



Pediatric Central IRB Meeting Agenda

March 11, 2010
11:00 a.m. – 1:25 p.m.

Agenda

I. General Business

- Next Meeting: April 8, 2010

II. Review/Approval of Minutes

- February 22, 2010

III. Adverse Event Review

IV. Continuing Review

AAML06P1, A Pilot Study of Lestaurtinib (CEP-701) in Combination with Chemotherapy in Young Patients with Relapsed or Refractory FLT3-mutant Acute Myeloid Leukemia (Protocol Version Date 02/26/07)

V. Continuing Review

ACCL0431, A Randomized Phase III Study of Sodium Thiosulfate for the Prevention of Cisplatin-Induced Ototoxicity in Children (Protocol Version Date 01/24/08)

VI. Continuing Review

ACNS0621, Cilengitide (EMD 121974) (IND# 59073) in Recurrent or Progressive and Refractory Childhood High-Grade Glioma: A Groupwide Phase II Study (Protocol Version Date 08/28/09)

VII. Continuing Review

ARAR0332, Treatment of Adrenocortical Tumors with Surgery plus Lymph Node Dissection and Multiagent Chemotherapy: A Groupwide Phase III Study (Protocol Version Date 12/22/09 (active Protocol Version Date 08/30/06))

VIII. Continuing Review

AREN0533, Treatment of Newly Diagnosed Higher Risk Favorable Histology Wilms Tumors: A Groupwide Phase III Study (Protocol Version Date 06/17/08)

IX. Initial Review

ALL08B1, Classification of Newly Diagnosed Acute Lymphoblastic Leukemia (Protocol Version Date 11/10/09)

X. Expedited Reviews and Acknowledgements

Includes studies and letters reviewed and acknowledged from February 18, 2010 – March 5, 2010. Please contact the Operations Office if you would like to review any of the following submissions that were expedited.

Group Responses to Initial Reviews

ACNS0831, Phase III Randomized Trial of Post-Radiation Chemotherapy in Patients with Newly Diagnosed Ependymoma Ages 1 to 21 Years: A Groupwide Phase III Study (Protocol Version Date 01/22/10)

Amendment Reviews

ALTE05N1, Umbrella Long-Term Follow-Up Protocol (Amendment #2, Protocol Version Date 02/02/10)

D9902, A COG Soft Tissue Sarcoma Diagnosis, Biology and Banking Protocol (Amendment #11, Protocol Version Date 02/19/10)

Group Responses to Amendment Reviews

AREN0532, Treatment for Very Low and Standard Risk Favorable Histology Wilms Tumor: A Groupwide Phase III Study (Amendment #4, Protocol Version Date 12/18/09)

Acknowledgements

ADVL0821 Reactivation of Accrual for Ten Additional Patients for Neuroblastoma (MIBG+ without measurable disease) Stratum – Effective February 12, 2010, A Phase II Study of IMC-A12 (Anti-IGF-I Receptor Monoclonal Antibody, IND# 100947, NSC# 742460) in Children with Relapsed/Refractory Solid Tumors: A COG Groupwide Phase II Study

ANHL04B1 Acknowledgement of Amendment #4 Activation – Effective March 1, 2010, Rare and Cutaneous Non-Hodgkin Lymphoma Registry (Protocol Version Date 01/25/10)

ADVL0221 Acknowledgement of Amendment #2 Activation – Effective March 1, 2010, A Phase II Study of Trabectedin (ET-743, Yondelis[®]) in Children with Recurrent Rhabdomyosarcoma, Ewing Sarcoma, or Nonrhabdomyosarcomatous Soft Tissue Sarcomas (Protocol Version Date 01/29/10)

AREN03B2 Acknowledgement of Amendment #4 Activation – Effective March 1, 2010, Renal Tumors Classification, Biology, and Banking Study (Protocol Version Date 01/27/10)
