National Cancer Institute

Clinical Trials and Translational Research Advisory Committee (CTAC)

National Clinical Trials Strategic Planning Subcommittee

September 24, 2012

5:00 p.m. – 6:00 p.m.

Conference Call Summary

Subcommittee Members

Dr. Joel E. Tepper (Chair)
Dr. James L. Abbruzzese
Dr. Jeffrey S. Abrams (NCI)
Dr. Nancy E. Davidson
Dr. James H. Doroshow (NCI)
Dr. Scott M. Lippman
Ms. Nancy Roach
Dr. George J. Weiner
Dr. Sheila A. Prindiville (NCI, Executive Secretary)

Dr. Leslie G. Ford (NCI) (absent)
Dr. Lori Minasian (NCI) (absent)

Other Attendees

Ms. Sarah R. Fabian
Dr. Deborah R. Jaffe
Ms. Anna T. Levy

I. Roll Call and Opening Remarks

Dr. Joel E. Tepper, Hector MacLean Distinguished Professor of Cancer Research of the Lineberger Comprehensive Cancer Center, called to order the conference call of the CTAC National Clinical Trials Strategic Planning Subcommittee and welcomed Subcommittee members and NCI staff.
Dr. Tepper read the Opening and Public Statements.

II. Update on the NCI National Clinical Trials Network (NCTN) Working Group

Drs. Robert Diasio chair of the NCTN Working Group, provided the Subcommittee with an update on the progress of the Working Group and a high level update on the progress of the Working Group's deliberations. During the call, the Subcommittee had the opportunity to review the Working Group's function statement, roster as well as background materials distributed at the NCTN July 11, 2012, meeting; a summary of the meeting's major outcomes was also provided. The goals of the Working Group are to (1) assess the strength and balance of active trials; (2) provide strategic advice to NCI, regarding opportunities and resource allocations; (3) provide advice on improving the scientific effectiveness of individual Scientific Steering Committees as well as the overall Scientific Steering Committee system.

Additionally, Dr. Diasio elaborated on the Working Group's aim to assess the pilot process used to review the colorectal clinical trial portfolio, the proposed criteria for evaluating trials as well as the

overall scoring system for each trial. In order to review all of the disease specific portfolios, the Working Group plans on have two or three additional meetings in the next year.

III. Update on the Early Therapeutics – Clinical Trials Network (ET-CTN)

Dr. Percy Ivy, Associate Chief of the NCI Division of Cancer Treatment and Diagnosis' Investigational Drug Branch presentation, first described the current Early Phase Therapeutics Network. The Network consists of 14 sites, enrolls 900-1200 patients annually, supports 188 ongoing studies and has completed 218 studies to date. Dr. Ivy mentioned the Network's accomplishments, which include the identification of molecular characteristics to explore predictive/pharmacodynamics markers.

The current Early Phase Therapeutics Network faces three major challenges: (1) accrual; (2) development of biomarkers; and (3) translation. In order to address the challenges, NCI proposes to redesign the network. The goals of the proposed network are to (1) research and develop new treatments; (2) enhance tumor characterization in Biomarker-driven studies; (3) augment the scientific communities understanding of cancer biology; as well as (4) educate and train young investigators. Dr. Ivy reviewed the proposed scientific and operational changes as well as the timeline for implementation. The next step will be to present the concept for the new network to the Board of Scientific Advisors at its November meeting.

IV. Wrap- Up

Dr. Tepper thanked all of the Subcommittee members for participating. There being no further business, the Subcommittee's conference call was adjourned.

Joel E. Tepper, M.D.
Chair

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