Developmental Therapeutics

Aflac Cancer & Blood Disorders Center
CHILDREN'S HEALTHCARE OF ATLANTA

BMT developmental therapy treatment protocols			
Study	**Clinical trial name**	**Phase**	**Age**
STAR Aba GvHD SCD	Abatacept for Graft Versus Host Disease Prophylaxis after Hematopoietic Stem Cell Transplantation for Pediatric Sickle Cell Disease: A Sickle Transplant Alliance for Research Trial https://clinicaltrials.gov/ct2/show/NCT02867800	Pilot	3 to <21 yr
Abatacept NMD	Abatacept for Post-Transplant Immune Suppression in Children and Adolescents Receiving Allogeneic Hematopoietic Stem Cell Transplants for Non-Malignant Diseases https://clinicaltrials.gov/ct2/show/NCT01917708	Pilot	1 to 21 yr
HGB-206	Clinical Study Protocol HGB-206: A Phase 1 Study Evaluating Gene Therapy by Transplantation of Autologous CD34+ Stem Cells Transduced Ex Vivo with the LentiGlobin BB305 Lentiviral Vector in Subjects with Severe Sickle Cell https://clinicaltrials.gov/ct2/show/NCT02140554	I	≥18 yr
Autologous MSCs for GvHD	A Phase I Study of Mesenchymal Stromal Cells for the Treatment of Acute and Chronic Graft versus Host Disease https://clinicaltrials.gov/ct2/show/NCT02359929	I	>12 yr
BP-U-004	Phase 1/2 Study of CaspaCide T cells from an HLA-partially Matched Family Donor after Negative Selection of TCR αβ+ T cells in Pediatric Patients Affected by Hematological Disorders https://clinicaltrials.gov/ct2/show/NCT03301168	I/II	≥1 mo to ≤26 yr
ST-400-01	A Phase 1/2, Open-label, Single-arm Study to Assess the Safety, Tolerability, and Efficacy of ST-400 Autologous Hematopoietic Stem Cell Transplant for Treatment of Transfusion-dependent β-thalassemia (TDT) https://clinicaltrials.gov/ct2/show/NCT03432364	I/II	≥18 yr
BIV003	A Phase 1/2, Open-Label, Multicenter, Single-Arm Study to Assess the Safety, Tolerability, and Efficacy of BIVV003 for Autologous Hematopoietic Stem Cell Transplantation in Patients with Severe Sickle Cell Disease	I/II	18 to 35 yr
Novartis CART FU	Protocol No.CCTL019A2205B: Long Term Follow-up of Patients Exposed to Lentiviral-Based CD19 directed CART Cell Therapy https://clinicaltrials.gov/ct2/show/NCT02445222	NA	any age *(received anti-CD19 directed CART therapy)*

CNS developmental therapy treatment protocols			
APEC1621SC	APEC1621SC: NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol https://clinicaltrials.gov/ct2/show/NCT03155620	NA	≥12 mo to ≤21 yr
AflacST1501	Aflac ST1501, A Phase I Study of Abemaciclib in Children with Newly Diagnosed Diffuse Intrinsic Pontine Glioma and in Children with Recurrent and Refractory Solid Tumors Including Malignant Brain Tumors https://clinicaltrials.gov/ct2/show/NCT02644460	I	≥2 to ≤25 yr
AflacST1601	Aflac ST1601: A Phase I Trial of Temozolomide and Everolimus in Children with Recurrent or Refractory Brain Tumors	I	>3 to <22 yr
COG ADVL1414	ADVL1414, A Phase 1 Study of Selinexor (KPT-330, IND# 125052), a Selective XPO1 Inhibitor, in Recurrent and Refractory Pediatric Solid Tumors, including CNS Tumors https://clinicaltrials.gov/ct2/show/NCT02323880	I	≥12 mo to ≤21 yr
COG ADVL1514	ADVL1514, A Phase I 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 https://clinicaltrials.gov/ct2/show/NCT02975882	I	≥12 mo to ≤21 yr

COG ADVL1615	ADVL1615, A Phase 1 Study of Pevonedistat (MLN4924 IND# 136078), a NEDD8 Activating Enzyme (NAE) Inhibitor, in Combination with Temozolomide and Irinotecan in Pediatric Patients with Recurrent or Refractory Solid Tumors https://clinicaltrials.gov/ct2/show/NCT03323034	I	Part A1: ≥12 mo to ≤21 yr Part A2: ≥6 mo to <12 mo
COG ADVL1921	Phase 1 Study to Evaluate the Safety and Pharmacokinetics of Palbociclib (Ibrance®) in Combination with Irinotecan and Temozolomide in Pediatric Patients with Recurrent or Refractory Solid Tumors https://clinicaltrials.gov/ct2/show/NCT03709680	I	≥2 to <21 yr
LOXO-EXT-17005	LOXO-EXT-17005: A Phase 1/2 Study of the TRK Inhibitor LOXO-195 in Adult and Pediatric Subjects with Previously Treated NTRK Fusion Cancers https://clinicaltrials.gov/ct2/show/NCT03215511	I/II	≥1 mo
PBTC-029B	PBTC-029B: A Phase 1 and Phase II and Re-Treatment Study of AZD6244 for Recurrent or Refractory Low Grade Glioma https://clinicaltrials.gov/ct2/show/NCT01089101	I/II	≥3 to ≤21 yr
PBTC-045	PBTC-045: A Safety and Preliminary Efficacy trial of MK-3475 (pembrolizumab; anti-PD-1) in Children with Recurrent, Progressive or Refractory Diffuse Intrinsic Pontine Glioma (DIPG), Non-brainstem High-grade Gliomas (NB-HGG), Ependymoma, Medullo-blastoma and Hypermutated Brain Tumors https://clinicaltrials.gov/ct2/show/NCT02359565	I	≥1 to ≤18 yr
PBTC-048	PBTC-048: Feasibility Trial of Optune for Children with Recurrent or Progressive Supratentorial High-grade Glioma and Ependymoma	I	≥5 to ≤21 yr

PBTC-050	PBTC-050: A Phase I and Surgical Study of Ribociclib and Everolimus (RAD001) in Children with Recurrent or Refractory Malignant Brain Tumors https://clinicaltrials.gov/ct2/show/NCT03387020	I	≥1 to ≤21 yr
PBTC-051	Phase I Study to Evaluate the Safety and Tolerability of the CD40 Agonistic Monoclonal Antibody APX005M in Pediatric Subjects with Recurrent/ Refractory Brain Tumors and Newly Diagnosed Brain Stem Glioma https://clinicaltrials.gov/ct2/show/NCT03389802	I	≥1 to ≤21 yr
PBTC-053	A Pediatric Brain Tumor Consortium Phase I/II and Surgical Study of CX-4945 in Patients with Recurrent SHH Medulloblastoma https://clinicaltrials.gov/ct2/show/NCT03904862	I/II	≥3 to ≤18 yr
EZH-102	A Phase 1 Study of the EZH2 Inhibitor Tazemetostat in Pediatric Subjects with Relapsed or Refractory INI1-Negative Tumors or Synovial Sarcoma https://clinicaltrials.gov/ct2/show/NCT02601937	I	≥6 mo to ≤21 yr
ONC014	ONC201 in Newly Diagnosed Diffuse Intrinsic Pontine Glioma and Recurrent Pediatric H3 K27M Gliomas https://clinicaltrials.gov/ct2/show/NCT03416530	I	≥2 to <19 yr
Ignyta RXDX-101-03	A Phase 1/1b, Open-Label, Dose-Escalation and Expansion Study of Entrectinib (RXDX-101) in Children and Adolescents with Recurrent or Refractory Solid Tumors and Primary CNS Tumors https://clinicaltrials.gov/ct2/show/NCT02650401	I/Ib	≥2 to <22 yr

COG ADVL1312	A Phase 1/2 Study of MK-1775 (AZD1775, IND# 121422) in Combination with Oral Irinotecan in Children, Adolescents, and Young Adults with Relapsed or Refractory https://clinicaltrials.gov/ct2/show/NCT02095132	I/II	>12 mo to ≤21 yr
CHLA MEK162	Phase I-II Study of MEK 162 for Children with Low-Grade Gliomas and Other Ras/Raf/ERK Pathway Activated Tumors https://clinicaltrials.gov/ct2/show/NCT02285439	I/II	≥1 to <18 yr
PBTC-029B	A Phase I and Phase II and Re-treatment Study of AZD6244 for Recurrent or Refractory Pediatric Low Grade Glioma https://clinicaltrials.gov/ct2/show/NCT01089101	I/II	≥3 to ≤21 yr
COG APEC1621D[REQ]	APEC1621D NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)—Phase 2 Subprotocol of LY3023414 in Patients with Solid Tumors https://clinicaltrials.gov/ct2/show/NCT03213678	II	≥12 mo to ≤21 yr
COG APEC1621H[REQ]	APEC1621H NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)—Phase 2 Subprotocol of Olaparib in Patients with Tumors Harboring Defects in DNA Damage Repair Genes https://clinicaltrials.gov/ct2/show/NCT03233204	II	≥12 mo to ≤21 yr
COG APEC1621J[REQ]	APEC1621J NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)—Phase 2 Subprotocol of BVD-523FB (Ulixertinib) in Patients with Tumors Harboring Activating MAPK Pathway Mutations	II	≥12 mo to ≤21 yr
COG ADVL1622	ADVL1622, 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 https://clinicaltrials.gov/ct2/show/NCT02867592	II	≥2 to ≤30 yr except ≤18 yr for MTC, RCC, and HCC
COG ADVL1823	ADVL1823, Larotrectinib (LOXO-101, NSC# 788607, IND# 141824) for Previously Untreated TRK Fusion Pediatric Solid Tumors and TRK Fusion Relapsed Pediatric Acute Leukemias https://clinicaltrials.gov/ct2/show/NCT03834961	II	≤30 yr

Aflac ST1502 CHOANOME II	AflacST1502: A Phase II Study of Sirolimus in Combination with Metronomic Chemotherapy in Children with Recurrent and/or Refractory Solid and CNS Tumors https://clinicaltrials.gov/ct2/show/NCT02574728	II	>12 mo to ≤30 yr
SJATRT	Phase 2 Study of Alisertib as a Single Agent in Recurrent or Progressive Central Nervous System (CNS) Atypical Teratoid Rhabdoid Tumors (AT/RT) and Extra-CNS Malignant Rhabdoid Tumors (MRT) and in Combination Therapy in Newly Diagnosed AT/RT (SJATRT) https://clinicaltrials.gov/ct2/show/NCT02114229	II	<22 yr
Leukemia developmental therapy treatment protocols			
ADVL1712	ADVL1712, A Feasibility Trial of MLN4924 (Pevonedistat, TAK 924, IND#142772) Given in Combination with Azacitidine, Fludarabine, and Cytarabine, in Children, Adolescents, and Young Adults with Relapsed or Refractory Acute Myeloid Leukemia or Relapsed Myelodysplastic Syndrome https://clinicaltrials.gov/ct2/show/NCT03813147	I	≥1 mo to ≤21 yr
AINV18P1	A Phase 1 Study of Palbociclib (IND# 141416), A CDK 4/6 Inhibitor, in Combination with Chemotherapy in Children with Relapsed Acute Lymphoblastic Leukemia (ALL) or Lymphoblastic Lymphoma (LL) https://clinicaltrials.gov/ct2/show/NCT03792256	I	≥12 mo to ≤31 yr
LEAP MTT	Matched Targeted Therapy (MTT) Recommendation for Patients with Recurrent, Refractory, or High Risk Leukemias https://clinicaltrials.gov/ct2/show/NCT02670525	Feasi-bility	≤30 yr
AbbVie M13-833	A Phase 1 Study of the Safety and Pharmacokinetics of Venetoclax in Pediatric and Young Adult Patients with Relapsed or Refractory Malignancies https://clinicaltrials.gov/ct2/show/NCT03236857	I	<25 yr
TACL 2016-003	Epigenetic Reprogramming in Relapse AML: A Phase 1 Study of Decitabine and Vorinostat Followed by Fludarabine, Cytarabine and G-CSF (FLAG) in Children and Young Adults with Relapsed/Refractory AML https://clinicaltrials.gov/ct2/show/NCT03263936	I	≥1 to ≤25 yr
AflacLL1602 ENCERT	ENCERT: A Phase 1 Trial using Everolimus in combination with Nelarabine, Cyclophosphamide and Etoposide in Relapsed T cell Lymphoblastic Leukemia/ Lymphoma https://clinicaltrials.gov/ct2/show/NCT03328104	I	>1 to <30 yr
TACL 2012-002	A Pilot Study of Vincristine Sulfate Liposome Injection (Marqibo®) in Combination with UK ALL R3 Induction Chemotherapy for Children, Adolescents, and Young Adults with Relapse of Acute Lymphoblastic Leukemia https://clinicaltrials.gov/ct2/show/NCT02879643	Pilot	≥1 to ≤21 yr

20140106 (formerly ONYX CFZ008)	Phase 1b Study of Carfilzomib in Combination with Induction Chemotherapy in Children with Relapsed or Refractory Acute Lymphoblastic Leukemia https://clinicaltrials.gov/ct2/show/NCT02303821	Ib/II	≤18 yr
AC220-A-U202 (ADVL1822)	A Phase 1/2, Multi-center, Dose-escalating Study to Evaluate the Safety, Pharmacokinetics, Pharmaconynamics, and Efficacy of Quizartinib Administered in Combination with Re-induction Chemotherapy, and as a Single-agent Continuation Therapy, in Pediatric Relapsed/Refractory AML Subjects Aged 1 Month to <18 Years (and Young Adults Aged up to 21 Years) with FLT3-ITD Mutations https://clinicaltrials.gov/ct2/show/NCT03793478	I/II	≥1 mo to <21 yr
COG AALL1521 [Incyte]	INCB 18424-269: A Phase 2 Study of JAK1/JAK2 Inhibitor Ruxolitinib with Chemotherapy in Children with *De Novo* High-Risk CRLF2-rearranged and/or JAK Pathway-mutant Acute Lymphoblastic Leukemia https://clinicaltrials.gov/ct2/show/NCT02723994	II	>1 to ≤21 yr
JNJ Darutumumab	An Open-label, Multicenter, Phase 2 Study Evaluating the Efficacy and Safety of Daratumumab in Pediatric and Young Adult Subjects ≥1 and ≤30 Years of Age With Relapsed/ Refractory Precursor B-cell or T-cell Acute Lymphoblastic Leukemia or Lymphoblastic Lymphoma https://clinicaltrials.gov/ct2/show/NCT03384654	II	≥1 to ≤30 yr
COG ADVL1521	ADVL1521: A Phase 2 Study of the MEK inhibitor Trametinib (IND #119346, NSC# 763093) in Children with Relapsed or Refractory Juvenile Myelomonocytic Leukemia https://clinicaltrials.gov/ct2/show/NCT03190915	II	≥2 to <22 yr
COG ADVL1823	ADVL1823, Larotrectinib (LOXO-101, NSC# 788607, IND# 141824) for Previously Untreated TRK Fusion Pediatric Solid Tumors and TRK Fusion Relapsed Pediatric Acute Leukemias https://clinicaltrials.gov/ct2/show/NCT03834961	II	≤30 yr

Lymphoma developmental therapy treatment protocols			
AINV18P1	A Phase 1 Study of Palbociclib (IND# 141416), A CDK 4/6 Inhibitor, in Combination with Chemotherapy in Children with Relapsed Acute Lymphoblastic Leukemia (ALL) or Lymphoblastic Lymphoma (LL) https://clinicaltrials.gov/ct2/show/NCT03792256	I	≥12 mo to ≤31 yr

AflacLL1602 ENCERT	ENCERT: A Phase 1 Trial using Everolimus in combination with Nelarabine, Cyclophosphamide and Etoposide in Relapsed T cell Lymphoblastic Leukemia/ Lymphoma https://clinicaltrials.gov/ct2/show/NCT03328104	I	>1 to <30 yr
COG ADVL1414	ADVL1414, A Phase 1 Study of Selinexor (KPT-330, IND# 125052), A Selective XPO1 Inhibitor, in Recurrent and Refractory Pediatric Solid Tumors, including CNS Tumors https://clinicaltrials.gov/ct2/show/NCT02323880	I	≥12 mo to ≤21 yr
COG ADVL1615	ADVL1615, A Phase 1 Study of Pevonedistat (MLN4924 IND# 136078), a NEDD8 Activating Enzyme (NAE) Inhibitor, in Combination with Temozolomide and Irinotecan in Pediatric Patients with Recurrent or Refractory Solid Tumors https://clinicaltrials.gov/ct2/show/NCT03323034	I	Part A1: ≥12 mo to ≤21 yr Part A2: ≥6 mo to <12 mo
COG ADVL1721	A Non-randomized, Open-label, Multi-center, Phase I/II Study of PI3K Inhibitor Copanlisib in Pediatric Patients with Relapsed/Refractory Solid Tumors or Lymphoma https://clinicaltrials.gov/ct2/show/NCT03458728	I/II	≥6 mo to ≤21 yr
JNJ Darutumumab	An Open-label, Multicenter, Phase 2 Study Evaluating the Efficacy and Safety of Daratumumab in Pediatric and Young Adult Subjects ≥1 and ≤30 Years of Age With Relapsed/ Refractory Precursor B-cell or T-cell Acute Lymphoblastic Leukemia or Lymphoblastic Lymphoma https://clinicaltrials.gov/ct2/show/NCT03384654	II	≥1 to ≤30 yr
APEC1621SC	APEC1621SC: NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol https://clinicaltrials.gov/ct2/show/NCT03155620	NA	≥12 mo to ≤21 yr
COG APEC1621D[REQ]	APEC1621D NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) – Phase 2 Subprotocol of LY3023414 in Patients with Solid Tumors https://clinicaltrials.gov/ct2/show/NCT03213678	II	≥12 mo to ≤21 yr

COG APEC1621H[REQ]	APEC1621H NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)—Phase 2 Subprotocol of Olaparib in Patients with Tumors Harboring Defects in DNA Damage Repair Genes https://clinicaltrials.gov/ct2/show/NCT03233204	II	≥12 mo to ≤21 yr
COG APEC1621J[REQ]	APEC1621J NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)—Phase 2 Subprotocol of BVD-523FB (Ulixertinib) in Patients with Tumors Harboring Activating MAPK Pathway Mutations	II	≥12 mo to ≤21 yr
AbbVie M13-833	A Phase 1 Study of the Safety and Pharmacokinetics of Venetoclax in Pediatric and Young Adult Patients with Relapsed or Refractory Malignancies https://clinicaltrials.gov/ct2/show/NCT03236857	I	<25 yr

Neuroblastoma developmental therapy treatment protocols			
APEC1621SC	APEC1621SC: NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol https://clinicaltrials.gov/ct2/show/NCT03155620	NA	≥12 mo to ≤21 yr
AflacST1501	Aflac ST1501, A Phase I Study of Abemaciclib in Children with Newly Diagnosed Diffuse Intrinsic Pontine Glioma and in Children with Recurrent and Refractory Solid Tumors Including Malignant Brain Tumors https://clinicaltrials.gov/ct2/show/NCT02644460	I	≥2 to ≤25 yr
AflacST1603 GemAbrax	AflacST1603: A Phase 1 Study Using Nab-paclitaxel (Abraxane®) in Combination with Gemcitabine for Pediatric Relapsed and Refractory Solid Tumors https://clinicaltrials.gov/ct2/show/NCT03507491	I	≥6 mo to ≤30 yr
AbbVie M13-833	A Phase 1 Study of the Safety and Pharmacokinetics of Venetoclax in Pediatric and Young Adult Patients with Relapsed or Refractory Malignancies https://clinicaltrials.gov/ct2/show/NCT03236857	I	<25 yr
Ignyta RXDX-101-03	A Phase 1/1b, Open-Label, Dose-Escalation and Expansion Study of Entrectinib (RXDX-101) in Children and Adolescents with Recurrent or Refractory Solid Tumors and Primary CNS Tumors https://clinicaltrials.gov/ct2/show/NCT02650401	I/Ib	≥2 to <22 yr

COG ADVL1412	A Phase 1/2 Study of Nivolumab (IND# 124729) in Children, Adolescents, and Young Adults with Recurrent or Refractory Solid Tumors as a Single Agent and in Combination with Ipilimumab https://clinicaltrials.gov/ct2/show/NCT02304458	I/II	Part B1 for NBL: ≥12 mo to ≤30 yr
COG ADVL1514	ADVL1514, A Phase I 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 https://clinicaltrials.gov/ct2/show/NCT02975882	I	≥12 mo to ≤21 yr
COG ADVL1615	ADVL1615, A Phase 1 Study of Pevonedistat (MLN4924 IND# 136078), a NEDD8 Activating Enzyme (NAE) Inhibitor, in Combination with Temozolomide and Irinotecan in Pediatric Patients with Recurrent or Refractory Solid Tumors https://clinicaltrials.gov/ct2/show/NCT03323034	I	Part A1: ≥12 mo to ≤21 yr Part A2: ≥6 mo to <12 mo
COG ADVL1921	Phase 1 Study to Evaluate the Safety and Phrmacokinetics of Palbociclib (Ibrance®) in Combination with Irinotecan and Temozolomide in Pediatric Patients with Recurrent or Refractory Solid Tumors https://clinicaltrials.gov/ct2/show/NCT03709680	I	≥2 to <21 yr
COG ADVL1614	ADVL1614: A Phase 1/2 Study of VX15/2503 (IND# 136181) in Children, Adolescents, or Young Adults with Recurrent or Relapsed Solid Tumors https://clinicaltrials.gov/ct2/show/NCT03320330	I/II	≥12 mo to ≤30 yr
COG ADVL1721	A Non-randomized, Open-label, Multi-center, Phase I/II Study of PI3K Inhibitor Copanlisib in Pediatric Patients with Relapsed/Refractory Solid Tumors or Lymphoma https://clinicaltrials.gov/ct2/show/NCT03458728	I/II	≥ 6 mo to ≤21 yr
LOXO-EXT-17005	LOXO-EXT-17005: A Phase 1/2 Study of the TRK Inhibitor LOXO-195 in Adult and Pediatric Subjects with Previously Treated NTRK Fusion Cancers https://clinicaltrials.gov/ct2/show/NCT03215511	I/II	≥1 mo
COG APEC1621D[REQ]	APEC1621D NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) – Phase 2 Subprotocol of LY3023414 in Patients with Solid Tumors https://clinicaltrials.gov/ct2/show/NCT03213678	II	≥12 mo to ≤21 yr
COG APEC1621H[REQ]	APEC1621H NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)—Phase 2 Subprotocol of Olaparib in Patients with Tumors Harboring Defects in DNA Damage Repair Genes https://clinicaltrials.gov/ct2/show/NCT03233204	II	≥12 mo to ≤21 yr

COG APEC1621J[REQ]	APEC1621J NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)—Phase 2 Subprotocol of BVD-523FB (Ulixertinib) in Patients with Tumors Harboring Activating MAPK Pathway Mutations	II	≥12 mo to ≤21 yr
Aflac ST1502 CHOANOME II	AflacST1502: A Phase II Study of Sirolimus in Combination with Metronomic Chemotherapy in Children with Recurrent and/or Refractory Solid and CNS Tumors https://clinicaltrials.gov/ct2/show/NCT02574728	II	>12 mo to ≤30 yr
COG ADVL1622	ADVL1622, 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 https://clinicaltrials.gov/ct2/show/NCT02867592	II	≥2 to ≤30 yr except ≤18 yr for MTC, RCC, and HCC
COG ADVL1823	ADVL1823, Larotrectinib (LOXO-101, NSC# 788607, IND# 141824) for Previously Untreated TRK Fusion Pediatric Solid Tumors and TRK Fusion Relapsed Pediatric Acute Leukemias https://clinicaltrials.gov/ct2/show/NCT03834961	II	≤30 yr
NANT 2011-01[REQ]	NANT 2011-01: Randomized Phase II Study of ^{131}I-MIBG vs. ^{131}I-MIBG with Vincristine and Irinotecan vs. ^{131}I-MIBG with Vorinostat for Resistant/ Relapsed Neuroblastoma https://clinicaltrials.gov/ct2/show/NCT02035137	II	≥12 mo to ≤30 yr
NANT 2013-01	NANT 2013-01: A Phase I Dose Escalation Study of Autologous Expanded Natural Killer (NK) Cells for Immunotherapy of Relapsed Refractory Neuroblastoma with Dinutuximab +/- Lenalidomide https://clinicaltrials.gov/ct2/show/NCT02573896	I	≤30 yr
NANT 2015-02 [REQ]	NANT 2015-02: Phase 1 Study of Lorlatinib (PF-06463922), an Oral Small Molecule Inhibitor of ALK/ROS1, for Patients with ALK-driven Relapsed or Refractory Neuroblastoma https://clinicaltrials.gov/ct2/show/NCT03107988	I	≥12 mo

NANT 2017-01[REQ]	NANT 2017-01: A Phase I Study of ^{131}I-MIBG with Dinutuximab for Relapsed/Refractory Neuroblastoma (IND# 137554) https://clinicaltrials.gov/ct2/show/NCT03332667	I	≥1 to <30 yr
NANT 2004-05	Neuroblastoma Biology Study *(Any patient with high risk neuroblastoma who is not enrolled on a COG frontline therapeutic study is eligible if undergoing a disease eval.)*	Biology	≥31 days
NANT 2015-01	Neuroblastoma Precision Trial	Biology	≥1 to ≤30 yr
MIBG Access	An Open Label, Expanded Access Protocol Using ^{131}I-Metaiodobenzylguanidine (^{131}I-MIBG) Therapy in Patients with Refractory Neuroblastoma, Pheochromocytoma, or Paragangioma	Access to MIBG therapy	≥12 mo
AflacST17B1	AflacST17B1: Immunophenotyping and Cytokine Profiling of Patients Receiving Therapeutic 131I-MIBG for Relapsed/Refractory Neuroblastoma	Biology	≥1 to ≤30 yr
Solid tumor developmental therapy treatment protocols			
APEC1621SC	APEC1621SC: NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol https://clinicaltrials.gov/ct2/show/NCT03155620	NA	≥12 mo to ≤21 yr
AflacST1501	Aflac ST1501, A Phase I Study of Abemaciclib in Children with Newly Diagnosed Diffuse Intrinsic Pontine Glioma and in Children with Recurrent and Refractory Solid Tumors Including Malignant Brain Tumors https://clinicaltrials.gov/ct2/show/NCT02644460	I	≥2 to ≤25 yr

AflacST1603 GemAbrax	AflacST1603: A Phase 1 Study Using Nab-paclitaxel (Abraxane®) in Combination with Gemcitabine for Pediatric Relapsed and Refractory Solid Tumors https://clinicaltrials.gov/ct2/show/NCT03507491	I	≥6 mo to ≤30 yr
AbbVie M13-833	A Phase 1 Study of the Safety and Pharmacokinetics of Venetoclax in Pediatric and Young Adult Patients with Relapsed or Refractory Malignancies https://clinicaltrials.gov/ct2/show/NCT03236857	I	<25 yr
COG ADVL1615	ADVL1615, A Phase 1 Study of Pevonedistat (MLN4924 IND# 136078), a NEDD8 Activating Enzyme (NAE) Inhibitor, in Combination with Temozolomide and Irinotecan in Pediatric Patients with Recurrent or Refractory Solid Tumors https://clinicaltrials.gov/ct2/show/NCT03323034	I	Part A1: ≥12 mo to ≤21 yr Part A2: ≥6 mo to <12 mo
Ignyta RXDX-101-03	A Phase 1/1b, Open-Label, Dose-Escalation and Expansion Study of Entrectinib (RXDX-101) in Children and Adolescents with Recurrent or Refractory Solid Tumors and Primary CNS Tumors https://clinicaltrials.gov/ct2/show/NCT02650401	I/Ib	≥2 to <22 yr
LOXO-EXT-17005	LOXO-EXT-17005: A Phase 1/2 Study of the TRK Inhibitor LOXO-195 in Adult and Pediatric Subjects with Previously Treated NTRK Fusion Cancers https://clinicaltrials.gov/ct2/show/NCT03215511	I/II	≥1 mo
COG ADVL1312	A Phase 1/2 Study of MK-1775 (AZD1775, IND# 121422) in Combination with Oral Irinotecan in Children, Adolescents, and Young Adults with Relapsed or Refractory Solid Tumors https://clinicaltrials.gov/ct2/show/NCT02095132	I/II	>12 mo to ≤21 yr
COG ADVL1412	A Phase 1/2 Study of Nivolumab (IND# 124729) in Children, Adolescents, and Young Adults with Recurrent or Refractory Solid Tumors as a Single Agent and in Combin-ation with Ipilimumab https://clinicaltrials.gov/ct2/show/NCT02304458	I/II	Parts A&C ≥12 mo to <18 yr Part B ≥12 mo to ≤30 yr
COG ADVL1414	ADVL1414, A Phase 1 Study of Selinexor (ad-330, IND# 125052), A Selective XPO1 Inhibitor, in Recurrent and Refractory Pediatric Solid Tumors, including CNS Tumors https://clinicaltrials.gov/ct2/show/NCT02323880	I	≥12 mo to ≤21 yr

COG ADVL1514	ADVL1514, A Phase I 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 https://clinicaltrials.gov/ct2/show/NCT02975882	I	≥12 mo to ≤21 yr
COG ADVL1921	Phase 1 Study to Evaluate the Safety and Phrmacokinetics of Palbociclib (Ibrance®) in Combination with Irinotecan and Temozolomide in Pediatric Patients with Recurrent or Refractory Solid Tumors https://clinicaltrials.gov/ct2/show/NCT03709680	I	≥2 to <21 yr
COG ADVL1614	ADVL1614: A Phase 1/2 Study of VX15/2503 (IND# 136181) in Children, Adolescents, or Young Adults with Recurrent or Relapsed Solid Tumors https://clinicaltrials.gov/ct2/show/NCT03320330	I/II	≥12 mo to ≤30 yr
COG ADVL1721	A Non-randomized, Open-label, Multi-center, Phase I/II Study of PI3K Inhibitor Copanlisib in Pediatric Patients with Relapsed/Refractory Solid Tumors or Lymphoma https://clinicaltrials.gov/ct2/show/NCT03458728	I/II	≥ 6 mo to ≤21 yr
EZH-102	A Phase 1 Study of the EZH2 Inhibitor Tazemetostat in Pediatric Subjects with Relapsed or Refractory INI1-Negative Tumors or Synovial Sarcoma https://clinicaltrials.gov/ct2/show/NCT02601937	I	≥6 mo to ≤21 yr
COG APEC1621D[REQ]	APEC1621D NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) – Phase 2 Subprotocol of LY3023414 in Patients with Solid Tumors https://clinicaltrials.gov/ct2/show/NCT03213678	II	≥12 mo to ≤21 yr
COG APEC1621H[REQ]	APEC1621H NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)—Phase 2 Subprotocol of Olaparib in Patients with Tumors Harboring Defects in DNA Damage Repair Genes https://clinicaltrials.gov/ct2/show/NCT03233204	II	≥12 mo to ≤21 yr

COG APEC1621J[REQ]	APEC1621J NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)—Phase 2 Subprotocol of BVD-523FB (Ulixertinib) in Patients with Tumors Harboring Activating MAPK Pathway Mutations	II	≥12 mo to ≤21 yr
Aflac ST1502 CHOANOME II	AflacST1502: A Phase II Study of Sirolimus in Combination with Metronomic Chemotherapy in Children with Recurrent and/or Refractory Solid and CNS Tumors https://clinicaltrials.gov/ct2/show/NCT02574728	II	>12 mo to ≤30 yr
COG ADVL1622	ADVL1622, 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 https://clinicaltrials.gov/ct2/show/NCT02867592	II	≥2 to ≤30 yr except ≤18 yr for MTC, RCC, and HCC
COG ADVL1823	ADVL1823, Larotrectinib (LOXO-101, NSC# 788607, IND# 141824) for Previously Untreated TRK Fusion Pediatric Solid Tumors and TRK Fusion Relapsed Pediatric Acute Leukemias https://clinicaltrials.gov/ct2/show/NCT03834961	II	≤30 yr
SJATRT	Phase 2 Study of Alisertib as a Single Agent in Recurrent or Progressive Central Nervous System (CNS) Atypical Teratoid Rhabdoid Tumors (AT/RT) and Extra-CNS Malig-nant Rhabdoid Tumors (MRT) and in Combination Therapy in Newly Diagnosed AT/RT (SJATRT) https://clinicaltrials.gov/ct2/show/NCT02114229	II	<22 yr