

## Pediatric Central IRB Meeting Agenda

Thursday, December 14, 2017

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### I Reports for 11/01/17 – 11/30/17

- Pediatric CIRB Local Context Subcommittee Report
  - Expedited Reviews and Study Acknowledgements
  - Study Activation Acknowledgements
  - Amendment Activation Acknowledgements
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### II Continuing Review

**AALL1131**, A Phase III Randomized Trial for Newly Diagnosed High Risk B-Lymphoblastic Leukemia (B-ALL) Including a Stratum Evaluating Dasatinib (IND#73789, NSC#732517) in Patients with Ph-like Tyrosine Kinase Inhibitor (TKI) Sensitive Mutations (Protocol Version Date 06/02/16)

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### III Amendment Review

**AALL1131**, A Phase III Randomized Trial for Newly Diagnosed High Risk B-Lymphoblastic Leukemia (B-ALL) Including a Stratum Evaluating Dasatinib (IND#73789, NSC#732517) in Patients with Ph-like Tyrosine Kinase Inhibitor (TKI) Sensitive Mutations (Amendment #6, Protocol Version Date 10/20/17)

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### IV Amendment Review

**AEWS1221**, Randomized Phase 3 Trial Evaluating the Addition of the IGF-1R Monoclonal Antibody Ganitumab (AMG 479, NSC# 750008, IND# 120449) to Multiagent Chemotherapy for Patients with Newly Diagnosed Metastatic Ewing Sarcoma (Amendment #3C, Protocol Version Date 11/30/17)

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### V Amendment Review

**APEC1621B**, NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) - Phase 2 Subprotocol of JNJ-42756493 (Erdafitinib) in Patients with Tumors Harboring FGFR1/2/3/4 Alterations (Amendment #1, Protocol Version Date 11/22/17)

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### VI Amendment Review

**APEC1621G**, NCI Pediatric MATCH (Molecular Analysis for Therapy Choice) - Phase 2 Subprotocol of Vemurafenib in Patients with Tumors Harboring BRAF V600 Mutations (Amendment #1, Protocol Version Date 11/22/17)

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### VII Amendment Review

**AALL1631**, International Phase 3 trial in Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) testing imatinib in combination with two different cytotoxic chemotherapy backbones (Amendment #1, Protocol Version Date 11/09/17)

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### VIII Amendment Review

**ARST1431**, A Randomized Phase 3 Study of Vincristine, Dactinomycin, Cyclophosphamide (VAC) Alternating with Vincristine and Irinotecan (VI) Versus VAC/VI Plus Temsirolimus (TORI, Torisel, NSC# 683864, IND# 122782) in Patients

with Intermediate Risk (IR) Rhabdomyosarcoma (RMS) (Amendment #1A, Protocol Version Date 11/20/17)

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**IX Continuing Review**

**AHEP0731**, Treatment of Children with All Stages of Hepatoblastoma with Temsirolimus (IND#122782, NSC#683864) Added to High Risk Stratum Treatment: A Groupwide Phase III Study (Protocol Version Date 09/25/15)

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**X Continuing Review**

**AHOD1331**, A Randomized Phase 3 Study of Brentuximab Vedotin (SGN-35, IND #117117) for Newly Diagnosed High-Risk Classical Hodgkin Lymphoma (cHL) in Children and Young Adults (Protocol Version Date 06/14/17)

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**XI Continuing Review**

**AAML1531**, Risk-stratified Therapy for Acute Myeloid Leukemia in Down Syndrome: A COG Groupwide Phase III Study (Protocol Version Date 09/29/16)

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**XII Continuing Review**

**ALTE15N2**, LEAHRN (Late Effects After High-Risk Neuroblastoma) Study (Protocol Version Date 02/27/17)

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**XIII Continuing Review**

**AGCT1531**, A Phase 3 Study of Active Surveillance for Low risk and a Randomized Trial of Carboplatin vs. Cisplatin for Standard Risk Pediatric and Adult Patients with Germ Cell Tumors (Protocol Version Date 03/17/17)

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