

**National Cancer Institute
3rd Meeting of the
CLINICAL TRIALS ADVISORY COMMITTEE
Building 31, C Wing, 6th Floor, Conference Room 10
9000 Rockville Pike
Bethesda, Maryland**

Wednesday, November 14, 2007 - 8:00 a.m. – 4:30 p.m. - Open to the Public

8:00 a.m. – 8:10 a.m.

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| I. Call to Order and Opening Remarks | Dr. Niederhuber |
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| ▪ Consideration of July 11, 2007 Minutes | |
| ▪ Confirmed Future Meeting Dates | |
| February 4, 2008 | Monday |
| June 25, 2008 | Wednesday |
| December 8, 2008 | Monday |
| March 4, 2009 | Wednesday |

8:10 a.m. – 8:45 a.m.

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| II. Director's Update | Dr. Niederhuber |
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8:45 a.m. – 9:00 a.m.

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| III. Legislative Update | Ms. Erickson |
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9:00 a.m. – 9:25 a.m.

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| IV. CTWG Implementation Update | Dr. Prindiville |
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9:25 a.m. – 10:00 a.m.

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| V. Interface of the Translational Research Working Group (TRWG)
Report and the Clinical Trials Working Group (CTWG) Report | Dr. Doroshow |
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10:00 a.m. – 10:20 a.m.

COFFEE BREAK

10:20 a.m. – 11:00 a.m.

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| VI. Investigational Drug Steering Committee: Clinical Trial Design
Task Force Report | Dr. Ivy |
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11:00 a.m. – 11:30 a.m.

VII. Recently Approved Concepts

RTOG 0436: A Phase III Trial Evaluating the Addition of Cetuximab to Paclitaxel, Cisplatin, and Radiation for Patients With Esophageal Cancer Who Are Treated Without Surgery

Dr. Mooney

GOG-CVM-0704: A Randomized Phase III Trial of Cisplatin Plus Paclitaxel With or Without Bevacizumab Versus the Non-platinum Doublet, Topotecan Plus Paclitaxel, With and Without Bevacizumab in Stage IVB, Recurrent, or Persistent Carcinoma of the Cervix.

Dr. Trimble

11:30 a.m. – 12:30 p.m.

LUNCH

12:30 p.m. – 1:30 p.m.

VIII. Biomarker, Imaging, and Quality of Life Supplemental Funding Program

Introduction

Dr. Prindiville

Recommendations for Prioritization of Quality of Life Studies Conducted in Association with NCI-Funded Clinical Trials

Dr. Bruner

Implementation of the Program

Dr. Prindiville

1:30 p.m. – 2:30 p.m.

IX. Update: Institutional Barriers to Clinical Trials

Dr. Dilts
Dr. Sandler

2:30 p.m. – 2:50 p.m.

COFFEE BREAK

2:50 p.m. – 3:30 p.m.

X. CTWG Informatics Initiatives Update

Dr. Buetow

3:30 p.m. – 4:15 p.m.

XI. CTWG Evaluation Plan: Results from the Baseline Feasibility Analysis

Dr. Doroshov

4:15 p.m. – 4:30 p.m.

XII. New Business

Dr. Niederhuber

4:30 p.m.

Adjournment