

National Center for Advancing Translational Sciences

Triennial Report on Monitoring Adherence to the NIH Policy on the Inclusion of Women and Minorities in Clinical Research (FY 2019 - 2021)

I. Overview

A. NCATS Mission

The mission of the National Center for Advancing Translational Sciences (NCATS) at the National Institutes of Health (NIH) is to catalyze the generation of innovative methods and technologies that will enhance the development, testing and implementation of diagnostics and therapeutics across a wide range of human diseases and conditions.

Several thousands of diseases affect humans, of which about 500 have any FDA-approved treatment. NCATS was officially established in fiscal year 2012 to transform the process of how science is translated from a discovery into treatments, so that cures for disease can be delivered to patients faster. NCATS strives to develop innovations to reduce, remove or bypass costly and time-consuming bottlenecks in the research pipeline to speed the delivery of new drugs, diagnostics and medical devices to patients.

Translation is the process of turning observations in the laboratory and clinic into interventions that improve the health of individuals and the public, and NCATS studies it as a science, focused on understanding the scientific and operational principles underlying each step of the translational process. Rather than targeting a particular disease, NCATS focuses on common features of diseases and common processes of research translation where an innovation may have broad applications and benefit.

B. NCATS Portfolio

The Center is actively testing this translational science strategy through its programs and initiatives. The NCATS Office of Rare Diseases' Platform Vector-Gene Therapy (PaVe-GT) project tests the efficiency of gene therapy trials by using the same gene delivery vehicle and manufacturing methods for four different rare diseases. This project is also foundational to a larger NIH platform effort, the Bespoke Gene Therapy Consortium of The Accelerating Medicines Partnership® (AMP®) program. In addition, through programs in its Division of Pre-Clinical Innovation (DPI), the Center drives advances in early stages of the translational process, from target validation to first-in-human studies. The NCATS DPI intramural research program has many in-kind partnerships that help advance clinical studies conducted by their collaborators. By building partnerships, NCATS enables other ICs to leverage their funding for clinical research. When other NIH ICs use NCATS resources to carry out their clinical studies, those ICs report the inclusion enrollment data. So, although NCATS is deeply involved in clinical research, the collaborating ICs usually report on the participants

in the research. Occasionally, NCATS awards, such as small business development awards (SBIR/STTR), may include clinical studies.

Through its Division of Clinical Innovation, NCATS supports clinical and translational research, creating and sharing the expertise, tools and training needed to develop and deploy effective treatments in people. Through the Office of the Director, NCATS has established a centralized national data resource – the NCATS National COVID Cohort Collaborative (N3C) Data Enclave – that the research community is using to study COVID-19 and identify potential treatments as the pandemic continues to evolve. Our cross-cutting programs in rare diseases, translational technologies, strategic alliances, and other emerging areas address common scientific and organizational barriers to enable faster and more effective interventions that tangibly improve human health. NCATS’ Clinical and Translational Science Awards (CTSA) program is the largest program within NCATS and focuses on applying innovation through a network of meritorious institutions to improve the conduct of clinical research.

Finally, NCATS has no contracts involving clinical research during fiscal years (FY) 2019-2021. This report covers inclusion enrollment for NCATS extramural research studies from FY 2019 to 2021.

II. Strategies for Ensuring Compliance

NCATS uses several strategies in their program development to support the inclusion of a diverse population in clinical studies and workforce development. Funding announcements contain language requiring that women and minorities be included in all clinical research studies, as appropriate for the scientific goals of the work proposed. The former ([PAR-18-940](#)), and recent CTSA funding announcements ([PAR-21-293](#)) state that the application review and award decisions will include consideration of efforts to include special populations such as children, the elderly, rural populations, minorities, pregnant women, people with disabilities, and hard-to-reach populations. Applicants are encouraged to describe plans to collaborate with other centers to leverage resources for participant diversity and to set specific goals for inclusion of populations with health disparities.

NCATS ensures that all applicants, peer reviewers, NCATS science review officers, program officers and grants management officers are aware of the NIH policy on inclusion on the basis of sex/gender, race, ethnicity, and age in clinical research. Internet resources are available for NCATS staff to learn about [including diverse populations in clinical research](#).

A. Peer Review

For proposed research projects, inclusion is first addressed in peer review. Reviewers on NIH peer review panels are given specific [guidance](#) (please see https://grants.nih.gov/grants/peer/guidelines_general/Review_Human_subjects_Inclusion.pdf) on reviewing inclusion on the basis of sex/gender, race, ethnicity, and age when considering clinical research applications.

Reviewers evaluate applications for the appropriateness of the proposed plan for inclusion by sex/gender, race and ethnicity and age.

Unacceptable inclusion plans must be reflected in the priority score of the application and documented in the Summary Statement. Initial review groups make recommendations as to the acceptability of the proposed study population with respect to the inclusion policies. If issues are raised in review, program staff notify principal investigators, who are required to address these issues prior to funding. Applications with unacceptable inclusion plans receive a bar to funding; an award is not issued until an acceptable resolution is received.

The NCATS Inclusion Policy Officer is available to review the resolution of unacceptable inclusion plans and to concur on revised plans before plans are considered appropriate.

B. Program Monitoring and Grants Management Oversight

Prior to award, program staff are responsible for reviewing the inclusion information in the application and Summary Statement and indicating whether the plans are scientifically appropriate. Program staff monitor actual enrollment progress in annual progress reports and consult with investigators when necessary. Grants management staff ensure that appropriate terms and conditions of award are included in Notices of Award, and that information is appropriately documented in the official grant file.

C. Intramural

Although the NCATS Division of Pre-clinical Investigation provides resources for clinical research supported by other NIH ICs, at present it does not support any clinical research on its own. Therefore, this report does not include intramural inclusion reporting.

D. NCATS training approaches

All new scientific staff attend the NIH Core Curriculum. NCATS extramural staff also attend trainings presented by the NCATS Extramural Staff Training and Learning Initiative (NESTLI). NESTLI is a program that provides staff the training needed to develop knowledge and competencies in NCATS relevant policies and procedures. As part of NESTLI, NCATS Program Officials/Program Directors and Scientific Review Officers attended training on April 16, 2021: "Council Closed Session Preparation", which included the handling of inclusion issues arising as a result of peer review. Grants management staff participates in continuous training in areas of policy, process, and leadership and are required to be certified by the NIH Grants Management Certification Review Board every three years. Staff can access the archived training on the NIH staff intranet. Finally, the NCATS Inclusion Policy Officer is available to provide training and guidance to staff.

III. Analysis and Interpretation of Data

Tables of NCATS inclusion data are provided in the appendix to this report. Inclusion enrollment data by Research Condition and Disease Categorization (RCDC) category are available through this link:

<https://report.nih.gov/RISR/>.

As shown in Table 2-1, the number of NCATS inclusion enrollment records for extramural studies decreased by approximately 6% between FY 2019 and 2022. Most studies involve populations in the United States and the majority include both male and female participants (~70%). Of the studies involving only one sex, the data show more females than males. These numbers have been affected by the erroneous inclusion of two relatively large studies that focused on issues affecting females only; they have been corrected in the database. No NIH-defined Phase III clinical trials are being supported in 2021, consistent with NCATS authorizing language which precludes support of NIH-Defined Phase III trials, except for the provision in the 21st Century Cures Act, which allows the conduct of Phase III clinical trials investigating rare diseases (<https://ncats.nih.gov/files/PHS-act-update.pdf>)¹ and studies supported under the [Accelerating COVID-19 Therapeutic Interventions and Vaccines](#) (ACTIV) public-private partnership coordinated by the Foundation for the National Institutes of Health, which includes the Biomedical Advanced Research and Development Authority (BARDA), Centers for Disease Control and Prevention (CDC), and the U.S. Food and Drug Administration (FDA); other government agencies including the Department of Defense (DOD) and Department of Veterans Affairs (VA); The Operation (formerly known as Operation Warp Speed); the European Medicines Agency (EMA); and representatives from academia, philanthropic organizations, and numerous biopharmaceutical companies.

NCATS' total inclusion numbers are relatively small (Table 2-1) because CTSA-leveraged activities, which represent the majority of the NCATS budget, are reported by other NIH entities. Examples are supplements to CTSA institutions as part of the Rapid Acceleration of Diagnostics-Underserved Populations initiative, [RADx Programs | National Institutes of Health \(NIH\)](#), and also as part of the NIH Community Engagement Alliance (CEAL) Against COVID-19, [Community Engagement Alliance \(CEAL\) Against COVID-19 Disparities | Community Engagement Alliance \(nih.gov\)](#). The NCATS inclusion enrollment records for extramural studies show decreased minority participation in research between FY 2019 and 2021 (Table 5-1-1-C). The numbers of female clinical research participants surpassed the number of male participants. The participation of Hispanic

¹ 42 USC 287: National Center for Advancing Translational Sciences
As amended by the 21st Century Cures Act

(b) CLINICAL TRIAL ACTIVITIES.—

(1) IN GENERAL.—The Center may develop and provide infrastructure and resources for all phases of clinical trials research. Except as provided in paragraph (2), the Center may support clinical trials only through the end of phase IIB.

(2) EXCEPTION.—The Center may support clinical trial activities through the end of phase III for a treatment for a rare disease or condition (as defined in section 360b of title 21) so long as—

(A) the Center gives public notice for a period of at least 120 days of the Center's intention to support the clinical trial activities in phase III;

(B) no public or private organization provides credible written intent to the Center that the organization has timely plans to further the clinical trial activities or conduct clinical trials of a similar nature beyond phase IIB; and

(C) the Center ensures that support of the clinical trial activities in phase III will not increase the Federal Government's liability beyond the award value of the Center's support.

Metrics Based on Inclusion Data Records (IERS)

Table 2-1. Total NCATS Inclusion Data Records (IERS) for NIH-Defined Extramural and Intramural Clinical Research Reported Between Fiscal Years 2019 and 2021

Fiscal Year	Total IERS	IERS Without Enrollment	IERS With Enrollment	US Site IERS	Non-US Site IERS	Female Only IERS	Male Only IERS	IERS Excluding Male only and Female only*
2019	420	200	220	219	1	38	8	174
2020	581	353	228	226	2	36	9	183
2021	449	262	187	185	2	33	9	145

*Inclusion Data Records (IERS) excluding male only and female only include unknown sex/gender, and combination of unknown and any sex/gender(s).

Total Enrollment: All NIH-Defined Clinical Research

Table 5-1-1-C. Enrollment for NCATS: All NIH-Defined Clinical Research, Sex/Gender by Race and Ethnicity
Reported Between Fiscal Years 2019 and 2021

Fiscal Year	Sex Gender	Minority	% Minority	Total Enrollment	% Total	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2019	Female	3,944	38.7	10,199	41.9	6,286	61.6	2,052	20.1	1,861	18.2
2019	Male	2,758	36.9	7,466	30.6	4,419	59.2	1,401	18.8	1,646	22.0
2019	Unknown	1,244	18.6	6,698	27.5	3,227	48.2	443	6.6	3,028	45.2
2020	Female	5,819	41.0	14,185	43.2	7,796	55.0	1,846	13.0	4,543	32.0
2020	Male	5,005	40.3	12,431	37.9	6,689	53.8	1,479	11.9	4,263	34.3
2020	Unknown	776	12.5	6,219	18.9	1,989	32.0	325	5.2	3,905	62.8
2021	Female	4,772	24.0	19,861	67.9	14,652	73.8	855	4.3	4,354	21.9
2021	Male	3,631	43.3	8,390	28.7	3,578	42.6	648	7.7	4,164	49.6
2021	Unknown	104	10.3	1,013	3.5	158	15.6	0	0.0	855	84.4

Fiscal Year	Sex Gender	American Indian Alaska Native	% American Indian Alaska Native	Asian	% Asian	Black African American	% Black African American	Native Hawaiian Pacific Islander	% Native Hawaiian Pacific Islander	White	% White	More Than One Race	% More Than One Race	Unknown Not Reported	% Unknown Not Reported
2019	Female	95	0.9	439	4.3	1,279	12.5	17	0.2	4,880	47.8	450	4.4	3,039	29.8
2019	Male	54	0.7	393	5.3	874	11.7	19	0.3	3,270	43.8	184	2.5	2,672	35.8
2019	Unknown	38	0.6	260	3.9	313	4.7	10	0.1	2,939	43.9	203	3.0	2,935	43.8
2020	Female	38	0.3	413	2.9	1,634	11.5	12	0.1	6,047	42.6	2,091	14.7	3,950	27.8
2020	Male	22	0.2	404	3.2	1,253	10.1	15	0.1	5,215	42.0	2,001	16.1	3,521	28.3
2020	Unknown	16	0.3	134	2.2	195	3.1	4	0.1	1,793	28.8	106	1.7	3,971	63.9
2021	Female	73	0.4	312	1.6	1,629	8.2	12	0.1	13,009	65.5	2,057	10.4	2,769	13.9
2021	Male	22	0.3	220	2.6	854	10.2	9	0.1	2,764	32.9	2,072	24.7	2,449	29.2
2021	Unknown	1	0.1	3	0.3	88	8.7	0	0.0	48	4.7	12	1.2	861	85.0

The data presented in this report show only inclusion data records labeled as prospective data. Inclusion data records labeled as existing data are excluded.