Developmental Therapies Protocol List

March 2021

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

BMT developmental therapy treatment protocols				
Disease type	**Study**	**Clinical trial name**	**Phase**	**Age**
GvHD	**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
Non-Malig	**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)	I/II	≥18 yr
SCD	**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
ALL	**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				
Disease type	**Study**	**Clinical trial name**	**Phase**	**Age**
	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
	AflacST1901 – Peds WP1066	AflacST1901: A Phase I Study of WP1066 in Children with Refractory and Progressive or Recurrent Malignant Brain Tumors https://clinicaltrials.gov/ct2/show/NCT04334863	I	≥3 to 25 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/showNCT03323034	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
	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/NCT02650401	I/II	≥1 mo
	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-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
	PBTC-055	PBTC-055: Phase I/II Trial of Dabrafenib, Trametinib, and Hydroxychloroquine (HCQ) for BRAF V600E-mutant or Trametinib and HCQ for BRAF Fusion/Duplication Positive or NF1-associated Recurrent or Refractory Gliomas in Children and Young Adults https://clinicaltrials.gov/ct2/show/NCT04201457	I/II	≥1 to ≤30 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 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 https://clinicaltrials.gov/ct2/show/NCT03698994	II	≥12 mo to ≤21 yr
	COG APEC1621K[REQ]	APEC1621K NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)—Phase 2 Subprotocol of AG-120 (Ivosidenib) in Patients with Tumors Harboring IDH1 Mutations https://clinicaltrials.gov/ct2/show/NCT04195555	II	≥12 mo to ≤21 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
	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

	CTCCs for MB	Circulating Tumor Cell Clusters as a Novel Biomarker for Medulloblastoma Treatment (CTCCs for MB)	Biology	≤21 yr
Leukemia developmental therapy treatment protocols				
Disease type	**Study**	**Clinical trial name**	**Phase**	**Age**
AML	**PEPN1812**	PEPN1812: A Phase 1 Trial of the CD123 X CD3 Dual Affinity Re-targeting Antibody Flotetuzumab (NSC#808294, IND#145986) in Children, Adolescents, and Young Adults with Relapsed or Refractory Acute Myeloid Leukemia	I	<21 yr
ALL	**AINV18P1**	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
ALL	**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
ALL	**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
ALL	**TACL 2017-002**	A TACL Phase 1/2 Study of PO Ixazomib in Combination with Chemotherapy for Childhood Relapsed or Refractory Acute Lymphoblastic Leukemia and Lymphoblastic Lymphoma https://clinicaltrials.gov/ct2/show/NCT03817320	I/II	≤21 yr
ALL	**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
AML	**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

AML	**TACL 2016-002**	TACL2016-002: A TACL Phase 1/2 Study of Nivolumab in Combination with 5-azacytidine in pediatric patients with relapsed/refractory acute myeloid leukemia (BMS reference CA209-9JY)	I/II	>1 to ≤30 yr
ALL	**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
ALL	**JNJ Daratumumab**	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
JMML	**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
ALL/AML	**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				
Disease type	**Study**	**Clinical trial name**	**Phase**	**Age**
Lymphoma	**AINV18P1**	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
Lymphoma	**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
Lymphoma	**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
Lymphoma	**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/showNCT03323034	I	Part A1: ≥12 mo to ≤21 yr Part A2: ≥6 mo to <12 mo
Lymphoma	**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
Lymphoma	**JNJ Daratumumab**	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

NHL	**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
NHL	**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
NHL	**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
NHL	**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 https://clinicaltrials.gov/ct2/show/NCT03698994	II	≥12 mo to ≤21 yr
NHL	**COG APEC1621K**[REQ]	APEC1621K NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)—Phase 2 Subprotocol of AG-120 (Ivosidenib) in Patients with Tumors Harboring IDH1 Mutations https://clinicaltrials.gov/ct2/show/NCT04195555	II	≥12 mo to ≤21 yr
NHL	**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				
	Study	**Clinical trial name**	**Phase**	**Age**
	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 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 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/NCT02650401	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 https://clinicaltrials.gov/ct2/show/NCT03698994	II	≥12 mo to ≤21 yr
	COG APEC1621K[REQ]	APEC1621K NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)—Phase 2 Subprotocol of AG-120 (Ivosidenib) in Patients with Tumors Harboring IDH1 Mutations https://clinicaltrials.gov/ct2/show/NCT04195555	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 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 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 2017-01REQ	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
	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				
Disease type	**Study**	**Clinical trial name**	**Phase**	**Age**
	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/showNCT03323034	I	Part A1: ≥12 mo to ≤21 yr Part A2: ≥6 mo to <12 mo
	Colorado 18-2740	A Phase I/Ib Study of Losartan in Combination with Sunitinib in the Treatment of Pediatric and Adult Patients with Relapsed or Refractory Osteosarcoma https://clinicaltrials.gov/ct2/show/NCT03900793	I/Ib	10 to 40 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

	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/NCT02650401	I/II	≥1 mo
	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 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 https://clinicaltrials.gov/ct2/show/NCT03698994	II	≥12 mo to ≤21 yr
	COG APEC1621K[REQ]	APEC1621K NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)—Phase 2 Subprotocol of AG-120 (Ivosidenib) in Patients with Tumors Harboring IDH1 Mutations https://clinicaltrials.gov/ct2/show/NCT04195555	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 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
	COG ARST1921	ARST1921, A Safety, Pharmacokinetic and Efficacy Study of a γ-Secretase Inhibitor, Nirogacestat (PF-03084014; IND# 146375), in Children and Adolescents with Progressive, Surgically Unresectable Desmoid Tumors https://clinicaltrials.gov/ct2/show/NCT04195399	II	>12 mo to <18 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