

***June 19, 2008

**National Cancer Institute
5th Meeting of the
CLINICAL TRIALS ADVISORY COMMITTEE
Building 31, C Wing, 6th Floor, Conference Room 10
9000 Rockville Pike
Bethesda, Maryland**

Wednesday, June 25, 2008 - OPEN

8:00 a.m. – 8:15 a.m.

I. Call to Order and Opening Remarks

Dr. Niederhuber

- Consideration of February 4, 2008, Minutes
- Confirmed Future Meeting Dates

December 8, 2008	Monday
March 4, 2009	Wednesday
July 15, 2009	Wednesday
November 4, 2009	Wednesday
March 10, 2010	Wednesday
July 14, 2010	Wednesday
November 17, 2010	Wednesday

8:15 a.m. – 9:00 a.m.

II. Director's Update

Dr. Niederhuber

9:00 a.m. – 9:15 a.m.

III. Legislative Update

Ms. Erickson

9:15 a.m. – 9:45 a.m.

IV. Clinical Trials: NCI-FDA Interactions

Dr. Mooney

9:45 a.m. – 9:55 a.m.

Recognition of Retiring Members

9:55 a.m. – 10:15 a.m.

COFFEE BREAK

10:15 a.m. – 10:30 a.m.

V. CTAC Ad hoc Coordination Subcommittee Report

Dr. Abbruzzese

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10:30 a.m. – 11:00 a.m.

VI. Translational Research Working Group (TRWG) Update

Dr. Matrisian

11:00 a.m. – 11:45 a.m.

VII. Symptom Management Steering Committee (SxQOL SC)
Update and Recently Approved Concept:

Dr. Bruner
Dr. Fisch

Phase III Double-Blind, Placebo Controlled Study of Gabapentin
for the Treatment of Delayed CINV (Chemotherapy-Induced
Nausea and Vomiting) in Patients Receiving Highly or Moderately
Emetogenic Chemotherapy

11:45 a.m. – 12:30 p.m.

VIII. Barriers to the Utilization of the NCI Central IRB

Ms. McArthur

12:30 p.m. – 1:30 p.m.

LUNCH

1:30 p.m. – 2:45 p.m.

IX. Report of the Correlative Science Working Group

- Introduction to the Biomarker, Imaging, and Quality of Life
Supplemental Funding Program

Dr. Prindiville

- Biomarker Supplement

Dr. Smith

COG-AAML0531: Biomarkers for risk identification and
risk-based therapy in pediatric AML

- Quality of Life Supplements

Dr. Minasian

NSABP B-45 – QOL Correlative Study: Bio-behavioral
Mechanisms for Fatigue

GOG UC 0604 – Validation of PROMIS Tool For Fatigue in
Conjunction with Treatment for Endometrial CA

2:45 p.m. – 3:30 p.m.

X. Clinical Trials Database Update

Dr. Buetow

3:30 p.m. – 3:45 p.m.

COFFEE BREAK

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3:45 p.m. – 4:45 p.m.

XI. Analysis of Cooperative Groups Clinical Trials Costs

Dr. Hautala

4:45 p.m. – 5:00 p.m.

XII. New Business

Dr. Niederhuber

- Subcommittee and Working Group Updates
- Future Agenda Items

5:00 p.m.

ADJOURNMENT