DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH
NATIONAL CANCER INSTITUTE
43rd CLINICAL TRIALS AND TRANSLATIONAL RESEARCH ADVISORY COMMITTEE (CTAC) MEETING

Summary of Meeting
November 4, 2020

Webinar

CLINICAL TRIALS AND TRANSLATIONAL RESEARCH ADVISORY COMMITTEE
Summary of Meeting
November 4, 2020

The 43rd meeting of the Clinical Trials and Translational Research Advisory Committee (CTAC) of the National Cancer Institute (NCI) was on Wednesday, November 4, 2020, at 11:01 a.m. The CTAC chair, Dr. Loehrer, presided.[1] The meeting was adjourned at 2:26 p.m.

Chair
Patrick J. Loehrer, Sr.

CTAC Members
Debra L. Barton
Charles D. Blanke
Janet Ellen Dancey
Nancy E. Davidson
Anjelica Q. Davis
Adam P. Dicker
Timothy J. Eberlein
David M. Gershenson
Ernest T. Hawk
Michael V. Knopp
Anne-Marie R. Langevin
Mia Levy
Sumithra J. Mandrekar
Lynn M. Matrisian
Neal J. Meropol
Augusto C. Ochoa
Roman Perez-Soler
Gloria M. Petersen
Steven T. Rosen (absent)
Victor M. Santana
Dan Theodorescu
Julie M. Vose

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

Executive Secretary
Sheila A. Prindiville, NCI

Presenters
Rick Bangs, MBA, Patient Advocate, Bladder Cancer Advocacy Network
Nancy E. Davidson, MD, 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
Adam P. Dicker, MD, PhD, Professor and Chair, Department of Radiation Oncology, Sidney Kimmel Cancer Center, Thomas Jefferson University
James H. Doroshow, MD, Deputy Director, Clinical and Translational Research; Director, Division of Cancer Treatment and Diagnosis, NCI

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

Silvia C. Formenti, MD, Sandra and Edward Meyer Professor of Cancer Research and Chair, Department of Radiation Oncology, Weill Cornell Medicine; Radiation Oncologist in Chief, NewYork-Presbyterian/Weill Cornell Medical Center

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

Kim Norris, President, Lung Cancer Foundation of America

M.K. Holohan, JD, Director, Office of Government and Congressional Relations, NCI

Norman E. Sharpless, MD, Director, NCI

TABLE OF CONTENTS
Wednesday, November 4, 2020

I. Call to Order and Opening Remarks

Patrick J. Loehrer, Sr., MD

Dr. Loehrer called the 43rd meeting of CTAC to order and welcomed participants. He introduced Dr. Schneider, who was representing the U.S. Food and Drug Administration in place of Richard Pazdur, MD, at this meeting.

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 became available for viewing at https://videocast.nih.gov/watch=38785 after the meeting.

The next CTAC meeting, which will take place on March 17, 2021, will again be virtual. The subsequent meeting will be on July 14, 2021, and Dr. Loehrer hoped that the July meeting would be held in person.

Motion. A motion to accept the minutes of the 41st CTAC meeting, held on March 12, 2020, was approved.

II. NCI Director's Update

Norman E. Sharpless, MD

NCI Appropriations. Over the past few years, base funding for NCI has increased steadily, reflecting the broad bipartisan agreement in Congress that cancer research is a good use of federal funds. In addition to its standard annual appropriation, NCI has received funding for the Cancer Moonshot, created by the 21st Century Cures Act, each year since 2017. This 5-year program is starting to bear fruit in the form of exciting scientific and translational opportunities. NCI also received $50 million for the Childhood Cancer Data Initiative in fiscal year (FY) 2020 to learn from and make progress for every child with cancer in the United States. Additional NCI appropriations in FY 2020 included $306 million for COVID-19 serology research and $414 million for emergency use.

The House of Representatives passed an emergency pandemic-related funding bill that was still being discussed at the time of this meeting and could include some funding for NIH. The COVID-19 pandemic has had a major impact on cancer research and cancer clinical trials across the country. NCI expects to incur pandemic-related costs in FY 2021; funds to address these missed opportunities would be valuable.

NCI, like the rest of the federal government, is operating under a continuing resolution that expires on December 11, 2020. Congress will decide whether to pass another continuing resolution or an appropriations package before that date to avert a federal government shutdown.

Increasing the R01 Payline. The National Cancer Act gave NCI the opportunity to provide a bypass budget, or professional judgment budget, directly to Congress. This budget describes the opportunities in cancer research that could be supported by additional funding.

Dr. Sharpless highlighted one of the many exciting opportunities described in the FY 2022 bypass budget, released in September 2020: achieving a 15 percent payline for R01 grant applications in FY 2025. This plan, known as the "15 by 25 initiative," will be challenging to implement. For example, the $200 million increase in the research project grant (RPG) pool between FY 2019 and FY 2020 raised the

payline from 8 percent to 10 percent. In comparison, the Cancer Centers Program, which is one of the most popular and perhaps most successful programs at NCI, has an annual budget of $300 million.

Increasing the R01 payline to 15 percent would require strong support from Congress and the administration, but NCI is optimistic because the basic, translational, and health services research conducted through R01 grants has been so valuable to progress in cancer. Additional funding for the RPG pool also provides a way to support investigators who will face greater challenges than in the past to obtain funding from foundations that are experiencing pandemic-related fundraising challenges.

Response to the COVID-19 Pandemic. Drs. Doroshow, Prindiville, and Loehrer, along with others, were authors of a recent article in the *Journal of the National Cancer Institute* that described the impact of the COVID-19 pandemic on cancer clinical trials and related social justice issues.

Dr. Sharpless highlighted some of the many activities that NCI has undertaken in response to the pandemic. Early on, NCI began providing as much flexibility as possible with deadlines and use of carryover funds so that grantees could continue their research in spite of pandemic-related disruptions. In addition, NCI determined that allowing clinical trial participants to receive certain types of medical care close to home rather than at study sites was not a protocol deviation. The institute also determined that study sites could ship oral drugs, including those with an investigational new drug designation, directly to participants so they would not have to risk exposure to the novel coronavirus during clinic visits. Study sites were also permitted to obtain informed consent from participants remotely. The cancer research community has embraced these efforts and used them heavily, and patients appreciate the flexibility. One silver lining of the pandemic for NCI is that it has learned how to do things differently in clinical trials, and Dr. Sharpless predicted that some of these changes are here to stay.

In April 2020, Congress appropriated $306 million for NCI for coronavirus research needs involving serology and related technologies. NCI has used some of these funds to launch the Serological Sciences Network for COVID-19, the nation's largest coordinated effort to study the immune response to COVID-19. The network aims to combat the pandemic by improving the ability to test for SARS-CoV-2 infection, especially among diverse populations, and speed the development of treatments and vaccines. This new program was implemented rapidly; the institute received the funds in late April and issued its first grants in October. This program now has eight U54 centers of excellence and 13 U01 awards for research on basic science of serology and its relationship to other aspects of the immune system, as well as on increasing the capacity for serology testing nationally. The network gives samples to NCI for its serology-related activities, including the validation of testing kits and other technologies for the U.S. Food and Drug Administration.

The NCI COVID-19 in Cancer Patients Study, which began within 6 weeks of the study's conception, is examining the impact of COVID-19 on people with cancer. This issue is important because of the increased risk of complications in people with certain comorbidities and the potential for long-term complications of COVID-19. This trial is supported by NCI's National Clinical Trials Network, Experimental Therapeutics Clinical Trials Network, and Community Oncology Research Program. The trial has activated more than 800 sites and is enrolling participants in almost all 50 states. The trial's protocol was recently amended to include enrollment of children. In contrast to the many registry studies underway, this is a clinical trial that includes informed consent, longitudinal follow-up, and robust specimen collection so that investigators can learn about biology and predictive markers in the study population.

NCI has been very concerned about the pandemic's impact on people with cancer, who face delays in screening and diagnosis as well as deferred care. A recent NCI Cancer Intervention and Surveillance Modeling Network report published in *Science* estimated that 10,000 excess deaths from

breast cancer and colon cancer will occur over the next decade. This estimate, which is equivalent to a 1 percent increase, is probably very conservative. NCI modeling has shown effects on diagnosis and care for other types of cancer, including lung cancer and pancreatic cancer. Dr. Sharpless is particularly concerned about the more than 50 percent decrease in new cancer diagnoses in the United States and United Kingdom in some time periods during the pandemic. The number of new cancers would not be expected to drop, so it is likely that diagnoses of cancer have been delayed, resulting in detection of cancer at later stages that are associated with poorer outcomes.

The pandemic's impact on cancer clinical trials is evident in the 50 percent decline in weekly enrollment rates in early April. Although recruitment in National Clinical Trials Network studies has rebounded, some large screening trials that were not meeting their recruitment targets before the pandemic now face additional recruitment challenges. To address this need, NCI convened the CTAC *ad hoc* Working Group on Cancer Screening Trials, chaired by Dr. Davidson. This working group will advise NCI on the real-world impact of the pandemic on screening trials, the scientific questions that can be answered, and strategies for overcoming these challenges. NCI has asked the group to focus first on the Tomosynthesis Mammographic Imaging Screening Trial. NCI is committed to the women participating in this study and to ensuring that their contributions will be maximally informative.

An unexpected positive outcome during the pandemic has been the lessons learned about the use of telehealth to deliver medical care. Patients appreciate the convenience of seeing some of their doctors by telehealth. NCI needs to do research to learn, for example, about the benefits and drawbacks of telehealth and how providers use telehealth for cancer care. NCI issued a request for information in July 2020 to identify research gaps related to the delivery of cancer-related care by telehealth technologies, and it is now determining which funding opportunities, if any, to issue.

Other Updates. An upcoming article in the *New England Journal of Medicine* reports that some of the decline in lung cancer mortality in recent years was due to new cancer drugs for subtypes of non–small-cell lung cancer. Because they only include outcomes through 2016, these data probably reflect the effects of kinase inhibitors and perhaps improvements in surgery and chemotherapy. However, 2016 was too early to show the effects of new immunotherapies.

In August 2020, NCI and Cancer Research UK jointly launched a new Cancer Grand Challenges partnership to solicit profound and unanswered questions in cancer research from large interdisciplinary teams around the world. NCI will allocate funds every other year to this program. Funds will go to the institute's Grand Challenges program in the alternate years, so this new partnership will not use funding budgeted for NCI's investigator-initiated research pool.

Recent events have brought to the fore the problem of racial injustice in the United States. NCI has developed a structure to help promote a more just and equitable society. For example, NCI has formed an equity council that Dr. Sharpless chairs with Dr. Gray. This council has three topic-based working groups focused on enhancing research to address cancer health disparities, ensuring diversity of the cancer research workforce, and promoting an inclusive and equitable community at NCI. The working groups are now developing action plans.

NCI is also coordinating the network portion of the NIH Common Fund's Faculty Institutional Recruitment for Sustainable Transformation program, which aims to enhance and maintain cultures of inclusive excellence in the biomedical research community. This program will provide cooperative agreements to institutions that are committed to the advancement of diverse faculty members.

In 2021, NCI will commemorate the 50th anniversary of the National Cancer Act. This act created the Cancer Centers Program, the Frederick National Laboratory for Cancer Research, and the

Surveillance, Epidemiology, and End Results Program. This anniversary is important for everyone interested in cancer, including patients, caregivers, and scientists.

Questions and Discussion

Dr. Loehrer asked about the likelihood that NCI will receive the up to $3 billion needed to raise the R01 payline to 15 percent by 2025. Dr. Sharpless replied that the likelihood is difficult to assess. NCI cannot accomplish this goal by simply redirecting some funding from other programs; it will need help from Congress, which has a great deal of interest in funding biomedical research for many reasons, including the pandemic.

III. Recognition Ceremony

Norman E. Sharpless, MD
James H. Doroshow, MD

Dr. Doroshow thanked the retiring CTAC members— Drs. Eberlein, Fingert, Gershenson, Ochoa, Perez-Soler, Petersen, and Theodorescu—for their service on CTAC.

The Cancer Clinical Investigator Team Awards recognize and support outstanding clinical investigators at NCI-Designated Cancer Centers who are engaged in NCI-funded collaborative clinical trials. Candidates are nominated each year by NCI cancer center directors, and each recipient receives $60,000 per year for 2 years. Of the 114 recipients of this award between 2009 and 2018, 96 percent still hold academic clinical research positions. The recipients in 2020 are:

- Pavani Chalasani, MD, MPH, University of Arizona Comprehensive Cancer Center
- Heather Cheng, MD, PhD, Fred Hutchinson Cancer Research Center
- Sara Federico, MD, St. Jude Comprehensive Cancer Center, St. Jude Children's Research Hospital
- Muhammad Furqan, MD, Holden Comprehensive Cancer Center, University of Iowa
- Siwen Hu-Lieskovan, MD, PhD, Huntsman Cancer Institute, University of Utah
- Brian Jonas, MD, PhD, University of California at Davis Comprehensive Cancer Center
- Lakshmi Nayak, MD, Dana Farber Cancer Institute
- Rayne Rouce, MD, Dan L. Duncan Comprehensive Cancer Center, Baylor College of Medicine

IV. Legislative Update

M.K. Holohan, JD

At the time of this meeting, ballots for the national election on November 3 were still being counted in many states, and the final results of the presidential and congressional races were not yet known.

The House Democrats planned to hold their leadership elections on November 18–19, 2020. The top three Democrats—Speaker Nancy Pelosi (CA), Majority Leader Steny H. Hoyer (MD), and Majority Whip James E. Clyburn (SC)—were running uncontested for another term. The Democratic Steering and Policy Committee planned to meet the week of November 30 to nominate committee chairs. House Republicans planned to hold their leadership election on November 17. The top three House Republicans—Minority Leader Kevin McCarthy (CA), Minority Whip Steve Scalise (LA), and Republican Conference Chairwoman Liz Cheney (WY)—were running unopposed. The House Republican Steering Committee will meet later to choose leaders and members of other committees. Elections for the Senate are expected to happen at approximately the same time as those for the House.

On May 15, 2020, the House of Representatives passed the $3 trillion Health and Economic Recovery Omnibus Emergency Solutions Act, which would provide $4 billion to NIH to prevent, prepare for, and respond to the novel coronavirus. This sum would include $300 million to offset the costs related to reductions in laboratory productivity resulting from the pandemic. The Senate did not obtain the votes needed to advance a $300 billion package in September or a $500 billion package in October.

The current continuing resolution ends on December 11, 2020. The House passed an appropriations bill in July that included a $5.5 billion increase for NIH. The Senate was likely to release its appropriations bill on November 10. Appropriations might be combined with a COVID-19 supplement into one large package. Over time, continuing resolutions have become more common and lasted longer, and they create budgeting complications for NIH and NCI.

This is a time of great uncertainty. NCI's Office of Government and Congressional Relations will continue to monitor the funding activities of Congress and provide reports to NCI's advisory boards. Ms. Holohan invited CTAC members with questions to email or call her after the meeting.

Questions and Discussion

In response to a comment about support for cancer research, Ms. Holohan replied that Congress has shown major bipartisan support for cancer research funding, and there is every reason to expect this support to continue.

V. Translational Research Strategy Subcommittee Update

Nancy E. Davidson, MD

Dr. Davidson provided an update on the activities of the CTAC *ad hoc* Translational Research Strategy Subcommittee (TRSS), which she co-chairs with Chi V. Dang, MD, PhD. The subcommittee's mission is to survey scientific horizons and provide broad advice to NCI's advisory boards and leaders on how to enhance and broaden the institute's translational research portfolio.

Two *ad hoc* working groups—on glioblastoma and radiation oncology—were formed under the TRSS. CTAC reviewed and approved the report of the *ad hoc* Working Group on Glioblastoma during its July 2019 meeting. NCI released a request for applications on August 27, 2020, to establish the NCI Glioblastoma Therapeutics Network, which will support discovery and development of glioblastoma therapies.

On October 5, 2020, the TRSS reviewed and accepted the report of the *ad hoc* Working Group on Radiation Oncology, co-chaired by Dr. Dicker and Dr. Formenti, who will present this report to CTAC after Dr. Davidson's presentation.

Motion. A motion carried to accept the summaries of the TRSS meetings on May 8, 2019; July 8, 2019; and October 5, 2020.

Dr. Davidson and Dr. Dang recently met with NCI leaders to discuss next steps for the TRSS. So far, the subcommittee has focused on responding to requests from NCI. But in the future, the TRSS might identify research gaps for NCI to address.

VI. Radiation Oncology Working Group Report

Adam P. Dicker, MD, PhD
Silvia C. Formenti, MD

Dr. Dicker explained that the mission of the Translational Research Strategy Subcommittee (TRSS) *ad hoc* Working Group on Radiation Oncology was to survey the scientific horizons to identify the following:

- Knowledge gaps in radiation oncology translational research
- The most provocative and impactful radiation oncology translational research questions to advance cancer treatment
- The most important opportunities for the application of new technologies in radiation oncology translational research

The working group was formed in May 2019 and met in person on October 7, 2019, to review the research landscape, identify gaps and opportunities, and develop draft recommendations to NCI. In October 2020, the TRSS reviewed and accepted the working group's draft report for submission to CTAC. At that time, the TRSS provided valuable feedback, which the working group has integrated into the latest version of the report.

Radiation Oncology: Background and Challenges. Radiation oncologists are recognized leaders in quality, innovation, and value in multidisciplinary cancer care. The use of radiation has been used to treat cancer for more than 100 years. More than half of patients with cancer receive radiation therapy at some point during their disease course for locally advanced or metastatic disease, and some patients receive multiple courses of radiation. Radiation can cure early-stage tumors and improve tumor control and survival when used alone or in combination with surgery, chemotherapy, or both for many locally advanced tumors. The addition of chemotherapy to radiotherapy has increased the cure rate for many cancer types and is one of the most important advances in cancer care in the past 30 years.

Innovation in the past two decades has been driven primarily by advances in technology that have made this treatment modality safer. Recent advances include the development of stereotactic radiation treatment, proton and particle therapy, and brachytherapy. Tumor irradiation causes various biological consequences that can be leveraged to enhance the effects of radiation.

Major knowledge gaps remain in understanding the effects of radiotherapy on healthy and malignant tissue in humans. For precision medicine, a better understanding of the biological consequences of radiation therapy is required to incorporate molecular tumor characteristics and the immune microenvironment into treatment planning. Large volumes of data are generated through radiotherapy, including imaging and dosimetry data, and these data are integrated into electronic medical records. However, radiation oncologists believe that they lack training opportunities in bioinformatics, genomics, and immunology to leverage these large amounts of data for research and improved patient care.

Working Group Recommendations. Dr. Formenti stated that the working group's overarching recommendation is to establish an agile and effective, coordinated, national effort to advance the study of the biologic mechanisms of radiotherapy through preclinical and translational research studies to develop promising radiotherapeutic approaches to advance cancer care.

Other recommendations in the working group report are to:

I. Prioritize and support research to investigate the translational mechanistic interactions and

biologic consequences of ionizing radiation to facilitate bench-to-bedside-and-back research.

II. Support the longitudinal collection of clinically annotated biospecimens before, during, and after radiation therapy for research purposes.
III. Develop a coordinated infrastructure to support translational research, which could include a centralized validation laboratory designed to leverage the expertise of investigators, accelerate discovery, and validate key findings.
IV. Prioritize and support the development of animal and preclinical model systems (with normal tissue toxicity and radiation response) that are specific to radiation therapy and use shared resources.
V. Develop a multidisciplinary workforce to develop stakeholders with the expertise to conduct studies in translational, preclinical, and clinical radiation oncology.

Questions and Discussion

Dr. Loehrer asked how NCI could lead the effort described in Recommendation V, especially in low-income countries that have limited access to radiotherapy. Bhadrasain Vikram, MD, of NCI explained that the working group did not discuss international aspects of the issue, and other federal efforts are addressing these needs. The focus of this working group is on domestic capabilities, an area that still requires a great deal of work.

Dr. Loehrer said that NCI has an opportunity to assist with workforce development in other parts of the world where needed expertise is lacking, although such assistance was not part of the working group's discussions of workforce development. C. Norman Coleman, MD, of NCI noted that artificial intelligence and other new technologies can make radiotherapy simpler to use in settings with fewer resources. By addressing workforce development needs in other countries, NCI has an opportunity to address social problems and develop research opportunities for cancer. Dr. Formenti added that enhancing understanding of mechanisms might clarify the effects of radiotherapy and simplify it in ways that could make it more accessible and cost-effective worldwide.

Dr. Formenti said that the use of radiation modalities around the world could provide insights into the best ways to use these very expensive treatment modalities. Dr. Dicker added that collaborating with international groups working with the same diseases could provide opportunities to determine whether the treatment algorithms used in certain parts of the world have biases. For example, an algorithm that is effective in a North American population might need to be modified for an Asian subpopulation with the same type of cancer.

Dr. Schneider asked about the U.K.-based RT-Drug Combinations Consortium, which is mentioned in the working group report. Dr. Dicker replied that this public–private partnership is generating preclinical data to show whether combining certain drugs with radiotherapy can improve outcomes. Dr. Dicker did not know whether the results of this consortium's efforts have been translated to the bedside yet, but the group serves as a good example of bringing like minds together.

Dr. Loehrer suggested that the working group discuss how to determine when certain types of radiation therapy should and should not be used. Dr. Dicker said that one question in the field is whether to irradiate the entire tumor in a homogenous manner or to treat only the biologically active part of the tumor and preserve the immune microenvironment. The fact that a given type of radiotherapy is available does not mean that it should be used in every patient.

Motion. A motion carried to accept the report of the Radiation Oncology Working Group.

VII. Enhancing the Value of NCI Task Force and Steering Committee Patient Advocates via the NCI Patient Advocate Steering Committee

Rick Bangs, MBA
Kim Norris

Mr. Bangs and Ms. Norris are former co-chairs of the NCI Patient Advocate Steering Committee (PASC), which helps ensure that patient advocates on scientific steering committees and their task forces are effectively and consistently integrated into the evaluation and monitoring of clinical trials. While leading PASC, Mr. Bangs and Ms. Norris clarified the PASC mission to focus on best practices for advocates, address common concerns, identify training needs, and share information between steering committee and task force advocates.

PASC identified four core competencies for steering committee and task force advocates: cancer and research, roles of steering committee and task force advocates, NCI processes, and effective engagement. PASC created working groups to address orientation for new members, mentoring, and concept reviews. Outcomes of these activities included new descriptions of the roles of steering committee and task force advocates, a new concept review form with guiding questions, a training and orientation program that includes mentorship for new members, and a presentation brief for advocates. PASC also identified markers of success for the committee. A secure PASC website provides a wealth of useful resources to members.

Next steps include potentially writing a description of the process described by Mr. Bangs and Ms. Norris and submitting it for publication. In addition, PASC should consider how to leverage the processes and tools developed beyond PASC.

Questions and Discussion

Dr. Loehrer said that cancer center directors would be interested in the resources that Mr. Bangs and Ms. Norris had described. A presentation at the annual meeting of the Association of American Cancer Institutes is one way to spread the word to this audience.

To show the advocates' impact, Dr. Meropol suggested that PASC collect perspectives from steering committee and task force chairs on the roles of advocates in these groups as well as data on changes to proposals resulting from advocate comments.

Dr. Blanke asked whether Mr. Bangs and other advocates interact with patient advocates representing other chronic diseases to share best practices. Mr. Bangs described an e-mail list that reaches patient advocates across the research advocacy spectrum. He agreed that sharing best practices with advocates representing other chronic diseases could be useful because these advocates probably have many shared experiences. Ms. Norris agreed but noted that more communication is also needed among advocates representing different kinds of cancer.

Dr. Ochoa asked whether PASC tracks participation by advocates from underserved populations in steering committees and task forces and whether they face any barriers to participation. Amy Williams, Acting Director of the Office of Advocacy Relations (OAR) at NCI, said that OAR does track the activities of all advocates, including those from underrepresented populations. OAR has a robust network of research advocates that includes representatives of a broad range of minority populations, and it ensures that all are effectively engaged. More and more, research advocates are helping OAR identify other advocates from diverse backgrounds.

Dr. Knopp reported that one challenge for the Imaging Steering Committee has been to help advocates understand some of the technical issues discussed. He suggested that PASC create a handbook for steering committee and task force chairs outlining appropriate ways to educate advocates about the history, goals, and challenges of their committee or task force, as well as ways to integrate new advocate members.

Dr. Loehrer noted that in many cases, advocates are only asked their opinions at the end of a discussion. He suggested, instead, that each discussion by a steering committee or task force begin with an introduction of the patient advocate and a presentation by the advocate on what matters to patients. Ms. Norris replied that steering committees and task forces have become more accepting of advocates, and these groups are more willing to listen to advocates as well as seek their opinions than in the past.

Dr. Gershenson suggested that PASC offer workshops to train research advocates to better contribute to research development. Ms. Norris explained that at least one company already does this and does it very well. The challenge is making more advocates aware of this type of opportunity and ensuring that advocates obtain this training.

Dr. Barton noted that the NCI Community Oncology Research Program sites could also benefit from the resources that PASC has developed. She suggested that PASC develop a readily accessible toolkit for anyone who might find these materials useful. As chair of the Symptom Management Quality of Life Steering Committee for 6 years, Dr. Barton has never had a cross-community dialogue on best practices for maximizing the contributions of advocates. She suggested engaging patient advocates throughout each protocol's trajectory, including after the protocol is activated. Advocates could, for example, weigh in on challenges with recruitment or amendments.

Dr. Matrisian said that she did not believe that the NCI Specialized Programs of Research Excellence have ever had the type of structure established by PASC to make advocates more productive and useful. She suggested that PASC expand its materials to address the need for advocate contributions to translational research projects. Dr. Matrisian also suggested that PASC develop a concept evaluation form for advocates to use for translational studies.

VIII. CTAC Strategic Planning Working Group Report

Patrick J. Loehrer, Sr., MD

CTAC established the Strategic Planning Working Group in October 2019 to assess NCI's strategic vision for its clinical trials system for 2030 and beyond and to make recommendations to achieve that vision. The working group has now completed its report. Although the working group focused on clinical treatment trials, many of the issues in the report could apply to prevention, symptom science, and other types of trials.

The report calls for a dramatic decrease in regulatory hurdles, streamlined processes for trial design and execution, a focus on essential endpoints, and an increase in the efficiency of data collection. The goal is to conduct flexible, faster, simpler, and less expensive clinical trials that are seamlessly integrated into clinical practice. Dr. Loehrer highlighted a selection of the 15 recommendations identified in the report. The recommendations are organized into the following themes:

- Trial complexity and cost
- Decentralized trial activities
- Promotion of accrual and access
- New data collection approaches
- Patient-reported outcomes data for clinical trials

- Operational burden
- Statistical issues
- Workforce outreach and training

The report also recommends the following operational initiatives at NCI:

- Develop a single Cancer Therapy Evaluation Program point of contact to provide information and assistance on the regulatory procedures required for international site participation in NCI trials.
- Provide NCI with central institutional review board guidance on local context assessments and local noncompliance responses, and simplify the NCI central institutional review board's electronic infrastructure.
- Assess the statistical consequences of patient-level data collection deviations and incremental morbidity and mortality increases due to COVID-19.

NCI will develop an implementation roadmap for the recommended actions and identify goals and milestones.

Questions and Discussion

Dr. Dicker noted that pharmaceutical companies were hit hard by COVID-19, and many of them are therefore establishing their own decentralized virtual trials that are changing the roles of community sites in accruing study participants. Dr. Dicker suggested that the working group report include plans for NCI to address decentralized trials.

Dr. Davidson asked about next steps. Dr. Prindiville replied that NCI will develop an implementation plan for the working group's recommendations. At future meetings, NCI is likely to ask CTAC, as well as others at NCI, for feedback on NCI's ideas for implementing the recommendations.

Dr. Doroshow added that NCI will form expert groups that can help NCI develop its implementation plan. Some of the recommendations will require funding, and Dr. Doroshow will then be responsible for finding the needed resources. These steps will require assistance from CTAC.

Motion. A motion carried to accept the report of the CTAC Strategic Planning Working Group.

IX. Ongoing and New Business

Patrick J. Loehrer, Sr., MD

CTAC currently has two working groups: the CTAC Strategic Planning Working Group, chaired by Dr. Loehrer, and the recently formed CTAC Cancer Screening Trials Working Group, chaired by Dr. Davidson. The Translational Research Strategy Subcommittee is examining translational research across NCI and includes members not only of CTAC, but also of the National Cancer Advisory Board, and the Board of Scientific Advisors. The subcommittee provides advice on how to enhance and broaden the institute's translational research portfolio. NCI and the subcommittee are examining ways to make this group more proactive now that it has responded to requests from NCI for advice on radiation oncology and glioblastoma research. CTAC will hear more about the work of all these groups at future meetings.

Other announcements were as follows:

- CTAC's next meeting, on March 17, 2021, will again be virtual. No decisions have been made about whether subsequent CTAC meetings will be virtual or in person.

- NCI will provide more orientation to new CTAC members, including additional details on CTAC activities.
- CTAC members should send agenda items for future meetings to Dr. Prindiville and Dr. Loehrer.

X. Adjournment

Patrick J. Loehrer, Sr., MD

There being no further business, the 43rd meeting of CTAC was adjourned at 2:26 p.m. on Wednesday, November 4, 2020.

Appendix

October 2020

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

CHAIR

Patrick J. Loehrer, Sr., MD 2021
Director
Indiana University Melvin and
Bren Simon Cancer Center
Associate Dean for Cancer Research
Indiana University School of Medicine
Indianapolis, Indiana

MEMBERS

Debra L. Barton, PhD, RN, FAAN 2021
Associate Dean for Research and Rackham Graduate Studies
Mary Lou Willard French Endowed Chair
Department of Systems, Populations, and Leadership
Professor of Nursing
Professor of Psychiatry
University of Michigan School of Nursing
Ann Arbor, Michigan

Charles D. Blanke, MD 2024
Chair, SWOG Cancer Research Network
Professor
Knight Cancer Institute
Oregon Health and Sciences University
Portland, Oregon

Janet Ellen Dancey, MD, FRCPC 2021
Professor
Department of Oncology
Queen's University
Director, Canadian Cancer Trials Group
Kingston, Ontario
Canada

Nancy E. Davidson, MD (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

Anjelica Q. Davis, MPA (NCRA) 2021
President
Fight Colorectal Cancer
Springfield, Missouri

Adam P. Dicker, MD, PhD 2024
Professor and Chair
Department of Radiation Oncology
Sidney Kimmel Cancer Center
Thomas Jefferson University
Philadelphia, Pennsylvania

Timothy J. Eberlein, MD 2021
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

David M. Gershenson, MD 2021
Professor of Gynecology
Department of Gynecologic Oncology and Reproductive Medicine
Division of Surgery
The University of Texas MD Anderson Cancer Center
Houston, Texas

Ernest T. Hawk, MD **2024**
Vice President and Head
Division of Cancer Prevention and Population Sciences
T. Boone Pickens Distinguished Chair for Early Prevention of Cancer
The University of Texas MD Anderson Cancer Center
Houston, Texas

Michael V. Knopp, MD* **2023**
Professor of Radiology
Department of Radiology
Novartis Chair of Imaging Research
The Ohio State University
Columbus, Ohio

Anne-Marie R. Langevin, MD **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

Mia Levy, MD, PhD* **2024**
Director
Rush University Cancer Center
System Vice President
Rush System for Health
Chicago, Illinois

Sumithra J. Mandrekar, PhD **2024**
Professor of Biostatistics and Oncology
Associate Director, Biostatistics Shared Resource
Mayo Clinic College of Medicine and Science
Rochester, Minnesota

Lynn M. Matrisian, PhD, MBA **2021**
Chief Science Officer
Pancreatic Cancer Action Network
Washington, DC

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

Augusto C. Ochoa, MD **2021**
Director
Stanley S. Scott Cancer Center
Professor, Department of Pediatrics
Louisiana State University Health Sciences Center
New Orleans, Louisiana

Roman Perez-Soler, MD (BSC) **2021**
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, PhD **2021**
Deputy Director
Mayo Clinic Cancer Center
Professor of Epidemiology
Department of Health Sciences Research
Mayo Clinic College of Medicine
Rochester, Minnesota

Steven T. Rosen, MD, FACP **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

Victor M. Santana, MD **2023**
Associate Director for Clinical Research
Vice President, Clinical Trials Administration
St. Jude Children's Research Hospital
Memphis, Tennessee

Dan Theodorescu, MD, PhD **2020**
Director
Samuel Oschin Comprehensive Cancer Institute
Cedars-Sinai Medical Center
Los Angeles, California

Julie M. Vose, MD **2023**
Neumann M. and Mildred E. Harris Professor
Chief, Division of Oncology/Hematology
Department of Internal Medicine
University of Nebraska Medical Center
Omaha, Nebraska

***Ex Officio* Members**

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

James H. Doroshow, MD
Deputy Director
Clinical and Translational Research
Director
Division of Cancer Treatment and Diagnosis
National Cancer Institute
National Institutes of Health
Bethesda, Maryland

Paulette S. Gray, PhD
Director
Division of Extramural Activities
National Cancer Institute
National Institutes of Health
Bethesda, Maryland

Michael J. Kelley, MD, FACP
National Program Director for Oncology
Veterans Health Administration
Department of Veterans Affairs
Durham, North Carolina

Anthony Kerlavage, PhD
Director
Center for Biomedical Informatics and
Information Technology
Office of the Director
National Cancer Institute
National Institutes of Health
Bethesda, Maryland

Richard Pazdur, MD, FACP
Director
Oncology Center of Excellence
U.S. Food and Drug Administration
Silver Spring, Maryland

Xiufen Sui, MD, MS
Biostatistician
Center for Clinical Standards and Quality
Center for Medicare and Medicaid
Innovation
Baltimore, Maryland

Executive Secretary

Sheila A. Prindiville, MD, MPH
Director
Coordinating Center for Clinical Trials
Office of the Director
National Cancer Institute
National Institutes of Health
Bethesda, Maryland

***pending appointment**