

CURRENTLY ENROLLING HEM/ONC STUDIES as of 01/31/19

1. COG Clinical Trials

Leukemia	
AALL1331 (PI: Becton)	Risk-Stratified Randomized Phase III Testing of Blinatumomab (IND#117467, NSC#765986) in First Relapse of Childhood B-Lymphoblastic Leukemia
AALL1521/Incyte (PI: Becton)	A Phase 2 Study of the JAK1/JAK2 Inhibitor Ruxolitinib with Chemotherapy in Children with De Novo High-Risk CRLF2-Rearranged and /or JAK Pathway-Mutant Acute Lymphoblastic Leukemia
AALL1621 (PI: Becton)	A Phase 2 Study of Inotuzumab Ozogamicin (NSC# 772518, IND# 133494) in Children and Young Adults with Relapsed or Refractory CD22+ B-Acute Lymphoblastic Leukemia
AALL1631 (PI: Becton)	International Phase 3 Trial in Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia Ph+ ALL Testing Imatinib in Combination with Two Different Cytotoxic Chemotherapy Backbones
AAML1331 (PI: Becton)	A Phase III Study for Patients with Newly Diagnosed Acute Promyelocytic Leukemia (APL) using Arsenic Trioxide and All-Trans Retinoic Acid

CNS	
ACNS0831 (PI: Becton)	Phase III Randomized Trial of Post-Radiation Chemotherapy in Patients with Newly Diagnosed Ependymoma Ages 1 to 21 years
ACNS1422 (PI: Becton)	A Phase 2 Study of Reduced Therapy for Newly Diagnosed Average-Risk WNT-Driven Medulloblastoma Patients
ACNS1721 (PI: Becton)	A Phase 2 Study of Veliparib (ABT-888, IND # 139199) and Local Irradiation, Followed by Maintenance Veliparib and Temozolomide, in Patients with Newly Diagnosed High-Grade Glioma (HGG) without H3 K27M or BRAFV600E Mutations

Germ Cell Tumor	
AGCT1531 (PI: Becton)	A Phase 3 Study of Active Surveillance for Low Risk and a Randomized Trial of Carboplatin vs. Cisplatin for Standard Risk Pediatric and Adult Patients with Germ Cell Tumors
AGCT1532 (PI: Becton)	A Randomized Phase 3 Trial of Accelerated versus Standard BEP Chemotherapy for Patients with Intermediate and Poor-risk Metastatic Germ Cell Tumors

Liver	
AHEP1531 (PI: Becton)	Pediatric Hepatic Malignancy International Therapeutic Trial (PHITT)

Late Term Effects	
ALTE03N1 (PI: Becton)	Key Adverse Events after Childhood Cancer
ALTE05N1 (PI: Becton)	Umbrella Long-term Follow-up Protocol

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ALTE11C2 (PI: Becton)	Health Effects after Anthracycline and Radiation Therapy (HEART): Dexrazoxane and Prevention of Anthracycline-related Cardiomyopathy
ALTE15N2 (PI: Becton)	LEAHRN (Late Effects After High-Risk Neuroblastoma) Study
ALTE1621 (PI: Becton)	Pharmacologic Reversal of Ventricular Remodeling in Childhood Cancer Survivors at Risk for Heart Failure (PREVENT-HF): A Phase 2b Randomized Placebo-Controlled (Carvedilol) Trial
ACNS1631 (PI: Becton)	A Randomized Web-based Physical Activity Intervention among Children and Adolescents with Acute Lymphoblastic Leukemia

Lymphoma

AHOD1331 (PI: Becton)	A Randomized Phase III Study of Brentuximab Vedotin (SGN-35, IND #117117) for Newly Diagnosed High-Risk Classical Hodgkin Lymphoma (cHL) in Children and Adolescents
ANHL12P1 (PI: Becton)	A Randomized Phase II study of Brentuximab Vedotin (NSC# 749710) and Crizotinib (NSC# 749005) in Patients with Newly Diagnosed Anaplastic Large Cell Lymphoma (ALCL) IND #117117

Neuroblastoma

ANBL00B1 (PI: Becton)	Neuroblastoma Classification Biology Studies
ANBL1232 (PI: Becton)	Utilizing Response- and Biology-Based Risk Factors to Guide Therapy in Patients with Non-High-Risk Neuroblastoma
ANBL1531 (PI: Becton)	A Phase 3 Study of 131I-Metaiodobenzylguanidine (131I-MIBG) or Crizotinib Added to Intensive Therapy for Children with Newly Diagnosed High-Risk Neuroblastoma (NBL) (IND# 134379)

Renal

AREN03B2 (PI: Becton)	Renal Tumors Classification, Biology, and Banking Study
AREN1721 (PI: Becton)	A Randomized Phase 2 Trial of Axitinib/Nivolumab combination therapy vs single agent Axitinib or Nivolumab for the treatment of TFE/Translocation Renal Cell Carcinoma across all age groups

Sarcoma/Rhabdomyosarcoma/Osteosarcoma/Ewing's Sarcoma

AEWS1221 (PI: Becton)	Randomized Phase II Trial Evaluating the Addition of the IGF-1R Monoclonal Antibody Ganitumab (AMG 479, NSC# 750008, IND# 120449) to Multiagent Chemotherapy for Patients with Newly Diagnosed Metastatic Ewing Sarcoma
ARST1431 (PI: Becton)	Randomized Phase 3 Study of Vincristine, Dactinomycin, Cyclophosphamide (VAC) Alternating with Vincristine and Irinotecan (VI) Versus VAC/VI Plus Temsirolimus in Patients with Intermediate Risk (IR) Rhabdomyosarcoma (RMS)

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Solid Tumors	
ADVL1322/Novartis (PI: Becton)	A Phase II Trial of Pazopanib NSC# 737754, IND# 65747 in Children with Refractory Solid Tumors
ADVL1521 (PI: Becton)	A Phase 2 Study of the MEK inhibitor Trametinib (IND#119346, NSC#763093) in Children with Relapsed or Refractory Juvenile Myelomonocytic Leukemia
ADVL1622 (PI: Becton)	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

PEDIATRIC MATCH	
APEC1621SC (PI: Becton)	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol
APEC1621A (PI: Becton)	Phase 2 Subprotocol of LOXO-101 in Patients with Tumors Harboring Actionable NTRK Fusions
APEC1621B (PI: Becton)	Phase 2 subprotocol of JNJ-42756493 (Erdafitinib) in patients with tumors harboring FGFR1/2/3/4 alterations
APEC1621C (PI: Becton)	Phase 2 Subprotocol of Tazemetostat for Patients with Tumors Harboring Alterations in EZH2 or Members of the SWI/SNF Complex
APEC1621D (PI: Becton)	Phase 2 Subprotocol of LY3023414 in Solid Tumors
APEC1621E (PI: Becton)	Phase 2 Subprotocol of Selumetinib in Patients with Tumors Harboring Activating MAPK Pathway Mutations
APEC1621F (PI: Becton)	Phase 2 Subprotocol of Ensartinib in Patients with Tumors Harboring ALK or ROS1 Genomic Alterations
APEC1621G (PI: Becton)	Phase 2 Subprotocol of Vemurafenib in Patients with Tumors Harboring Actionable BRAF V600 Mutations
APEC1621H (PI: Becton)	Phase 2 Subprotocol of Olaparib in Patients with Tumors Harboring Defects in DNA Damage Repair Genes
APEC1621I (PI: Becton)	Phase 2 subprotocol of Palbociclib in Patients with Tumors Harboring Activating Alterations in Cell Cycle Genes
APEC1621J (PI: Becton)	Phase 2 Subprotocol of BVD-523FB (ulixertinib) in Patients with Tumors Harboring Activating MAPK Pathway Mutations

PROJECT EVERY CHILD	
APEC14B1 (PI: Becton)	Project: EveryChild, A Registry, Eligibility Screening, Biology and Outcome Study

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2. Innovative Cancer Therapeutics

CNS	
Head Start 4 (PI: Bielamowicz)	Newly Diagnosed Children (Less Than 10 Years Old) With Medulloblastoma And Other Central Nervous System Embryonal Tumors . Clinical And Molecular Risk-Tailored Intensive And Compressed Induction Chemotherapy Followed By Consolidation With Randomization To Either Single-Cycle Or To Three Tandem Cycles Of Marrow-Ablative Chemotherapy With Autologous Hematopoietic Progenitor Cell Rescue
NMTRC ONC-403-001 (PI: Bielamowicz)	A Two-Part Study of TB-403 in Pediatric Subjects with Relapsed or Refractory Medulloblastoma , Neuroblastoma, Ewing Sarcoma, or Alveolar Rhabdomyosarcoma

Leukemia - Ref/Rel	
POETIC 14-01 (PI: Bielamowicz)	Phase I Study of Carfilzomib in Combination with Cyclophosphamide and Etoposide for Children with Relapsed and Refractory Solid Tumors and Leukemias (<i>Duplicate in Solid Tumor section</i>)
POETIC 16-01 (PI: Bielamowicz)	Phase I/II Study of Neratinib in children and Pediatric Patients with Relapsed or Refractory Solid Tumors or Hematologic Malignancies (<i>Duplicate in Solid Tumor section</i>)
POETIC GO40871 (PI: Bielamowicz)	PENDING - Phase I/II Study of Idasanutlin in combination with either standard chemotherapy or Venetoclax for ref/rel ALL, AML, or NB.

Neurofibromatosis	
MEK-NF-201	PENDING - A Phase I/II Trial of MEK inhibitor PD-0325901 for NF1

Hodgkin Lymphoma - Upfront	
C25004 (PI: Bielamowicz)	An Open-Label Study of Brentuximab Vedotin +Adriamycin, Vinblastine, and Dacarbazine in Pediatric Patients With Advanced Stage Newly Diagnosed Hodgkin Lymphoma

Lymphoma Ref/Rel	
POETIC 16-01 (PI: Bielamowicz)	Phase I/II Study of Neratinib in children and Pediatric Patients with Relapsed or Refractory Solid Tumors or Hematologic Malignancies

Neuroblastoma - High risk or ref/rel	
NMTRC 012 (PI: Bielamowicz)	Pediatric Precision Laboratory Advanced Neuroblastoma Therapy A Pilot Study Using Molecular Guided Therapy with Induction Chemotherapy followed by maintenance with DFMO for Subjects with Newly Diagnosed High-Risk Neuroblastoma
NMTRC 014 (PI: Bielamowicz)	Neuroblastoma Maintenance Therapy Trial Using DFMO
NMTRC 011	Tocapone & Oxaliplatin for refractory/relapsed Neuroblastoma

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POETIC GO40871 (PI: Bielamowicz)	PENDING - Phase I/II Study of Idasanutlin in combination with either standard chemotherapy or Venetoclax for ref/rel ALL, AML, or NB.
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Ewing Sarcoma - 1st relapse

CL-PTL-130 (PI: Bielamowicz)	A Multi-Center Phase III, Randomized, Open-Label Trial of Vigil (bi-shRNAfurin and GMCSF Augmented Autologous Tumor Cell Immunotherapy) in combination with Irinotecan and Temozolomide as a Second-Line Regimen for Ewing's Sarcoma (Sponsor ID# CL-PTL 130)
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Solid Tumors - ref/rel

POETIC G029665 (PI: Bielamowicz)	A Phase I/II Multicenter, Open Label, Dose Escalation Study Of The Safety And Pharmacokinetics Of Cobimetinib In Pediatric And Young Adult Patients With Previously Treated Solid Tumors
POETIC 14-01 (PI: Bielamowicz)	Phase I Study of Carfilzomib in Combination with Cyclophosphamide and Etoposide for Children with Relapsed and Refractory Solid Tumors and Leukemias (<i>Duplicate in Leukemia - Ref/Rel section</i>)
POETIC 16-01 (PI: Bielamowicz)	Phase I/II Study of Neratinib in children and Pediatric Patients with Relapsed or Refractory Solid Tumors or Hematologic Malignancies (<i>Duplicate in Leukemia - Ref/Rel section</i>)

Biomarkers in Anthracycline Cardiotoxicity

Douglass - Fellow Research (PI: Stine)	Plasma biomarkers in anthracycline cardiotoxicity
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3. Supportive Care

SUPPORTIVE CARE

205844 (PI: Mian)	Home or Away From Home: Patient-Centered Outcomes Related To The Management of Neutropenia Which are Most Important to Children with AML and Their Caregivers. Aim 2: AML Neutropenia Patient-Centered Outcomes
204052 (PI: Mian)	Community Central Line Infection Prevention Trial

4. Hematology

HEMATOLOGY

CETB115E2201 (PI: Farrar)	A phase II, open-label, non-controlled, intra-patient dose- escalation study to characterize the pharmacokinetics after oral administration of eltrombopag in pediatric patients with refractory, relapsed or treatment naïve severe aplastic anemia or recurrent aplastic anemia
1VIT17044 (PI: Cray)	A Multicenter, Randomized, Active-Controlled Study to Investigate the Efficacy and Safety of Intravenous Ferric Carboxymaltose in Pediatric Patients with Iron Deficiency Anemia

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AG348-C-008 (PI: Crary)	Pyruvate Kinase Deficiency Global Longitudinal Registry
	ITP ICON 1 (PI: Stine): Physician Treatment Decisions and Patient-Reported Outcomes in Pediatric Refractory Immune Thrombocytopenia
	ITP ICON 2 (PI: Stine): Retrospective review of off-label thrombopoietin receptor agonist (TPO-RA) use in pediatric patients: Data from the Pediatric ITP Consortium of North America

5. Hemophilia

Hemophilia	
SB-525-1603	Phase 1.2 open label, Adaptive dose ranging study to assess the safety and tolerability of SB-525 (recombinant AAV2/6 human factor 8 gene therapy) in adult subjects with severe hemophilia A
Dimensions	A longterm follow up study to evaluate the safety, tolerability and efficacy of adeno-associated virus (AAV) rh10-mediated gene transfer of huma factor IX in adults with Moderate/severe Hemophilia B
CT-AMT-061-02 (PI: Crary)	Phase III, open-label, single-dose, multi-center multinational trial investigating a serotype 5 adeno-associated viral vector containing the Padua variant of a codon-optimized human factor IX gene (AAV5-hFIXco-Padua, AMT-061) administered to adult subjects with severe or moderately severe hemophilia B

6. Sickle Cell

SICKLE CELL	
VACRP (PI: Mack)	Developmental Changes of Normal Pupil Size and Reactivity in Pediatric Patients with Sickle Cell Disease
B5201002 (PI: Crary)	A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of Rivipansel (GMI-1070) in the Treatment of Vaso-Occlusive Crisis in Hospitalized Subjects With Sickle Cell Disease
B5201003 (PI: Crary)	AN OPEN-LABEL EXTENSION STUDY TO EVALUATE THE SAFETY OF RIVIPANSEL (GMI-1070) IN THE TREATMENT OF ONE OR MORE VASO-OCCLUSIVE CRISES IN HOSPITALIZED SUBJECTS WITH SICKLE CELL DISEASE
Alvarez - Fellow Research (PI: Crary)	Platelet Microparticles and Platelet Glycoprotein VI Receptor Haplotypes in Pediatric Patients with Sickle Cell Disease
DSPLACE part 1 (PI: Saccente)	Dissemination and Implementation of Stroke Prevention Looking at the Care Environment
DSPLACE part 2 (PI: Saccente)	Dissemination and Implementation of Stroke Prevention Looking at the Care Environment
Kidds-DOTT (PI: Crary)	Prospective Multi-Center evaluation of the Duration of Therapy for Thrombosis in Children (the "Kids-DOTT" Trial)

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(PI: Mack)	Pupillometry Changes to Detect Pain and Analgesic Response in Vaso-Occlusive Pediatric Sickle Cell Disease Patients
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7. Vascular Malformations

VASCULAR MALFORMATIONS

VACRP (PI: Cray)	Pharmacokinetics of Intralesional Bleomycin Injections for Vascular Malformations
VMCOAG (PI: Mack)	Analyzing Coagulation Dynamics in Vascular Malformations with Thromboelastography

8. Langerhans Cell Histiocytosis (LCH)

LCH

LCH-IV (PI: Stine)	International Collaborative Treatment Protocol for Langerhans Cell Histiocytosis
LCH-CLO (PI: Stine)	Phase II Study of Clofarabine in Patients with Recurrent or Refractory Langerhans Cell Histiocytosis
NACHO-BIO (PI: Stine)	A Translational Biology Platform to Advance Understanding of Pathogenesis and Improve Outcomes for Patients with Histiocytic Disorders
	HLH in LCH (PI: Stine): Hemophagocytic Lymphohistiocytosis (HLH) in Langerhans cell histiocytosis (LCH): A multi-institutional retrospective descriptive study
	Non-LCH or RHD (PI: Stine): INTERNATIONAL RARE HISTIOCYTIC DISORDERS REGISTRY (IRHDR)