National Institutes of Health
National Cancer Institute
Clinical Trials and Translational Research Advisory Committee (CTAC)
NCI Clinical Trials Strategic Planning Subcommittee
Tuesday, July 8, 2014, 2:00 p.m. – 3:00 p.m. ET
Webinar

CTAC Subcommittee Members
Dr. James L. Abbruzzese
Dr. Nancy E. Davidson
Dr. Scott M. Lippman (Chair)
Ms. Nancy Roach
Dr. George J. Weiner

Ad hoc Member
Dr. Joel E. Tepper (absent)

NCI Liaisons
Dr. Jeffrey S. Abrams (absent)
Dr. James H. Doroshow
Dr. Leslie G. Ford (absent)
Dr. Lori Minasian

Executive Secretary
Dr. Sheila A. Prindiville

Guest Speaker
Dr. Robert Diasio

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1. Roll Call and Opening Remarks

Dr. Scott Lippman called to order the CTAC Clinical Trials Strategic Planning Subcommittee at approximately 2:05 p.m. and welcomed Subcommittee members, NCI staff and guests. Dr. Lippman read the Opening and Public Statements. He then explained that the purpose of the call was to review the final report of the NCI Clinical Trials Network (NCTN) Working Group and to discuss the presentation to be given to the CTAC on Wednesday, July 16, 2014.

2. NCI National Clinical Trials Network (NCTN) Working Group Final Report

Dr. Robert Diasio, a co-chair of the NCI NCTN Working Group, stated the objectives of his presentation were to discuss the final report of the NCI National Clinical Trials Network (NCTN) Working Group (WG) and to brief the Subcommittee on the recommendations presented to the NCI. During his presentation, Dr. Diasio reviewed the structure of the report, the process the WG went through to evaluate and analyze 13 trial portfolios and their approach to the NCTN trial prioritization and strategic assessment. The WG's deliberations showcased the value of the shareholders' multiple perspectives. The three aspects of NCTN trial prioritization that were emphasized are as follows:

- prospective disease-specific priority setting
- identification of trial categories generally considered high or low priority
- cross-disease prioritization in response to NCI resource constraints.

Dr. Diasio noted that the approach for setting strategic priorities was new and that the WG had gone to great lengths to reach a consensus on specific principles related to disease-specific priority setting. The WG foresees that the NCTN Groups will utilize these principles to guide concept development and that

the Scientific Steering Committees (SSCs) will find the principles useful during the evaluation of concepts.

Furthermore, the WG developed principles related to cross-disease prioritization. Dr. Diasio emphasized that the intent is to only invoke the principles in response to NCI resource constraints and that the principles are limited to resource-intensive trials. In conjunction with these efforts, the NCI convened the Cross Disease Prioritization Working Group to administer a pilot process that prioritized two SSC approved concepts for large (approximately 1000 patient) trials. Dr. Doroshow noted that a final decision will be made regarding these trials once the overall accrual data for the year have been evaluated. It was also noted that the WG used "1000 patients" as their definition for resource intensive trials and that other definitions could be used in the future.

Dr. Diasio noted that the WG encouraged NCI to establish a Prioritization Group that will utilize the proposed cross-disease prioritization criteria during future prioritization activities for resource intensive trials.

Finally, Dr. Diasio emphasized the need to periodically assess clinical trial portfolios across diseases and noted that the assessment will be discussed in detail at the July 16th meeting of the NCI Clinical Trials and Translational Research Advisory Committee (CTAC).

The Subcommittee unanimously approved the motion to accept the NCI NCTN Working Group's final report with one minor modification: Change the 1-Exceptional rating to Outstanding to mirror the NIH peer review voting algorithm, pages 29 and 46 of the report.

3. Discussion of the Presentations to the CTAC – July 16, 2014

Dr. Lippman briefed the Subcommittee on Drs. George Sledge's and Jeff Abrams' presentations related to the NCI NCTN WG's final report and NCI's plans to implement the NCTN WG's Cross-Portfolio Recommendations. It was noted that the status of the implementation plan and process are included in the WG's report.

4. Remaining NCTN Working Group Charge and Future Subcommittee Agenda Items

Over the last two years, Dr. Lippman noted that the NCTN WG completed the first two components of its charge: (1) assess the strength and balance of the active NCTN clinical trials portfolio and (2) recommend new strategic priorities and directions for the NCTN and that these activities included the SSC Evaluation Pilot. He commended the WG co-chairs and members for their service to NCI and the national cancer clinical trials community.

Further, it was also noted that there were two additional charges noted on the function statement: (3) review and assess the CTWG Evaluation process and results, and (4) provide strategic advice to enhance NCTN clinical trial operations. These charges were not addressed due to the fact that the first two tasks were the highest priority and time consumptive. With regards to the third charge, the NCTN WG co-chairs presented the pilot evaluation of the Scientific Steering Committees as well as data on clinical trial conduct, such as trial accrual rates, to CTAC in March 2014. The Subcommittee discussed that there is still value in discussing these topics, yet an additional working group is not needed at this time. NCI could present the additional data to the Subcommittee as it becomes available. The Subcommittee could then decide if further deliberation is needed by a working group or if the information should be

presented directly to CTAC. The Subcommittee also discussed the pros and cons of reviewing the full NCI clinical trials portfolio beyond the NCTN including investigator-initiated grants and early phase studies as a future Subcommittee agenda item.

5. Wrap-up and Adjournment

Dr. Lippman thanked the Subcommittee members for participating and adjourned the meeting at approximately 2:55 p.m.

Scott Lippman, M.D.

Chair of the CTAC Clinical Trials
Strategic Planning Subcommittee

Sheila Prindiville, M.D., M.P.H.

Executive Secretary