

**Pediatric Central IRB Meeting Agenda**  
**Thursday, November 9, 2017**

**Agenda**

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**I Reports for 10/01/17 – 10/31/17**

- Pediatric CIRB Local Context Subcommittee Report
  - Expedited Reviews and Study Acknowledgements
  - Study Activation Acknowledgements
  - Amendment Activation Acknowledgements
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**II Study Chair Response to Tabled Initial Review**

**ADV1614**, A Phase 1/2 Study of VX15/2503 in Children, Adolescents, or Young Adults with Recurrent or Relapsed Solid Tumors (Protocol Version Date 10/09/17)

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**III Continuing 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) (Protocol Version Date 08/23/17)

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**IV Continuing Review**

**APEC1621SC**, NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Study (Protocol Version Date 08/22/17)

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**V Continuing Review**

**APEC1621A**, NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) – Phase 2 Subprotocol of LOX\_101 (Larotrectinib) in Patients with Tumors Harboring Actionable NTRK Fusions (Protocol Version Date 07/11/17)

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**VI Continuing 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 10/05/17)

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**VII Continuing Review**

**APEC1621C**, NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) – Phase 2 Subprotocol of Tazemetostat in Patients with Tumors Harboring Alterations in EZH2 or Members of the SWI/SNF Complex (Protocol Version Date 10/03/17)

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**VIII Continuing Review**

**APEC1621D**, NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) – Phase 2 Subprotocol of Ly3023414 in Patients with Solid Tumors (Protocol Version Date 03/24/17)

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**IX Continuing Review**

**APEC1621E**, NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) – Phase 2 Subprotocol of Selumetinib (AZD6244 Hydrogen Sulfate) in Patients with Tumors Harboring Activating MAPK Pathway Mutations (Protocol Version Date 07/11/17)

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**X Continuing 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 07/11/17)

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**XI Continuing 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 07/11/17)

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**XII Continuing 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 10/02/17)

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