



**Pediatric Central IRB Meeting Agenda**  
**Thursday, September 14, 2017**

**Agenda**

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**I Reports for 06/01/17 – 06/30/17**

- Pediatric CIRB Local Context Subcommittee Report
  - Expedited Reviews and Study Acknowledgements
  - Study Activation Acknowledgements
  - Amendment Activation Acknowledgements
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**II Initial 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 (Protocol Version Date 08/22/17)

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**III Initial Review**

**ADVL1614**, A Phase 1/2 Study of VX15/2503 in Children, Adolescents, or Young Adults with Recurrent or Relapsed Solid Tumors (Protocol Version Date 07/07/17)

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**IV Initial Review**

**PBTC-051**, Phase I Study to Evaluate the Safety and Tolerability of the CD40 Agonistic Monoclonal Antibody APX005M in Pediatric Subjects with Recurrent/Refractory Brain Tumors and Newly Diagnosed Brain Stem Glioma (Protocol Version Date 08/10/17)

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**V Amendment Review**

**ACCL1633**, The Effectiveness of Lactobacillus plantarum (LBP, IND #17339) in Preventing Acute Graft-versus-Host Disease (GVHD) in Children undergoing Alternative Hematopoietic Progenitor Cell Transplantation (HCT) (Activation Amendment, Protocol Version Date 08/08/17)

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**VI Continuing Review**

**AALL1231**, A Phase III Randomized Trial Investigating Bortezomib (NSC# 681239; IND# 58443) on a Modified Augmented BFM (ABFM) Backbone in Newly Diagnosed T- Lymphoblastic Leukemia (T-ALL) and T- Lymphoblastic Lymphoma (T-LLy): A Groupwide Phase III Study (Protocol Version Date 04/27/17)

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**VII Continuing Review**

**AALL0434**, Intensified Methotrexate, Nelarabine (Compound 506U78; IND # 52611) and Augmented BFM Therapy for Children and Young Adults with Newly Diagnosed T-cell Acute Lymphoblastic Leukemia (ALL) or T-cell Lymphoblastic Lymphoma: A Groupwide Phase III Study (Protocol Version Date 03/24/16)

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**VIII Continuing Review**

**ACNS1123**, Phase 2 Trial of Response-Based Radiation Therapy for Patients with Localized Central Nervous System Germ Cell Tumors (CNS GCT): A Groupwide Phase II Study (Protocol Version Date 06/01/15)

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**IX Continuing Review**

**AALL1331**, Risk-Stratified Randomized Phase III Testing of Blinatumomab (IND# 117467, NSC#765986) in First Relapse of Childhood B-Lymphoblastic Leukemia (B-ALL): A Groupwide Phase III Study (Protocol Version Date 08/02/17)

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**X Continuing Review**

**ADVL1622**, Phase 2 Trial of XL184 (Cabozantinib) an Oral Small-Molecule Inhibitor of Multiple Kinases, in Children and Young Adults with Refractory Sarcomas, Wilms Tumor, and Other Rare Tumors (Protocol Version Date 02/09/17)

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**XI Continuing Review**

**AALL1621**, A Phase 2 Study of Inotuzumab Ozogamicin (NSC# 772518, IND#TBD) in Children and Young Adults with Relapsed or Refractory CD22+ B-Acute Lymphoblastic Leukemia (B-ALL) (Protocol Version Date 06/20/17)

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**XII Continuing Review**

**AAML1331**, A Phase III Study for Patients with Newly Diagnosed Acute Promyelocytic Leukemia (APL) using Arsenic Trioxide and All-Trans Retinoic Acid (Amendment #1, Protocol Version Date 10/11/16)

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**XIII Potential Unanticipated Problem Review**

**AALL1131**, A Phase III Randomized Trial for Newly Diagnosed High Risk B-Lymphoblastic Leukemia (B-ALL) Testing Clofarabine (IND# 73789, NSC# 606869) in the Very High Risk Stratum: A Groupwide Phase III Study (Protocol Version Date 06/02/16)

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