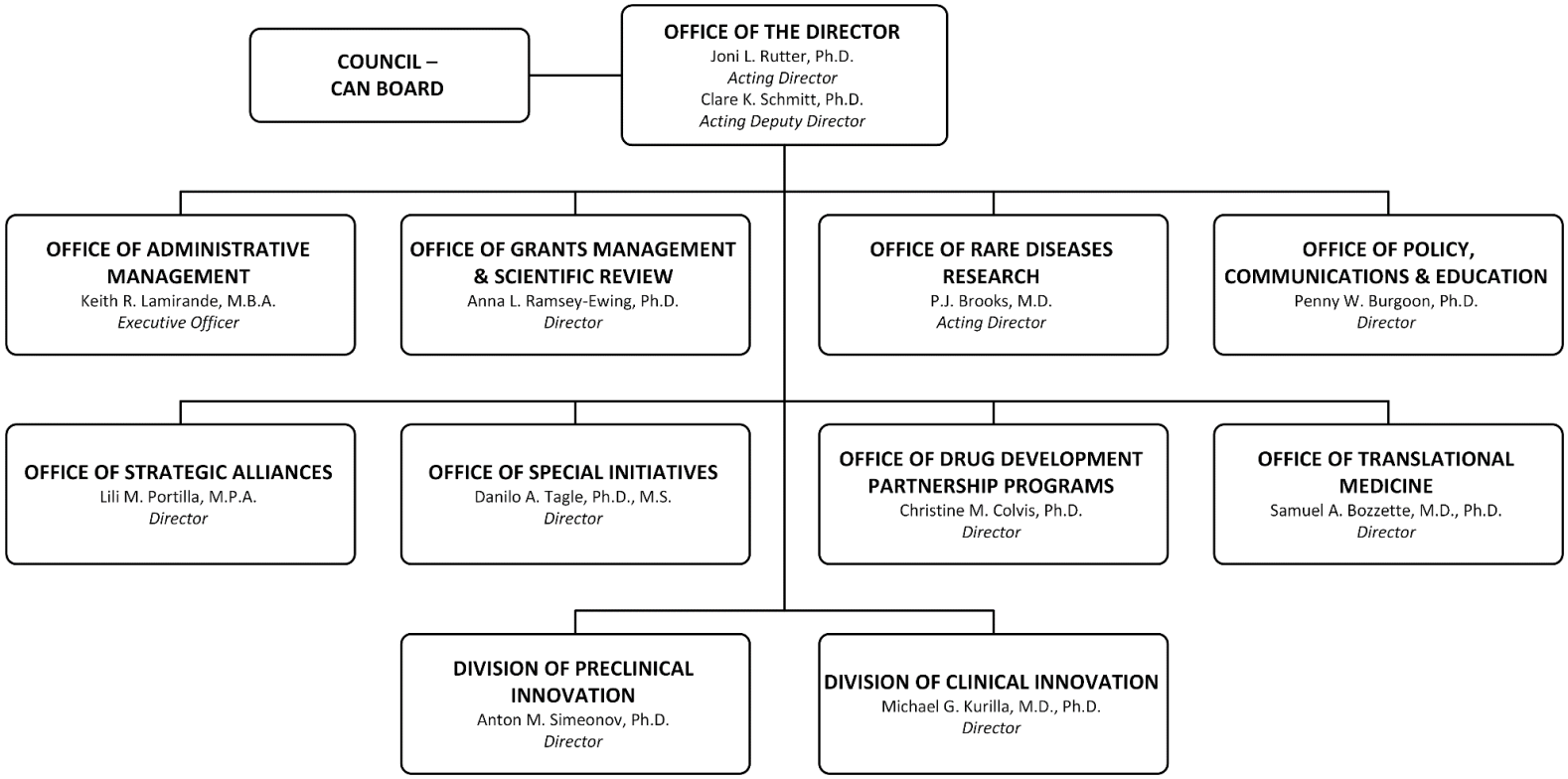

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Budget Authority by Activity [1,2,3]
(Dollars in Thousands)

	FY 2021 Final		FY 2022 CR		FY 2023 President's Budget		FY 2023 +/- FY 2022 CR	
Budget Activity	**FTE**	**Amount**	**FTE**	**Amount**	**FTE**	**Amount**	**FTE**	**Amount**
Clinical and Translational Science Activities		$585,082		$586,841		$599,349		$12,508
Reengineering Translational Sciences		$159,970		$160,429		$163,848		$3,419
Cures Acceleration Network		$55,814		$55,996		$57,190		$1,194
Rare Diseases Research and Therapies		$51,986		$52,155		$53,267		$1,112
TOTAL	**237**	**$852,853**	**277**	**$855,421**	**298**	**$873,654**	**21**	**$18,233**

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

[2] Amounts for each budget activity combine funding for extramural research, intramural research, and research management and support components of the activity

[3] NCATS funds rare diseases research in all four of its budget activities. Rare Diseases Research and Therapies is for those programs solely dedicated to rare diseases research.

Justification of Budget Request

National Center for Advancing Translational Sciences

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 2021 Final	FY 2022 Continuing Resolution	FY 2023 President's Budget	FY 2023 +/- FY 2022
BA	$852,853,000	$855,421,000	$873,654,000	+$18,233,000
FTE	237	277	298	+21

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

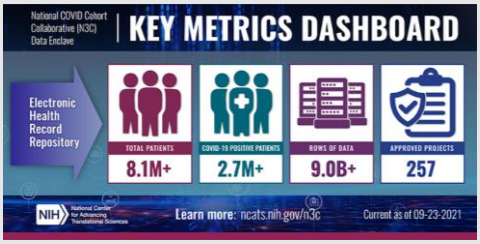
Overall Budget Policy: The FY 2022 President's Budget request is $873.7 million, an increase of $18.2 million or 2.1 percent compared to the FY 2022 CR level.

Program Descriptions

Overview: NCATS' mission serves the changing public health landscape by accelerating the translation of scientific research for improved human health. The Center supports efforts that reduce, remove, or bypass the costly and time-consuming bottlenecks that impede development of effective medical interventions. Since its creation in FY 2012, NCATS has made great strides in bringing the concept of "translation as a science" to the forefront of the biomedical research ecosystem. In reality, many scientific discoveries fail to translate into successful treatments. There is a need to understand the failures and explore novel methods which will expedite success. This is the entire premise for why NCATS exists: applying the scientific method to understand why translation is often unsuccessful, taking on cutting-edge scientific projects which break the mold of traditional NIH-supported approaches to research, and by doing so, discovering new ways to improve translation and increase chances of successful translation into human health interventions. Disease-universal translational science approaches enable NCATS to conduct and support research where opportunities emerge and to create applied knowledge for additional impact, using lessons-learned to answer other research questions, or by taking pilot project discoveries and applying them to larger-scale efforts. NCATS' investigators and collaborators can achieve breakthroughs that are then disseminated back to the clinical and translational community for their application. All of NCATS' programs and initiatives involve multiple organizational units within the Center and engage cross-cutting teams both inside and outside NIH, harnessing diverse expertise and perspectives to accelerate innovation.

National COVID Cohort Collaborative (N3C)

Health care providers utilize multiple treatment approaches for COVID-19, and there is still no standard of care. Vast amounts of clinical data are being generated, which can advance research efforts to improve patient care. There is an urgent need to make this information available for study on a national scale to answer research questions such as what therapies work better than others, why do some people show no symptoms, and what are the long-term health consequences of being infected with SARS-CoV2?



NCATS, the CTSA Program institutions, and the CTSA Center for Data to Health (CD2H) met the call for action, forming the **National COVID Cohort Collaborative (N3C)**, a secure, centralized, national data source of harmonized patient data rapidly accessible to researchers for studying COVID-19. CD2H is instrumental in the development of the N3C operations and shared governance model. The CTSA Program institutions are key contributors of patient data. NCATS created and manages the N3C Data Enclave; negotiated the agreements for contribution and access to the data; and established the measures to keep the data secure. A **key initial finding: hospitalization and inpatient mortality rates are higher in patients from rural areas**.[1]

[1] www.medrxiv.org/content/10.1101/2021.10.05.21264543v1

I. Scientific and Operational Innovations to Accelerate the Translation of Clinical Research

NCATS' flagship **Clinical and Translational Science Awards (CTSA) Program** supports a dynamic suite of initiatives focused on fostering and improving clinical and translational science and research. A nationwide network of biomedical research institutions forms the backbone of the program in addressing important roadblocks in clinical translation by working locally, regionally, and nationally. Career development and training components of the CTSA program enhance the institutional activities by cultivating and sustaining future leaders of the biomedical research workforce. Several consortium-wide activities innovate to test novel recruitment and participant engagement strategies, data-driven approaches for participant identification and trial site selection, and coordinate network-wide efforts to explore and test ways to utilize and share clinical data more efficiently.

At the Ready: Responding to National Health Emergencies

The CTSA Program, through its vast network and access to a wide range and diversity of the U.S. population, quickly harnessed its expertise and resources to address the current public health emergencies caused by the COVID-19 pandemic and the opioid crisis.

Making COVID-19 health data accessible and usable for research to inform patient care, the National COVID Cohort Collaborative (N3C): Announced on September 2, 2020, the NCATS' N3C initiative leverages the expertise and broad reach of the CTSA Program to provide one of the largest collections of health data from COVID-19 patients in the United States. Continued investment in harmonization, usability, and analysis of data derived from electronic health records (EHRs) serves to advance research using real-world data gathered in the clinical settings. N3C contributes to the development of innovative artificial intelligence and machine learning methods that are critical to driving innovation in data science and translating clinical data into

health interventions. See the Program Portrait for more details and visit the N3C website for up-to-date information.[5]

Rapid Activation and Expansion of Clinical Trials to Test COVID-19 Therapies: NCATS' CTSA Program is a fully functioning national network of clinical trial-ready institutions, capable of addressing complex clinical research needs. The resources and expertise were deployed to rapidly engage in COVID-19 clinical trials testing a variety of interventions, speeding clinical trial recruitment, and expanding the diversity of trial participants. As part of the NIH ACTIV initiative, NCATS coordinates two large COVID-19 clinical trials. The first trial, launched shortly after the onset of the pandemic, evaluates the safety and efficacy of three therapeutics that could restore balance to an overactive immune system.[6] The second, launched in April 2021, is a large clinical trial to test the safety and effectiveness of over-the-counter and repurposed drugs, including ivermectin and fluvoxamine, for COVID-19 patients with mild-to-moderate symptoms.[7] This trial fills a need to understand self-administered at-home treatment options for people with COVID-19 who do not yet need to be hospitalized. NCATS support also enabled the expansion of trials testing convalescent plasma treatment for COVID-19.[8] The CTSA program COVID-19 response follows on past successful examples, such as the CTSA Trial Innovation Network (TIN) involvement in the NIH Helping to End Addiction Long-term® (HEAL) Initiative to rapidly pivot and respond to public health needs.

No One Left Behind: Addressing Health Disparities and Rural Health

NCATS is committed to reducing health disparities and the significant burden of conditions that disproportionately affect rural, minority, and other underserved populations. Examples of this commitment include:

- Expanding outreach through the CTSA Program network to include institutions able to address the needs of medically underserved communities.
- Enabling **CTSA Collaborative Innovation Awards** to include NIGMS-funded NIH Institutional Development Award Program Infrastructure for Clinical and Translational Research (IDeA-CTR) institutions who build research capacity in states with medically underserved communities.
- Partnering with NIGMS and their IDeA-CTR institutions to contribute COVID-19 patient data to the N3C, thereby making COVID-19 patient information from rural communities available for study.
- Preparing for consultation with Tribal Nations to explore potential opportunities to understand the impacts of the COVID pandemic on these communities through the N3C.
- Working on NIH-wide COVID-19 community engagement efforts via the CTSA, including the NIH RADx Underserved Populations initiative (RADx®-UP) and CEAL to raise awareness, alleviate barriers, and reduce the burden of the disease among underserved and COVID-19 vulnerable populations.

[5] ncats.nih.gov/n3c
[6] ncats.nih.gov/news/releases/2020/nih-begins-large-clinical-trial-to-test-immune-modulators-for-treatment-of-covid-19
[7] www.nih.gov/news-events/news-releases/large-clinical-trial-study-repurposed-drugs-treat-covid-19-symptoms
[8] ncats.nih.gov/news/releases/2020/nih-expands-clinical-trials-to-test-convalescent-plasma-against-covid-19

Renewing Investments in the CTSA Program

NCATS and the CTSA Program have made great progress together in addressing critical challenges to the nation's clinical and translational research and infrastructure, and improving the efficiency, quality, and impact of the process for turning observations into interventions that improve the health of individuals and communities. The CTSA Program has been a cornerstone in the Nation's responses to the opioid crisis, and particularly the pandemic, with rapid implementation of multiple clinical trials testing COVID-19 therapeutics. In moving the program forward, stakeholders identified needs for: increased institutional flexibilities; sharing best practices, tools, and materials; developing uniform guidance for research, training, and education; and enhancing ways to support and reward teams. Taking this feedback into account, NCATS is utilizing ways to support the CTSA Program that allow institutions to prioritize their strengths; provide streamlined application and award management processes; emphasize the importance of clinical partnerships critical to achieving the objectives of this national program; incorporate research to tackle health disparities; and stabilize funding provided to institutions by allowing up to seven years, rather than the typical five, for the primary institutional awards.

Budget Policy: The FY 2023 President's Budget request for Clinical and Translational Science Activities is $599.3 million, an increase of $12.5 million or 2.1 percent compared with the FY 2022 CR level. NCATS will maintain the same number of CTSA institutions as funded in FY 2022, which is 61 hubs.

II. High-Risk, Transformative Efforts for High-Need Cures: Cures Acceleration Network (CAN)

Overview: The **Cures Acceleration Network (CAN)**, as authorized by Congress, supports transformative efforts to advance the development of high-need cures and reduce significant barriers between research discovery and clinical trials. CAN authorities enable NCATS programs and initiatives that are extraordinarily innovative in both their scientific strategies and operational management, with tremendous potential to be applied broadly to numerous diseases and disorders.

Platform-based approaches to address common therapeutic and diagnostic barriers

NCATS supports novel research areas identified as obstacles in translating discovery to patient applications, through approaches and innovations which can benefit multiple diseases or patient groups. "Platform-based approaches" – with broad impact and potential for scalability – are core to the NCATS mission. The CAN Review Board identified gene therapy for rare diseases as a high-need area where NCATS can have a significant impact by identifying and/or eliminating barriers to gene therapy development. Increasing efficiency in gene therapies will help bring cutting-edge health interventions to more patients and is an especially promising avenue for treating diseases caused by a single gene. Through leadership of the **Bespoke Gene Therapy Consortium (BGTC)**, and funding of a BGTC Coordinating Center, NCATS will collaborate with multiple public and private organizations to optimize the multiple necessary steps (e.g., clinical-grade vector production and toxicity testing) of the gene therapy development process to help meet unmet medical needs of rare disease patients. This work is a major component of the

Foundation for NIH (FNIH) Gene Therapy Accelerating Medicines Partnership® (AMP®) and builds upon existing NCATS programs, such as the **Platform Vector Gene Therapy (PaVe-GT)** project, which tests if it is possible to significantly increase the efficiency of gene therapy trial startup by using a standardized process, with the same gene-delivery vehicle (vector) and methods for four different rare diseases.

NCATS' human cell-based platforms can enhance translation from early-stage disease modeling to late-stage therapeutic testing. The NCATS CAN **Tissue Chips Program** develops human tissue chips that accurately model the structure and function of human organs to help predict drug safety in humans more rapidly and effectively. During the program's inception, it has focused on developing physiologically relevant models for toxicity testing. The current focus of the program is on disease modeling and efficacy testing that may inform clinical trial design, selection of drug candidates, or research endpoints for clinical trials. NCATS' **Scanning for Conditions with Electronic Nose Technology (SCENT)** program is moving forward at NCATS through the CAN program for diseases other than COVID-19. It was previously selected by the NIH Rapid Acceleration of Diagnostics Radical (RADx-rad) program to non-invasively detect infections in symptomatic and asymptomatic COVID-19 patients. It fosters development and deployment of diagnostics which can detect chemical compounds released into the air from the skin and breath, indicative of disease. NCATS also supports collaborations between scientists at NCATS and external partners with the **NCATS 3-D Tissue Bioprinting** and **Stem Cell Translation** laboratories and developing human tissue or cell-based research resources, as well as corresponding assays and protocols for drug screening. This work is applied to urgent public health needs such as identifying non-opioid pain treatments (as part of the NIH HEAL initiative) and antiviral therapeutics (as part of the NIH APP).

Bridging Knowledge Gaps through Translation to Break Biomedical Data Silos

Endless amounts of research data and information can be found in a multitude of forms such as databases, electronic health records, and clinical trial research libraries. Relationships across different data types are not readily explorable when the data types are stored in their own language, such as gene sequences, clinical signs and symptoms, and drug effects. The **NCATS Biomedical Data Translator Program** (Translator) is a multi-phase effort to develop a data translator, bridging these data types and enabling the exploration of novel data relationships.

Finding New Treatment Options: Designing Chemical Compounds Important to Biology

Designing and developing new biologically active chemicals is largely a manual, artisanal process and is slow, low yield, and difficult to reproduce. NCATS is transforming chemistry from an individualized craft to a modern, information-based science through **A Specialized Platform for Innovative Research Exploration (ASPIRE)** and its **Design Challenges,** which aim to combine traditionally separate drug development activities into one connected environment. Uniting virtual and physical components, and applying artificial intelligence and machine learning, NCATS will explore operational efficiencies that can help bring novel effective treatments to more patients more quickly. By addressing long-standing challenges in the field of chemistry, including lack of standardization, low reproducibility, and an inability to

predict how new chemicals will behave, ASPIRE is designed to bring novel, safe, and effective treatments to more patients more quickly.

Budget Policy: The FY 2023 President's Budget request for the Cures Acceleration Network is $57.2 million, an increase of $1.2 million or 2.1 percent compared with the FY 2022 CR level.

III. Collaborations to Advance the Translation of Biomedical Research into Patient Impacts: Reengineering Translational Sciences

Translation of scientific discovery from the laboratory to the clinic requires a team effort, in that scientists from different disciplines must contribute their respective expertise to solve challenging and complex problems. Diverse thinking from multiple research disciplines and stakeholders is crucial to uptake of research interventions by the public and patients. Several NCATS programs embody this by leveraging expertise and resources both within the Center, as well as across the federal government, the academic research community, and pharmaceutical and technology sectors.

Strategies for Repurposing Drugs and Therapeutics

If existing drugs could treat other diseases, why not find ways to explore them? In the context of the COVID-19 pandemic, the idea of repurposing, or better understanding what existing molecules, drugs, or FDA-approved therapies may be used for a new purpose, has come to the forefront. NCATS has long focused in this area, recognizing that repurposing can bypass many of the translational bottlenecks that newly designed therapies can hit during the development process. NCATS supports repurposing initiatives with the goal of speeding the drug and therapeutics development process. The **NCATS Pharmaceutical Collection (NPC)** is a comprehensive, publicly accessible collection of drugs approved for clinical use that are suitable for high-throughput screening. COVID-19-related drug repurposing data captured through this program are available through the **OpenData Portal,** as described in the Program Portrait.

Using Old Drugs in New Ways: OpenData Portal

A collection of approved drugs is a valuable resource for drug repurposing, where drugs are tested for new indications. NCATS' scientists built the OpenData Portal to openly and quickly share COVID-19-related drug repurposing data and experiments for all approved drugs.[1] NCATS researchers developed the portal by using SARS-CoV-2-related assays to screen over 10,000 compounds, including the NCATS Pharmaceutical Collection of nearly 3,000 approved drugs, for their activity against the virus. The Portal also includes data conducted in animal models, which were curated by the NIH ACTIV Preclinical Working Group with support from the FNIH. NCATS makes these datasets immediately available, including the testing protocols used to generate them, to the scientific community as soon as the screens are completed.

[1] opendata.ncats.nih.gov

Enabling Therapeutics Development by Solving Translational Challenges

The **Early Translation Branch (ETB)** kick-starts the discovery pathway toward new cures by creating tools needed to "de-risk" potential therapeutic targets. The goal is to uncover new small

molecule therapeutics and advance the process of therapeutic development through a model of collaborative research where external disease experts partner with ETB's drug discovery teams, who provide access to small molecule screening, medicinal chemistry, and informatics expertise. The **Therapeutics Development Branch (TDB)** looks at later-stage interventions, choosing specific projects as use cases to break translational research barriers. A collaborative science model prioritizes efficacy, efficiency, and rapid development. NCATS works intentionally at this unpredictable stage to "de-risk" therapeutic candidates to enable biomedical research companies to conduct clinical trials and seek regulatory approval. This is a particularly compelling strategy for rare disease therapeutic development, yet it also holds promise for common diseases as well. New directions for ETB and TDB include (1) antiviral candidate identification and testing to prepare for future infectious disease outbreaks, as part of the NIH APP, in partnership with the National Institute of Allergy and Infectious Diseases and the Biomedical Advanced Research and Development Authority; (2) RNA-directed therapies for rare genetic diseases; and (3) expanded resources for understanding drug combination therapies by combining multiple analytical chemistry and drug screening activities. These matrix approaches will be used in partnership with the National Cancer Institute on lymphomas which commonly require multidrug therapies.

Emerging Ethical Considerations in Translational Science

Understanding the legal and societal implications of innovative translational research is key to the public's uptake of health interventions. Renewed for FY 2023, the NCATS **Translational Ethics Collaboratories Program** supports sustainable trans-disciplinary collaborative teams with expertise and flexibility to anticipate and conduct research in ethical issues related to emerging areas of translational science. Each collaboratory will provide ethics research consultations in their areas of expertise.

Translational Scientists: Training in a New Discipline for the Future

Developing the next generation of translational scientists in a way that identifies this as a new discipline is a priority for NCATS. In addition to training and career development support through the NCATS CTSA Program, NCATS is newly launching and exploring additional ways to prepare scientists for research with an eye to translation of research findings into the clinical setting. Training and education activities reach the next-generation of scientists at both the national and local levels, such as **Online Education Modules to Advance Understanding of Translational Science Principles**, and **NCATS-FDA Translational Science Interagency Fellowships**.

Budget Policy: The FY 2023 President's Budget request for Innovations to Advance the Translation of Biomedical Research Discoveries into Patient Impacts: Reengineering Translational Sciences is $163.8 million, an increase of $3.4 million or 2.1 percent compared with the FY 2022 CR level.

IV. Harnessing Translational Science Strategies for Rare Disease Research and Therapies

Rare diseases collectively are a significant health problem. There are more than 25-30 million people living with rare diseases in the United States alone, about the same number as those living with diabetes. Rare diseases disproportionately affect children, and the vast majority have no FDA-approved treatment. This accounts for an enormous burden of suffering and premature death, not to mention financial and economic productivity losses to families, communities, and the nation. The economic burden of rare disease reached nearly $1 trillion in the United States in a single year alone.[9]

NCATS seeks to grow its multi-pronged strategy to address scientific and operational roadblocks for rare diseases, such as how to handle complex, often large, disparate, and/or disaggregated data, clinical trial readiness, developing therapeutics, and working collaboratively with the patients and their families. The rare disease portfolio is a core component of the NCATS mission, as addressing translational science needs and overcoming obstacles to translate findings into cures has the potential to address many rare diseases at one time.

Application of Informatics to Rare Disease

Using all available existing data and reported research results to identify novel treatments is key to advancing treatments for diseases which do not affect many individuals. Data science and informatics activities are therefore key, since siloed and disparate data types can be exceedingly difficult to access, organize, and interpret. One such example of NCATS' application of data informatics approaches is the **Rare Disease Informatics Platform (RDIP)** detailed in the Program Portrait.

Rare Diseases Informatics Platform (RDIP)

RDIP was borne out of the difficulty and unreliability of extracting rare disease patient data from existing healthcare systems databases and supports the collection, integration, and analysis of rare disease data from diverse sources. The goal of RDIP is to provide timely, objective, reliable information on rare disease prevalence, disease course, research activities, and utilization to inform rare disease research prioritization and identify public health needs. An RDIP pilot initiative, **Impact of Rare Diseases on Patients and Healthcare Systems (or IDeaS)**, is a small-scale 14-disease prototype that seeks to better quantify and understand the burden of rare diseases to the healthcare system. This initiative, a collaboration between NCATS and United States and Australian academic and industry partners, recently published a paper demonstrating that in every case, the cost per patient per year for rare disease patients exceeded costs for non-rare diseases patients of the same age.[1] Results from the IDeaS initiative-supported study of medical and insurance records indicates health care costs for people with a rare disease have been underestimated and are three to five times greater than the costs for people without a rare disease. Also, the study provides new evidence of the potential impact of rare diseases on public health, suggesting that nationwide medical costs for individuals with rare diseases are **~$400 billion, on par with costs for cancer, heart failure, and Alzheimer's disease.** The findings underscore an urgent need for more research, and earlier and more accurate diagnoses of and interventions for these disorders.

[1] ojrd.biomedcentral.com/articles/10.1186/s13023-021-02061-3

Addressing Roadblocks to Gene-Targeted Therapies

As aforementioned, the Cures Acceleration Network (CAN) Review Board identified **gene-targeted therapies for rare diseases** as a high need area in need

[9] everylifefoundation.org/burden-study/#about-study

of expedited paths towards clinical trials, and de-risking for uptake by the private sector. The **Platform Vector Gene Therapy (PaVe-GT) program** and leadership of the **Bespoke Gene Therapy Consortium,** described in Section II, are examples of how NCATS leverages CAN authorities in its commitment to rare disease research. In addition, NCATS supports several opportunities for advancing rare disease gene therapies beyond CAN initiatives. The path to diagnosing a rare disease is a journey unto itself. Early diagnosis of rare diseases is crucial to provide gene-targeted therapies to patients. In 2021, NCATS convened a virtual workshop and published a request for input on Facilitating the Early Diagnosis and Equitable Delivery of Gene-Targeted Therapies to Individuals with Rare Diseases. The workshop convened over 2,000 participants representing patient groups, academic and industry researchers, and government stakeholders, all focused on early diagnostic strategies for rare genetic diseases. The meeting generated a great deal of interest in the patient and industry communities and identified potential avenues for NCATS to support equitable and efficacious delivery of genetic therapies to rare disease patients.

Collaborative Approaches to Engaging the Public and the Rare Disease Community

Shortening diagnostic odyssey of rare disease diagnosis: FY 2023 funding will support programs under a new initiative focused on rare disease diagnosis through multidisciplinary approaches (including combining machine-learning, genomic analysis, and clinical consultation) which can be readily integrated into the primary care or secondary care clinical setting. Most rare disease patients experience years-long delays and often need to consult with multiple physicians and specialists before obtaining a correct diagnosis. NCATS-supported projects to **shorten the rare diseases diagnostic odyssey** will further the planning and development of rapid diagnostic strategies to benefit hard-to-diagnose or undiagnosed patients seen by front-line healthcare providers.

Patients as scientific stakeholders: Patient engagement, and dissemination of information to the public, is a crucial component of collaborative rare disease research. The **Rare Diseases Clinical Research Network (RDCRN)** involves physician-scientists and their multidisciplinary teams working together with patient groups as part of the research team to advance medical research on rare diseases.

Public understanding of rare diseases: The **Genetics and Rare Diseases Information Center (GARD)** provides a public service not available elsewhere by providing readily accessible and clear information about rare diseases. As an information "clearinghouse," GARD provides understandable information, in both English and Spanish, on rare diseases to the public and individual inquiry services to rare diseases patients and families.

Rare Disease Clinical Trial Readiness

Many Americans living with a rare disease have difficulty getting an effective treatment, and only around five percent of rare diseases currently have an FDA-approved therapy. To close this gap in care, NCATS created the **Clinical Trial Readiness (CTR) for Rare Diseases, Disorders, and Syndromes Program** to support projects focused on collecting the data needed to move promising rare disease therapies and diagnostics into clinical trials. Renewed in FY 2023, this

program spans biomarker assessment and validation, research models of disease, and clinical outcome assessment development and validation.

Budget Policy: The FY 2023 President's Budget request for Harnessing Translational Science Strategies for Rare Disease Research and Therapies is $53.3 million, an increase of $1.1 million or 2.1 percent compared with the FY 2022 CR level. NCATS funds rare diseases research in all four of its budget activities. Rare Diseases Research and Therapies describes programs solely dedicated to rare diseases research.

Summary

Foundational investments combined with cross-cutting and collaborative approaches, and expertise in forging partnerships and alliances, allow NCATS to take on ambitious projects, extrapolate lessons learned to inform science, and advance cures and health interventions. NCATS is making progress addressing translational roadblocks, but there are many reminders that there is much more to do. The lack of many treatments relative to the number of human diseases, the need for additional robust support of rare disease research and continued need for a nimble organization that can address emerging public health crises such as the COVID-19 pandemic, are all reminders that there is much further to go in growing the translational science portfolio in an ever-changing scientific landscape.

NATIONAL INSTITUTES OF HEALTH
National Center for Advancing Translational Sciences

Appropriations History

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
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	$707,335,000	$713,849,000	$705,903,000
Rescission				$0
2018	$557,373,000	$718,867,000	$729,094,000	$742,354,000
Rescission				$0
2019	$685,087,000	$751,219,000	$806,787,000	$806,373,000
Rescission				$0
2020	$694,112,000	$845,783,000	$849,159,000	$832,888,000
Rescission				$0
Supplemental				$36,000,000
2021	$787,703,000	$840,051,000	$890,009,000	$855,421,000
Rescission				$0
2022	$878,957,000	$897,812,000	$878,072,000	$855,421,000
Rescission				$0
2023	$873,654,000			

[1] Budget Estimate to Congress includes mandatory financing.

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Authorizing Legislation

	PHS Act/ Other Citation	U.S. Code Citation	2022 Amount Authorized	FY 2022 CR	2023 Amount Authorized	FY 2023 President's Budget
Research and Investigation	Section 301	42§241	Indefinite	$855,421,000	Indefinite	$873,654,000
National Center for Advancing Translational Sciences	Section 401(a)	42§281	Indefinite		Indefinite	
Total, Budget Authority				$855,421,000		$873,654,000

NATIONAL INSTITUTES OF HEALTH

National Center for Advancing Translational Sciences

Amounts Available for Obligation [1]

(Dollars in Thousands)

Source of Funding	FY 2021 Final	FY 2022 CR	FY 2023 President's Budget
Appropriation	$855,421	$855,421	$873,654
Secretary's Transfer	-$2,568	$0	$0
OAR HIV/AIDS Transfers	$0	$0	$0
Subtotal, adjusted budget authority	$852,853	$855,421	$873,654
Unobligated balance, start of year	$0	$0	$0
Unobligated balance, end of year (carryover)	$0	$0	$0
Subtotal, adjusted budget authority	**$852,853**	**$855,421**	**$873,654**
Unobligated balance lapsing	-$61	$0	$0
Total obligations	$852,792	$855,421	$873,654

[1] Excludes the following amounts (in thousands) for reimbursable activities carried out by this account:
FY 2021 - $32,810 FY 2022 - $32,910 FY 2023 - $32,910

NATIONAL INSTITUTES OF HEALTH
National Center for Advancing Translational Sciences

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

		FY 2022 CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
Total compensable workyears:				
	Full-time equivalent	277	298	21
	Full-time equivalent of overtime and holiday hours	0	0	0
	Average ES salary	$204	$204	$0
	Average GM/GS grade	13.2	13.2	0.0
	Average GM/GS salary	$129	$135	$6
	Average salary, Commissioned Corps (42 U.S.C. 207)	$125	$130	$6
	Average salary of ungraded positions	$150	$157	$7
	OBJECT CLASSES	**FY 2022 CR**	**FY 2023 President's Budget**	**FY 2023 +/- FY 2022**
	Personnel Compensation			
11.1	Full-Time Permanent	$23,043	$25,511	$2,468
11.3	Other Than Full-Time Permanent	$13,538	$15,330	$1,793
11.5	Other Personnel Compensation	$1,345	$1,395	$50
11.7	Military Personnel	$334	$347	$13
11.8	Special Personnel Services Payments	$2,464	$2,556	$92
11.9	**Subtotal Personnel Compensation**	**$40,724**	**$45,139**	**$4,416**
12.1	Civilian Personnel Benefits	$13,435	$14,959	$1,524
12.2	Military Personnel Benefits	$285	$296	$11
13.0	Benefits to Former Personnel	$0	$0	$0
	Subtotal Pay Costs	**$54,444**	**$60,394**	**$5,950**
21.0	Travel & Transportation of Persons	$60	$311	$251
22.0	Transportation of Things	$126	$129	$3
23.1	Rental Payments to GSA	$0	$0	$0
23.2	Rental Payments to Others	$0	$0	$0
23.3	Communications, Utilities & Misc. Charges	$82	$84	$2
24.0	Printing & Reproduction	$0	$0	$0
25.1	Consulting Services	$21,414	$21,877	$463
25.2	Other Services	$83,474	$88,429	$4,955
25.3	Purchase of Goods and Services from Government Accounts	$52,396	$54,259	$1,862
25.4	Operation & Maintenance of Facilities	$464	$464	$0
25.5	R&D Contracts	$3,810	$7,244	$3,434
25.6	Medical Care	$2,389	$2,487	$98
25.7	Operation & Maintenance of Equipment	$5,786	$5,905	$118
25.8	Subsistence & Support of Persons	$0	$0	$0
25.0	**Subtotal Other Contractual Services**	**$169,733**	**$180,665**	**$10,931**
26.0	Supplies & Materials	$7,604	$6,839	-$765
31.0	Equipment	$3,222	$2,907	-$315
32.0	Land and Structures	$0	$0	$0
33.0	Investments & Loans	$0	$0	$0
41.0	Grants, Subsidies & Contributions	$620,149	$622,325	$2,175
42.0	Insurance Claims & Indemnities	$0	$0	$0
43.0	Interest & Dividends	$0	$0	$0
44.0	Refunds	$0	$0	$0
	Subtotal Non-Pay Costs	**$800,977**	**$813,260**	**$12,283**
	Total Budget Authority by Object Class	**$855,421**	**$873,654**	**$18,233**

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

NATIONAL INSTITUTES OF HEALTH

National Center for Advancing Translational Sciences

Salaries and Expenses

(Dollars in Thousands)

Object Classes	FY 2022 CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
Personnel Compensation			
Full-Time Permanent (11.1)	$23,043	$25,511	$2,468
Other Than Full-Time Permanent (11.3)	$13,538	$15,330	$1,793
Other Personnel Compensation (11.5)	$1,345	$1,395	$50
Military Personnel (11.7)	$334	$347	$13
Special Personnel Services Payments (11.8)	$2,464	$2,556	$92
Subtotal, Personnel Compensation (11.9)	**$40,724**	**$45,139**	**$4,416**
Civilian Personnel Benefits (12.1)	$13,435	$14,959	$1,524
Military Personnel Benefits (12.2)	$285	$296	$11
Benefits to Former Personnel (13.0)	$0	$0	$0
Subtotal Pay Costs	**$54,444**	**$60,394**	**$5,950**
Travel & Transportation of Persons (21.0)	$60	$311	$251
Transportation of Things (22.0)	$126	$129	$3
Rental Payments to Others (23.2)	$0	$0	$0
Communications, Utilities & Misc. Charges (23.3)	$82	$84	$2
Printing & Reproduction (24.0)	$0	$0	$0
Other Contractual Services			
Consultant Services (25.1)	$14,416	$14,725	$309
Other Services (25.2)	$83,474	$88,429	$4,955
Purchase of Goods and Services from Government Accounts (25.3)	$29,257	$31,973	$2,716
Operation & Maintenance of Facilities (25.4)	$464	$464	$0
Operation & Maintenance of Equipment (25.7)	$5,786	$5,905	$118
Subsistence & Support of Persons (25.8)	$0	$0	$0
Subtotal Other Contractual Services	**$133,396**	**$141,495**	**$8,099**
Supplies & Materials (26.0)	$7,604	$6,839	-$765
Subtotal Non-Pay Costs	**$141,268**	**$148,858**	**$7,590**
Total Administrative Costs	**$195,712**	**$209,253**	**$13,540**

NATIONAL INSTITUTES OF HEALTH
National Center for Advancing Translational Sciences

Detail of Full-Time Equivalent Employment (FTE)

Office	FY 2021 Final			FY 2022 CR			FY 2023 President's		
	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Office of the Director									
Direct:	7	-	7	8	-	8	9	-	9
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	7	-	7	8	-	8	9	-	9
Office of Administrative Management									
Direct:	47	-	47	48	-	48	51	-	51
Total:	47	-	47	48	-	48	51	-	51
Office of Grants Management and Scientific Review									
Direct:	33	-	33	37	-	37	39	-	39
Reimbursable:	1	-	1	1	-	1	1	-	1
Total:	34	-	34	38	-	38	40	-	40
Office of Rare Diseases Research									
Direct:	7	-	7	7	-	7	8	-	8
Total:	7	-	7	7	-	7	8	-	8
Office of Policy, Communications, and Education									
Direct:	15	-	15	16	-	16	17	-	17
Total:	15	-	15	16	-	16	17	-	17
Office of Strategic Alliances									
Direct:	8	-	8	9	-	9	9	-	9
Total:	8	-	8	9	-	9	9	-	9
Office of Special Initiatives									
Direct:	3		3	3		3	3		3
Reimbursable:	1		1	1		1	1		1
Total:	4	-	4	4	-	4	4	-	4
Office of Drug Development Partnership Programs									
Direct:	3		3	3		3	3		3
Reimbursable:	1		1	1		1	1		1
Total:	4	-	4	4	-	4	4	-	4
Office of Translational Medicine									
Direct:	4		4	4		4	4		4
Total:	4		4	4		4	4		4
Division of Pre-Clinical Innovation									
Direct:	74	1	75	99	1	100	109	1	110
Reimbursable:	5	-	5	5	-	5	5	-	5
Total:	79	1	80	104	1	105	114	1	115
Division of Clinical Innovation									
Direct:	25	2	27	33	1	34	36	1	37
Total:	25	2	27	33	1	34	36	1	37
Total	234	3	237	275	2	277	296	2	298
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
2019	13.1
2020	13.0
2021	13.2
2022	13.2
2023	13.2

NATIONAL INSTITUTES OF HEALTH
National Center for Advancing Translational Sciences

Detail of Positions [1]

GRADE	FY 2021 Final	FY 2022 CR	FY 2023 President's Budget
Total, ES Positions	1	1	1
Total, ES Salary	$199,300	$203,700	$203,700
General Schedule			
GM/GS-15	24	28	30
GM/GS-14	48	56	60
GM/GS-13	63	73	78
GS-12	22	26	27
GS-11	9	10	11
GS-10	0	0	0
GS-9	3	3	4
GS-8	0	0	0
GS-7	4	5	5
GS-6	0	0	0
GS-5	0	0	0
GS-4	0	0	0
GS-3	0	0	0
GS-2	0	0	0
GS-1	0	0	0
Subtotal	173	201	215
Commissioned Corps (42 U.S.C. 207)			
Assistant Surgeon General	0	0	0
Director Grade	1	1	1
Senior Grade	1	1	1
Full Grade	1	0	0
Senior Assistant Grade	0	0	0
Assistant Grade	0	0	0
Subtotal	3	2	2
Ungraded	77	89	95
Total permanent positions	180	186	200
Total positions, end of year	254	293	313
Total full-time equivalent (FTE) employment, end of year	237	277	298
Average ES salary	$199,300	$203,700	$203,700
Average GM/GS grade	13.2	13.2	13.2
Average GM/GS salary	$125,551	$128,941	$134,872

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