

National Cancer Institute
6th Meeting of the
CLINICAL TRIALS ADVISORY COMMITTEE
Building 31, C Wing, 6th Floor, Conference Room 10
9000 Rockville Pike
Bethesda, Maryland
Monday, December 8, 2008 - OPEN

8:00 a.m. – 8:10 a.m.

- I. Call to Order and Opening Remarks Dr. Niederhuber
- Introduction of New Members
 - Consideration of June 25, 2008 Minutes
 - Confirmed Future Meeting Dates:

March 4, 2009	Wednesday
July 15, 2009	Wednesday
November 4, 2009	Wednesday
March 10, 2010	Wednesday
July 14, 2010	Wednesday
November 17, 2010	Wednesday

8:10 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. Standardization of Clinical Trials Agreements: Joint NCI-CEO
Roundtable Project Dr. Doroshow

9:45 a.m. – 10:15 a.m.

- V. Cooperative Group Clinical Trials Complexity Funding Model Dr. Mooney

10:15 a.m. – 10:30 a.m.

COFFEE BREAK

10:30 a.m. – 11:15 a.m.

VI. Head and Neck Scientific Steering Committee Update

Dr. Forastiere
Dr. Schuller
Dr. Trotti

11:15 a.m. – 11:45 a.m.

VII. Biomarker, Imaging and Quality of Life Studies Funding Program
Changes for 2009

Dr. Prindiville
Dr. Jacobson

11:45 a.m. – 12:30 p.m.

VIII. CMS Clinical Trials Phase I and Phase II Policy

Dr. Fitterman

12:30 p.m. – 1:15 p.m.

LUNCH

1:15 p.m. – 2:00 p.m.

IX. CTWG Informatics Initiatives Update
Clinical Trials Management Systems (CTMS) Steering Committee
Report
Clinical Trials Reporting Program (CTRP)

Dr. Buckner
Dr. Buetow

2:00 p.m. – 2:45 p.m.

X. TRWG Implementation Update

Dr. Matrisian

2:45 p.m. – 3:00 p.m.

COFFEE BREAK

3:00 p.m. – 3:45 p.m.

XI. CTEP Process Analysis

Dr. Dilts

3:45 p.m. – 4:30 p.m.

XII. NCI Community Cancer Centers Program

Overview

Clinical Trials Component

Dr. Johnson

Ms. Denicoff

4:30 p.m. – 4:45 p.m.

XIII. Subcommittee/Working Group Updates and New Business

Dr. Niederhuber

4:45 p.m.

ADJOURNMENT