DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
NATIONAL CANCER INSTITUTE
26th CLINICAL TRIALS AND TRANSLATIONAL RESEARCH ADVISORY COMMITTEE (CTAC) MEETING

Summary of Meeting
March 4, 2015

Webinar

CLINICAL TRIALS AND TRANSLATIONAL RESEARCH ADVISORY COMMITTEE WEBINAR
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The 26th meeting of the Clinical Trials and Translational Research Advisory Committee (CTAC) of the National Cancer Institute (NCI) was held by webinar on Wednesday, March 4, 2015, at 11:00 a.m. CTAC Chair Dr. Abbruzzese presided.[1] The meeting adjourned at 12:58 p.m.

Chair
James L. Abbruzzese

CTAC Members
Susan G. Arbuck
David F. Arons
Curt I. Civin (absent)
Kevin J. Cullen (absent)
Nancy E. Davidson
J. Philip Kuebler
Scott M. Lippman
Mary S. McCabe (absent)
Edith P. Mitchell
Nikhil C. Munshi
Lisa A. Newman
Nancy Roach
Peter G. Shields
George W. Sledge, Jr.
Chris H. Takimoto (absent)
Gillian M. Thomas
Miguel A. Villalona-Calero
George J. Weiner
Louis M. Weiner

***Ad Hoc* Members**
Susan M. Blaney
Walter J. Curran
Michael L. LeBlanc
David A. Mankoff

***Ex Officio* Members**
James H. Doroshow, NCI
Paulette S. Gray, NCI
Rosemarie Hakim, CMS
Lee J. Helman, NCI
Michael J. Kelley, VA (absent)
Richard Pazdur, FDA
Alan S. Rabson, NCI (absent)

Executive Secretary
Sheila A. Prindiville, NCI

Presenters
Jeffrey S. Abrams, MD, Associate Director, Cancer Therapy Evaluation Program (CTEP), Division of Cancer Treatment and Diagnosis (DCTD), NCI
James L. Abbruzzese, MD, Chief, Division of Medical Oncology and Associate Director for Clinical Research, Department of Medicine, Duke Cancer Institute, Duke University Medical Center
Andrea M. Denicoff, RN, MS, Nurse Consultant, Clinical Investigation Branch, CTEP, DCTD, NCI
James H. Doroshow, MD, Deputy Director for Clinical and Translational Research, NCI
Lee J. Helman, MD, Senior Investigator, Pediatric Oncology Branch; Scientific Director for Clinical Research, Center for Cancer Research, NCI
Jeffrey A. Moscow, MD, Senior Investigator, Investigational Drug Branch, CTEP, DCTD, NCI

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

TABLE OF CONTENTS

WEDNESDAY, MARCH 4, 2015

I. Welcome and Chair's Update

James L. Abbruzzese, MD

Dr. Abbruzzese called the 26th meeting of CTAC to order and welcomed participants to the meeting. He also introduced new members, Dr. Blaney and Dr. Curran, who had recently been appointed to CTAC and who are completing the clearance process. Dr. Abbruzzese welcomed Thomas A. Buchholz, MD, Executive Vice President and Physician in Chief, University of Texas M.D. Anderson Cancer Center, to the webinar. Dr. Buchholz is the chair of the NCI Steering Committee Co-chairs.

Dr. Abbruzzese 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.

Motion. A motion to accept the minutes of the 25th CTAC meeting held on November 12, 2014, was approved unanimously.

This meeting did not include a legislative update. CTAC members received a summary by e-mail of recent legislative initiatives that are relevant to CTAC's work. This summary was also posted on the NCI Division of Extramural Activities' website.

Dr. Abbruzzese provided updates on three CTAC working groups. The first two are new working groups established under the auspices of CTAC to assess progress on the initiatives related to the Recalcitrant Cancer Research Act of 2012.

Pancreatic Ductal Adenocarcinoma (PDAC) Progress Working Group. This group's purpose is to assess the progress and identify advances in research related to the initiatives of the scientific framework for PDAC. The working group will focus on four initiatives identified by the 2013 CTAC Pancreatic Cancer Working Group in its report to Congress, *Scientific Framework for Pancreatic Ductal Adenocarcinoma (PDAC)*, available at http://deainfo.nci.nih.gov/advisory/ctac/workgroup/pc/PDACframework.pdf:

- understand the biological relationship between PDAC and diabetes mellitus
- evaluate longitudinal screening protocols for biomarkers for early detection of PDAC and its precursors
- study new therapeutic approaches in immunotherapy
- develop new treatment approaches that interfere with RAS oncogene-dependent signaling pathways

Dr. Abbruzzese chairs the PDAC Working Group, which has 12 other members. The working group plans to hold a WebEx meeting in May. The group will form four subgroups to review the status of research supported by NIH and non-NIH activities related to each of the four initiatives and to identify gaps in each area. The working group will provide periodic updates on its activities to CTAC.

The National Institute of Diabetes and Digestive and Kidney Diseases has issued a request for applications, *Consortium for the Study of Chronic Pancreatitis, Diabetes and Pancreatic Cancer Clinical Centers (CSCPDPC -CCs) (U01)*, available at http://grants.nih.gov/grants/guide/rfa-files/RFA-DK-14-027.html. This initiative will support research on the relationship between PDAC and diabetes, and applications are due April 2, 2015.

Small-Cell Lung Cancer (SCLC) Working Group. The purpose of this group is to assess the progress and identify advances in research related to the initiatives of the scientific framework for SCLC. Objectives are to:

- build better research tools for the study of SCLC
- expand comprehensive genomic profiling of SCLC
- investigate new diagnostic approaches for SCLC
- focus therapeutic development efforts on specific molecular vulnerabilities of SCLC
- examine the mechanisms underlying both the high rate of initial response and rapid emergence of drug and radiation resistance

Charles M. Rudin, MD, PhD, Chief, Thoracic Oncology Service, Memorial Sloan Kettering Cancer Center, has agreed to chair the working group. The next steps for the group are to select its members and develop a scope of work.

Clinical Trials Informatics Working Group. This group's purpose is to provide extramural expertise and advice on the implementation of clinical trials informatics initiatives. The group's co-chairs are Dr. Louis Weiner and Warren Kibbe, PhD, Director, NCI Center for Biomedical Informatics and Information Technology. Dr. Prindiville explained that the Coordinating Center for Clinical Trials is working with the co-chairs to select working group members.

II. NCI Update

James H. Doroshow, MD
Lee J. Helman, MD

In his State of the Union Address on January 30, 2015, President Barack Obama announced the creation of the White House's Precision Medicine Initiative. This new research effort is designed to revolutionize how we improve health and treat disease. Francis S. Collins, MD, PhD, Director of NIH, and Harold E. Varmus, Director of NCI, recently published an article on the initiative in the *New England Journal of Medicine.*

The President's 2016 budget includes a $215 million appropriation request for the following purposes:

- $130 million to NIH to develop a voluntary national research cohort of at least a million volunteers for research on the development and impact of genetics on a wide range of medically important conditions
- $70 million to NCI to support clinical trials that use genomic markers and next-generation sequencing, including the development of a database to house information from clinical trials
- $10 million to the U.S. Food and Drug Administration (FDA) to develop the capacity to interpret information from next-generation sequencing platforms and more easily certify sequencing platforms instead of certifying one mutation at a time (a task that would be impossible)
- $5 million to the Office of the National Coordinator for Health Information Technology (ONC) to develop interoperability standards for electronic health records and requirements that address privacy and enable the secure exchange of data across systems to support precision medicine

Dr. Collins is soliciting input from an expert panel on the national research cohort. The panel will consider such issues as whether existing cohorts can be used or whether NIH will need to form new

cohorts. It was mentioned that Dr. Doroshow—along with Kathy Hudson, PhD, Deputy Director Science, Outreach, and Policy at NIH, and representatives of ONC and the FDA—recently briefed the House and Senate appropriations committees on the initiative's activities. Dr. Doroshow hopes that the final 2016 appropriation includes the requested $215 million to establish this initiative.

As a follow-up to the discussion of the NIH Intramural Research Program's long-range plan at CTAC's November 12, 2014, meeting, Dr. Helman recently gave presentations with John I. Gallin, MD, Director, NIH Clinical Center, and Michael M. Gottesman, MD, Chief, Laboratory of Cell Biology at NCI's Center for Cancer Research, to cancer center directors on opportunities for collaboration between intramural and extramural investigators at NIH. Dr. Gallin discussed the Opportunities for Collaborative Research at the Clinical Center, a U01 award that supports collaboration between intramural and extramural investigators and gives extramural researchers access to the valuable resources of the NIH Clinical Center. Dr. Gottesman discussed the Lasker Awards. Dr. Helman emphasized the interest of NCI's Center for Cancer Research and Division of Cancer Epidemiology and Genetics in enhancing collaborations with extramural colleagues to better support NCI's research.

Questions and Discussion

Dr. Mitchell asked whether the Precision Medicine Initiative would include activities that target personalized medicine in minority populations. Many minority groups have higher incidence rates and mortality rates from cancer than members of the majority population. Dr. Doroshow responded that the initiative is at a very early stage, and Congress has not yet allocated its funding. If the initiative receives the requested allocation, Dr. Doroshow said, it is critical that the funds include resources to collect information that is relevant to underserved populations.

Dr. Helman asked for clarification on ONC. Dr. Doroshow explained that ONC supports the adoption of electronic health records across the nation.

Dr. Mankoff suggested that NCI's planning for the Precision Medicine Initiative take into account aspects of trials beyond genomic techniques, such as issues related to investigational drugs and imaging, that could affect the initiative's success.

Dr. George Weiner reported that the cancer center directors appreciated the discussion about the extramural and intramural collaborations and looked forward to the next steps.

III. Proposed Periodic Strategic Assessment of the NCI National Clinical Trials Network (NCTN) Scientific Steering Committee (SSC) Portfolios

Jeffrey Abrams, MD

According to CTAC's NCTN Working Group, periodic assessments of the NCTN trial portfolios could provide essential feedback to the SSCs, NCTN groups, and NCTN research bases and help ensure that trials in each portfolio address the community's strategic priorities. These assessments would benefit from greater involvement of portfolio-specific experts. The working group noted that the next strategic assessment should begin 3–5 years from the NCTN Working Group assessment. The group recommended against convening a large committee to conduct detailed assessments of trials in each portfolio.

As a result of this input, NCI proposed that the SSCs conduct self-assessments of their portfolios and that a new CTAC working group be convened to review the quality and objectivity of the SSCs' self-assessments.

In the first round of this self-assessment process, the plan is to have the SSCs only review concepts that began after the last assessment. The criteria for the assessment would include:

- alignment with strategic priorities
- relevance to NCTN Working Group recommendations for improvement of the portfolio
- unique suitability for federal clinical trials system
- clinical importance
- scientific contribution
- feasibility

The self-assessments would also include rationales for all disapprovals of concepts.

Each SSC would present its assessment report to the new CTAC Assessment Working Group. This working group would include some CTAC members, NCTN group chairs, and NCTN group statisticians. The working group would analyze the quality and objectivity of each steering committee's portfolio assessment and adherence to the group's strategic priorities. The working group would also perform cross-portfolio analyses, generate cross-portfolio recommendations, evaluate the assessment process, and develop recommendations for future assessments. The group would report the results of the individual portfolio assessments and the cross-portfolio analysis to CTAC.

The Cancer Therapy Evaluation Program would provide the SSCs and the CTAC working group with an overview of the portfolio-specific clinical trials landscape and trial-specific information (such as concept summaries and trial status).

NCI plans to form the CTAC Assessment Working Group and orient the group members in the summer of 2015. The intent is to have the SSCs complete their self-assessments between November 2015 and October 2016. The committees will present their assessment reports to the CTAC Assessment Working Group between January 2016 and April 2017. From March 2016 to November 2017, the working group will present its portfolio-specific assessment reports to CTAC. During the March 2018 CTAC meeting, the working group will present its cross-portfolio analysis to CTAC.

Motion. A motion was approved unanimously to create the CTAC Assessment Working Group, which will conduct periodic cross-portfolio analyses of NCTN SSC portfolios.

IV. Phase II Clinical Trials Component of the Experimental Therapeutics Clinical Trials Network (ETCTN)

Jeffrey A. Moscow, MD

Role of NCI's Division of Cancer Treatment and Diagnosis (DCTD) in Developing New Anticancer Agents and Combinations. DCTD collaborates with pharmaceutical companies and academic medical centers to develop new anticancer agents and combinations of agents. DCTD's role is to expand indications of novel agents and the understanding of their biology. NCI assumes regulatory responsibility for the trials and for the agents or combinations studied in these trials. DCTD is developing approximately 60 drugs targeting a wide range of cancer-related pathways and antigens.

This strategy has contributed to Food and Drug Administration (FDA) approval of eight agents or combinations in multiple types of cancer. FDA approval is pending for one agent; two agents or combinations are in pivotal trials as a result of development in the DCTD program.

Role of the ETCTN. The ETCTN is the network of clinical trial sites and infrastructure that is solely devoted to the conduct of the earliest clinical studies of investigational new drug (IND) agents sponsored by NCI. The program ensures the development of NCI's IND agents to the point of handoff to the National Clinical Trials Network and/or back to a pharmaceutical company. NCI has a suite of services to support the ETCTN, including the Cancer Trials Support Unit and Central Institutional Review Board.

ETCTN Phase I and II Components. The ETCTN has two distinct clinical components: a phase I UM1 grant program and a phase II N01 contract program. Both programs support lead organizations and multiple affiliated centers that contribute to accrual and scientific goals. NCI recently solicited new applications for the phase I program as part of the formation of the ETCTN. The expiration of the phase II contracts provides an opportunity to turn the ETCTN into a unified grant program that can be effective in the era of targeted therapies.

Requirements for early-phase trials have evolved. The disease-focused context traditionally associated with phase II trials is often required now in phase I studies. Today's trials incorporate disease-specific biomarkers for eligibility and proof of target engagement for early-stage drug development. The pharmaceutical industry has already adopted flexible early-phase study designs and can quickly build phase II end points into phase I studies when a signal of activity is detected.

To respond to this new environment, NCI has developed new phase II program goals:

- shorten the duration of the period from phase I initiation through proof of activity by placing pharmacology-focused investigators (phase I) and disease-focused investigators (phase II) in the same program to quickly explore signals of activity
- enhance biomarker incorporation into the phase II study design
- maintain experienced phase II investigators in ETCTN and on ETCTN project teams that develop early-phase studies
- expand the pool of eligible patients for rare tumor subtypes
- further leverage ETCTN centralized clinical trial support resources

NCI plans to combine its phase I grant program and phase II contract program into a single ETCTN UM1 core grant program. UM1 grantees will be eligible to compete for supplements to expand their phase II expertise. NCI currently has 13 phase I grantees and 7 phase II contractors, and it plans to offer up to 10 supplements to UM1 centers. NCI will publish a limited-competition request for applications shortly for the UM1 phase II supplements. The focus will be on scientific leadership/expertise for ETCTN phase II studies.

Inclusion of NCI Cancer Centers in ETCTN. In addition to creating a unified ETCTN program, NCI's Cancer Therapy Evaluation Program (CTEP) plans to open the ETCTN program to allow scientists in the NCI-designated cancer centers program to propose clinical trials and to increase access to patients with rare tumors. Currently, 27 NCI-designated cancer centers are affiliated with the ETCTN. The new NCI Early Therapeutics Opportunity Program (ETOP) will open the ETCTN to the NCI cancer centers that will not be included as grantees or affiliates in the UM1 phase II supplement through a supplement to their P30 grant.

ETOP has two components. The program's phase II study leadership component will allow investigators at NCI-designated cancer centers not affiliated with the ETCTN to submit letters of intent to CTEP to request full ETCTN clinical trial support, salary reimbursement, and funds for accrual at the principal investigator's institution. The program's phase II study accrual component will allow NCI cancer centers to open selected ETCTN phase II studies that require screening for rare tumors. NCI will offer opportunities to compete for approximately 15 phase II accrual supplements to non-ETCTN cancer centers after NCI awards the revised UM1 grants. These supplements will support research study costs per patient but not screening costs.

Timeline. NCI plans to announce the study leadership component soon after announcing the UM1 phase II supplement awardees in January 2016. Letters of intent may be submitted any time after the announcement. NCI will also announce the phase II accrual program soon after it announces the UM1 revision awardees, and dates for acceptance of P30 supplement applications are to be determined. NCI hopes that these initiatives will help accrue an additional 90–100 patients a year. The budgets are $9 million per year for the UM1 phase II supplements and $1 million for the cancer centers pilot collaboration program.

Questions and Discussion

In response to a question from Dr. Davidson about the phase II contract program budget, Dr. Moscow replied that this budget is approximately $7 million.

Dr. Abbruzzese asked whether CTAC members could share Dr. Moscow's slides with current UM1 grantees so that they have time to consider how to respond to this opportunity. Dr. Doroshow replied that the slides are publicly available and may be shared.

Dr. LeBlanc asked about the scope of the phase II trials that NCI plans to start. Dr. Moscow replied that NCI tries to conduct phase II trials that are biomarker intensive and can provide as much information as possible from the patients who participate. The ETCTN supports both randomized and nonrandomized trials at early stages of clinical drug development but not large, potentially practice-changing trials.

Dr. Abbruzzese said that consolidating the current grant and contract programs into a single program makes sense.

V. Accrual Activities in the National Clinical Trials Network (NCTN)

Andrea Denicoff, MS, RN

NCTN Meeting to Address Accrual Challenges in NCTN Clinical Trials in Adolescents and Young Adults. NCI and the Foundation for the National Institutes of Health cosponsored this meeting on December 4–5, 2014. This meeting brought together all NCTN grantees soon after the program started. Its goals were to develop consensus around key operational accrual challenges in the NCTN, identify potential strategies to address those challenges, and establish a group devoted to NCTN accrual issues. The meeting included approximately 75 representatives of NCTN groups and lead academic participating sites as well as representatives of several NCI divisions and offices. Areas explored included accrual strengths and challenges across stakeholders and case studies of trial accrual challenges.

Resource Needs for NCTN Trials. The biggest concern of cancer centers at the meeting was the local activation costs at study sites before a study even opens. These costs include formulating a trial budget, obtaining institutional review board (IRB) approval, preparing Medicare and insurance coverage analyses, and entering the protocol into electronic medical record software. These steps can be time consuming and costly. However, many NCTN sites have leveraged their NCTN funding to obtain additional support from federal and nonfederal sources for such activities as biospecimen collection, eye examinations, and clinical testing. In addition, use of the NCI Central IRB (CIRB) by the NCTN sites as the IRB of record for all the NCTN studies covered by the CIRB will decrease use of local resources.

Action Steps from the Meeting. Action steps from the meeting include developing strategies to support accrual across the NCTN, creating processes to build and maintain the implementation of such strategies, and continuing to address challenging trials. Meeting participants also called for increased awareness of trials for adolescents and young adults, engaging patient advocate input early on feasibility and patient education issues, and considering underserved and minority patient issues in trials with large samples.

Another major action step is to create a Network Accrual Core Team (ACT) to provide the NCTN and the NCI Community Oncology Research Program (NCORP) with an inclusive forum to maximize accrual across the networks through communication and collaboration. NCI is currently putting together the ACT, which will address issues in specific trials and create task forces to address more systemic issues (such as trial-specific templates or accrual metrics) as needed. The ACT will report to the NCTN Management Committee.

NCTN trials last for several years, and the network needs to keep investigators engaged throughout these trials. NCTN will assess investigator interest early and often by, for example, conducting surveys early in the protocol development process to assess feasibility of and interest in trials and, if trials are lagging, to quickly understand the reasons. Another need identified at the December meeting is to succinctly promote trials to specific investigators and target communications by specialty or interest area. NCI must clearly communicate trials' rationales and advantages of participation and make it easy for investigators and administrators to search for and find trials.

Investigators at the meeting reported the perception that NCI cancer centers give greater priority to investigator-initiated trials than NCTN trials. NCI therefore needs to raise the value of NCTN trials at sites and cancer centers by developing a recognizable brand for the NCTN that investigators can use to leverage resources in their cancer centers. Suggested approaches are to recognize sites that accrue many patients and encourage those sites to share their expertise.

Precision medicine and rare disease trials need to accrue patients from across the country and might require just-in-time activation if some cancer centers have stringent guidelines about not opening national trials at local sites that might only accrue one or two patients a year. NCI's CIRB takes less than a week to activate a trial, but rapid activation at some local sites might be challenging when a given patient must be accrued quickly.

NCI Response. NCI held an internal retreat on February 6–7, 2015, to address NCI issues from the December 2014 meeting and develop an action plan. NCI presented the concept for the ACT to the NCTN Management Committee, which was very supportive of this concept. NCI is now inviting representatives to join the ACT.

NCI is building on network efficiencies to address the resource concerns of cancer centers. For example, all enrollment into NCTN trials is done through the Oncology Patient Enrollment Network, and all sites use the Medidata Rave clinical data management system. The Cancer Trials Support Unit (CTSU) website posts all trial-specific materials for all NCTN trials, and more than 75 percent of all NCTN sites have enrolled in the NCI C IRB.

The new CTSU dashboard enables sites to obtain information on all of their trials in one place. Sites can configure the dashboard in many different ways to suit their needs. The CTSU is expanding the dashboard in response to feedback from presentations at NCTN group meetings. The CTSU is also developing the CTSU Report Information and Subscription Portal, a single location for subscribing to CTSU e-mail notifications and reports.

Questions and Discussion

Dr. Kuebler commented that the accrual meeting did not include community investigators or NCORP representatives, who face many of the same issues as cancer centers in initiating and carrying out trials. Dr. Kuebler encouraged NCI to include community representatives in the ACT. Ms. Denicoff explained that this meeting was for NCTN grantees only, but it did include NCORP representatives. The ACT will include community investigators and NCORP representatives.

Dr. Mankoff suggested that the ACT include correlative science investigators, such as pathologists and imaging specialists, who might be interested in key correlates in trials that could boost accrual and local interest. The Web-based tools that Ms. Denicoff described might also be of interest to investigators focused on correlative science.

Ms. Roach supported the idea of using surveys to assess ETCTN investigator perspectives in advance. Such information can help identify barriers before they arise.

VI. New Business

James L. Abbruzzese, MD

The year 2015 marks the 10th anniversary of the Clinical Trials Working Group (CTWG) report. Drs. Abbruzzese, Doroshow, and Prindiville plan to recognize this anniversary at CTAC's July 2015 meeting. Key components of the meeting may include reviewing the progress to date and considering future directions of the NCI clinical trials system. The meeting might begin by highlighting progress on the overarching goals in the CTWG summary vision statement: coordination, prioritization, scientific quality, standardization, and operational efficiency. Breakout groups would then discuss what CTAC has done over the past 10 years and how CTAC could help NCI address each of these CTWG goals in the future. The breakout groups could provide a preliminary report to the entire CTAC at the July meeting. Each group would then continue to meet by teleconference to develop recommendations for CTAC, perhaps in time for the November 2015 meeting. This approach would help identify priorities for clinical trials and CTAC for the next 10 years.

Questions and Discussion

Ms. Roach suggested considering what NCI would lack if CTAC were eliminated. Dr. Abbruzzese said that many techniques are available to generate comments about the role of CTAC and future strategies. He invited CTAC members to communicate any other ideas on the proposal for the July 2015 meeting to him and Dr. Prindiville.

Appendix

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

CHAIR

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