

**Pediatric CIRB Meeting Agenda**

**September 11, 2025**

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**I. Amendment**

**ACCL1932**, Letermovir Prophylaxis for Cytomegalovirus in Pediatric Hematopoietic Cell Transplantation (Version Date 07/17/25)

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**II. Continuing 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 (Version Date 12/03/24)

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**III. Continuing Review**

**AAML18P1**, Stopping Tyrosine Kinase Inhibitors (TKI) to Assess Treatment-Free Remission (TFR) in Pediatric Chronic Myeloid Leukemia - Chronic Phase (CML-CP) (Version Date 10/06/20)

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**IV. Continuing Review**

**ACCL2433**, Risk-Based 6MP Adherence Enhancement Strategies in Children, Adolescent and Young Adults with ALL – A Pilot Study (Version Date 03/21/25)

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**V. Continuing Review**

**ACNS1833**, A Phase 3 Randomized Non-Inferiority Study of Carboplatin and Vincristine versus Selumetinib (NSC# 748727, IND# 77782) in Newly Diagnosed or Previously Untreated Low-Grade Glioma (LGG) not associated with BRAFV600E Mutations or Systemic Neurofibromatosis Type 1 (NF1) (Version Date 05/15/25)

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## **VI. Continuing Review**

**ARST2031**, A Randomized Phase 3 Trial of Vinorelbine, Dactinomycin, and Cyclophosphamide (VINO-AC) Plus Maintenance Chemotherapy with Vinorelbine and Oral Cyclophosphamide (VINO-CPO) vs Vincristine, Dactinomycin and Cyclophosphamide (VAC) plus VINO-CPO Maintenance in Patients with High Risk Rhabdomyosarcoma (HR-RMS) (Version Date 01/31/25)

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## **VII. Continuing Review**

**PBTC-059**, Phase 1 Trial of Autologous HER2-specific CAR T cells in Pediatric Patients with Refractory or Recurrent Ependymoma (Version Date 12/20/23)

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## **VIII. Continuing Review**

**PEPN2011**, A Phase 1/2 Study of Tegavivint (IND#156033, NSC#826393) in Children, Adolescents, and Young Adults with Recurrent or Refractory Solid Tumors, Including Lymphomas and Desmoid Tumors (Version Date 02/13/23)

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## **IX. Continuing ReReview**

**ARST2032**, A Prospective Phase 3 Study of Patients with Newly Diagnosed Very Low-risk and Low-risk Fusion Negative Rhabdomyosarcoma (Version Date 12/05/22)

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