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 2016 - 2018)

I. Background/Overview

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.

NCATS was officially established in fiscal year 2012 to transform the translational science process so that new treatments and cures for disease can be delivered to patients faster. NCATS, one of 27 Institutes and Centers (ICs) at NIH, 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 patients.

NCATS develops, demonstrates, and disseminates innovations that reduce, remove, or bypass system-wide bottlenecks in the translational science process. NCATS defines translation as the process of turning observations in the laboratory and clinic into interventions that improve the health of individuals and the public – from diagnostics and therapeutics to medical procedures and behavioral changes. Translational science is the field of investigation focused on understanding the scientific and operational principles underlying each step of the translational process. Rather than targeting a particular disease, NCATS focuses on what is common across diseases and the translational process. The central challenge that NCATS and the translational science field face is that the development of new medical interventions takes too long, costs too much, and too often ends in failure. It can take on average 14 years and $1 billion to $2 billion to develop a new drug, with a failure rate exceeding 95 percent. Additionally, of the thousands of diseases that affect humans, only about 500 have any FDA-approved treatment. NCATS programs and initiatives span the translational science spectrum, which covers each stage of research. These stages include basic research, pre-clinical research, clinical research, clinical implementation, and public health. The translational process is multidirectional; starting at any stage and potentially going directly to any other stage.

NCATS' organization of divisions and offices span the entire spectrum of translational science. Through programs in its Division of Pre-Clinical Innovation, the Center drives advances in early stages of the translational process, from target validation to first-in-human 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. 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.

The Clinical and Translational Science Awards (CTSA) program is the largest program within NCATS and, provides resources for other NIH institutes and centers (ICs) to support clinical research. The NCATS 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.

Finally, NCATS has no contracts involving clinical research during fiscal years (FY) 2016-2018.

This report covers inclusion enrollment for NCATS extramural research studies from FY 2016 to 2018.

II. Strategies for Ensuring Compliance

The NCATS program development process involves several strategies 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 (RFA-TR-14-009), and recent CTSA funding announcement (PAR-18-940) 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 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.

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 reviews the resolution of unacceptable inclusion plans and must 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, 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 Program Officials/Program Directors and Scientific Review Officers attended training on May 11, 2018: *Ensuring Inclusion in NIH Clinical Research: Policies and Procedures for Grants and Contracts.* 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 guidance to staff.

III. Analysis and Interpretation of Data

Tables of NCATS inclusion data are provided in the appendix to this report. As shown in Table 2-1, the number of NCATS inclusion enrollment records for extramural studies increased by approximately 20% between FY 2016 and 2018. Most studies involve populations in the United States and the majority include both male and female participants. Of the studies involving only one sex, most recently more have included females than males. Note that NCATS authorizing language 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]

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[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;

Therefore, this report includes no enrollment data for Phase III clinical trials. Additionally, as stated, the NCATS intramural program did not support clinical research during FY 2016-2018.

The NCATS inclusion enrollment records for extramural studies show increased minority participation in research between FY 2016 and 2018 (Table 5-1-1-C). The numbers of male and female clinical research participants were roughly comparable each year. The participation of Hispanic populations has steadily increased, with equivalent numbers of male and female Hispanic participants each year.

NCATS recognizes the importance of diversity in its research. For FY 2019, NCATS has a plan for increasing minority participation and expects to see significant increases in FY2019 and beyond. Congressional report language in 2018 noted the importance of translational science and education for improving public health. Starting in FY 2019, NCATS intends to leverage the CTSA Program to improve health outcomes for rural, minority, and special populations.

NCATS intends to apply our innovative translational science paradigm to addressing health disparities in vulnerable and underserved populations. In FY 2019, NCATS plans to conduct a workshop on rural and health disparities research to identify systemic roadblocks to progress and potential solutions. The Center will build on these efforts with the development of a new CTSA Program funding opportunity for FY 2020 funding, which will develop and test clinical and translational research solutions to health disparities, including rural health outcomes, underserved, and vulnerable populations. The number of awards funded under the CTSA program, the largest research program at NCATS, was 57 in FY 2016 and 2017, and increased to 58 in FY 2018 (See https://ncats.nih.gov/ctsa/funding/table for additional information about studies funded under the CTSA program).

(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.

In January 2019, data on the sex/gender, race and ethnicity of participants in NCATS clinical research by research, condition, and disease category will be available on the NIH RePORT website at https://report.nih.gov/RISR/.

IV. Additional information

The 21st Century Cures Act, enacted December 13, 2016 included several new requirements related to inclusion of participants in clinical research. As a result, NIH updated its policy on the Inclusion of Women and Minorities on November 28, 2017 to require studies that are both NIH-defined Phase III clinical trials applicable clinical trials to report the results of analyses by sex/gender and/or race/ethnicity to ClinicalTrials.gov. This requirement is effective for competing grant awards on December 13, 2017, contract solicitations and intramural studies initiated after this date. Additionally, NIH revised its Inclusion of Children Policy on December 19, 2017. The revised policy, now called the NIH Policy and Guidelines on the Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects, applies to individuals of all ages and requires reporting of participant age at enrollment in annual progress reports. The policy is effective for applications submitted or after January 25, 2019, and contract solicitations and intramural studies initiated after this date.

The 21st Century Cures Act amended the frequency of the Report of the Director of NIH on the inclusion of women and minorities from biennial to triennial. Thus, this first triennial report includes provides information on inclusion of participants in NIH clinical research from FY 2016 – 2018. Section IV of the FY 2015 and FY 2016 Report of the Advisory Committee on Research on Women's Health includes IC reports on monitoring adherence to the NIH Policy on the Inclusion of Women and Minorities as Subjects in Clinical Research, as will the current report for fiscal years 2017 and 2018.

Appendix

Section 2: Metrics Based on Inclusion Data Records (IDRs)

Table 2-1. NCATS Total Inclusion Data Records (IDRs) for NIH-Defined Extramural and Intramural Clinical Research Reported Between FY 2016 and FY 2018

Fiscal Year	Total IDRs	IDRs Without Enrollment	IDRs With Enrollment	US Site IDRs	Non-US Site IDRs	Female Only IDRs	Male Only IDRs	IDRs Excluding Male-only and Female-only*
2016	32	5	27	24	3	2	3	22
2017	92	19	73	72	1	13	5	55
2018	229	42	187	186	1	33	8	146

* Inclusion Data Records (IDRs) 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. NCATS Enrollment for All NIH-Defined Clinical Research, Sex/Gender by Race and Ethnicity

Year	Sex Gender	Minority	% Minority	Total Enrollment	% Total	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2016	Female	558	23.9	2,339	58.5	1,769	75.6	127	5.4	443	18.9
2016	Male	817	49.3	1,657	41.4	1,398	84.4	84	5.1	175	10.6
2016	Unknown	0	0.0	3	0.1	1	33.3	0	0.0	2	66.7
2017	Female	1,570	44.9	3,499	52.2	2,585	73.9	528	15.1	386	11.0
2017	Male	1,685	53.3	3,162	47.2	2,457	77.7	375	11.9	330	10.4
2017	Unknown	9	23.7	38	0.6	5	13.2	6	15.8	27	71.1
2018	Female	3,653	41.8	8,729	54.4	4,125	47.3	2,004	23.0	2,600	29.8
2018	Male	2,802	39.3	7,124	44.4	3,341	46.9	1,491	20.9	2,292	32.2
2018	Unknown	84	42.2	199	1.2	64	32.2	65	32.7	70	35.2

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
2016	Female	13	0.6	233	10.0	161	6.9	3	0.1	1,807	77.3	28	1.2	94	4.0
2016	Male	16	1.0	578	34.9	130	7.8	1	0.1	869	52.4	19	1.1	44	2.7
2016	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	1	33.3	0	0.0	2	66.7
2017	Female	19	0.5	568	16.2	419	12.0	4	0.1	2,082	59.5	77	2.2	330	9.4
2017	Male	16	0.5	979	31.0	298	9.4	4	0.1	1,571	49.7	37	1.2	257	8.1
2017	Unknown	0	0.0	0	0.0	4	10.5	0	0.0	3	7.9	2	5.3	29	76.3
2018	Female	143	1.6	824	9.4	845	9.7	13	0.1	3,366	38.6	349	4.0	3,189	36.5
2018	Male	92	1.3	797	11.2	548	7.7	18	0.3	2,686	37.7	160	2.2	2,823	39.6
2018	Unknown	0	0.0	1	0.5	20	10.1	0	0.0	23	11.6	4	2.0	151	75.9

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