



Pediatric Central IRB Meeting Agenda

Thursday, May 11, 2017
11:00am – 2:45 pm Eastern Time

Agenda

I. General Business

- **Next Meeting Dates:** Monday, May 15, 2017 AND Thursday, June 8, 2017
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II. Review/Approval of Minutes

- April 13, 2017
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III. Continuing Review

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 01/04/17)

IV. Continuing Review

AAML1031, A Phase III Randomized Trial for Patients with de novo AML using Bortezomib and Sorafenib (IND#114480; NSC# 681239, NSC# 724772) for Patients with High Allelic Ratio FLT3/ITD (Protocol Version Date 02/04/16)

V. Continuing Review

ADVL1515, A Phase 1 Study of LY2606368, a CHK1/2 Inhibitor, in Pediatric Patients with Recurrent or Refractory Solid Tumors, including CNS Tumors (Protocol Version Date 12/16/16)

VI. Continuing Review

AOST1521, A Phase 2 Study of GPNMB-targeted Antibody-Drug Conjugate, CDX-011 (Glembatumumab Vedotin, CR011-vcMMAE), in Recurrent or Refractory Osteosarcoma (Protocol Version Date 09/06/16)

VII. Continuing Review

ACCL15N1CD, Use of Evidence-Based Supportive Care Clinical Practice Guidelines in Pediatric Oncology (Protocol Version Date 08/31/16)

VIII. Amendment Review

ADVL1513, A Phase 1 Study of Entinostat, an Oral Histone Deacetylase Inhibitor, in Pediatric Patients with Recurrent or Refractory Solid Tumors, including CNS Tumors and Lymphoma (Amendment #1, Protocol Version Date 04/10/17)

IX. Initial Review

APEC1621F, NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) – Phase 2 Subprotocol of Ensartinib in Patients with Tumors Harboring ALK or ROS1 Genomic Alterations (Protocol Version Date 03/13/17)

X. Initial Review

APEC1621G, NCI Pediatric MATCH (Molecular Analysis for Therapy Choice)- Phase 2 Subprotocol of Vemurafenib in Patients with Tumors Harboring BRAF V600 Mutations (Protocol Version Date 04/25/17)

XI. Initial Review

APEC1621H, NCI-COG Pediatric Match (Molecular Analysis for Therapy Choice)- A Phase 2 Subprotocol of Olaparib in Patients with Tumors Harboring Defects in DNA Damage Repair Genes (Protocol Version Date 05/01/17)

XII. Educational/Recruitment Materials

APEC1621SC, NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol (Protocol Version Date 03/20/17)
