

Pediatric CIRB Meeting Agenda

April 10, 2025

I. Initial Review

AALL2331, A Phase 2/3 Randomized Trial Investigating Daratumumab on a Modified Augmented BFM (aBFM) Backbone in Newly Diagnosed T-Lymphoblastic Leukemia (T-ALL) and T-Lymphoblastic Lymphoma (T-LL) (Version Date 03/11/25)

II. Continuing Review

AALL1732, A Phase 3 Randomized Trial of Inotuzumab Ozogamicin (IND#:133494, NSC#: 772518) for Newly Diagnosed High-Risk B-ALL; Risk-Adapted Post-Induction Therapy for High-Risk B-ALL, Mixed Phenotype Acute Leukemia, and Disseminated B-LLy (Version Date 10/12/23)

III. Continuing Review

ACCL1931, A Randomized Trial of Levocarnitine Prophylaxis to Prevent Asparaginase-Associated Hepatotoxicity in Adolescents and Young Adults Receiving Acute Lymphoblastic Leukemia Therapy (Version Date 12/19/24)

IV. Continuing Review

ALTE2321, Walking Juntos: Developing and Testing a Culturally-Tailored Mobile Health and Social Media Physical Activity Intervention Among Adolescent and Young Adult Childhood Cancer Survivors (Version Date 05/28/24)



V. Continuing Review

AREN1921, Treatment of Newly Diagnosed Diffuse Anaplastic Wilms Tumors (DAWT) and Relapsed Favorable Histology Wilms Tumors (FHWT) (Version Date 02/21/25)

VI. Continuing Review

ASCT2031, A Multi-Center, Phase 3, Randomized Trial of Matched Unrelated Donor (MUD) versus HLA-Haploidentical Related (Haplo) Myeloablative Hematopoietic Cell Transplantation for Children, Adolescents, and Young Adults (AYA) with Acute Leukemia or Myelodysplastic Syndrome (MDS) (Version Date 06/28/24)