

National Center for Advancing Translational Sciences

CONGRESSIONAL JUSTIFICATION
FY 2022

Department of Health and Human Services
National Institutes of Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

National Center for Advancing Translational Sciences (NCATS)

<u>FY 2022 Budget Table of Contents</u>	<u>Page No.</u>
Director’s Overview.....	3
IC Fact Sheet.....	7
Major Changes in Budget Request	9
Budget Mechanism Table	10
Appropriations Language	11
Summary of Changes.....	12
Budget Graphs	13
Organization Chart	14
Budget Authority by Activity	15
Justification of Budget Request	16
Program Descriptions.....	16
Appropriations History	27
Authorizing Legislation	28
Amounts Available for Obligation	29
Budget Authority by Object Class	30
Salaries and Expenses	31
Detail of Full-Time Equivalent Employment (FTE)	32
Detail of Positions	33

Director's Overview

NIH's theme for the FY 2022 President's Budget, "Science in Service to Society," is particularly relevant for NCATS, since our mission is to address scientific and operational roadblocks in order to accelerate the development of treatments and cures. Science benefits society in many ways, and the most direct and tangible benefits for most people are the interventions – diagnostics, drugs, devices, behavioral treatments – that prevent and treat diseases that affect them. The efficiency and effectiveness of the process by which interventions are developed and implemented (called "translation") must be dramatically improved if these public health benefits are to be realized. NCATS was established in FY 2012 to address the wide and increasing disparity between basic scientific insights and successful interventions developed from these promising beginnings. NCATS develops and disseminates translational science knowledge, technologies, expertise, and collaborative networks that allow translational researchers working on different diseases to more effectively and efficiently advance their intervention development projects, including those for urgent public health needs and underrepresented or underserved populations.



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

Responding to Pressing Health Needs

The COVID-19 pandemic dominated research efforts in 2020 and 2021 and will likely do so for the next several years. It illustrated – as the opioid crisis has – the acute need to improve and speed translation and NCATS' central role in realizing that goal. Since the causes of translational inefficiency are similar across diseases, NCATS' translational science advances apply broadly. NCATS is well positioned to respond to pressing health needs and can shift rapidly to apply our technologies to changing disease-specific translational priorities. Thus, when the COVID-19 crisis hit in 2020, NCATS pivoted virtually all of its capacities and programs to addressing it. We generated and immediately made publicly available data on the activity of all approved drugs that could potentially be used to fight the SARS-CoV-2 virus, created new human cell-based 3D tissue and tissue chip models of COVID-19 to test potential therapies, and applied our drug development expertise to promising therapeutic approaches so they could be rapidly tested in the clinic. We marshalled the unique national resource that is the NCATS Clinical and Translational Science Awards (CTSA) Program and its Trial Innovation Network, to coordinate and perform myriad leading-edge clinical trials of potential COVID-19 treatments, including important trials of immunomodulators and convalescent plasma. And with the CTSA Program hubs and Center for Data to Health, we created the NCATS National COVID Cohort Collaborative (N3C), which is an unprecedented resource of privacy-protected COVID-19 patient data, that in less than four months aggregated the COVID-19 test data of one million patients in a secure federal enclave that is freely available to researchers to answer critical questions about COVID-19 susceptibility, response to treatment, and potential long-term health effects.

While NCATS' response to the COVID-19 pandemic is the single largest application of the Center's programs on a specific disease, befitting the unprecedented scope of the pandemic, we have pivoted multiple times in the past to address urgent health needs, each time making major contributions to their solutions and applying translational science innovations and learnings from each situation to subsequent NCATS programs. NCATS is playing a major role in the NIH response to the opioid epidemic, with preclinical drug development and clinical effectiveness trials that are part of the NIH Helping to End Addiction Long-termSM (HEAL) Initiative; similarly, NCATS rapidly produced and made public clinic-ready drug repurposing data during the Zika and Ebola epidemics.

Closing the Gap in Health Disparities

The stark disparities in COVID-19 incidence and death among racial and ethnic populations in our country have been one of the most painful aspects of the pandemic: African-American, Hispanic/Latino, and American Indians/Alaska Natives are contracting and dying from COVID-19 at rates more than double those of White and Asian populations. While the reasons are complex and under intense study, the immediate imperative is to do everything we can to reduce these disparities in prevention, diagnosis, and treatment of COVID-19.

A fundamental cause of such disparities, which are seen in other diseases like diabetes and hypertension, is the lack of inclusion of affected populations and communities in research at all levels. The opportunity for patients and communities to be included is not enough; like any relationship, the fundamental ingredient is trust. Trust in medical research has historically been lost in many minority communities, and its restoration requires persistent commitment and establishment of a track record of inclusion and benefit for all. NCATS views this as a critical translational science challenge, the solution of which is obligatory for the benefits of new interventions to reach all populations in need. For this reason, patient focus is a core value of all NCATS programs, and engaging patients and communities in every phase of the translational process is a key CTSA Program goal.

The CTSA Program hubs across the country have long prioritized the development of strong community engagement research programs and dedicated resources to building partnerships with community organizations and representatives. They are developing and sharing tools and resources to facilitate community engagement, educating researchers and communities, and engaging communities in the research process. These efforts have made the hubs trusted community partners and have enabled them to rapidly pivot to address COVID-19 health disparities. They are connecting with underserved and vulnerable populations and swiftly implementing strategies and interventions to reduce disparities and improve health outcomes for those who are disproportionately affected by the COVID-19 pandemic. Both the recently launched NIH RADxSM Underserved Populations (RADxSM-UP) program and the NIH Community Engagement Alliance (CEAL) Against COVID-19 Disparities initiative are utilizing the CTSA Program hubs' strong community partnerships and long-standing community-engaged research efforts across the country to facilitate the inclusion and participation of African Americans, Hispanic/Latinos, American Indian/Alaska Natives, and other groups in diagnostic testing and vaccine and therapeutic clinical trials.

Rural health disparities are also an important focus for NCATS. The community engagement research components of CTSA Program hubs in rural states are focused on increasing rural participation in clinical and translational research, and the Trial Innovation Network is testing new trial designs and remote technologies to increase the reach of clinical research into rural areas. To assure representation of rural and medically underserved populations in NCATS' signature COVID-19 data initiative, the N3C, NCATS partnered with the NIH National Institute of General Medical Sciences (NIGMS) to include patient data from Institutional Development Award Program Infrastructure for Clinical and Translational Research (IDeA-CTR) institutions.

Capitalizing on Foundational Investments

The current unprecedented opportunities in translation were brought about by decades of support for basic science, which has created the abundant discoveries that are the “seed corn” for subsequent translation. Analogous foundational investments in translational science only began with the creation of NCATS approximately 10 years ago. In that time, NCATS has made rapid progress in understanding and eliminating translational roadblocks and as a result, NCATS resources, activities, and research programs are now available to address emerging translational and public health issues such as the COVID-19 pandemic and highly needed gene therapies for rare diseases. The NCATS funding increase over the five past years has accelerated this progress and allowed the Center to address additional areas of opportunity and need. Within the Cures Acceleration Network (CAN) component of NCATS, the increase allowed the Tissue Chips program, Biomedical Data Translator data integrator, 3D human tissue printing for drug screening, and A Specialized Platform for Innovative Research Exploration, known as ASPIRE which is for automated chemistry/biology/informatics engineering platform, to all achieve prototypes in record time. Each of these efforts, which are further described below, promises to revolutionize productivity in current translational bottleneck areas. The CTSA Program Trial Innovation Network, a breakthrough national network for translational medicine, has allowed innovative clinical trials to be designed and performed rapidly for multiple interventions across dozens of diseases, including multiple pain indications in the NIH's HEAL InitiativeSM, and large multisite trials of convalescent plasma, immunomodulators, and other drugs for COVID-19. In rare diseases, which often have common molecular and genetic causes, NCATS has changed the paradigm for therapeutic development by shifting focus from working on one-disease-at-a-time to working on many-diseases-at-a-time. For example, NCATS is testing platform therapeutic approaches, such as in the PaVe-GT, or Platform Vector Gene Therapy, program, to develop gene therapy for four different rare diseases at the same time using a common delivery system.

Through these and other advances, NCATS is realizing its mission to transform the way interventions are developed and disseminated, in order to get more treatments to more people more quickly. Our systematic, disease-universal translational science approaches are enabling NCATS and its collaborators to achieve technological and therapeutic breakthroughs that are being rapidly disseminated to the entire research community for their utilization. In the coming years, we plan to further accelerate this progress using the lessons learned and novel paradigms and platforms created for the COVID-19 pandemic, applying our new capabilities and knowledge to accelerate treatments and cures for all human diseases.

Overall Budget Policy: The FY 2022 President's Budget request is \$879.0 million, an increase of \$23.5 million or 2.8 percent compared to the FY 2021 Enacted level. This increase will allow NCATS to pay non-competing grant awards at their committed levels and fund high priority new awards.



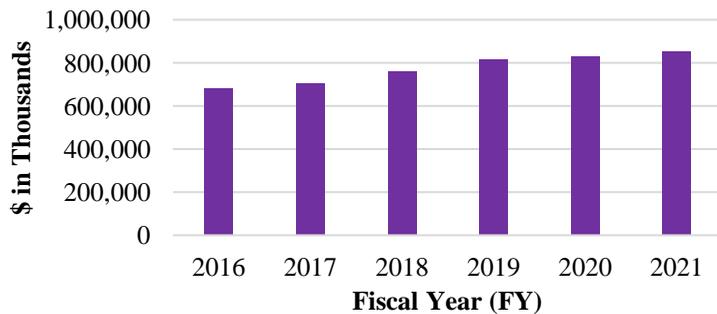
NCATS “Unique” Mission

NCATS was established in Fiscal Year 2012 to **shorten the journey from scientific observation to clinical intervention so that new treatments and cures for disease can reach patients faster**. The Center strives to develop innovations to reduce, remove, or bypass costly and time-consuming bottlenecks in the translational research pipeline to speed the delivery of new drugs, diagnostics, and medical devices to people who need them. NCATS studies translation on a system-wide level as a scientific and operational problem.



Joni L. Rutter, Ph.D., became the NCATS Acting Director on April 16, 2021. She is internationally recognized for her work in basic and clinical research in human genetics.

Appropriations History



FY 2022 President’s Budget (PB) is \$879.0 million.

NCATS Strategy for Bringing More Treatments to More People, More Quickly

With the aim of accelerating translational research to benefit all diseases and disorders, NCATS supports the development of innovative research tools and technologies, along with expertise and collaborative teams, that can quickly pivot to address urgent public health issues. In addition, by using its networks to draw together experts with necessary and complementary skills, knowledge, and experience, NCATS enables research projects to cut through operational roadblocks. These robust yet nimble approaches are being leveraged to address public health emergencies, including the opioid crisis and COVID-19 pandemic.

NCATS Facts (FY 2020):

- ~ 3,000 drugs and compounds in the NCATS Pharmaceutical Collection (NPC) for drug screening
- 60 Clinical and Translational Science Awards (CTSA) hubs
- One Trial Innovation Network, including three Trial Innovation Centers (TICs) and one Recruitment Innovation Center (RIC)
- The Rare Disease Clinical Research Networks (RDCRN) consists of 20 consortia studying more than 200 rare diseases
- 230 active intramural research collaborations
- 22 patents issued for NCATS’ inventions (2018-2020)

Developing More Treatments for More People, More Quickly

Identifying and Testing Potential Therapies

Faster: One potential strategy against SARS-CoV-2, the novel coronavirus behind the disease COVID-19 and a worldwide pandemic, is to use old drugs in new ways. This approach of drug repurposing can cut the time it takes to develop FDA-approved drugs from as long as 10 to 15 years to just one to two years.

- NCATS created a research resource, the **OpenData Portal**, to openly share COVID-19-related drug repurposing data and experiments. It built the portal by using SARS-CoV-2-related assays to screen over 10,000 compounds, including nearly 3,000 approved drugs in the **NCATS Pharmaceutical Collection**, for their activity against the virus.

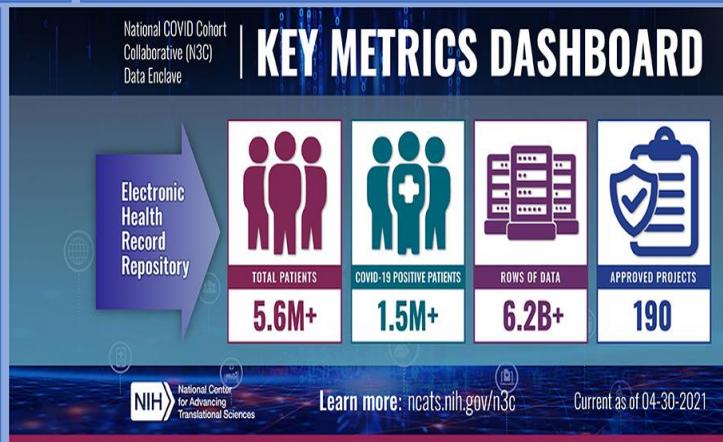
Improving the Conduct of Clinical Trials:

Clinical trials often struggle to recruit participants, leading to costly delays and even, in some cases, failure of a trial.

- The **Clinical and Translational Science Awards (CTSA) Program** and **Trial Innovation Network (TIN)** are supporting the expansion of two randomized placebo-controlled clinical trials to test convalescent plasma as a treatment in adults hospitalized with COVID-19. Trial investigators leveraged these NCATS-funded resources to add enrollment sites and recruit participants, including those from communities disproportionately affected by the pandemic.

Focusing on the Patient: Partnering and engaging with patients and communities is crucial, and NCATS looks for opportunities to include their perspectives in research efforts.

- For the millions of people living with a rare disease, COVID-19 presents challenges -- from reduced access to medical care to heightened anxiety and stress. The **Rare Diseases Clinical Research Network (RDCRN)** surveyed the rare diseases community to assess the impact of the pandemic on individuals with rare diseases, their families and their caregivers, better understand their needs, and inform future research efforts.
- NCATS is an active partner in the **NIH Community Engagement Alliance (CEAL) Against COVID-19 Disparities** to facilitate the inclusion and participation of African Americans, Hispanic/Latinos, American Indians and other groups in vaccine and therapeutic clinical trials. Several CEAL efforts have leveraged community engagement expertise and resources from NCATS' CTSA Program.



Making Data Accessible to Support Research:

- The **National COVID Cohort Collaborative (N3C)** quickly built a centralized national data enclave and analytics platform to systematically collect clinical, laboratory, and diagnostic data on COVID-19 treated patients. With over 70 participating institutions, including more than 40 CTSA Program hubs, the data enclave contains information from over 3.7 million patient records, which have been harmonized to facilitate data analysis and speed COVID-19 research. NCATS is the steward of the data, overseeing access and myriad data protections.

NATIONAL INSTITUTES OF HEALTH
National Center for Advancing Translational Sciences

Major Changes in the Fiscal Year 2022 President's Budget Request

The budget request for NCATS of \$879.0 million represents a \$23.5 million or 2.8 percent increase from the FY 2021 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 (+\$3.3 million; total \$63.1 million):

The total number of awards funded, excluding SBIR/STTR, will increase from 92 to 97 awards, and the number of non-competing awards funded will decrease from 63 to 52.

Research Centers (+\$0.8 million; total \$417.9 million):

NCATS will fund a total of 60 hub center awards under the Clinical and Translational Science Awards (CTSA) Program in FY 2022, the same number funded as in both FY 2020 and FY 2021.

Research and Development Contracts (+\$6.3 million; total \$75.6 million):

NCATS will increase support to the National COVID Cohort Collaborative (N3C) and Genetic and Rare Diseases Information Center (GARD) in FY 2022.

Research Management and Support (+\$7.3 million; total \$65.0 million):

Increased funding will support additional FTE staff as well as support trans-NIH initiatives, including a new cybersecurity effort, as well as other HHS-wide initiatives.

**NATIONAL INSTITUTES OF HEALTH
National Center for Advancing Translational Sciences**

Budget Mechanism - Total¹

(Dollars in Thousands)

MECHANISM	FY 2020 Final		FY 2021 Enacted		FY 2022 President's Budget		FY 2022 +/- FY 2021 Enacted	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
<u>Research Projects:</u>								
Noncompeting	51	\$41,784	63	\$44,827	52	\$41,415	-11	-\$3,413
Administrative Supplements	(4)	576	(11)	1,450	(1)	100	(-10)	-1,350
<u>Competing:</u>								
Renewal	0	0	0	0	0	0	0	0
New	34	16,100	29	13,432	45	21,563	16	8,131
Supplements	0	0	0	0	0	0	0	0
Subtotal, Competing	34	\$16,100	29	\$13,432	45	\$21,563	16	\$8,131
Subtotal, RPGs	85	\$58,460	92	\$59,710	97	\$63,078	5	\$3,368
SBIR/STTR	31	19,852	34	23,427	30	21,317	-4	-2,110
Research Project Grants	116	\$78,312	126	\$83,137	127	\$84,395	1	\$1,258
<u>Research Centers:</u>								
Specialized/Comprehensive	0	\$10,848	0	\$10,645	0	\$10,640	0	-\$4
Clinical Research	60	412,440	60	406,405	60	407,257	0	852
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	60	\$423,288	60	\$417,050	60	\$417,897	0	\$848
<u>Other Research:</u>								
Research Careers	60	\$58,914	60	\$59,747	60	\$61,995	0	\$2,247
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	37	41,237	38	40,634	27	43,883	-11	3,249
Other Research	97	\$100,152	98	\$100,381	87	\$105,877	-11	\$5,496
Total Research Grants	273	\$601,752	284	\$600,567	274	\$608,169	-10	\$7,602
<u>Ruth L. Kirschstein Training Awards:</u>								
	<u>FTTPs</u>		<u>FTTPs</u>		<u>FTTPs</u>		<u>FTTPs</u>	
Individual Awards	0	\$0	0	\$0	0	\$0	0	\$0
Institutional Awards	495	30,675	483	28,779	483	30,426	0	1,646
Total Research Training	495	\$30,675	483	\$28,779	483	\$30,426	0	\$1,646
Research & Develop. Contracts <i>(SBIR/STTR) (non-add)</i>	103 (8)	\$48,500 (4,932)	114 (6)	\$69,271 (1,558)	120 (6)	\$75,556 (3,908)	6 (0)	\$6,285 (2,350)
Intramural Research	56	98,896	83	99,086	105	99,811	22	725
Res. Management & Support <i>SBIR Admin. (non-add)</i>	131 (0)	53,065 (327)	156 (0)	57,717 (330)	172 (0)	64,995 (390)	16 (0)	7,278 (60)
Construction		0		0		0		0
Buildings and Facilities		0		0		0		0
Total, NCATS	187	\$832,888	239	\$855,421	277	\$878,957	38	\$23,536

¹ All items in italics and brackets are non-add entries.

**NATIONAL INSTITUTES OF HEALTH
National Center for Advancing Translational Sciences**

NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES

For carrying out section 301 and title IV of the PHS Act with respect to translational sciences, [~~\$855,421,000~~]~~\$878,957,000~~: Provided, That up to [~~\$60,000,000~~]*10 percent of the amounts made available under this heading* shall be available to implement section 480 of the PHS Act, relating to the Cures Acceleration Network[: Provided further, That at least \$586,841,000 is provided to the Clinical and Translational Sciences Awards program].

NATIONAL INSTITUTES OF HEALTH
National Center for Advancing Translational Sciences

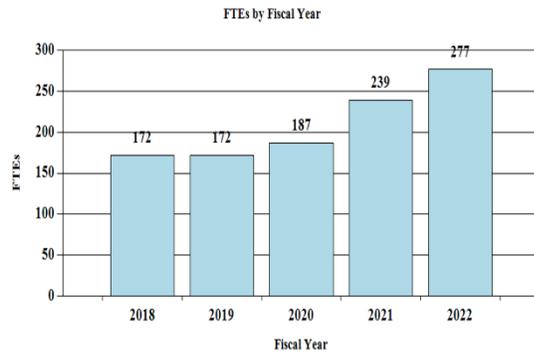
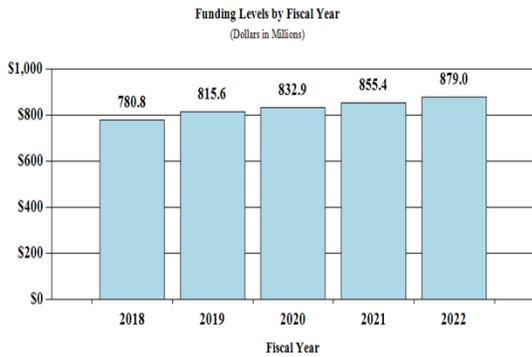
Summary of Changes

(Dollars in Thousands)

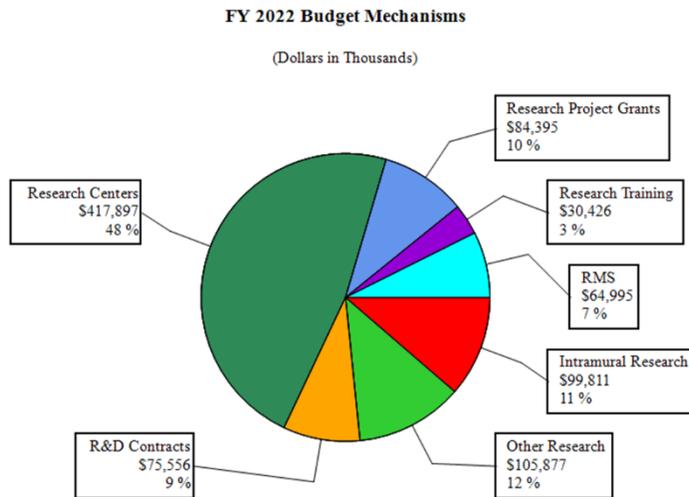
FY 2021 Enacted		\$855,421				
FY 2022 President's Budget		\$878,957				
Net change		\$23,536				
CHANGES	FY2021 Enacted		FY 2022 President's Budget		Built-In Change from FY 2021 Enacted	
	FTEs	Budget Authority	FTEs	Budget Authority	FTEs	Budget Authority
A. Built-in:						
1. Intramural Research:						
a. Annualization of January 2021 pay increase & benefits		\$12,229		\$21,668		\$33
b. January FY 2022 pay increase & benefits		12,229		21,668		330
c. Paid days adjustment		12,229		21,668		0
d. Differences attributable to change in FTE		12,229		21,668		3,449
e. Payment for centrally furnished services		3,569		3,747		178
f. Cost of laboratory supplies, materials, other expenses, and non-recurring costs		83,288		74,396		1,807
Subtotal						\$5,799
2. Research Management and Support:						
a. Annualization of January 2021 pay increase & benefits		\$27,546		\$33,135		\$76
b. January FY 2022 pay increase & benefits		27,546		33,135		755
c. Paid days adjustment		27,546		33,135		0
d. Differences attributable to change in FTE		27,546		33,135		2,843
e. Payment for centrally furnished services		263		276		13
f. Cost of laboratory supplies, materials, other expenses, and non-recurring costs		29,909		31,584		851
Subtotal						\$4,539
Subtotal, Built-in						\$10,338
CHANGES	FY2021 Enacted		FY 2022 President's Budget		Program Change from FY 2021 Enacted	
	No.	Amount	No.	Amount	No.	Amount
B. Program:						
1. Research Project Grants:						
a. Noncompeting	63	\$46,277	52	\$41,515	-11	-\$4,763
b. Competing	29	13,432	46	21,863	17	8,431
c. SBIR/STTR	34	23,427	29	21,017	-5	-2,410
Subtotal, RPGs	126	\$83,137	127	\$84,395	1	\$1,258
2. Research Centers	60	\$417,050	60	\$417,897	0	\$848
3. Other Research	98	100,381	87	105,877	-11	5,496
4. Research Training	483	28,779	483	30,426	0	1,646
5. Research and development contracts	114	69,271	120	75,556	6	6,285
Subtotal, Extramural		\$698,618		\$714,151		\$15,533
6. Intramural Research	<u>FTEs</u> 83	\$99,086	<u>FTEs</u> 105	\$99,811	<u>FTEs</u> 22	-\$5,074
7. Research Management and Support	156	57,717	172	64,995	16	2,738
8. Construction		0		0		0
9. Buildings and Facilities		0		0		0
Subtotal, Program	239	\$855,421	277	\$878,957	38	\$13,198
Total built-in and program changes						\$23,536

NATIONAL INSTITUTES OF HEALTH National Center for Advancing Translational Sciences

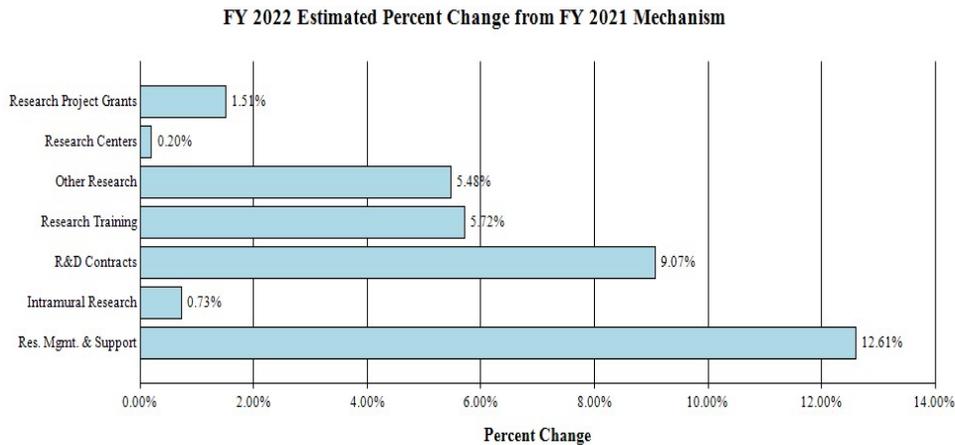
History of Budget Authority and FTEs:



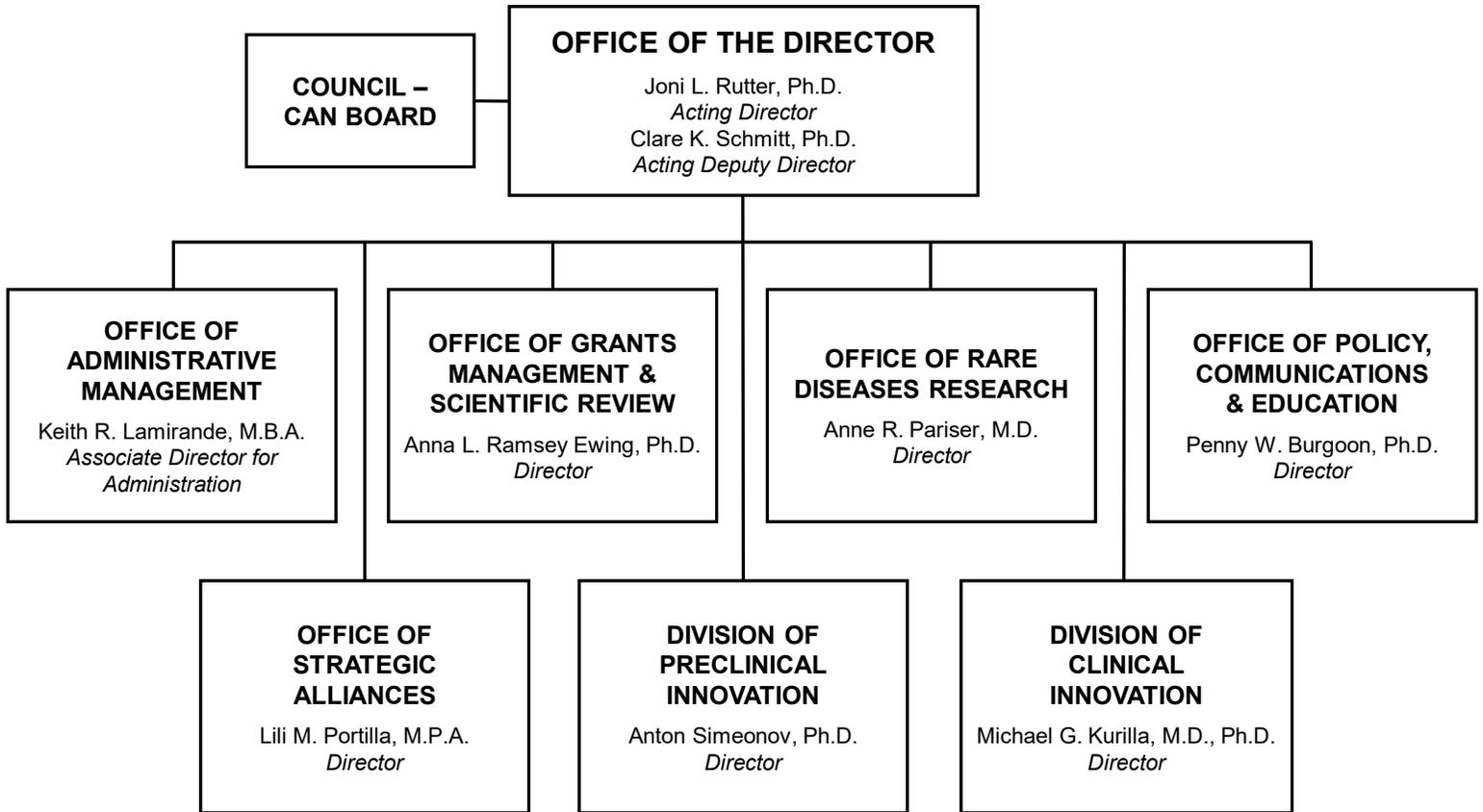
Distribution by Mechanism:



Change by Selected Mechanism:



NATIONAL INSTITUTES OF HEALTH
National Center for Advancing Translational Sciences



NATIONAL INSTITUTES OF HEALTH
National Center for Advancing Translational Sciences

Budget Authority by Activity¹
(Dollars in Thousands)

Budget Activity²	FY 2020 Final		FY 2021 Enacted		FY 2022 President's Budget		FY 2022 +/- FY 2021 Enacted	
	FTE	Amount	FTE	Amount	FTE	Amount	FTE	Amount
Clinical and Translational Science Activities	22	\$578,146	26	\$586,841	35	\$601,512	9	\$14,671
Cures Acceleration Network	7	49,100	8	56,000	10	57,400	2	1,400
Reengineering Translational Sciences	158	205,642	205	212,580	232	220,045	27	7,465
TOTAL	187	\$832,888	239	\$855,421	277	\$878,957	38	\$23,536

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

**NATIONAL INSTITUTES OF HEALTH
National Center for Advancing Translational Sciences**

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 2020 Final	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
BA	\$832,888,000	\$855,421,000	\$878,957,000	+\$23,536,000
FTE	187	239	277	+38

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

Program Descriptions and Accomplishments

NCATS’ mission serves society by accelerating the translation of scientific research for improved human health. The Center supports efforts that reduce, remove, or bypass costly and time-consuming bottlenecks impeding the development of effective medical interventions. Since its creation in 2011, NCATS has made great strides in addressing translational science roadblocks. Yet, these are still early days for applying translational science and shifting thinking about translational research. Traditionally, translational research has been considered a “pipeline” where basic science moves through the pipeline as that understanding translates to improved human health. A pipeline suggests that there is no change from the beginning to the end, just movement. Yet many scientific discoveries fail to translate into successful treatments. This is the entire premise for why NCATS exists: to try to apply the scientific method to understanding why translation is often unsuccessful and learn new ways to improve translation and increase our chances of success. NCATS’ systematic, disease-universal translational science approach enables NCATS to conduct and support research where opportunities emerge. NCATS investigators and collaborators can achieve breakthroughs that are then disseminated back to the clinical and translational community for their application. This includes the current COVID-19 pandemic, where NCATS has readily applied its translational science tools, technologies, expertise, and collaborative networks to address this urgent public health issue.

NCATS is organized in a manner to promote a nimble approach to conducting and supporting translational science research. As such, our activities (as described below) are organized into three high level areas: 1) scientific and operational innovations to accelerate the translation of clinical research, 2) high-risk, transformative efforts for high-need cures: Cures Acceleration Network (CAN), and 3) scientific and operational innovations to re-engineer translation of biomedical research discoveries. All NCATS programs and initiatives described crosscut our organizational units and are focused on reducing silos, fostering communications and collaborations, applying innovation, and creating economies of scale.

NATIONAL INSTITUTES OF HEALTH
National Center for Advancing Translational Sciences

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 hubs forms the backbone of the program in addressing important roadblocks in clinical translation by working locally, regionally, and nationally. The Program's **Trial Innovation Network (TIN)** is a national collaboratory to test novel recruitment and participant engagement strategies, data-driven approaches for participant identification and trial site selection, and adaptive trial designs to respond to information gained throughout a trial. The TIN is being leveraged in the NIH Helping to End Addiction Long-termSM (HEAL) Initiative Pain Management Effectiveness Research Network, which is comparing the effectiveness of existing pain treatments and new approaches to prevent and manage pain while reducing the risk of opioid addiction. The **National Center for Data to Health (CD2H)** develops and coordinates network-wide efforts that explore and test ways to utilize and share clinical data more efficiently (see the program portrait below).

Ready and Responsive to a National Health Emergency

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

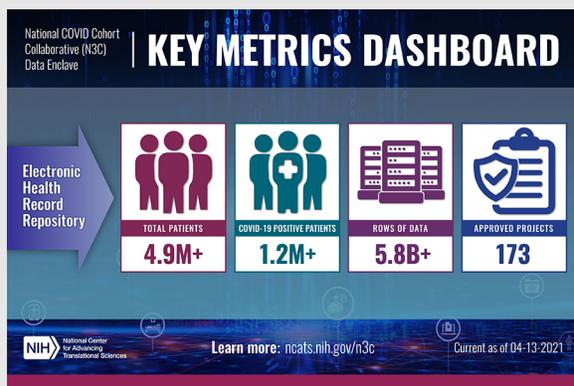
Rapid Activation and Expansion of Randomized Clinical Trials to Test COVID-19 Therapies: NCATS CTSA Program is a fully functioning national network of clinical trial-ready institutions, capable of addressing complex clinical research needs. NCATS and the CTSA Program have deployed the resources and expertise to rapidly expand two clinical trials to test use of convalescent plasma as a therapy for COVID-19. Convalescent plasma is the liquid part of blood from individuals who have recovered from COVID-19, and preliminary observational studies indicate that convalescent plasma may improve outcomes among severely ill and hospitalized patients with COVID-19. Plasma contains antibody proteins that may help fight infection.¹ As part of the NIH Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) initiative, NCATS is also coordinating and overseeing a large clinical trial to evaluate the safety and efficacy of three immune modulator drugs in hospitalized adults with COVID-19.

¹ ncats.nih.gov/news/releases/2020/nih-expands-clinical-trials-to-test-convalescent-plasma-against-covid-19

NATIONAL INSTITUTES OF HEALTH
National Center for Advancing Translational Sciences

National COVID Cohort Collaborative (N3C)

Health care providers have utilized multiple treatment approaches for COVID-19, and a standard of care for this novel disease is still being established. There are vast amounts of clinical data being generated, which could advance research efforts to improve patient care, but the information is stored in different formats and the process of agreeing to share data involves time-consuming negotiations. 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 national network of CTSA Program hub institutions, and the CTSA Center for Data to Health (CD2H) met the call for action, formed the **National COVID Cohort Collaborative**, and created the platform to store and manage the data, the **N3C Data Enclave**. The N3C is focused on providing a centralized, national data source of harmonized patient data rapidly accessible to researchers for studying COVID-19. CD2H has been instrumental in the development of the N3C operations and shared governance model of the collaborative. The CTSA Program hub 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.

This trial uses an adaptive master protocol, which will enable coordinated and efficient evaluation of multiple investigational agents as they become available.²

Making COVID-19 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 data from COVID-19 patients in the United States. See the Program Portrait for more details and visit the N3C website for up-to-date information.³

Closing the Gap in Health Disparities and Rural Health

NCATS is committed to having its programs reduce health disparities and the significant burden of conditions that disproportionately affect rural, minority, and other underserved populations. NCATS expanded the CTSA Program network with outreach to include institutions able to address the needs of medically underserved communities. The Center changed the eligibility requirements of the **CTSA Collaborative Innovation Awards** to include NIGMS-funded NIH Institutional Development Award Program Infrastructure for Clinical and Translational Research (IDeA-CTR) institutions. NIGMS also provided administrative supplements to IDeA-CTR institutions to

collaborate with NCATS by contributing COVID-19 patient data to the **National COVID Cohort Collaborative**, thereby making COVID-19 patient information from rural communities available for study. In addition, NCATS is participating in a trans-NIH initiative, **Implementing a Maternal health and PRenancy Outcomes Vision for Everyone (IMPROVE)**, to comprehensively address issues associated with maternal mortality. Eligible CTSA hubs will receive administrative supplements to understand and eliminate health disparities among

² ncats.nih.gov/news/releases/2020/nih-begins-large-clinical-trial-to-test-immune-modulators-for-treatment-of-covid-19

³ ncats.nih.gov/n3c

NATIONAL INSTITUTES OF HEALTH
National Center for Advancing Translational Sciences

populations disproportionately affected by maternal morbidity and mortality. The IMPROVE approach will also address geographic disparities and social determinants of health, including socioeconomic standing.

Towards Strengthening the CTSA Program

To identify ways to improve the efficiency and effectiveness of clinical research and translational science, NCATS asked numerous stakeholders for input on ways to strengthen the CTSA Program. Recurring themes from the input included needs, such as increased flexibility and diversity across hubs; sharing best practices, tools, and materials; developing uniform guidance for research, training, and education; and, enhancing ways to support and reward teams. NCATS will use these ideas to enhance the CTSA Program in the future. NCATS will share any planned updates for the CTSA Program with the House and Senate Appropriations Committees. NCATS also plans to create a new **CTSA Program Small Grants Program** to support small self-contained research projects with a goal of addressing roadblocks in translational science and/or operations that limit the efficiency and effectiveness of translation. Support will be provided for a variety of clinical and translational science research projects, including pilot and feasibility studies, secondary data analysis of existing data, small, self-contained research projects, development of research methodology, and development of new research technology.

Budget Policy: The FY 2022 President's Budget request for Clinical and Translational Science Activities is \$601.5 million, an increase of \$14.7 million or 2.5 percent compared with the FY 2021 Enacted level. NCATS will maintain the same number of CTSA hubs as funded in FY 2021, which is 60 hubs.

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

The **Cures Acceleration Network (CAN)** supports transformative efforts to advance the development of high-need cures and reduce significant barriers between research discovery and clinical trials. CAN provides NCATS with authorities for programs and initiatives that are highly innovative in both their scientific strategies and operational management and that have tremendous potential to be applied broadly to numerous diseases and disorders, if successful. Below are highlighted CAN-supported programs.

Developing New Approaches to Connecting and Translating Existing Data

Researchers and clinicians generate seemingly endless amounts of data and information, which can be found in a multitude of forms such as databases, electronic health records, and clinical trial research libraries. These data are often siloed and 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. A potential solution to this problem, **NCATS Biomedical Data Translator Program (Translator)** is a multi-phase effort that will, in effect, develop a data translator that will bridge these data types and enable the exploration of novel data relationships. With completion of the feasibility phase, NCATS is funding new teams

NATIONAL INSTITUTES OF HEALTH
National Center for Advancing Translational Sciences

of scientists, physicians, bioinformaticists, and programmers to begin the development phase of the Translator.

Human Cell-Based Modeling: Tissue Chips and Three Dimensional (3-D) Biofabricated Tissues

Human cell-based models are becoming a highly valuable approach to address significant issues in translating from early stage disease modeling to late stage therapeutic testing. Tissue chips — small, 3-D bioengineered devices using human tissues that model human organs — could improve drug testing and development by predicting more accurately how safe and effective drugs are before they are tested in people. The **CAN Tissue Chips Program** is now moving to exploring how to inform clinical trials planning and execution. This project will generate highly needed information regarding the potential use of tissue chips to inform clinical trial design and elucidate the disease biology; inform an understanding of past trial successes and failures; assist with the selection of drug candidates for clinical trials; and improve the selection of patient populations and identification of reliable clinical trial endpoints. In addition, when the COVID-19 pandemic struck, investigators began researching if tissue chips could help speed the development of COVID-19 treatments. A lung-on-a-chip project initially funded to study influenza infection and its use for drug screening was able to rapidly pivot to testing existing antiviral therapies for their potential to treat COVID-19. NCATS has successfully supported intramural-extramural pilot collaborations to develop and implement the use of biofabricated 3-D skin tissue models for drug screening by providing evidence that, together with accompanying relevant assay readouts, these models can be used as robust in vitro drug screening platforms. The **NCATS 3-D Tissue Bioprinting laboratory** can print high-density skin tissues and develop corresponding assays for drug screening platforms. In order to provide further evidence for the advantages of 3-D models for drug screening, the next step for the program is to develop platforms with additional disease tissues models.

Rare Disease Gene Therapy Strategies and Common Barriers

While many gene therapy trials are underway, all gene therapy programs face common barriers, such as manufacturing bottlenecks, that cause multiyear delays and drive costs up. The CAN Review Board identified gene therapy for rare diseases as a high need area where NCATS can have a great and immediate positive impact by identifying and/or eliminating barriers to future product development. As a result, NCATS is hosting workshops with several partners to address important barriers, such as developing more platforms, addressing capacity for vector manufacturing, and understanding immune responses. NCATS also initiated the **Platform Vector Gene Therapy (PaVe-GT)** pilot program to test 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. Expansion of this program is requested for FY 2022. In addition, building on the initial successes of PaVe-GT, NCATS is establishing a **Consortium for Innovation in Large-Scale Gene Vector Production**, which will aim to reduce the bottleneck related to gene vector production. The Consortium will focus on providing clinical grade vectors for academic and government-funded clinical trials, but standardization and data sharing efforts will benefit the private sector as well. These efforts will

NATIONAL INSTITUTES OF HEALTH
National Center for Advancing Translational Sciences

address and remove the translational research roadblocks that are slowing the development of gene therapies for rare and neglected diseases, which currently have no commercial interest.

Designing Chemical Compounds Important to Biology

Designing and developing new biologically active chemicals is largely a manual, artisanal process, and more than 99.9 percent of the possible chemicals that could be biologically relevant remain unexplored. A **Specialized Platform for Innovative Research Exploration (ASPIRE)** builds on the power of recent and emerging automated, technological innovations and will utilize information-based science to address issues in the field of chemistry, including the lack of standardization and low reproducibility and predictability of chemical behavior.

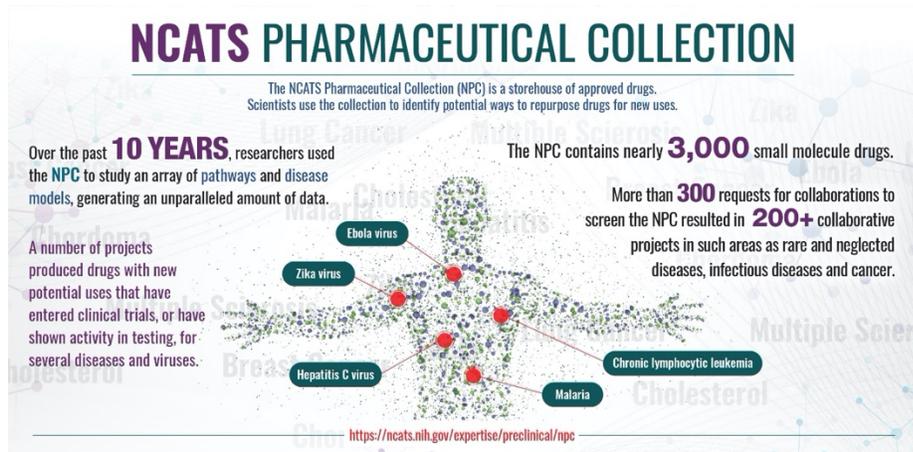
As a companion to the ASPIRE technology and platform development, the **NCATS ASPIRE Design Challenges** were launched to encourage innovative and catalytic approaches toward solving the opioid crisis and are supported through NIH's HEAL InitiativeSM. The 2018 ASPIRE Design Challenge solicited proposals for innovative and catalytic approaches toward solving the opioid crisis by developing next-generation addiction-free analgesics using new chemistries, data-mining tools, and analytical technologies. The 2020 ASPIRE Reduction-to-Practice Challenge seeks promising approaches for developing a working prototype that integrates four Design Challenge areas: a chemistry database, an electronic synthetic chemistry portal, predictive algorithms, and biological assays. Working prototypes of an integrated platform will be sent to one or more NCATS-designated laboratories for independent validation and testing.

Budget Policy: The FY 2022 President's Budget request for the Cures Acceleration Network is \$57.4 million, an increase of \$1.4 million or 2.5 percent compared with the FY 2021 Enacted level.

III. Scientific and Operational Innovations to Re-engineer Translation of Biomedical Research Discoveries

Several thousand diseases affect humans, and only about 500 have any treatment. A novel drug can take 10 to 15 years and more than \$2 billion to develop, and about 95 percent of human studies fail. Numerous scientific and operational roadblocks limit the speed of progress. Translation is a "team sport," therefore, tackling important translational hurdles includes both intramural and extramural programs and collaborations between them and external partners. As described below, NCATS has several important programs focused on re-engineering different aspects of translational research. NCATS strategically identifies opportunities to solve roadblocks that enable getting more treatments to more people more quickly.

NATIONAL INSTITUTES OF HEALTH
National Center for Advancing Translational Sciences
Strategies for Repurposing Drugs and Therapeutics



One important strategy for getting more treatments to more patients more quickly is to understand what existing molecules, drugs, or approved treatments may be able to be used for a different purpose. NCATS has robust programs focused on repurposing.

Repurposing existing drugs for new uses can speed the drug development process. Never has this strategy been more important than during the COVID-19 pandemic. The **NCATS Pharmaceutical Collection (NPC)** is a comprehensive, publicly accessible collection of approved 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 possible interventions. The 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. Testing of approved drugs saves time and money as the drugs have been extensively tested in humans and animal models, and detailed information is available on each drug, such as side effects, mode of action, formulation, and potential toxicity. Easy access to this information is critical during the COVID-19 pandemic, when there is an urgent need to quickly identify and test potential therapeutics.

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 Foundation for the National Institutes of Health (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

Another strategy for repurposing drugs leverages the power of crowdsourcing through the **CURE ID**. Created through a collaboration between the U.S. Food and Drug Administration (FDA) and NCATS, CURE ID is a platform that enables the crowdsourcing of medical information from health care professionals to facilitate the development of new treatments using repurposed drugs for difficult-to-treat infectious diseases. The CURE ID app was recently updated to boost the platform's effectiveness to address the COVID-19 pandemic. The app includes frequently updated information on most clinical trials submitted to clinicaltrials.gov for COVID-19 drugs, biologics, and vaccines.

NATIONAL INSTITUTES OF HEALTH
National Center for Advancing Translational Sciences

Harnessing Translational Science Strategies for Rare Disease

The juxtaposition of the words “rare” and “public health” may seem like a contradiction, but 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. Like our ongoing challenge program indicates, rare diseases are not rare.⁴ 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.

NCATS has developed a 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, getting ready for clinical trials, developing therapeutics, and working collaboratively with the community.

Engaging the Public: It is essential for the public to have readily accessible and clear information about rare diseases. The Genetics and Rare Diseases Information Center (GARD) provides a public service not available elsewhere. As an information “clearinghouse,” GARD provides understandable information on rare diseases to the public and individual inquiry services to rare diseases patients and families.

Application of Informatics to Rare Diseases: It can be exceedingly difficult to access, organize, and understand different types of data, particularly for rare diseases. NCATS is applying the power of data informatics approaches in different ways to rare diseases through a new **Rare Disease Informatics Platform (RDIP)** detailed in the Program Portrait. In addition, with the volume of rare diseases information, inquiries, and website traffic increasing substantially each year, NCATS is striving to incorporate machine-learning techniques into GARD to maintain timely and accurate rare diseases trusted-source information easily accessible by the public. The GARD information knowledge base will also be expanded into the RDIP in an effort to further understand and communicate rare diseases data and information.

Rare Disease Clinical Trial Readiness: Many Americans living with a rare disease have difficulty getting an effective treatment, and only around 5 percent of rare diseases currently have an FDA-approved therapy. To close this gap in care, NCATS created the **Clinical Trial**

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. A 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, in collaboration with NCATS, United States and Australian academic and industrial partners, aims to develop methodology that can more accurately estimate rare disease prevalence and healthcare utilization applicable to multiple rare diseases across different healthcare information systems.

⁴ ncats.nih.gov/funding/challenges/rare-diseases-challenge-2020

NATIONAL INSTITUTES OF HEALTH
National Center for Advancing Translational Sciences

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. This may include biomarker assessment and validation, clinical outcome assessment (COA) development and validation, animal models, or identifying populations. The goal is to improve the chances that these candidate therapies or diagnostics will succeed in clinical trials.

Addressing Roadblocks to Gene Therapy: Because treatments for rare diseases are so highly needed but difficult to pursue, NCATS is leveraging the Cures Acceleration Network, or CAN, to address high need issues related to the development of gene therapies for rare diseases. The **Platform Vector Gene Therapy (PaVe-GT) program** (described under CAN) is testing a standardized process using the same gene-delivery vehicle (vector) and methods for four different rare diseases. If successful, it will significantly increase the efficiency of gene therapy trial startup.

Working in Collaborative Teams: 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. This close partnership 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 launched an online survey to find out how the pandemic is impacting individuals with rare diseases, their families, and their caregivers, and is collaborating with the National Institute of Allergy and Infectious Diseases (NIAID) to assess the impact of COVID-19 on rare disease patients. 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.

Enabling Therapeutics Development

To get more treatments to more patients more quickly, it is essential to enable more efficient therapeutics development at early and later translational stages. In the Division of Preclinical Innovation, 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. New directions for ETB include creation of an antibody probe development group, highly important in light of the COVID-19 pandemic, expansion of tools for guiding probe development, partnering across NCATS divisions/offices/programs to foster translational science fellow training, and to expand resources for the Assay Guidance Manual, a free, best-practices online resource devoted to the successful development of robust, early-stage drug discovery assays.

Later stage pre-clinical therapeutics development helps break bottlenecks in the drug development process, using specific projects as use case examples. NCATS Division of Preclinical Innovation **Therapeutics Development Branch (TDB)** provides a collaborative

NATIONAL INSTITUTES OF HEALTH
National Center for Advancing Translational Sciences

science model which is unprecedented in its efficiency in developing treatments, particularly for rare diseases, to the point at which biopharmaceutical companies will adopt them for clinical trials and regulatory approval. NCATS works intentionally in this unpredictable stage of therapy development that is particularly expensive and failure prone. Many research projects are abandoned at this stage because they are deemed too risky for industry investment, thus preventing potentially life-saving treatments from reaching patients. Project teams “de-risk” therapeutic candidates and make them more attractive for adoption by outside business partners, a strategy that may prove fruitful as NCATS pivots to leveraging this program for COVID-19.

Emerging Ethical Considerations in Translational Science

A newer area that NCATS has recently begun exploring is the role of ethical issues in translational science. As NCATS continues to address important translational science roadblocks and leverage new technological innovations in doing so, it is essential that research also be considered and conducted in the context of an ethical framework. The NCATS **Translational Ethics Collaboratories Program** will support sustainable trans-disciplinary collaborative teams with expertise and flexibility to anticipate and conduct research in ethical issues, including legal and societal implications, of an emerging area of translational science. The program is designed to provide models for collaboration across disciplines, institutions, and approaches needed to address known and emerging ethical issues in designing and conducting research in moving novel discoveries and technologies to improve human health. Each collaboratory will provide outreach to translational science research community, including providing ethics research consultations in their area of expertise.

Rapid Diagnostics to Address Translational Roadblocks

The overall goal of the **Scanning for Conditions with Electronic Nose Technology, or SCENT, Program** is to foster the development of and to deploy noninvasive and portable diagnostics devices that enable healthcare providers to save time and lives by more quickly pinpointing what tests are necessary and what treatment options are most appropriate. Planned for FY 2022, SCENT seeks to advance novel biosensing technologies that are innovative, safe, and effective using integrated artificial intelligence, pattern recognition, and machine learning systems that would make it possible for the detection, diagnosis, prediction, and monitoring of diseases in clinical, community, and everyday settings. Given the urgency of the COVID-19 pandemic, the NIH Rapid Acceleration of Diagnostics Radical (RADx-rad) Program selected the NCATS SCENT program specifically to develop a noninvasive, portable sensing device to detect volatile organic compounds (VOCs, i.e., scents or odors) emanating from skin or oral cavities associated with symptomatic and asymptomatic COVID-19 patients.

Translational Scientists: Training for the Future

Developing the next generation of translational scientists is a priority for NCATS. How can NCATS continue working to get more treatments to more patients more quickly if there is a limited workforce specifically trained to research translational science roadblocks in the laboratory and the clinic? While the NCATS CTSA Program already has robust training and career development activities, NCATS is also exploring additional strategies and opportunities to

NATIONAL INSTITUTES OF HEALTH
National Center for Advancing Translational Sciences

train the next generation of translational scientists. One example is the **NCATS-FDA Translational Science fellowship**, a Translational Science Interagency Fellowship (TSIF) program initiated to train a cadre of postdoctoral and staff scientists in translational science research and research-related regulatory review. This effort, recently established through a partnership between NCATS, FDA, and the U.S. Department of Health and Human Services (HHS), will create a workforce with a combined skill set that can work across the translational science spectrum and move new technologies, products, or translational processes forward more efficiently. Fellows in this program will build awareness of regulatory requirements into the early stages of the technology development, preclinical, and clinical translational science process, plus develop strategies to improve planning throughout research and regulatory review.

Budget Policy: The FY 2022 President's Budget request for Reengineering Translational Sciences is \$220.0 million, an increase of \$7.5 million or 3.5 percent compared with the FY 2021 Enacted level.

Summary

Six strategic principles guide NCATS' focus and its programs: catalytic, generalizable, innovative, collaborative, patient-focused, and measurable.⁵ NCATS is making progress addressing translational roadblocks, yet rare diseases, the lack of many treatments relative to the number of diseases, and the COVID-19 pandemic are reminders that there is much more to do. As NCATS focuses on the future, it strives to address more translational hurdles. The future is in the power of data: analyzing it in new and different ways and sharing it widely in order to ensure that science is conducted in service to society.

⁵ ncats.nih.gov/strategicplan/principles

**NATIONAL INSTITUTES OF HEALTH
National Center for Advancing Translational Sciences**

Appropriations History

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
2013	\$639,033,000		\$631,346,000	\$575,366,498
Rescission				\$1,150,733
Sequestration				(\$28,879,442)
2014	\$665,688,000		\$661,264,000	\$633,267,000
Rescission				\$0
2015	\$657,471,000			\$635,230,000
Rescission				\$0
2016	\$660,131,000	\$643,111,000	\$699,319,000	\$685,417,000
Rescission				\$0
2017 ¹	\$685,417,000	\$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			

¹ Budget Estimate to Congress includes mandatory financing.

**NATIONAL INSTITUTES OF HEALTH
National Center for Advancing Translational Sciences**

Authorizing Legislation

	PHS Act/ Other Citation	U.S. Code Citation	2021 Amount Authorized	FY 2021 Enacted	2022 Amount Authorized	FY 2022 President's Budget
Research and Investigation National Center for Advancing Translational Sciences	Section 301	42§241	Indefinite	\$855,421,000	Indefinite	\$878,957,000
	Section	42§281	Indefinite		Indefinite	
Total, Budget Authority				\$855,421,000		\$878,957,000

NATIONAL INSTITUTES OF HEALTH
National Center for Advancing Translational Sciences

Amounts Available for Obligation¹

(Dollars in Thousands)

Source of Funding	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget
Appropriation	\$832,888	\$855,421	\$878,957
Mandatory Appropriation: (non-add)			
<i>Type 1 Diabetes</i>	(0)	(0)	(0)
<i>Other Mandatory financing</i>	(0)	(0)	(0)
Rescission	0	0	0
Sequestration	0	0	0
Secretary's Transfer	0	0	0
Subtotal, adjusted appropriation	\$832,888	\$855,421	\$878,957
OAR HIV/AIDS Transfers	0	0	0
HEAL Transfer from NINDS	0	0	0
Subtotal, adjusted budget authority	\$832,888	\$855,421	\$878,957
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	\$832,888	\$855,421	\$878,957
Unobligated balance lapsing	-32	0	0
Total obligations	\$832,856	\$855,421	\$878,957

¹ Excludes the following amounts (in thousands) for reimbursable activities carried out by this account:

FY 2020 - \$17,288 FY 2021 - \$14,000 FY 2022 - \$12,746

NATIONAL INSTITUTES OF HEALTH
National Center for Advancing Translational Sciences

Budget Authority by Object Class¹

(Dollars in Thousands)

	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021 Enacted
Total compensable workyears:			
Full-time equivalent	239	277	38
Full-time equivalent of overtime and holiday hours	0	0	0
Average ES salary	\$199	\$205	\$5
Average GM/GS grade	13.0	13.0	0.0
Average GM/GS salary	\$127	\$128	\$2
Average salary, Commissioned Corps (42 U.S.C. 207)	\$107	\$110	\$3
Average salary of ungraded positions	\$178	\$183	\$5
OBJECT CLASSES	FY 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
Personnel Compensation			
11.1 Full-Time Permanent	18,951	23,250	4,299
11.3 Other Than Full-Time Permanent	7,703	14,130	6,428
11.5 Other Personnel Compensation	1,105	1,434	329
11.7 Military Personnel	432	444	12
11.8 Special Personnel Services Payments	1,727	1,766	39
11.9 Subtotal Personnel Compensation	\$29,917	\$41,025	\$11,108
12.1 Civilian Personnel Benefits	9,414	13,322	3,909
12.2 Military Personnel Benefits	444	456	12
13.0 Benefits to Former Personnel	0	0	0
Subtotal Pay Costs	\$39,774	\$54,803	\$15,029
21.0 Travel & Transportation of Persons	256	261	5
22.0 Transportation of Things	102	104	2
23.1 Rental Payments to GSA	0	0	0
23.2 Rental Payments to Others	0	0	0
23.3 Communications, Utilities & Misc. Charges	200	204	4
24.0 Printing & Reproduction	0	0	0
25.1 Consulting Services	17,826	17,682	-145
25.2 Other Services	80,453	71,406	-9,047
25.3 Purchase of goods and services from government accounts	54,578	58,473	3,895
25.4 Operation & Maintenance of Facilities	5,840	5,841	0
25.5 R&D Contracts	4,994	9,084	4,090
25.6 Medical Care	3,173	3,290	117
25.7 Operation & Maintenance of Equipment	3,582	3,646	64
25.8 Subsistence & Support of Persons	0	0	0
25.0 Subtotal Other Contractual Services	\$170,447	\$169,423	-\$1,024
26.0 Supplies & Materials	7,963	8,107	143
31.0 Equipment	7,330	7,462	132
32.0 Land and Structures	0	0	0
33.0 Investments & Loans	0	0	0
41.0 Grants, Subsidies & Contributions	629,347	638,595	9,249
42.0 Insurance Claims & Indemnities	0	0	0
43.0 Interest & Dividends	2	0	-2
44.0 Refunds	0	0	0
Subtotal Non-Pay Costs	\$815,647	\$824,154	\$8,507
Total Budget Authority by Object Class	\$855,421	\$878,957	\$23,536

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 2021 Enacted	FY 2022 President's Budget	FY 2022 +/- FY 2021
Personnel Compensation			
Full-Time Permanent (11.1)	\$18,951	\$23,250	\$4,299
Other Than Full-Time Permanent (11.3)	7,703	14,130	6,428
Other Personnel Compensation (11.5)	1,105	1,434	329
Military Personnel (11.7)	432	444	12
Special Personnel Services Payments (11.8)	1,727	1,766	39
Subtotal Personnel Compensation (11.9)	\$29,917	\$41,025	\$11,108
Civilian Personnel Benefits (12.1)	\$9,414	\$13,322	\$3,909
Military Personnel Benefits (12.2)	444	456	12
Benefits to Former Personnel (13.0)	0	0	0
Subtotal Pay Costs	\$39,774	\$54,803	\$15,029
Travel & Transportation of Persons (21.0)	\$256	\$261	\$5
Transportation of Things (22.0)	102	104	2
Rental Payments to Others (23.2)	0	0	0
Communications, Utilities & Misc. Charges (23.3)	200	204	4
Printing & Reproduction (24.0)	0	0	0
Other Contractual Services:			
Consultant Services (25.1)	17,826	17,682	-145
Other Services (25.2)	80,453	71,406	-9,047
Purchases from government accounts (25.3)	33,085	36,499	3,414
Operation & Maintenance of Facilities (25.4)	5,840	5,841	0
Operation & Maintenance of Equipment (25.7)	3,582	3,646	64
Subsistence & Support of Persons (25.8)	0	0	0
Subtotal Other Contractual Services	\$140,787	\$135,075	-\$5,713
Supplies & Materials (26.0)	\$7,963	\$8,107	\$143
Subtotal Non-Pay Costs	\$149,309	\$143,749	-\$5,559
Total Administrative Costs	\$189,083	\$198,552	\$9,469

NATIONAL INSTITUTES OF HEALTH
National Center for Advancing Translational Sciences

Detail of Full-Time Equivalent Employment (FTE)

OFFICE/DIVISION	FY 2020 Final			FY 2021 Enacted			FY 2022 President's		
	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Division of Clinical Innovation									
Direct:	20	2	22	24	2	26	33	2	35
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	20	2	22	24	2	26	33	2	35
Division of Pre-Clinical Innovation									
Direct:	48	1	49	80	1	81	99	1	100
Reimbursable:	6	-	6	5	-	5	5	-	5
Total:	54	1	55	85	1	86	104	1	105
Office of Administrative Management									
Direct:	37	-	37	45	-	45	47	-	47
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	37	-	37	45	-	45	47	-	47
Office of Grants Management and Scientific Review									
Direct:	31	-	31	34	-	34	37	-	37
Reimbursable:	2	-	2	-	-	-	-	-	-
Total:	33	-	33	34	-	34	37	-	37
Office of Policy, Communications, and Education									
Direct:	14	-	14	14	-	14	16	-	16
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	14	-	14	14	-	14	16	-	16
Office of Rare Diseases Research									
Direct:	6	-	6	6	-	6	7	-	7
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	6	-	6	6	-	6	7	-	7
Office of Strategic Alliances									
Direct:	6	-	6	7	-	7	8	-	8
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	6	-	6	7	-	7	8	-	8
Office of the Director									
Direct:	13	-	13	20	-	20	21	-	21
Reimbursable:	1	-	1	1	-	1	1	-	1
Total:	14	-	14	21	-	21	22	-	22
Total	184	3	187	236	3	239	274	3	277
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								
2018	12.6								
2019	13.1								
2020	13.0								
2021	13.0								
2022	13.0								

**NATIONAL INSTITUTES OF HEALTH
National Center for Advancing Translational Sciences**

Detail of Positions¹

GRADE	FY 2020 Final	FY 2021 Enacted	FY 2022 President's Budget
Total, ES Positions	1	1	1
Total, ES Salary	196,146	199,400	204,783
General Schedule			
GM/GS-15	27	27	28
GM/GS-14	40	42	44
GM/GS-13	43	56	66
GS-12	21	24	28
GS-11	7	4	6
GS-10	0	0	0
GS-9	7	7	7
GS-8	0	0	0
GS-7	3	3	3
GS-6	0	1	1
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	148	164	183
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	1	1
Senior Assistant Grade	0	0	0
Assistant Grade	0	0	0
Subtotal	3	3	3
Ungraded	63	71	90
Total permanent positions	152	168	187
Total positions, end of year	215	239	277
Total full-time equivalent (FTE) employment, end of year	187	239	277
Average ES salary	196,146	199,400	204,783
Average GM/GS grade	13.0	13.0	13.0
Average GM/GS salary	124,504	126,544	128,442

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