DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH
NATIONAL CANCER INSTITUTE
29th CLINICAL TRIALS AND TRANSLATIONAL RESEARCH ADVISORY COMMITTEE MEETING

Summary of Meeting
March 9, 2016

Building 31 C, Conference Room 10
National Institutes of Health
Bethesda, MD

CLINICAL TRIALS AND TRANSLATIONAL RESEARCH ADVISORY COMMITTEE
BETHESDA, MD
Summary of Meeting
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The 29th meeting of the Clinical Trials and Translational Research Advisory Committee (CTAC) of the National Cancer Institute (NCI) was held by webinar on Wednesday, March 9, 2016, at 11:00 a.m. The CTAC chair, Dr. Nancy E. Davidson, presided.[1] The meeting was adjourned at 1:00 p.m.

Chair
Nancy E. Davidson

CTAC Members
David F. Arons
Susan M. Blaney
Kevin J. Cullen
Walter J. Curran
Gwendolyn A. Fyfe* (absent)
David M. Gershenson*
Michael L. LeBlanc
Patrick J. Loehrer, Sr.*
David A. Mankoff
Mary S. McCabe
Edith P. Mitchell
Nikhil C. Munshi
Augusto C. Ochoa*
Gloria M. Petersen*
George W. Sledge, Jr.
Chris H. Takimoto
Miguel A. Villalona-Calero
George J. Weiner
Louis M. Weiner

***Ex Officio* Members**
James H. Doroshow, NCI
Paulette S. Gray, NCI
Rosemarie Hakim, Centers for Medicare & Medicaid Services
Lee J. Helman, NCI
Michael J. Kelley, Department of Veterans Affairs (absent)
Richard Pazdur, U.S. Food and Drug Administration (absent)

Acting Director
Douglas R. Lowy, NCI

Executive Secretary
Sheila A. Prindiville, NCI

Presenters
Jeffrey S. Abrams, MD, Associate Director, Cancer Therapy Evaluation Program, Division of Cancer Treatment and Diagnosis, NCI
Helen Chen, MD, Associate Chief, Investigational Drug Branch, Cancer Therapy Evaluation Program, Division of Cancer Treatment and Diagnosis, NCI
Nancy E. Davidson, MD, Director, University of Pittsburgh Cancer Institute, University of Pittsburgh
James H. Doroshow, MD, Deputy Director for Clinical and Translational Research, NCI

*pending appointment

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

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WEDNESDAY, MARCH 9, 2016

I. Call to Order and Opening Remarks

Nancy E. Davidson, MD

Dr. Davidson called the 29th meeting of CTAC to order at 11:00 a.m. and welcomed participants to the meeting.

Dr. Davidson reviewed the confidentiality and conflict-of-interest practices required of CTAC members during their deliberations. She invited members of the public to send written comments on issues discussed during the meeting to Dr. Prindiville within 10 days of the meeting. An announcement was made that NIH Events Management was videocasting the meeting and that the videocast would be available for viewing following the meeting at http://videocast.nih.gov.

Motion. A motion to accept the minutes of the 28th CTAC meeting held on November 4, 2015, was approved unanimously.

II. NCI Deputy Director's Update

James H. Doroshow, MD

Budget. NCI received a $265 million increase in its Fiscal Year (FY) 2016 budget. The increase will be allocated as follows:

- $70 million for the Precision Medicine Initiative in Oncology
- $55 million to the Vice President's Cancer Initiative
- $50 million for increased fixed costs
- $50 million to the type 2 research project grant (RPG) pool
- $30 million to the new and competing RPG pool
- $10 million increase for cancer center support grants

To provide context, this increase is about the same as the FY 2000 NCI funding level, adjusted for inflation. The President's FY 2017 proposed budget, which includes further increases, would continue to be at an inflation-adjusted budget of FY 2000. Dr. Doroshow did note, however, that NCI is grateful for these increases.

Precision Medicine Initiative in Oncology. The $70 million is to expand clinical trials in precision oncology, improve predictive oncology, create new animal models to increase understanding of cancer biology, and create a national cancer knowledge system. Part of the money will support housing clinical and genomic data.

NCI Molecular Analysis for Therapy Choice (NCI-MATCH). This trial began in August 2015 and was paused in November after 800 patients enrolled. This was NCI's fastest-ever recruitment for a therapeutic clinical trial. The pause was necessary to increase the capacity of the laboratories that prepare and analyze the specimens and to test the specimens already collected. The trial is expected to expand from 10 arms to more than 20 arms when it reopens in May. The agents to be tested in the additional arms have already been identified. This trial will make new drugs available to patients across the country.

The Vice President's Cancer Initiative. This project is in the early planning stages. Among the initiative's aims are to develop new cancer screening and prevention methods, develop vaccines, become better at data sharing, increase participation in clinical trials, make better use of the findings from

completed clinical trials, and increase immunotherapy trials. Among the ideas that NCI is considering within this program are developing a drug formulary that would make compounds more widely available to investigators, developing drugs against pediatric cancers, increasing genomic characterization of tumor stroma, and developing an exceptional opportunities fund. There is discussion among federal agencies about how they can work together to share data. A Blue Ribbon Panel composed of researchers and other stakeholders will help decide how to use increased funding that NCI may receive in 2017. The panel will evaluate ideas and report to the National Cancer Advisory Board (NCAB) in June.

Other updates. Based on recommendations by a subcommittee of the NCAB for restructuring cancer center funding, many of the NCI-designated cancer centers will receive increased funding in their base awards in 2016. Two of the seven centers doing basic research will receive increases, 12 of the 17 clinical centers will receive increases, and 7 of the 45 comprehensive cancer centers will receive an increase. NCI will continue to allocate funds in a way that will enhance the centers, which conduct most of the NCI-funded extramural research. If NCI receives a funding increase in 2017, it may be able to implement other parts of the plan and provide additional resources to these centers.

Additional updates included the following:

- The NCAB Specialized Programs of Research Excellence Working Group report is anticipated to be presented at the joint NCAB–Board of Scientific Advisors meeting in June.
- The funding plan for the Early Detection Research Network was approved.
- Institutions receiving phase II supplements to the Experimental Therapeutics Clinical Trial Network (ETCTN) have been notified.
- The winning institutions in the re-competition of the Chemical Biology Consortium have been notified.

Questions and Discussion

Douglas R. Lowy, MD, Acting Director, NCI, said that there is evidence of bipartisan support for NCI and NIH in Congress. He recently attended a forum of the American Association for Cancer Research in which two members of Congress—a Republican and a Democrat—expressed strong support for increased funding for NIH and NCI.

Dr. George Weiner said that the Precision Medicine Initiative in Oncology is exciting, but it is putting stress on local clinical trials operations because of the new way of enrolling and tracking patients. To be successful, it will be necessary to help clinical trials offices participate in the initiative and find ways to make that transition smooth. Dr. Doroshow agreed, saying that the most underfunded components of cancer centers are the clinical trials offices. If NCI receives an increase in 2017 beyond that needed for the previously mentioned baseline increase, NCI would be interested in proposals from the centers about how they would use the additional support.

III. Opportunities in Cancer Immunotherapy

Introduction

James H. Doroshow, MD

One of the stated objectives of the Precision Medicine Initiative for Oncology was to expand immunotherapy trials. Dr. Doroshow explained that the purpose of this session was to get CTAC's input on how to best use resources in this area.

Dr. Doroshow presented an inventory of extramural funding for immunotherapy in FY 2014. He noted that these grants focus on manipulating the immune system and do not include studies of therapeutic antibodies such as bevacizumab or trastuzumab. There were approximately 400 single-project grants. The Division of Cancer Biology applied 6 percent of its funding to immunotherapy; the Division of Cancer Treatment and Diagnosis (DCTD), 13 percent; the Small Business Innovation Research Program, 12 percent; the Center for Cancer Training, 8 percent; and the Division of Cancer Prevention, 1 percent. The proportion of multiproject grants containing immunotherapy was about 25 percent.

There has been a steady increase in the number of immunotherapy trials since 2010. Immunotherapy agents under cooperative research and development agreements in the NCI portfolio include check point inhibitors, cytokines, T cell–engaging bispecific antibodies, vaccines, and other immune modulators. The list of agents continues to grow. The compounds are from multiple companies, allowing many projects to go forward.

Summary of the Division of Cancer Treatment and Diagnosis Cancer Immunotherapy Workshop

Helen Chen, MD

General Perspectives and Scientific Challenges

Dr. Chen said this workshop, held in January 2016 in Rockville, brought together thought leaders to discuss opportunities and gaps in cancer immunology and immunotherapy and to suggest steps that NCI could take to foster progress in the field. Participants included basic and clinical scientists from NCI, academic institutions, and industry.

There have been recent breakthroughs showing the potential of immunotherapy. There is interest in investing in the field from academia, scientific organizations, philanthropy, and industry. There is insufficient molecular and cellular understanding of the interplay of the tumor, the microenvironment, and the immune system. Without this, it is difficult to optimize the further development of immunotherapy.

The workshop included presentations and 6 hours of panel discussions on three essential questions. Dr. Chen asked CTAC members to weigh in on these same questions:

- What is limiting the success of cancer immunotherapy in the clinic?
- What is needed in the research community to make scientific progress?
- What initiatives should NCI support or create to accelerate progress?

The participants said that much is unknown about the mechanisms of action of immunotherapy. They identified the following as limiting further success in immunotherapy:

- A superficial understanding of the underlying biology and mechanisms of drug actions.
- A lack of biomarkers, biomarker assays, and instrumentation that can be used in cancer patients.
- A lack of large, publicly accessible datasets of immune parameters and computational methods to help use the data.

The participants said the following is needed to make progress in the field:

- Basic science investigations, including reverse translation (bedside-to-bench and back-to-bedside).
- Biomarker strategies that are suitable for the complexity of the biology of immunotherapy.
- Large public immune "atlas" database.

What Should NCI Do?

The participants said that NCI must prioritize immunotherapy by providing greater investment in areas that industry would not or cannot prioritize, including the following:

- Support basic science research.
- Train new-generation cancer immunologists in informatics and basic and translational research.
- Strengthen the infrastructure for centers of excellence to enable bed-to-bench-to-bed translational research.
- Create a database and common platforms to integrate and mine data.
- Create a large public database of cancer immunology similar to The Cancer Genome Atlas.

The workshop participants made the following recommendations about basic science:

- Solicit ideas about provocative questions on immunology for basic research. For example, how does anti-PD-1 regulate T cells?
- Create and share new animal models, develop a database of animal models, and support development of animal models that can approximate the interplay between tumors and the immune system.

The workshop participants made the following recommendations about clinical research:

- Prioritize translational studies that align with industry efforts. Industry has already made a big investment in this area.
- Conduct studies to enhance scientific understanding as opposed to conducting studies just for clinical proof of principle.
- Establish stable support for centers of excellence with integrated and dedicated teams who understand the science.
- Expand cancer center capacities for adoptive T-cell therapy (ACT), especially for approaches that are not an industry priority. The field has had success, but it needs more basic and clinical studies to improve the response rate and extend benefits in patients. DCTD can partner with the NCI intramural program that has pioneered many cell therapy techniques or with cell therapy companies in this area of research. Also, some centers within the NCI National Clinical Trials Network (NCTN) have capacity for ACT, and more centers could be established.

Workshop participants made the following recommendations for biomarkers:

- Support biomarker development, from marker discovery to assay development and clinical validation.
- Develop guidelines and procedures for biospecimen banking and tissue collection.
- Establish core laboratories to provide service for key immune assays and panels.
- Generate reference samples or reagents for assay standardization.
- Establish a database or common platform for integration and analysis of clinical and biomarker data across trials.

Dr. Chen concluded by summarizing the overarching actions recommended by the workshop participants:

- Provide platforms and tools for clinical and biomarker data across trials.
- Develop a cancer immunology atlas.
- Foster collaboration across different fields and funding resources.

Discussion of Opportunities
Jeffrey S. Abrams, MD

Dr. Abrams moderated the discussion and began by asking for comments on the recommendations produced by the immunotherapy workshop as reported by Dr. Chen.

Dr. Takimoto said that combination immunotherapy will be a key to success, but there are many possible combinations and new agents. A key question is how those combinations will be prioritized. The biomarker work, which could provide insight into which mechanisms are most promising, is important.

Dr. Munshi, noting that ACT requires gene transfer technology, suggested improving the technology to transfer genetic material to immune cells.

Dr. Ochoa asked whether there was consideration of trying immunotherapy in the early stage of the disease or as a preventive approach. Patients chosen for clinical trials are often those patients who have advanced cancer or who have failed another therapy. Immunotherapy could be used as a vaccine to prevent disease.

Dr. Abrams said that there was little discussion of prevention because the workshop was focused on treatment. That said, vaccines do hold great promise. Toby T. Hecht, PhD, Associate Director, Translational Research Program, NCI, added that a vaccine could make an impact if there is a precursor that expresses a neoantigen that is present in the later disease. Dr. Lowy said that the cancer initiative begun by Vice President Joseph Biden may develop novel vaccines against infectious and noninfectious causes of cancer.

Dr. Curran said that the NCTN is considering using immunotherapy as adjuvant therapy with solid tumors that are curable using surgery or radiotherapy. It will be necessary to do the foundational science to understand the mechanism. For example, what is the best sequence for treatment with radiotherapy and immunotherapy?

Dr. Mankoff said that there is a problem with clinical trial endpoints for immunotherapy—current imaging methods cannot differentiate tumor progression from an immune infiltrate. Given that nonprogression of tumors may be an endpoint, this inability to assess response and progression is a

problem. This area of research should be given priority, particularly in developing biomarkers. He also said that the preclinical and early clinical development of imaging probes is ripe for stimulation by NCI.

Dr. Abrams said that when the Cancer Imaging Program holds its workshop in May, one of the topics of discussion will be imaging and immunotherapy.

Dr. Cullen suggested conducting health economics research to show how success in cancer immunotherapy is being limited by cost.

Dr. Louis Weiner expressed support for developing the Cancer Immune Atlas as a complement to The Cancer Genome Atlas. He asked how the Cancer Immune Atlas will be developed and how it would be linked to genomics information.

Dr. Magdalena Thurin, PhD, Program Director, Cancer Diagnosis Program, NCI, said that this issue has not yet been discussed. The genome atlas has the advantage that there is one accepted approach to understanding the mutational landscape of tumors. Sequencing is standardized, and data can be collected across centers. That is not true for the immune atlas. The first step would be to decide on the platform or approach that would be used.

Dr. Thurin also commented on developing vaccines for certain cancers. One problem is that patients have many different types of mutations. The advantage of immunotherapy is that it is personalized medicine.

Dr. Weiner said that sequencing has value, but that knowing the location of the immune infiltrate and cytokines relative to the tumor may be just as important. This is an area that requires in-depth thought, because this would be the foundational platform for work in immunotherapy. It is important to get this right, but NCI is ideally suited to carry out this type of large-scale enterprise.

Dr. Warren A. Kibbe, PhD, Director, Center for Biomedical Informatics and Information Technology, NCI, said that there is an opportunity to bring together data from the fields of immunobiology and immunotherapy, although how to bring that together with data on cancer has not been worked out. Scientists and physicians do not know everything that needs to be measured, but that should not prevent them from starting this work.

Dr. Loehrer suggested establishing a registry of patients who respond poorly to immunotherapy to develop a profile of who should not be treated and why.

Dr. Davidson agreed that the recommended tasks for NCI, which included support for basic science, clinical research, biomarkers, and tool development, were reasonable priorities, although quite comprehensive. She asked whether NCI should undertake all these tasks or whether other NIH Institutes and Centers (ICs) could share the work. She suggested that the Clinical and Translational Science Awards (CTSA) Program funded through the National Center for Advancing Translational Sciences (NCATS) would be a possible partner.

Dr. Abrams said that there is agreement, particularly at the basic science level, that other ICs could support some of the work. The challenge is bringing knowledge of cancer to some of this work. It would be harder for other ICs to become involved in cancer clinical trials and biomarker studies, but NIH should attempt to leverage the expertise of the other ICs in this field.

Dr. Davidson asked whether these projects would be funded through existing mechanisms. Dr. Abrams said that it will probably be a combination of existing programs and new initiatives. Immunotherapy has become part of the mainstream of oncology, and many outside of NIH are interested in doing this research. Immunotherapy could attract more sources of funding for clinical trials, but funding research on biomarkers may be more difficult.

Dr. Doroshow asked for the committee's thoughts about the proposed ACT production facilities. Is this a pressing national priority? Dr. Cullen said that medium and larger cancer centers are trying to build that capability. He wasn't sure whether NCI should be encouraged to build regional or national facilities.

Dr. Davidson said it is an important scientific direction, but it is best to have shared facilities through a network or center of excellence at the beginning because the facilities are expensive to operate. It may be possible to build more later.

Dr. Sledge said that building even a few ACT facilities would expend NCI's entire budget increase this year. He advised NCI to support the science, not the infrastructure.

Dr. Munshi suggested a study of neoantigen-directed treatments. Dr. Abrams agreed that this area of research is the ultimate in precision medicine and one that the government must fund because private entities are unlikely to. This approach has shown some impressive successes with patients, but the question is how to scale it up in a way that doesn't break the bank.

Dr. Loehrer suggested that NCI inventory cancer centers to see what programs they have. There may be opportunities for centers to collaborate, which could reduce costs. Dr. Abrams agreed that NCI should investigate this idea. Dr. Davidson said that NCI should also determine what core laboratories exist within the NCTN.

Dr. Ochoa said that NCI should create more T32 grants to educate the next generation of researchers in this cutting-edge science. Dr. Abrams noted that this was an important recommendation from the immunotherapy workshop, and NCI will consider it.

Dr. Doroshow thanked the CTAC members for their ideas and said NCI will consider which ones can be implemented with the resources available. The Vice President's initiative may lead to increased resources. Dr. Lowy said that the next steps are to set priorities, decide how to scale up the effort, and examine how to form public-private partnerships.

IV. Experimental Therapeutics Topics

NCI Patient-Derived Models Repository Supporting Cancer Discovery and Therapeutics Development

James H. Doroshow, MD

Dr. Doroshow presented a summary of the NCI patient-derived models repository, a project that Dr. Harold E. Varmus began 4 years ago. The repository will include xenografts, tumor cell cultures, and organoids from primary and metastatic cancers.

The initial focus is to develop 1,000 models that are not available commercially or in the academic community. The goal is to make a variety of clinically annotated, molecularly characterized models available to principal investigators at relatively low cost.

The repository will include circulating tumor cells and tumor samples to develop animal models and to conduct pharmacodynamic studies and high-throughput screening. The repository receives samples from two NCI clinics, 16 comprehensive cancer centers, and 23 ETCTN and NCI Community Oncology Research Program (NCORP) centers. The repository currently has 2,000 blood and tissue specimens.

The focus initially was on samples not well-represented in other collections, including head and neck cancer, bladder cancer, and sarcomas. NCI is working with a rare tumors foundation to refer patients with rare diseases to the NIH Clinical Center. It would be difficult to find these rare tumors in any other way. A member of the Frederick Advisory Committee suggested working with institutions that have warm autopsy protocols to help develop models from different metastatic sites within an individual patient.

Maintaining good quality control of the *in vivo* models is difficult but essential. About one-quarter of the models received from outside sources were unsuitable for propagation. For example, instead of being prostate cancer or bladder cancer, some were Epstein-Barr virus (EBV)–related human lymphoid tumors that develop spontaneously in immunocompromised mice. NCI is working to ensure that its models contain what their labels claim.

Some cancers, such as colon cancers, are easier to propagate than others, so the success rates have varied. Overall, the success rate is about 69 percent. The repository, which has 230 models so far, must have enough disease and molecular heterogeneity to be useful to the research community.

The repository is also developing *in vitro* models. The goal is to develop conditionally reprogrammed, patient-derived tumor cell cultures, clonal cell lines, and cancer-associated fibroblasts. *In vitro* models have been developed for 10 cancer types. Culture characteristics for these models compared to their corresponding *in vivo* models are stored in the repository.

Maintaining quality control of *in vitro* models is even more difficult than for the *in vivo* models. Although NCI has done this rigorously, the repository still finds tumors that do not regrow and fibroblasts that regrow to tumors. That said, NCI has learned a lot and now has many cell lines that could be distributed in the future. Out of 775 cultures attempted, 460 were successful, resulting in 102 pure tumor cultures and 252 pure fibroblast cultures confirmed by flow cytometry. Work on the repository has demonstrated that it is possible to develop paired pure fibroblast cultures and tumor cell cultures and that their gene expression profiles are quite different.

In addition to the murine models, NCI has also developed a nude rat model to help study circulating tumor cells (CTCs), which cannot easily be studied in mice because of their low blood volume. As a result of this work, NCI will have a colony of tumors adapted to nude rats that can be studied for CTCs.

One important purpose of this research is to study the relationship between *in vitro* and *in vivo* sensitivity to drugs. There have been some initial findings to indicate this may be possible in models

testing the combination of temozolomide and veliparib (ABT-888) and the combination of the Wee-1 inhibitor MK-1775 plus carboplatin.

A pilot imaging study showed that a patient-derived xenograft metastasized spontaneously. This makes it a more useful model than a standard xenograft from a cell line, which requires manipulation to get metastasis. A follow-up study showed that a single cycle of ABT-888 plus temozolomide cured the mouse liver metastases. This is the type of data that will be available on the repository website so that investigators can choose the best models for their work.

NCI also performed a proof-of-mechanism preclinical clinical trial using patient-derived xenograft models carrying one or more actionable mutations from the MPACT (Molecular Profiling–Based Assignment of Cancer Therapeutics) trial, the first randomized trial designed to determine whether people with specific mutations will benefit from a specifically chosen targeted intervention and whether these interventions lead to better outcomes. Each animal was treated with the agents on each of the four arms of the MPACT study to see whether there is mutational prediction of the animal's response to treatment and, if not, why not.

One of the big issues is how to define a successful treatment in a mouse model; anything other than a cure in a mouse is hard to characterize. These mouse studies have shown some complete remissions and some intermediate responses. As a result of these studies, researchers are beginning to characterize the degree and duration of response as well as why some mice responded to therapies and why some did not, based on the genotyping data. NCI will publish some standard operating procedures for pre-clinical clinical trials soon.

NCI expects to go live with the repository website this summer. Investigators will be able to search for models by disease and by a variety of molecular characteristics and sample types, including solid tumor, cell line, DNA, RNA, or protein lysate. The website will be a resource for the research community—for example, to those competing for grants in the Small-Cell Lung Cancer Consortium announced earlier this year (PAR-16-049).

One of the lessons NCI has learned is that this work is difficult and expensive. It requires continued attention to quality control to ensure that what is labeled a bladder cancer is a bladder cancer. Deriving cell lines is resource intensive. However, providing investigators with clinically annotated, well-characterized cell lines and autologous-matched cancer-associated fibroblasts will aid in drug screening and in understanding tumor biology.

Dr. Doroshow closed by thanking his colleagues at NCI. He also thanked the investigators and patients at the NIH Clinical Center, NCI Cancer Centers, and NCORP sites supplying tissue and blood samples, who made this work possible.

Questions and Discussion

Dr. Davidson asked when the repository would be available. Dr. Doroshow replied that if CTAC members agreed that 75 models and 50 cell lines are sufficient, it could go live by summer. Once live, new models and cell lines will be added regularly until sufficient molecular heterogeneity is attained. The repository is also expected to have a large number of purified cancer-associated fibroblasts. Those cells die out, so the repository must continually replace them. Committee members agreed that the size proposed by Dr. Doroshow seemed appropriate for making the repository publicly available.

Dr. Munshi asked whether the repository would make data available to help determine the genomic reasons why some tumors did not propagate. Dr. Doroshow said that how extensively they would characterize tissues that did not propagate comes down to a question of resources. Some of those characteristics are already known. There is more success with large surgical specimens compared to specimens from an 18-gauge needle. The "take" rates are better for patients with advanced disease and for those who have not recently received chemotherapy. Dr. Doroshow said that it may be useful to sequence those specimens that did not take.

V. Closing Remarks

Nancy E. Davidson, MD

Dr. Davidson provided updates on the CTAC working groups.

The Pancreatic Cancer Working Group presented their first report in November 2015. James L. Abbruzzese, MD, Chief of Medical Oncology at Duke University, will continue to chair the group. The working group will provide another report later in the year.

The Small-Cell Lung Cancer Working Group will meet in April and is expected to be ready to report at the July meeting. Charles M. Rudin, MD, PhD, Chief of Thoracic Oncology at Memorial Sloan Kettering Cancer Center, is the chair.

The Clinical Trials Informatics Working Group has been meeting, and members expect to report later in the year. Dr. Louis Weiner and Dr. Kibbe cochair the group.

The Clinical Trials Strategic Assessment Working Group is expected to form later this year. The group will examine the steering committees' portfolio self-assessments and strategic priorities.

The Summary Vision Working Group is in the planning stages. Its focus will be to provide a vision and recommended actions to guide the NCI clinical trials enterprise over the next decade, extending the progress achieved by the 2005 Clinical Trials Working Group.

VIII. Adjournment

Nancy E. Davidson, MD

There being no further business, the 29th meeting of CTAC was adjourned at 1:00 p.m. on Wednesday, March 9, 2016.

Appendix

National Institutes of Health
National Cancer Institute
Clinical Trials and Translational Research Advisory Committee

CHAIR

Nancy E. Davidson, M.D. **2018**
Director
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University of Pittsburgh
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MEMBERS

David F. Arons, JD (NCRA) **2016**
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Vice Chair for Research
Department of Pediatrics
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Texas Children's Hospital
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Department of Gynecologic Oncology and Reproductive Medicine
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Department of Biostatistics
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Patrick J. Loehrer, Sr., MD* **2020**
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Associate Dean for Cancer Research
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David A. Mankoff, MD, PhD **2016**
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Gloria M. Petersen, PhD* **2019**
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Palo Alto, CA

Miguel A. Villalona-Calero, MD **2016**
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George J. Weiner, MD **2016**
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*pending appointment

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EXECUTIVE SECRETARY

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Bethesda, MD