



Pediatric Central IRB Meeting Agenda

Thursday, October 12, 2017

Agenda

I Reports for 09/01/17 – 09/30/17

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

ANBL1232, Utilizing Response- and Biology-Based Risk Factors to Guide Therapy in Patients with Non-High-Risk Neuroblastoma (Amendment #2, Protocol Version Date 09/13/17)

III 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 #1, Protocol Version Date 08/23/17)

IV Amendment 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 (Amendment #1, Protocol Version Date 10/03/17)

V Continuing Review

ALTE1621, Pharmacologic Reversal of Ventricular Remodeling in Childhood Cancer Survivors at Risk for Heart Failure (PREVENT-HF): A Phase 2b Randomized Placebo-Controlled (Carvedilol) Trial (Protocol Version Date 03/07/16)

VI Amendment Review

ALTE1621, Pharmacologic Reversal of Ventricular Remodeling in Childhood Cancer Survivors at Risk for Heart Failure (PREVENT-HF): A Phase 2b Randomized Placebo-Controlled (Carvedilol) Trial (Amendment #1, Protocol Version Date 08/23/17)

VII Continuing Review

AALL15P1, A Groupwide Pilot Study to Test the Tolerability and Biologic Activity of the Addition of Azacitidine (IND# 133688, NSC# 102816) to Chemotherapy in Infants with Acute Lymphoblastic Leukemia (ALL) and KMT2A (MLL) Gene Rearrangement (Protocol Version Date 03/17/17)

VIII Continuing Review

ADVL1514, A Phase 1 Study of ABI-009 (*nab*-Rapamycin) in Pediatric Patients with Recurrent or Refractory Solid Tumors, Including CNS Tumors as a Single Agent and in Combination with Temozolomide and Irinotecan (Protocol Version Date 05/18/17)

IX Amendment 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)
