# DEPARTMENT OF HEALTH AND HUMAN SERVICES
# NATIONAL INSTITUTES OF HEALTH
# NATIONAL CANCER INSTITUTE
# 38th CLINICAL TRIALS AND TRANSLATIONAL RESEARCH ADVISORY COMMITTEE (CTAC) MEETING

**Summary of Meeting**
**March 6, 2019**

**Webinar**

**CLINICAL TRIALS AND TRANSLATIONAL RESEARCH ADVISORY COMMITTEE**
**Summary of Meeting**
**March 6, 2019**

The 38th meeting of the Clinical Trials and Translational Research Advisory Committee (CTAC) of the National Cancer Institute (NCI) was held by webinar on Wednesday, March 6, 2019, at 11:00 a.m. The CTAC chair, Dr. Loehrer, presided.[1] The meeting was adjourned at 12:55 p.m.

**Chair**
Patrick J. Loehrer, Sr.

**CTAC Members**
David F. Arons
Debra L. Barton
Walter J. Curran, Jr.
Janet Ellen Dancey
Nancy E. Davidson
Timothy J. Eberlein
Howard J. Fingert
David M. Gershenson
Paul A. Godley (absent)
Anne-Marie R. Langevin
Michael L. LeBlanc
David A. Mankoff
Lynn M. Matrisian
Neal J. Meropol
Augusto C. Ochoa
Roman Perez-Soler
Gloria M. Petersen
Steven T. Rosen (absent)
Dan Theodorescu

**Ex Officio Members**
William L. Dahut, NCI (absent)
James H. Doroshow, NCI
Paulette S. Gray, NCI
Michael J. Kelley, U.S. Department of Veterans Affairs (absent)
Anthony Kerlavage, NCI
Richard Pazdur, U.S. Food and Drug Administration (absent)
Katherine Szarama, Centers for Medicare & Medicaid Services (absent)

**Executive Secretary**
Sheila A. Prindiville, NCI

**Presenters**
James Abbruzzese, MD, Duke Cancer Institute Distinguished Professor of Medical Oncology; Chief, Division of Medical Oncology, Department of Medicine; Associate Director for Clinical Research, Duke Cancer Institute, Duke University Medical Center
Alex Adjei, MD, PhD, Professor of Oncology and Pharmacology Consultant, Medical Oncology, Mayo Clinic
James Doroshow, MD, Deputy Director, Clinical and Translational Research; Director, Division of Cancer Treatment and Diagnosis, NCI
Laurie Gaspar, MD, MBA, Professor Emeritus, Department of Radiation Oncology, University of Colorado Denver
Patrick Loehrer, Sr., MD, Director, Indiana University Melvin and Bren Simon Cancer Center; Associate Dean for Cancer Research, Indiana University School of Medicine
Irina Lubensky, MD, Branch Chief, Pathology Investigation and Resources Branch, NCI
Norman E. Sharpless, MD, Director, NCI

[1]A roster of CTAC members and their affiliations is included as an appendix.

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**Wednesday, March 6, 2019**



## I. Call to Order and Opening Remarks

*Patrick J. Loehrer, Sr., MD*

Dr. Loehrer called the 38th meeting of CTAC to order and welcomed participants.

Dr. Loehrer reviewed the confidentiality and conflict-of-interest practices required of CTAC members during their deliberations. He invited members of the public to send written comments on issues discussed during the meeting to Dr. Prindiville within 10 days of the meeting. National Institutes of Health Events Management was videocasting the meeting, and the videocast would be available for viewing following the meeting at http://videocast.nih.gov.

Dr. Doroshow announced that Dr. Loehrer is the new CTAC chair. Dr. Doroshow expressed NCI's gratitude to Dr. Davidson for her wonderful efforts on behalf of CTAC as the committee's previous chair. Dr. Davidson is remaining on CTAC as the committee's Board of Scientific Counselors liaison.

**Motion:** A motion to accept the minutes of the 37th CTAC meeting held on November 7, 2018, was approved.

## II. NCI Director's Update

*Norman E. Sharpless, MD*

Dr. Sharpless thanked Dr. Davidson for her leadership of CTAC and welcomed Dr. Loehrer to his new role as CTAC chair. Dr. Sharpless commented that CTAC's advice to NCI is indispensable and therefore much appreciated.

**Research Project Grant (RPG) Pool**. The RPG pool funds R01, P01, and other grant mechanisms, primarily for investigator-initiated research, including a significant portfolio of clinical trials. Because of congressional support in fiscal year (FY) 2018, funding for NCI's Research Project Grants (RPG) pool had one of the largest increases since 2003, during the National Institutes of Health (NIH) budget doubling period. Dr. Sharpless expects a similar increase in total RPG pool funding in 2019.

However, despite NCI's efforts to prioritize funding for the RPG pool, paylines at NCI are low. For example, the payline for R01 awards for established investigators is 8 percent. NCI is funding more investigators and investing more money in the RPG pool than ever, but the institute has received a massive influx of new applications. Since 2009, the number of R01 applications to NCI increased by 60 percent, compared with 10 percent for all of NIH. In many ways, this is a good problem because NCI is receiving many ideas for great science. However, the increasing competition for NCI funds is challenging for investigators.

Because of the low overall paylines, NCI has given priority to the needs of early-stage investigators (ESIs). ESIs have completed their terminal research degree or their postdoctoral training within the past 10 years. The 21st Century Cures Act called on NIH to address the needs of ESIs, and NCI increased the total number of R01 and R01-equivalent grants to ESIs by more than 25 percent in 2018. NCI hopes to continue to increase this rate in 2019.

**NCI Budget.** NCI continues to receive strong support from Congress, which increased NCI funding by almost $180 million in 2019. Congress's appropriation of the NIH funding at the beginning of FY 2019 was very valuable in helping NCI plan for the entire fiscal year. In addition to increasing demands from the RPG pool, NCI continues to be challenged by the increasing costs of rent, utilities, mandatory assessments and transfers, training grant stipends, awards, and noncompeting out-year commitments to RPGs. NCI has therefore faced difficult decisions about where to make cuts without limiting the innovative ideas coming to the institute.

The President was expected to release his FY 2020 budget request in mid-March 2019, and Dr. Sharpless will testify before congressional appropriations committees. He went on to say that it is a privilege to explain the great work that NCI does to legislators. Members of Congress understand that NCI is making progress in combating cancer and views its investment in NCI as a good use of federal monies.

**Frederick National Laboratory for Cancer Research (FNLCR).** The FNLCR houses many functions that support NCI's intramural and extramural programs, including clinical trials. For example, the FNLCR has been responsible for much of The Cancer Genome Atlas and the molecular testing for NCI-MATCH (Molecular Analysis for Therapy Choice). Dr. Sharpless noted that NCI is thinking strategically about the goals for the FNLCR as a statement of work is being developed for the reissuance of the support award.

**CTAC Ad Hoc Working Groups**. Dr. Sharpless thanked CTAC members for their leadership and service in two CTAC ad hoc working groups on glioblastoma (chaired by Dr. Curran and Chi Van Dang, MD, PhD) and radiation oncology (chaired by Adam Dicker, MD, PhD, and Silvia Formenti, MD). These groups are identifying opportunities for translational therapeutic research.

## III. Discussion of the Progress in Pancreatic Ductal Adenocarcinoma (PDAC) Research Working Group Report

*James Abbruzzese, MD*

Dr. Loehrer explained that this session was a follow-up to Dr. Abbruzzese's presentation and CTAC's discussion at the last CTAC meeting on the findings of the Progress in PDAC Research Working Group. CTAC has now received the working group's report for discussion during this session.

***pending appointment**

The Progress in PDAC Research Working Group was convened to advise NCI of the relevance of initiatives in the 2014 PDAC scientific framework and to identify new research opportunities. The group's findings will help NCI complete the 5-year update of the PDAC scientific framework, which the institute will submit to Congress in 2019, as required by the Recalcitrant Cancer Research Act of 2012.

Dr. Abbruzzese said that the Progress in PDAC Research Working Group concluded that NCI has made a great deal of progress in many areas of PDAC research over the last 5 years. The working group focused its discussions in the report on four areas: PDAC biology (including genomics, metabolomics, and tumor biology); animal and human tissue models; risk, prevention, and screening; and diagnosis and treatment.

**Questions and Discussion**

Dr. Matrisian, a member of the Progress in PDAC Research Working Group, said that the report shows NCI's responsiveness to the Recalcitrant Cancer Research Act through the substantial progress made in the four focus areas of the report. NCI should be proud to send this report to Congress. The report, which will also be useful for NCI, describes opportunities to make even more progress in PDAC.

Dr. Mankoff, also a working group member, said that reviewing NCI's progress 5 years after the framework was developed was extremely helpful. When NCI created the initial framework, little new imaging technology was available. Five years later, existing imaging technology, such as computed tomography, has improved, and new technologies are producing important results on both detection and biomarkers to guide novel therapies. Dr. Mankoff encouraged NCI to consider implementing the next steps proposed in the conclusion of the report.

Dr. Meropol suggested that the treatment section of the report make more explicit the amount of additional research needed, in spite of the progress made. The report could point out, for example, that most people with PDAC, even those with early-stage PDAC, die of the disease. Dr. Abbruzzese agreed with Dr. Meropol's suggestion, noting that the report could highlight the need for funding to continue to make progress in the current initiatives, including in precision oncology, which is becoming more realistic for PDAC. Dr. Abbruzzese also pointed out that even when patients present with early-stage, resectable PDAC, their chance of surviving for 5 years is only 8 percent. PDAC biology is daunting, and the working group will strengthen the relevant language.

Dr. Loehrer suggested adding language to the conclusion about the unmet research needs in PDAC. He added that pancreatic cancer will be the second leading cause of cancer death by 2030.

Dr. Barton recommended that, given the complexity of PDAC and the associated morbidity and mortality, the report discuss the need for comprehensive care, including palliative care and psychosocial support services. These services are especially important in PDAC, where most of the population does not survive over the long term. Dr. Abbruzzese said that the report does mention cachexia and sarcopenia, which occur in patients with PDAC and contribute to disease morbidity. NCI comprehensive cancer centers are increasingly offering supportive and palliative care to all patients with advanced-stage cancer, including pancreatic cancer. But Dr. Abbruzzese agreed the report should not overlook this issue.

**Motion**. A motion carried to accept the progress report of the Progress in PDAC Working Group with the modifications recommended during this meeting.

## IV. Progress in Small Cell Lung Cancer (SCLC) Research Working Group Update

*Alex Adjei, MD, PhD*
*Laurie Gaspar, MD, MBA*

***pending appointment**

Dr. Loehrer explained that the Progress in SCLC Research Working Group was convened to advise NCI on the relevance of initiatives in the SCLC scientific framework developed 5 years ago and to identify new research opportunities in this area. The working group findings will help NCI update the SCLC framework, which is due to Congress in June 2019 in response to the Recalcitrant Cancer Research Act of 2012. Because CTAC will not meet again until July, the committee will approve the final report by email.

Dr. Gaspar reported that although rates of lung cancer, including SCLC, have been decreasing with smoking rates, SCLC is still a recalcitrant cancer in the United States. This is especially true for men, non-Hispanic whites, and those living in nonmetropolitan counties. This disease is responsible for 30,000 deaths per year, and its 5-year survival rate is less than 7 percent. Treatment over the past 35 years, which consists primarily of chemotherapy and sometimes radiation therapy, has changed very little. Patients typically respond initially to chemotherapy, but usually have an aggressive recurrence shortly thereafter. Although the availability of tissue specimens for research has increased, it is still limited. Early diagnostic approaches are also limited. The only known way to prevent SCLC is to avoid smoking.

After summarizing the recommendations from the 2014 scientific framework, Dr. Gaspar explained that the Progress in SCLC Research Working Group has met in person and by webinar. These meetings have provided updates on key scientific advances in the last 5 years, as well as opportunities to assess the continued scientific relevance of the initiatives in the 2014 framework and discuss NCI progress.

Dr. Adjei listed the key scientific advances for each of the five scientific initiatives from the 2014 scientific framework. The working group determined that NCI has addressed all five initiatives and the initiatives remain important. Although NCI has funded grants to address the initiatives, it is too early to report on their progress. Dr. Adjei then listed the working group's recommendations and the corresponding funding mechanisms of the SCLC Consortium supporting those recommendations.

Dr. Gaspar listed the members of the SCLC Consortium, which includes the principal investigators of consortium grants, NCI program staff and investigators, and principal investigators of other types of grants who are conducting SCLC research (associate members). The consortium has a coordinating center that provides cell line resources, tissue microarrays, a clinical correlates database, and other research resources. In 2018, NCI awarded 47 SCLC-related grants, compared with only 17 in 2012.

Dr. Gaspar ended the presentation by listing several gaps and opportunities in SCLC.

**Questions and Discussion**

Dr. Mankoff, a member of the Progress in SCLC Research Working Group, commented that advances in imaging technology can be leveraged to improve SCLC screening, such as by using computerized imaging techniques. The National Lung Cancer Screening Trial showed that screening was not very effective for SCLC, and discussions are ongoing about how to leverage these data for early detection. The working group identified some promising emerging approaches for the use of imaging biomarkers to guide therapies.

Dr. Curran asked about the working group's recommendations on leveraging industry activities, given the data now available from a breakthrough study. Companies are likely to invest substantial amounts in immuno-oncology products for SCLC and probably in the related science. Dr. Gaspar said that NCI partners with companies for some studies. Dr. Adjei added that NCI's National Clinical Trials Network is conducting SCLC studies that use compounds provided by industry. Many of these studies include biomarkers of interest to industry, and some are collecting tissue samples.

Dr. Perez-Soler, another working group member, suggested that the report emphasize more strongly that 98 percent of cases of SCLC are caused by tobacco use, a message that is particularly

important for policy makers. Dr. Gaspar agreed to add the suggested emphasis, noting that the working group had discussed smoking cessation and concerns about the growing use of electronic cigarettes.

Dr. Matrisian noted that the emphasis of the report was on translational research and how to translate those findings into clinical care. She asked whether the working group discussed the ongoing SCLC clinical trials. She recommended that the report address the importance of palliative and supportive care for patients with SCLC. Dr. Adjei said that the working group focused much of its in-person meeting on translational research. He noted that many clinical trials have failed, and the reasons for these failures are not known. The recommended translational research would collect samples and develop biomarkers to understand why some studies are successful and others are not. The working group also discussed a single study that would assess multiple targets and would collect biopsy and blood samples to better understand the disease.

Dr. Loehrer agreed that the working group's report provides an opportunity to educate Congress about the link between tobacco use and SCLC. With survival of just 2 to 4 months, untreated SCLC is the most aggressive tumor associated with tobacco use that Dr. Loehrer knew of, and the report should acknowledge this. He added that a small proportion of patients survive a long time with SCLC and suggested a longitudinal study to compare the biology underlying these exceptional cases with that of the vast majority of patients whose SCLC cannot be cured. A third suggestion from Dr. Loehrer was to list the research gaps and the research opportunities separately in the report.

Dr. Barton asked whether the populations whose data are used to inform the understanding of SCLC biology are diverse or homogeneous. Dr. Gaspar said that fewer SCLC specimens are available than specimens of other lung cancers, so most specimens probably come from a diverse population at initial diagnosis. However, studies are more common in patients seen at academic centers, who are likely to be less diverse. Dr. Adjei added that some early studies were in homogeneous groups, but the populations in larger studies have been more diverse. The working group has acknowledged the need to collect data on diverse patients, including patients who have no smoking history.

**Motion:** A motion carried to accept the recommendations presented at this meeting by the Progress in SCLC Research Working Group.

## V. Biospecimen Banks to Support NCI Clinical Trials

*Irina Lubensky, MD*

The biospecimen banks supporting NCI clinical trials collect, process, store, and distribute well-annotated clinical trial biospecimens for research. Currently, NCI supports the banks of the NCI National Clinical Trials Network (NCTN) and, as a pilot project, the Experimental Therapeutics Clinical Trials Network bank.

Five NCTN U24 cooperative grants support five NCTN biospecimen banks for each of the NCTN groups. The five banks share common documents, standard operating procedures, and operation templates for implementation by all banks. The specimens are collected by NCTN groups from phase II, phase III, and other clinical trials. The specimens are initially used by trial group investigators for integral and integrated biomarker studies. Any samples remaining in excess after trial requirements have been met become "legacy" specimens and are available for secondary correlative studies to all investigators (NCTN group or nongroup investigators) after they complete an NCTN biospecimen access process and receive approval by the NCTN Core Correlative Sciences Committee.

These specimens are best used for validation studies of predictive or prognostic biomarkers and for assay development and validation. The specimens are well annotated with clinical and outcome data and are not suitable for basic science studies. The banks contain solid tumor specimens from all organ sites and hematologic malignancies. Between 2013 and 2017, the banks distributed more than 440,000 samples. Dr. Lubensky shared details on the types and characteristics of the samples distributed by NCTN

***pending appointment**

banks from NCTN trials between 2013 and 2017, as well as numbers of samples collected each year during this period. To date, 572 publications have resulted from the use of bank specimens in scientific studies, and some resulted in change in clinical practice.

NCI launched NCTN Navigator, a clinical trials "legacy" specimen access resource, in April 2018. This tool consolidates the NCTN biospecimen inventory, connects biospecimens with clinical data, gives the research community access to the specimens, and tracks applications from investigators to use the biospecimens. The NCTN Front Door Service guides investigators through the query, application, and regulatory filing procedures. Investigators do not need to be associated with an NCTN group to request legacy biospecimens.

The rationale for NCI to keep supporting the biospecimen banks is that they are the only resource that supports NCI clinical trials and that the NCTN biospecimens are used in a wide range of validation studies for predictive and prognostic biomarkers and assay development. An external review panel agreed that the biospecimen banks are of high value, the specimens are unique, and NCI provides transparent access to legacy specimens through NCTN Navigator and other resources. Commercial and academic biospecimen resources cannot supply similar trial specimens for research from such a broad range of tumor types with such detailed annotations.

NCI plans to issue a U24 cooperative agreement for five NCTN biospecimen banks in 2020–2026. The plan includes funding for the first time for such functions as NCTN Biospecimen Navigator Front Door Service curation; processing, quality assurance, and quality control of approved legacy specimen applications; and processing of fresh tissue specimens from immunotherapy trials. The plan also includes expanding the Experimental Therapeutics Clinical Trials Network Bank pilot test into a separate early clinical trials bank, adding Pediatric Early Phase Clinical Trials Network biospecimen banking to the Children's Oncology Group NCTN bank, and adding NCI Community Oncology Research Program trial specimens to the NCTN banks.

Following her presentation Dr. Lubensky posed CTAC members with the following four questions: (1) Is the rationale/justification adequate for sustained NCI funding to cover the clinical trial banking infrastructure and previously unfunded processes and operations?; (2) What are the functions that NCTN and early trial banks need to fulfill in the future that require NCI investment?; (3) Will the current and future strategies for improved biospecimen access through NCTN Navigator help researchers and increase use of NCTN legacy specimens?; (4) What are the best ways to increase awareness of NCTN biospecimen bank resources in the research community, beyond the strategies the program is using currently?

**Questions and Discussion**

Dr. Curran noted that NCTN biospecimen bank leaders are asking for more clarity about the roles and responsibilities, including financial responsibilities, of the NCTN groups/Banks in regard to specimen processing for the Cancer Immune Monitoring and Analysis Centers (CIMACs) assays. Biospecimen bank leaders view the need to harmonize CIMAC efforts with those of the biospecimen banks as a challenge. Dr. Lubensky said that the NCTN Group Banking Committee has met with CIMAC and NCI representatives, and NCI is working to ensure that all banks use harmonized procedures for CIMAC tissue processing.

Dr. LeBlanc supported the plan to provide the additional resources needed to cover the costs of previously unfunded processes. Dr. Loehrer asked about the program's capacity to implement the proposed expansions. Dr. Lubensky said that the infrastructure to implement the expansion is in place, and the additional funding requested would enable NCTN Banks to hire more staff.

***pending appointment**

Dr. Loehrer asked whether the biospecimens in the banks are annotated in real time. For example, can an investigator simply push a button to send samples from all long-term survivors with small cell lung cancer for analysis? Dr. Lubensky said that the specimens in Navigator are fully annotated.

Meg Mooney, MD, MBA, Chief of NCI's Clinical Investigations Branch, explained that NCTN Navigator was designed to include all of the information available on specimens from the biospecimen banks. Investigators can therefore run appropriate searches and use the Front Door Service to make sure that the specimens they are seeking are available. For ongoing trials with an integral or integrated biomarker component, the annotations are collected in real time. NCI is trying to provide this type of service for all specimens that become available after a trial has ended and the results have been published. Dr. LeBlanc said that having the annotations in real time is very helpful.

Dr. Mankoff asked about the process for reviewing requests for specimens. Dr. Mooney replied that the NCTN Core Correlative Sciences Committee reviews all requests received through Navigator. Dr. Mankoff suggested triaging the requests, and Dr. Mooney said that her office is working with bankers and investigators to identify ways to perform this triaging.

Dr. Loehrer asked whether it is possible to identify samples from all patients with certain genetic mutations instead of certain types of cancer. Dr. Mooney said that if genomic data are collected, it should be possible to identify specimens from patients with certain genetic mutations from different databases. However, this process is not yet seamless. Dr. LeBlanc added that if a study's clinical data have been published, the patient-level data will become available as part of NCTN's data-sharing archive.

Dr. Loehrer agreed that the current and proposed future strategies will improve biospecimen access through Navigator and increase the use of NCTN legacy specimens. Dr. Curran recommended that the NCTN Navigator application process be reviewed on a regular basis to make sure, for example, that the process is as streamlined as possible and applications undergo the appropriate level of scrutiny. Dr. Mooney said that such regular reviews would be welcome. She added that the Core Correlative Sciences Committee, which has representatives from all NCTN groups, is addressing these types of issues.

Dr. Mankoff said that the review process is administered well. However, if the number of samples in the banks increases, it makes sense to review the application process from start to finish to make sure that it responds efficiently to investigator needs.

Dr. Lubensky explained the current strategies that the program is using to increase awareness of the biospecimen bank by listing NCTN Navigator and the biospecimen banks on the Division of Cancer Treatment and Diagnosis, Cancer Diagnosis Program, NCI Resources for Researchers website, as well as a Specimen Resource Locator database. NCI also hosts exhibits and gives presentations at national conferences.

Dr. Barton suggested that NCI develop a slide about the biospecimen banks to be used in all scientific presentations delivered by specimen users. The audiences for these presentations are most likely to want to use the biospecimens. She also suggested that NCI distribute brochures, postcards, and other giveaways listing the NCTN Navigator URL.

Mr. Arons suggested that NCI require grantees to submit information on their biospecimen collections to the NCI Specimen Resource Locator website. This would not mean that investigators must share their specimens, but it would help other investigators determine which specimens are available in which banks. Dr. Doroshow said that this suggestion is worth considering and noted that NCI does require investigators to list NCI resources in the acknowledgment sections of their journal articles.

## VI. New Business and Concluding Remarks

***pending appointment**

*Patrick J. Loehrer, Sr., MD*

Dr. Loehrer said that CTAC will next meet face to face on July 17, 2019, and the agenda will include an update from the Glioblastoma Working Group.

On March 14, 2019, the CTAC planning group will meet to discuss future meeting topics. CTAC members interested in participating in this meeting should contact Dr. Prindiville.

## VII. Adjournment

*Patrick J. Loehrer, Sr., MD*

There being no further business, the 38th meeting of CTAC was adjourned at 12:55 p.m. on Wednesday, March 6, 2019.

***pending appointment**

**Appendix**

# NATIONAL INSTITUTES OF HEALTH
## National Cancer Institute
## Clinical Trials and Translational Research Advisory Committee

### CHAIR

**Patrick J. Loehrer, Sr., MD** **2020**
Director
Indiana University Melvin and
Bren Simon Cancer Center
Associate Dean for Cancer Research
Indiana University School of Medicine
Indianapolis, Indiana

### MEMBERS

**David F. Arons, J.D. (NCRA)** **2019**
Chief Executive Officer
National Brain Tumor Society
Watertown, Massachusetts

**Debra L. Barton, Ph.D., R.N., F.A.A.N.** **2021**
Mary Lou Willard French Professor of
Oncology Nursing
University of Michigan School of Nursing
Ann Arbor, Michigan

**Walter J. Curran, Jr., M.D., F.A.C.R.** **2019**
Executive Director
Winship Cancer Institute of Emory University
Atlanta, Georgia

**Janet Ellen Dancey, M.D., F.R.C.P.C.** **2021**
Professor
Department of Oncology
Queen's University
Director, Canadian Cancer Trials Group
Kingston, Ontario
Canada

**Nancy E. Davidson, M.D. (BSC)** **2022**
Senior Vice President, Director and Full
Member, Clinical Research Division
Fred Hutchinson Cancer Research Center
President & Executive Director
Seattle Cancer Care Alliance Head, Division of
Medical Oncology, Department of Medicine
University of Washington
Seattle, Washington

**Timothy J. Eberlein, M.D.** **2020**
Director, Alvin J. Siteman Cancer Center
Spencer T. and Ann W. Olin Distinguished
Professor
Bixby Professor and Chairman
Department of Surgery
Washington University School of Medicine
in St. Louis
St. Louis, Missouri

**Howard J. Fingert, M.D., F.A.C.P.** **2020**
Senior Medical Director
Oncology Clinical Research
Millennium, The Takeda Oncology Research
Company
Takeda Pharmaceutical International, Inc.
Cambridge, Massachusetts

**David M. Gershenson, M.D.** **2020**
Professor of Gynecology
Department of Gynecologic Oncology and
Reproductive Medicine
Division of Surgery
The University of Texas
MD Anderson Cancer Center
Houston, Texas

***pending appointment**

**Paul A. Godley, M.D., Ph.D., M.P.P.** **2021**
Vice Dean for Diversity and Inclusion
Dickson Distinguished Professor of Medicine, Hematology/Oncology
Lineberger Comprehensive Cancer Center
University of North Carolina School of Medicine
Chapel Hill, North Carolina

**Anne-Marie R. Langevin, M.D.** **2021**
Greehey Distinguished Chair in Pediatric Oncology
Department of Pediatrics Hematology/Oncology
The University of Texas Health Science Center at San Antonio
San Antonio, Texas

**Michael L. LeBlanc, Ph.D.** **2019**
Member
Fred Hutchinson Cancer Research Center
University of Washington
Seattle, Washington

**David A. Mankoff, M.D., Ph.D.** **2019**
Gerd Muehllehner Professor of Radiology
Vice-Chair for Research
Department of Radiology
Perelman School of Medicine
University of Pennsylvania
Philadelphia, Pennsylvania

**Lynn M. Matrisian, Ph.D., M.B.A.** **2021**
Chief Science Officer
Pancreatic Cancer Action Network
Washington, D.C.

**Neal J. Meropol, M.D.** **2021**
Vice President of Research Oncology
Flatiron Health
New York, New York

**Augusto C. Ochoa, M.D.** **2019**
Director
Stanley S. Scott Cancer Center
Professor
Department of Pediatrics
Louisiana State University Health Sciences Center
New Orleans, Louisiana

**Roman Perez-Soler, M.D. (BSC)** **2020**
Chairman
Department of Oncology
Montefiore Medical Center
Deputy Director
Albert Einstein Cancer Center
Director
Division of Medical Oncology
Albert Einstein College of Medicine
Bronx, New York

**Gloria M. Petersen, Ph.D.** **2020**
Deputy Director, Mayo Clinic Cancer Center
Professor of Epidemiology
Department of Health Sciences Research
Mayo Clinic College of Medicine
Rochester, Minnesota

**Steven T. Rosen, M.D., F.A.C.P.** **2021**
Provost & Chief Scientific Officer
Director
Comprehensive Cancer Center and Beckman Research Institute
Irell & Manella Cancer Center Director's Distinguished Chair
Comprehensive Cancer Center
City of Hope
Duarte, California

**Dan Theodorescu, M.D., Ph.D.** **2020**
Director
Samuel Oschin Comprehensive Cancer Institute
Cedars-Sinai Medical Center
Los Angeles, California

**Ex Officio Members**

**William L. Dahut, M.D.**
Scientific Director for Clinical Research
Center for Cancer Research
National Cancer Institute
National Institutes of Health
Bethesda, Maryland

**James H. Doroshow, M.D.**
Deputy Director
Clinical and Translational Research
Director, Division of Cancer Treatment and Diagnosis
National Cancer Institute
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**Paulette S. Gray, Ph.D.**
Director
Division of Extramural Activities
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**Michael J. Kelley, M.D., F.A.C.P.**
National Program Director for Oncology
Veterans Health Administration
Department of Veterans Affairs
Durham, North Carolina

**Anthony Kerlavage, Ph.D**.
Acting Director, Center for Biomedical Informatics and Information Technology
Office of the Director
National Cancer Institute
National Institutes of Health
Bethesda, Maryland

**Richard Pazdur, M.D., F.A.C.P.**
Director
Oncology Center of Excellence
U.S. Food and Drug Administration
Silver Spring, Maryland

**Katherine Szarama, Ph.D.**
Epidemiologist
Centers for Medicare & Medicaid Services
Baltimore, Maryland

**Executive Secretary**

**Sheila A. Prindiville, M.D., M.P.H.**
Director
Coordinating Center for Clinical Trials
Office of the Director
National Cancer Institute
National Institutes of Health
Bethesda, Maryland