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 as Reported in FY2022–FY2024

I. Background/Overview

The National Institutes of Health (NIH) is required by the Public Health Service Act sec. 492B, 42 U.S.C. sec. 289a-2 to ensure the inclusion of women and racial and/or ethnic minority groups in all NIH-funded clinical research, in a manner that is appropriate to the scientific question under study. The goal of this requirement is to ensure that research findings can be generalized to the entire population.

The NIH Revitalization Act of 1993 (Public Law 103-43) further required the inclusion of women and racial and/or ethnic minority groups in all NIH-funded clinical research to ensure broad representation. The Act also mandates the Advisory Council of each NIH Institute and Center (IC) to prepare a biennial report detailing how the institute has complied with requirements. The 21st Century Cures Act later amended the reporting frequency from biennial to triennial. The 21st Century Cures Act further requires NIH to provide the inclusion data by Research, Condition and Disease Categorization (RCDC) on a website accessible to the public.

To adhere to these mandates, NIH has established policies and guidelines for the inclusion of women and racial and/or ethnic minorities as subjects in clinical research. Additionally, NIH ICs, including the National Center for Advancing Translational Sciences (NCATS), prepare triennial reports detailing their compliance with the inclusion policies. These reports analyze participant demographics and strategies to improve the inclusion of broad populations in clinical studies. The reports further analyze whether populations were included in a manner appropriate to the scientific question under study and the prevalence of the specific disease/condition in the population or subpopulation. This triennial report details how NCATS has adhered to the requirements for the inclusion of women and racial and/or ethnic minorities in NIH-defined clinical studies for fiscal years 2022–2024 (FY22–FY24).

A. NCATS Mission Statement

NCATS' mission is to turn research observations into health solutions through translational science, with the goal of delivering more treatments for all people more quickly. The center conducts and supports research and other activities that address long-standing challenges in translational research. NCATS studies this process as a science, focusing 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 shared processes of research translation where an innovation may have broad applications and benefits. This approach helps develop multiple treatments simultaneously, building models that better predict a person's response to treatment and improving clinical trials to ensure the results represent the entire population.

NCATS was officially established on Dec. 23, 2011, with the mission of transforming the translational process to accelerate the delivery of new treatments and cures to patients. The center focuses on developing innovations to reduce, eliminate or bypass costly and time-consuming bottlenecks in the research pipeline, ultimately speeding the availability of new drugs, diagnostics and medical devices. Although thousands of diseases affect humans, only about 500 currently have an FDA-approved treatment. To address this challenge, NCATS fosters collaboration across government, academia, industry and patient advocacy groups,

understanding that the successful translation of scientific discoveries into treatments requires partnerships. No single entity can achieve this alone. In this context, NCATS leads innovative and collaborative initiatives programs in translational science, not only generating impact through its own efforts but also providing broad benefits by collaborating with the scientific community as a whole.

The center leverages the power of data, cutting-edge technologies and collaborative teamwork. NCATS serves as a crucial connector, helping various elements of the research ecosystem work together more effectively and driving progress in medical discovery and treatment.

B. NCATS Research Portfolio

NCATS' research portfolio includes a broad range of activities to address long-standing challenges in translational research and transforming research observations into health solutions. The center is testing this translational science strategy through its programs and initiatives.

NCATS' portfolio for inclusion reporting includes studies supported by the following Divisions and Offices:

Extramural Research

- Division of Clinical Innovation (DCI)
- Division of Rare Diseases Research Innovation (DRDRI)
- Office of Drug Development Partnership Programs (ODDPP)
- Office of Special Initiatives (OSI)
- Office of Strategic Alliances (OSA)
- Office of Translational Medicine (OTM)

Intramural Research

- Division of Preclinical Innovation (DPI)

Although most clinical research at NCATS is funded through grant mechanisms, one contract funded human subjects research in FY23.

II. Strategies for Ensuring Compliance

Involving a broad range of participants in both preclinical and clinical research is critical to ensure more reliable research results that lead to effective treatments reaching people faster. NCATS uses several strategies in its program development to support the inclusion of women and racial and/or ethnic minorities in clinical studies and workforce development. In addition, NCATS ensures that all applicants, peer reviewers, scientific review officers, program officers and grants management officers are aware of NIH's policy on inclusion based on sex, race, ethnicity and age in clinical research. Online resources are available for NCATS staff to learn about the inclusion of various populations, such as women and racial and/or ethnic minorities, in clinical research.

A. Peer Review

For proposed research projects, inclusion is first addressed during peer review. Reviewers on NIH peer review panels are given specific guidance on reviewing inclusion on the basis of sex, race, ethnicity and age when considering clinical research applications. They evaluate applications for the appropriateness of the proposed plan for inclusion.

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 the principal investigator(s), who are required to address these issues prior to funding. Applications with unacceptable inclusion plans receive a bar to funding and the award is not issued until an acceptable resolution is received.

B. Program Monitoring and Grants Management Oversight

Prior to the 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 study 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 DPI 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

NIH created the Inclusion Learning Path known as the Monitoring Inclusion in Clinical Research to provide a suite of on-demand training courses on NIH inclusion policies and procedures for extramural program staff. NCATS extramural staff also attend training presented by the NCATS Extramural Staff Training and Learning Initiative (NESTLI). NESTLI is a program that provides staff with training to develop knowledge and competencies in NCATS-relevant policies and procedures. As part of NESTLI, NCATS staff can access the archived trainings on NCATS' intranet. In addition, grants management staff participate in continuous training in areas of policy, process and leadership and must be certified by the NIH Grants Management Certification Review Board every three years. Staff can access the archived training courses on NIH's intranet.

III. Analysis and Interpretation of Data

The appended tables show NCATS' inclusion enrollment data for clinical research studies from FY22 through FY24. Please note that the data reported for FY23 incorrectly included one Inclusion Enrollment Record (IER) based on an existing data set with 53,329 participants. For reporting purposes, existing data sets are not counted toward inclusion data. This error resulted in an inflated enrollment number for FY23. Because the study was a one-year project, it is not included in the FY24 inclusion data.

Additionally, the one non-U.S. site enrollment recorded in FY22 was incorrectly reported due to a misclassification in the Human Subjects System (HSS). HSS is a shared platform that allows grant recipients to electronically update and report data on human subjects and clinical trials to NIH, while also enabling agency staff to monitor and manage that data. This error has since been corrected.

A. NCATS Inclusion Enrollment Data

Tables of NCATS inclusion data for FY22 through FY24 are provided in the appendix to this report. FY24 inclusion enrollment data by RCDC category will be available on the RCDC Inclusion Statistics Report website at a later date but are available now by request. These data will now be published annually on this website.

As shown in Table 2-1 (Appendix A), the number of NCATS inclusion enrollment records (IERs) for extramural studies decreased by approximately 36% from FY22 to FY23, then increased by approximately 38% from FY23 to FY24. All enrollment records represent populations enrolled in the United States, and the majority (~78%) include both male and female participants. Among the enrollment records involving only one sex, more are female-only than male-only.

NCATS did not support any NIH-defined Phase 3 clinical trials in FY23 and FY24; the center's only NIH-defined Phase 3 enrollment record in this report period is for the ACTIV-6 study in FY22, which was part of the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public–private partnership. This is consistent with the center's authorizing language, which precludes support of NIH-defined Phase 3 trials, except for the provision in the 21st Century Cures Act allowing the conduct of these trials in two cases:

(1) Studies on rare diseases.[1]

(2) Studies with non-NCATS funds, such as supported under the ACTIV public–private partnership coordinated by the Foundation for the National Institutes of Health. ACTIV 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 (the former 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, Appendix A) because Clinical and Translational Science Award (CTSA)–leveraged activities, which represent the majority of

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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;
  (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.

the NCATS budget, are reported by other NIH entities. Examples of sources of NCATS inclusion numbers are supplements to CTSA institutions as part of the Rapid Acceleration of Diagnostics Underserved Populations (RADx-UP) initiative and also as part of the NIH Community Engagement Alliance (CEAL). The NCATS IERs for extramural studies show increased participation of racial and/or ethnic minoritiesin research in FY24 compared to FY22 and FY23 (Table 5-1-1-C, Appendix B). The number of female clinical research participants surpassed the number of male participants each year from FY22 to FY24. Additionally, the participation of Hispanic populations has decreased since FY22, while participation of only female Hispanic participants increased in FY24. Finally, the data show more female than male Hispanic participants each year.

B. Engagement

From FY22 to FY24, U.S. Congress report language in the NCATS budget appropriation urged the CTSA Program to increase engagement with a broad range of populations and racial and/or ethnic minority-serving institutions and to provide support for innovation in artificial intelligence, big data and workforce training. In FY24, the Senate specifically directed NIH and NCATS to expand their focus on women's health by leveraging the CTSA network, urging collaboration with the NIH Office of Research on Women's Health to better address the unique medical needs of women and enhance the dissemination of research outcomes. The CTSA Program has long prioritized engaging communities in the research process; the CTSAs develop and disseminate community engagement tools and resources and work to educate researchers and communities. These efforts have made the hubs trusted community partners, which has been demonstrated in addressing the opioid epidemic and the COVID-19 pandemic.

Other project areas have included improving access to clinical trials for rural communities, harnessing technology to deliver effective care that makes travel to a major medical center unnecessary to access specialists and specialized equipment and enhancing rural community outreach.

The center continued to build on these efforts and many others with updates in FY24 to the CTSA Program UM1 funding opportunity (PAR-24-272), which included developing and testing clinical and translational research solutions to address the health concerns of the population being studied, including rural health outcomes, communities with limited access and vulnerable populations. For additional information about activities funded under the CTSA program, please see the NCATS Funding Table. Clicking on underlined dollar amounts in the table will open a list of awards and award information. NCATS intends to strengthen our partnerships with collaborators at NIH, other federal agencies and nonfederal institutions to ensure that inclusion of women and racial and/or ethnic minorities is meaningfully addressed in all NCATS initiatives and activities that have a translational focus.

C. Research, Condition and Disease Categorization Report

To enhance the reporting of human subjects research, NIH has developed a system that displays enrollment data categorized by RCDC category. This system allows users to filter the inclusion enrollment database by specific RCDC codes, enabling detailed analysis of clinical research and clinical trial enrollment data for particular conditions or diseases. NCATS' inclusion enrollment data by RCDC category are published annually and can be accessed on the RCDC Inclusion Statistics Report website on NIH RePORT.

IV. Appendices

Note: The data presented in these appendices show only inclusion data records labeled as prospective data. Inclusion data records labeled as existing data are excluded.

Appendix A. Table 2-1. Total NCATS Inclusion Enrollment Records for NIH-Defined Extramural and Intramural Clinical Research Reported Between Fiscal Years 2022 and 2024.

Appendix B. Table 5-1-1-C. Enrollment for All NIH-Defined Clinical Research Studies, Sex by Race and Ethnicity.

Appendix A. Table 2-1. Total NCATS Inclusion Enrollment Records for NIH-Defined Extramural and Intramural Clinical Research Reported Between Fiscal Years 2022 and 2024

Metrics Based on Inclusion Enrollment Records

Fiscal Year	Total IERs	IERs Without Enrollment	IERs With Enrollment	U.S. Site IERs	Non-U.S. Site IERs	Female Only IERs	Male Only IERs	IERs Excluding Male Only and Female Only*
2022	568	254	314	313	1	57	11	246
2023	419	219	200	200	0	33	11	156
2024	526	250	276	276	0	48	11	217

Key: IER = inclusion enrollment records

* IERs excluding male only and female only include unknown sex and a combination of unknown and any sex(es).

Appendix B. Table 5-1-1-C. Enrollment for All NIH-Defined Clinical Research Studies, Sex by Race and Ethnicity

Total Enrollment: All NIH-Defined Clinical Research

Fiscal Year	Sex	Minority	% Minority	Total Enrollment	% Total	Not Hispanic	% Not Hispanic	Hispanic/ Latino	% Hispanic/ Latino	Unknown Not Reported	% Unknown Not Reported
2022	Female	36,512	45.3	80,662	52.1	44,250	54.9	30,047	37.3	6,365	7.9
2022	Male	25,320	41.3	61,241	39.5	34,631	56.5	21,096	34.4	5,514	9.0
2022	Unknown	3,415	26.3	13,006	8.4	3,697	28.4	2,673	20.6	6,636	51.0
2023	Female	17,738	42.2	41,990	56.4	37,554	89.4	3,735	8.9	701	1.7
2023	Male	11,445	36.6	31,308	42.0	28,650	91.5	2,443	7.8	215	0.7
2023	Unknown	128	10.6	1,202	1.6	724	60.2	30	2.5	448	37.3
2024	Female	19,854	69.4	28,593	52.0	16,005	56.0	11,659	40.8	929	3.2
2024	Male	10,048	41.0	24,499	44.6	20,420	83.4	1,939	7.9	2,140	8.7
2024	Unknown	437	23.7	1,842	3.4	791	42.9	45	2.4	1,006	54.6

(*cont*)

Fiscal Year	Sex	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
2022	Female	540	0.7	1,082	1.3	4,370	5.4	393	0.5	45,218	56.1	3,280	4.1	25,779	32.0
2022	Male	333	0.5	827	1.4	2,732	4.5	274	0.4	33,674	55.0	2,327	3.8	21,074	34.4
2022	Unknown	11	0.1	37	0.3	415	3.2	0	0.0	1,137	8.7	288	2.2	11,118	85.5
2023	Female	266	0.6	789	1.9	12,844	30.6	32	0.1	25,208	60.0	528	1.3	2,323	5.5
2023	Male	248	0.8	671	2.1	7,978	25.5	38	0.1	20,364	65.0	346	1.1	1,663	5.3
2023	Unknown	2	0.2	39	3.2	55	4.6	3	0.2	181	15.1	8	0.7	914	76.0
2024	Female	101	0.4	768	2.7	7,372	25.8	32	0.1	18,166	63.5	408	1.4	1,746	6.1
2024	Male	129	0.5	435	1.8	7,537	30.8	128	0.5	13,479	55.0	246	1.0	2,545	10.4
2024	Unknown	10	0.5	197	10.7	154	8.4	33	1.8	153	8.3	10	0.5	1,285	69.8

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