

2024 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 | 2024 |
| 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 | 04/14/2022 | 04/14/2024 | |

| | | |
|-----------------------------------------------|-------------------------------------------|-----------------------------|
| 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 | 17b. Closed | 17c. Partially Closed | Other Activities | 17d. Total |
| 0 | 0 | 0 | 0 | 0 |

Meetings and Dates
No Meetings

| | Current FY | Next 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 FY2023, the Committee met twice on November 9, 2022 (virtual meeting) and July 19, 2023 (hybrid meeting). The Committee's discussions were focused on the following items: an interim report of the Streamlining Clinical Trials Working Group, methods to leverage NCTN and NCORP clinical trial populations for observational cancer survivorship research, an update on the implementation of recommendations from the Cancer Screening Trials Working Group, a report of the Gastric and Esophageal Cancers Working Group, the Clinical Trials Innovation Unit, representation of women and underrepresented groups in clinical trials leadership, strategies for enhancing the clinical trials workforce, an update on the implementation of the Strategic Planning Working Group report, and mechanisms to accelerate electronic clinical trial study builds. The CTAC meeting summary from the meeting held on November 9, 2022 was approved.

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, five 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. The Committee will also have non-voting ex officio members which may include NCI Deputy Directors, select NCI Division Directors, an NCI intramural scientist engaged in clinical research, and 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 FY2023, the Committee met twice on November 9, 2022 (virtual meeting) and

July 19, 2023 (in-person/hybrid meeting). 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 October 4, 2022, October 25, 2022, November 30, 2022, and January 30, 2023.

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 33 authorized members including but not limited to 25 SGEs and 8 Ex Officio Members. There are currently 19 SGEs. There is currently no Ex Officio Member from the Department of Defense, as such there are only seven Ex Officio Members (James Doroshow, Paulette Gray, James Gulley, Michael Kelley, Anthony Keverlage, Richard Pazdur, and Xiufen Sui), which is a total of 28 members, five less than the Max number of members.

Vacancies/Members Rotating Off: The committee has 4 vacancies. Two members rotated-off (Neal

Meropol and Nancy Davidson). This is why the Charter states 33 potential members, but this ACR lists 28. Members: The terms for Nancy E.

Davidson, Michael Knopp, Neal Meropol, Victor Santana, and Julie Vose have changed due to an administrative extension. As such, their terms are different than what was reported in FY22.

Meetings: The committee was unable to meet three times during the fiscal year due to agenda topic scheduling difficulties. The DFO and Committee Decision Maker positions are held by the same individual because of the assignment of responsibilities within the Institute. The working group reports were deliberated on by the NCI Clinical Trials and Translational Research Advisory Committee.

Designated Federal Officer

SHEILA A. PRINDIVILLE DIRECTOR,
COORDINATING CENTER FOR CLINICAL
TRIALS

| Committee Members | Start | End | Occupation | Member Designation |
|--------------------------|--------------|------------|-------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------|
| BHATIA, SMITA | 07/06/2021 | 07/31/2025 | VICE CHAIR OF OUTCOMES FOR PEDIATRICS, PROFESSOR, DIVISION OF | Special Government |
| | | | HEMATOLOGY/ONCOLOGY, DEPARTMENT OF PEDIATRICS, UNIVERSITY OF ALABAMA AT BIRMINGHAM | Employee (SGE) Member |
| BLANKE, CHARLES | 09/27/2020 | 07/31/2024 | CHAIR, SWOG CANCER RESEARCH NETWORK, PROFESSOR, KNIGHT CANCER INSTITUTE, OREGON HEALTH AND SCIENCES UNIVERSITY | Special Government Employee (SGE) Member |
| | | | DIRECTOR, ALBERT EINSTEIN CANCER CENTER, CAROL AND ROGER EINIGER | Special Government |
| CHU, EDWARD | 07/06/2021 | 07/31/2025 | PROFESSOR OF CANCER MEDICINE, DEPARTMENT OF MEDICINE, ALBERT EINSTEIN COLLEGE OF MEDICINE | Employee (SGE) Member |

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| DICKER, ADAM | 07/06/2020 | 07/31/2024 | PROFESSOR AND CHAIR, DEPARTMENT OF RADIATION ONCOLOGY, SIDNEY KIMMEL CANCER CENTER, THOMAS JEFFERSON UNIVERSITY | Special Government Employee (SGE) Member |
| DOOLITTLE, GARY | 06/21/2022 | 07/31/2026 | CAPITOL FEDERAL MASONIC PROFESSOR, DIVISION OF MEDICAL ONCOLOGY, UNIVERSITY OF KANSAS MEDICAL CENTER | Special Government Employee (SGE) Member |
| DOROSHOW, JAMES | 07/01/2015 | 06/30/2025 | DEPUTY DIRECTOR, CLINICAL AND TRANSLATIONAL RESEARCH DIRECTOR, DIVISION OF CANCER TREATMENT AND DIAGNOSIS, NATIONAL CANCER INSTITUTE, NATIONAL INSTITUTES OF HEALTH | Ex Officio Member |
| GRAY, PAULETTE | 01/11/2007 | 06/30/2025 | DIRECTOR, DIVISION OF EXTRAMURAL ACTIVITIES, NATIONAL CANCER INSTITUTE, NATIONAL INSTITUTES OF HEALTH | Ex Officio Member |
| GULLEY, JAMES | 06/09/2022 | 06/30/2027 | NCI CLINICAL DIRECTOR, CENTER FOR CANCER RESEARCH, NATIONAL CANCER INSTITUTE, NATIONAL INSTITUTES OF HEALTH | Ex Officio Member |
| HAWK, ERNEST | 05/26/2020 | 07/31/2024 | VICE PRESIDENT AND HEAD DIVISION OF CANCER PREVENTION AND POPULATION SCIENCES, THE UNIVERSITY OF TEXAS MD ANDERSON CANCER CENTER | Special Government Employee (SGE) Member |
| KELLEY, MICHAEL | 03/11/2009 | 06/30/2025 | NATIONAL PROGRAM DIRECTOR FOR ONCOLOGY, VETERANS HEALTH ADMINISTRATION, DEPARTMENT OF VETERANS AFFAIRS | Ex Officio Member |
| KERLAVAGE, ANTHONY | 08/22/2017 | 06/30/2025 | DIRECTOR, CENTER FOR BIOMEDICAL INFORMATICS AND INFORMATION TECHNOLOGY, NATIONAL CANCER INSTITUTE, NATIONAL INSTITUTES OF HEALTH | Ex Officio Member |

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| KNOPP, MICHAEL | 03/14/2021 | 11/30/2023 | PROFESSOR OF RADIOLOGY, DEPARTMENT OF RADIOLOGY, NOVARTIS CHAIR OF IMAGING RESEARCH, THE OHIO STATE UNIVERSITY | Special Government Employee (SGE) Member |
| LERNER, SETH | 03/14/2021 | 07/31/2025 | VICE CHAIR FOR FACULTY AFFAIRS, BETH AND DAVE SWALM CHAIR IN UROLOGIC ONCOLOGY, PROFESSOR, SCOTT DEPARTMENT OF UROLOGY, BAYLOR COLLEGE OF MEDICINE | Special Government Employee (SGE) Member |
| LEVY, MIA | 11/08/2020 | 07/31/2024 | ASSOCIATE PROFESSOR, RUSH UNIVERSITY CANCER CENTER, CHIEF MEDICAL OFFICER, FOUNDATION MEDICINE, INC. | Special Government Employee (SGE) Member |
| MANDREKAR, SUMITHRA | 06/22/2020 | 07/31/2024 | 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 |

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|--------------------|------------|------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|
| 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 | DEPUTY DIRECTOR, 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 | 01/27/2024 | ASSOCIATE DIRECTOR FOR CLINICAL RESEARCH, VICE PRESIDENT, CLINICAL TRIALS ADMINISTRATION, 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 |
| SUI, XIUFEN | 07/01/2020 | 06/30/2025 | BIostatistician, CENTER FOR CLINICAL STANDARDS AND QUALITY, CENTER FOR MEDICARE AND MEDICAID INNOVATION | Ex Officio Member |
| VOSE, JULIE | 06/21/2020 | 01/27/2024 | 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: 26

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



Trust in government



| | |
|---------------------------------------------------|-------------------------------------|
| 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?

101

Number of Recommendations Comments

In addition to some general recommendations, the committee made the following recommendation: approved the interim report of the Streamlining Clinical Trials Working Group and approved the report of the Gastric and Esophageal Cancers Working Group.

What is the approximate Percentage of these recommendations that have been or

will be Fully implemented by the agency?

97%

% 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 ☒
Reallocated resources ☐

| | |
|-----------------------------------|-------------------------------------|
| 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/>.