

2025 Current Fiscal Year Report: National Cancer Institute Clinical Trials and Translational Research Advisory Committee

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1. Department or Agency	2. Fiscal Year
Department of Health and Human Services	2025
3. Committee or Subcommittee	3b. GSA Committee No.
National Cancer Institute Clinical Trials and Translational Research Advisory Committee	29125

4. Is this New Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	04/14/2024	04/14/2026	

8a. Was Terminated During Fiscal Year?	8b. Specific Termination Authority	8c. Actual Term Date
No		

9. Agency Recommendation for Next Fiscal Year	10a. Legislation Req to Terminate?	10b. Legislation Pending?
Continue	Not Applicable	Not Applicable

11. Establishment Authority Authorized by Law

12. Specific Establishment Authority	13. Effective Date	14. Committee Type	14c. Presidential?
42 USC 285a-2(b)(7)	11/20/1985	Continuing	No

15. Description of Committee Scientific Technical Program Advisory Board

16a. Total Number of Reports No Reports for this Fiscal Year

17a. Open 1 **17b. Closed** 0 **17c. Partially Closed** 0 **Other Activities** 0 **17d. Total** 1

Meetings and Dates

Purpose	Start	End
Program Advisory and/or Policy	11/06/2024	- 11/06/2024

Number of Committee Meetings Listed: 1

	Current Next	
	FY	FY
18a(1). Personnel Pmts to Non-Federal Members	\$0.00	\$0.00
18a(2). Personnel Pmts to Federal Members	\$0.00	\$0.00
18a(3). Personnel Pmts to Federal Staff	\$0.00	\$0.00
18a(4). Personnel Pmts to Non-Member Consultants	\$0.00	\$0.00
18b(1). Travel and Per Diem to Non-Federal Members	\$0.00	\$0.00
18b(2). Travel and Per Diem to Federal Members	\$0.00	\$0.00
18b(3). Travel and Per Diem to Federal Staff	\$0.00	\$0.00
18b(4). Travel and Per Diem to Non-member Consultants	\$0.00	\$0.00
18c. Other(rents,user charges, graphics, printing, mail, etc.)	\$0.00	\$0.00
18d. Total	\$0.00	\$0.00
19. Federal Staff Support Years (FTE)	0.00	0.00

20a. How does the Committee accomplish its purpose?

The Committee is composed of scientific leaders and public members knowledgeable in the fields of community oncology, surgical oncology, medical oncology, radiation oncology, patient advocacy, extramural clinical investigation, regulatory agencies, pharmaceutical industry, public health, clinical trials design, management and evaluation, drug development and developmental therapeutics, cancer education, cancer information services, community outreach, vaccine development, cellular oncology, molecular

oncology, pediatric oncology, clinical, basic and translational research, cancer center administration, cancer biology and diagnosis, cancer epidemiology, chemotherapy, oncology health care providers, pharmacology, pathology, biostatistics, quality of life, health care outcomes, pain management, cancer treatment and restorative care, and education of health professionals. The Committee provides advice to the NCI Director, NCI Deputy Directors, and the Director of each NCI Division on the NCI-supported national clinical trials enterprise to build a strong scientific infrastructure by bringing together a broadly developed and engaged coalition of stakeholders involved in the clinical trials process. In FY2024, the Committee met once on March 13, 2024 (virtual meeting). The Committee's discussions were focused on the following items: a final report of the Streamlining Clinical Trials Working Group; NCI's new precision medicine initiatives which include NCI's Molecular Diagnostic Network, ComboMatch, ImmunotherapyMatch, and MyeloMatch and the role of the Frederick National Laboratory for Cancer Research in support of these studies; and NCI's newly funded Cancer Screening Research Network; and the planned launch of the Vanguard Study on multi-cancer detection. The final report of the Streamlining Clinical Trials Working Group and the CTAC meeting summary from the meeting held on July 19, 2023 were approved and accepted by the Committee.

20b. How does the Committee balance its membership?

The Committee consists of up to 25 non-federal members appointed by the Director, National Cancer Institute. When necessary, four members will hold concurrent membership on either the

National Cancer Advisory Board, Board of Scientific Advisors, NCI Board of Scientific Counselors, or NCI Council of Research Advocates. Members are leaders knowledgeable in the fields of community oncology, surgical oncology, medical oncology, radiation oncology, patient advocacy, extramural clinical investigation, regulatory agencies, pharmaceutical industry, public health, clinical trials design, management and evaluation, drug development and developmental therapeutics, cancer education, cancer information services, community outreach, vaccine development, cellular oncology, molecular oncology, pediatric oncology, clinical, basic and translational research, cancer center administration, cancer biology and diagnosis, cancer epidemiology, chemotherapy, oncology health care providers, pharmacology, pathology, biostatistics, quality of life, health care outcomes, pain management, cancer treatment and restorative care, and education of health professionals. Non-voting ex officio members may include officials from the Food and Drug Administration, Centers for Medicare and Medicaid Services, the Department of Defense and Department of Veterans Affairs, and such other Federal officials as appointed by the NCI Director.

20c. How frequent and relevant are the Committee Meetings?

The Committee meets approximately three times each fiscal year. In FY2024, the Committee met once on March 13, 2024. The Committee's deliberations are an indispensable part of the review of a very large clinical trials and translational research program. In addition to the CTAC parent meetings, the ad hoc Streamlining Clinical Trials Working Group met on November 8,

2023, The working group's final report was accepted at the March 13, 2024 parent CTAC meeting. The ad hoc Strategic Planning Working Group met on July 17, 2024.

20d. Why can't the advice or information this committee provides be obtained elsewhere?

This Committee is composed of recognized biomedical research authorities from outside the NIH in order to secure unbiased and objective evaluations of clinical trials and translational research programs. Their recommendations are invaluable because the complex nature of the research requires a unique balance and breadth of expertise not available at NIH or from other established sources.

20e. Why is it necessary to close and/or partially closed committee meetings?

N/A

21. Remarks

Max Number of Members Total: The Charter allows the Committee to have 29 authorized members including but not limited to 25 SGEs and 4 Ex Officio Members. The max number of members was changed from 33 to 29 given changes to the charter. There are currently 19 SGEs in this ACR list. There are currently no Ex Officio Members from the Department of Defense and the Centers for Medicare and Medicaid Services. As such there are only two Ex Officio Members (Michael Kelley from the Department of Veteran's Affairs and Richard Pazdur from the U.S. Food and Drug Administration), which is a total of 21 members, eight less than the Max number of members. Vacancies/Members Rotating Off: The committee has 6 vacancies. Six members (Smita Bhatia, Seth P. Lerner, Carolyn

N. Mullar, Raphael E. Pollock, Suresh S. Ramalingam, and Victor M. Santana) and one chair (Julie M. Vose) will rotate-off on 7/31/2025 and no member on-boarded. This is why the Charter states 25 potential members, but this ACR lists 19. Members: Drs. Charles Blanke, Adam Dicker, Ernest Hawk, and Sumithra Mandrekar were administratively extended to 7/26/2025. As such, their term of service end dates is different than what was reported on the FY24 ACR. Dr. Raymond U. Osarogiagbon has terminated on 3/31/2025. As such, his term of service end date is different than what was reported on the FY24 ACR. Ex Officio Members: Meetings: CTAC is scheduled to meet three times during a fiscal year: The November 6, 2024, was open and held as a Hybrid meeting. The March 12, 2025, open/hybrid meeting was cancelled due to the meeting freeze per the President's Executive Order. The July 16, 2025, open/hybrid meeting is in the planning stage. The DFO and Committee Decision Maker positions are held by the same individual because of the assignment of responsibilities within the Institute.

Designated Federal Officer

SHEILA A. PRINDIVILLE DIRECTOR,
COORDINATING CENTER FOR CLINICAL
TRIALS

Committee Members	Start	End	Occupation	Member Designation
AZAD, NILOFER	02/04/2024	03/09/2026	Professor of Oncology, Sidney Kimmel Comprehensive Cancer Center, Johns Hopkins University	Special Government Employee (SGE) Member

BHATIA, SMITA	07/06/2021	07/31/2025	VICE CHAIR OF OUTCOMES FOR PEDIATRICS, PROFESSOR, Special DIVISION OF Government HEMATOLOGY/ONCOLOGY, Employee DEPARTMENT OF (SGE) PEDIATRICS, UNIVERSITY Member OF ALABAMA AT BIRMINGHAM
BLANKE, CHARLES	09/27/2020	07/26/2025	CHAIR, SWOG CANCER RESEARCH NETWORK, Special PROFESSOR, KNIGHT Government CANCER INSTITUTE, Employee OREGON HEALTH AND (SGE) SCIENCES UNIVERSITY Member
DICKER, ADAM	07/06/2020	07/26/2025	PROFESSOR AND CHAIR, Special DEPARTMENT OF Government RADIATION ONCOLOGY, Employee SIDNEY KIMMEL CANCER (SGE) CENTER, THOMAS Member JEFFERSON UNIVERSITY
DOOLITTLE, GARY	06/21/2022	07/31/2026	CAPITOL FEDERAL MASONIC PROFESSOR, Special DIVISION OF MEDICAL Government ONCOLOGY, UNIVERSITY Employee OF KANSAS MEDICAL (SGE) CENTER Member
HAWK, ERNEST	05/26/2020	07/26/2025	VICE PRESIDENT AND HEAD DIVISION OF Special CANCER PREVENTION AND Government POPULATION SCIENCES, Employee THE UNIVERSITY OF (SGE) TEXAS MD ANDERSON Member CANCER CENTER
KELLEY, MICHAEL	03/11/2009	06/30/2025	NATIONAL PROGRAM DIRECTOR FOR ONCOLOGY, VETERANS Ex Officio HEALTH ADMINISTRATION, Member DEPARTMENT OF VETERANS AFFAIRS
KOBAYASHI, KEN	09/08/2024	07/31/2028	Chief Medical Officer, Pyxis Oncology Special Government Employee (SGE) Member
LERNER, SETH	03/14/2021	07/31/2025	VICE CHAIR FOR FACULTY AFFAIRS, BETH AND DAVE Special SWALM CHAIR IN Government UROLOGIC ONCOLOGY, Employee PROFESSOR, SCOTT (SGE) DEPARTMENT OF Member UROLOGY, BAYLOR COLLEGE OF MEDICINE

MANDREKAR, SUMITHRA	06/22/2020	07/26/2025	PROFESSOR OF BIostatISTICS AND ONCOLOGY, GROUP STATISTICIAN, ALLIANCE FOR CLINICAL TRIALS IN ONCOLOGY DEPARTMENT OF QUANTITATIVE HEALTH SCIENCES, MAYO CLINIC	Special Government Employee (SGE) Member
MANNEL, ROBERT	06/21/2022	07/31/2026	DIRECTOR, PEGGY AND CHARLES STEPHENSON CANCER CENTER COLLEGE OF MEDICINE, UNIVERSITY OF OKLAHOMA HEALTH SCIENCES CENTER	Special Government Employee (SGE) Member
MESA, RUBEN	06/21/2022	07/31/2026	PRESIDENT, ENTERPRISE CANCER SERVICE LINE ATRIUM HEALTH, EXECUTIVE DIRECTOR, ATRIUM HEALTH WAKE FOREST BAPTIST COMPREHENSIVE CANCER CENTER, VICE DEAN FOR CANCER PROGRAMS, WAKE FOREST SCHOOL OF MEDICINE	Special Government Employee (SGE) Member
MULLER, CAROLYN	03/14/2021	07/31/2025	ASSOCIATE DIRECTOR OF CLINICAL RESEARCH, THE JUDY PUTMAN DIRKS ENDOWED PROFESSOR IN GYNECOLOGIC CANCER CARE, DEPARTMENT OF OBSTETRICS AND GYNECOLOGY, THE UNIVERSITY OF NEW MEXICO HEALTH SCIENCES CENTER	Special Government Employee (SGE) Member
OSAROGIAGBON, RAYMOND	02/01/2024	03/31/2025	Chief Scientist, Baptist Memorial Health Care Corporation, Adjunct Research Professor, Department of Medicine, Vanderbilt University	Special Government Employee (SGE) Member
PAZDUR, RICHARD	12/05/2006	06/30/2025	DIRECTOR, ONCOLOGY CENTER OF EXCELLENCE, U.S. FOOD AND DRUG ADMINISTRATION	Ex Officio Member
POLLOCK, RALPH	07/06/2021	07/31/2025	KATHLEEN WELLENREITER KLOTZ CHAIR IN CANCER RESEARCH, DIRECTOR, THE OHIO STATE UNIVERSITY COMPREHENSIVE CANCER CENTER	Special Government Employee (SGE) Member

RAMALINGAM, SURESH	07/06/2021	07/31/2025	PROFESSOR, WINSHIP CANCER INSTITUTE OF EMORY UNIVERSITY, ROBERTO C. GOIZUETA DISTINGUISHED CHAIR FOR CANCER RESEARCH, ASSISTANT DEAN FOR CANCER RESEARCH, DEPARTMENT OF HEMATOLOGY AND MEDICAL ONCOLOGY, EMORY UNIVERSITY SCHOOL OF MEDICINE	Special Government Employee (SGE) Member
SANTANA, VICTOR	08/02/2020	07/31/2025	DIRECTOR FOR GLOBAL RESEARCH, DEPARTMENT OF GLOBAL PEDIATRIC MEDICINE, ST. JUDE CHILDREN'S RESEARCH HOSPITAL	Special Government Employee (SGE) Member
SPEARS, PATRICIA	03/13/2022	07/31/2026	SCIENTIFIC RESEARCH MANAGER, PATIENT ADVOCATE, LINEBERGER COMPREHENSIVE CANCER CENTER, UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL	Special Government Employee (SGE) Member
VOSE, JULIE	06/21/2020	07/31/2025	NEUMANN M. AND MILDRED E. HARRIS PROFESSOR, CHIEF, DIVISION OF ONCOLOGY/HEMATOLOGY, DEPARTMENT OF INTERNAL MEDICINE, UNIVERSITY OF NEBRASKA MEDICAL CENTER	Special Government Employee (SGE) Member
WILDING, GEORGE	06/21/2022	07/31/2026	PROFESSOR EMERITUS AND DIRECTOR EMERITUS, UNIVERSITY OF WISCONSIN, MADISON	Special Government Employee (SGE) Member

Number of Committee Members Listed: 21

Narrative Description

NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability. The NIH works toward that mission by utilizing the National Cancer Institute Clinical Trials and Translational Research Advisory Committee (CTAC). The CTAC conducts and provides oversight and implementation of clinical trials across the Institute.

The Committee consists of up to 25 members. When necessary, five members will hold concurrent membership on either the National Cancer Advisory Board, Board of Scientific Advisors, Board of Scientific Counselors, or NCI Council of Research Advocates. Members will be authorities in the fields of community oncology, surgical oncology, medical oncology, radiation oncology, patient advocacy, extramural clinical investigation, regulatory agencies, pharmaceutical industry, public health, clinical trials design, management and evaluation, drug development and developmental therapeutics, cancer education, cancer information services, community outreach, vaccine development, cellular oncology, molecular oncology, pediatric oncology, clinical, basic and translational research, cancer center administration, cancer biology and diagnosis, cancer epidemiology, chemotherapy, oncology health care providers, pharmacology, pathology, biostatistics, quality of life, health care outcomes, pain management, cancer treatment and restorative care, and education of health professionals.

What are the most significant program outcomes associated with this committee?

	Checked if Applies
Improvements to health or safety	<input checked="" type="checkbox"/>
Trust in government	<input type="checkbox"/>
Major policy changes	<input checked="" type="checkbox"/>
Advance in scientific research	<input checked="" type="checkbox"/>
Effective grant making	<input type="checkbox"/>
Improved service delivery	<input type="checkbox"/>
Increased customer satisfaction	<input type="checkbox"/>
Implementation of laws or regulatory requirements	<input type="checkbox"/>
Other	<input type="checkbox"/>

Outcome Comments

N/A

What are the cost savings associated with this committee?

Checked if Applies

None	<input type="checkbox"/>
Unable to Determine	<input checked="" type="checkbox"/>
Under \$100,000	<input type="checkbox"/>
\$100,000 - \$500,000	<input type="checkbox"/>
\$500,001 - \$1,000,000	<input type="checkbox"/>
\$1,000,001 - \$5,000,000	<input type="checkbox"/>
\$5,000,001 - \$10,000,000	<input type="checkbox"/>
Over \$10,000,000	<input type="checkbox"/>
Cost Savings Other	<input type="checkbox"/>

Cost Savings Comments

NIH-supported basic and clinical research accomplishments often take many years to unfold into new diagnostic tests and new ways to treat and prevent diseases.

What is the approximate Number of recommendations produced by this committee for the life of the committee?

103

Number of Recommendations Comments

In addition to some general recommendations, the committee made the following recommendation: approved the final report of the Streamlining Clinical Trials Working Group.

What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?

98%

% of Recommendations Fully Implemented Comments

The percentage of recommendations implemented stated above was developed at the time the Annual Comprehensive Review report was prepared. Additional information is available through the RePORT (Research Portfolio Online Reporting Tool) website. RePORT provides access to reports, data, and analyses of NIH research activities that advance the mission of the NIH, including information on NIH expenditures, strategic plans, reports on NIH funding, and reports on the organization and people involved in NIH research and research training. The RePORT website is located at <http://report.nih.gov>.

What is the approximate Percentage of these recommendations that have been or will be Partially implemented by the agency?

3%

% of Recommendations Partially Implemented Comments

The percentage of recommendations implemented stated above was developed at the time the Annual Comprehensive Review report was prepared. Additional information is available through the RePORT (Research Portfolio Online Reporting Tool) website. RePORT provides access to reports, data, and analyses of NIH research activities that advance the mission of the NIH, including information on NIH expenditures, strategic plans, reports on NIH funding, and reports on the organization and people involved in NIH research and research training. The RePORT website is located at <http://report.nih.gov>.

Does the agency provide the committee with feedback regarding actions taken to implement recommendations or advice offered?

Yes ☒ No ☐ Not Applicable ☐

Agency Feedback Comments

The agency provided feedback to the various NCI advisory boards with periodic updates at meetings. Information is provided to the public at each meeting. The public can view information related to the Committee through the committee's official website.

What other actions has the agency taken as a result of the committee's advice or recommendation?

Checked if Applies

Reorganized Priorities	<input checked="" type="checkbox"/>
Reallocated resources	<input type="checkbox"/>
Issued new regulation	<input type="checkbox"/>
Proposed legislation	<input type="checkbox"/>
Approved grants or other payments	<input type="checkbox"/>
Other	<input checked="" type="checkbox"/>

Action Comments

The committee makes recommendations to federal staff on the NCI-supported national clinical trials enterprise to build a strong scientific infrastructure by bringing together a broadly developed and engaged coalition of stakeholders involved in the clinical trials process. Based on the recommendations of this committee, NCI has restructured its clinical trials infrastructure to enhance efficiency and scientific quality, instituted policy changes, developed scientific frameworks for recalcitrant cancers, and constituted oversight working groups.

Is the Committee engaged in the review of applications for grants?

No

Grant Review Comments

N/A

How is access provided to the information for the Committee's documentation?

Checked if Applies

Contact DFO	<input checked="" type="checkbox"/>
Online Agency Web Site	<input checked="" type="checkbox"/>
Online Committee Web Site	<input checked="" type="checkbox"/>
Online GSA FACA Web Site	<input checked="" type="checkbox"/>
Publications	<input checked="" type="checkbox"/>
Other	<input checked="" type="checkbox"/>

Access Comments

Information on CTAC can be found at the NCI Division of Extramural Activities: Advisory Boards, Committees and Review Groups website at <http://deainfo.nci.nih.gov/advisory/ctac/ctac.htm>. Each NCI committee's charter, minutes, agenda, roster, future meeting dates, meeting Power Points and reports are located here. Additionally, the public may view the CTAC meetings (both live and on demand) via the NIH Videocast at the following website: <http://videocast.nih.gov/>.