

Developmental Therapies Protocol List

October 2021

Check with the lead coordinator for up-to-date information about study enrollment and stratum availability.

CNS developmental therapy treatment protocols					
Disease type	Study	Clinical trial name	Phase	Age	Local PI
	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	I	≥2 to ≤25 yr	Thomas Cash, MD AflacDevTReferral@choa.org
	AflacST1901 – Peds WP1066	AflacST1901: A Phase I Study of WP1066 in Children with Refractory and Progressive or Recurrent Malignant Brain Tumors	I	≥3 to 25 yr	Tobey MacDonald, MD AflacDevTReferral@choa.org
	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	I	≥12 mo to ≤21 yr	Jason Fangusaro, MD AflacDevTReferral@choa.org
	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	I	≥12 mo to ≤21 yr	Jason Fangusaro, MD AflacDevTReferral@choa.org

	<u>COG ADVL1921</u>	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	I	≥2 to <21 yr	Thomas Cash, MD AflacDevTReferral@choa.org
	<u>UCSD Cabozantinib cisRA</u>	A National Phase I Study of Cabozantinib in Combination with 13-cis-Retinoic Acid in Children with Relapsed or Refractory Solid Tumors	I	≥2 to ≤26 yr	Dolly Aguilera, MD AflacDevTReferral@choa.org
	<u>PBTC-045</u>	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	I	≥1 to ≤18 yr	Jason Fangusaro, MD AflacDevTReferral@choa.org
	<u>PBTC-048</u>	PBTC-048: Feasibility Trial of Optune for Children with Recurrent or Progressive Supratentorial High-grade Glioma and Ependymoma	I	≥5 to ≤21 yr	Jason Fangusaro, MD AflacDevTReferral@choa.org
	<u>PBTC-051</u>	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	I	≥1 to ≤21 yr	Jason Fangusaro, MD AflacDevTReferral@choa.org
	<u>PBTC-053</u>	A Pediatric Brain Tumor Consortium Phase I/II and Surgical Study of CX-4945 in Patients with Recurrent SHH Medulloblastoma	I/II	≥3 to ≤18 yr	Jason Fangusaro, MD AflacDevTReferral@choa.org

	<u>PBTC-055</u>	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	I/II	≥1 to ≤30 yr	Jason Fangusaro, MD AflacDevTReferral@choa.org
	<u>ONC014</u>	ONC201 in Newly Diagnosed Diffuse Intrinsic Pontine Glioma and Recurrent Pediatric H3 K27M Gliomas	I	≥2 to <19 yr	Tobey MacDonald, MD AflacDevTReferral@choa.org
	<u>Ignitya RXDX-101-03</u>	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	I/Ib	≥2 to <22 yr	Thomas Cash, MD AflacDevTReferral@choa.org
	<u>COG APEC1621D^{REQ}</u>	APEC1621D NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)—Phase 2 Subprotocol of LY3023414 in Patients with Solid Tumors	II	≥12 mo to ≤21 yr	Himalee Sabnis, MD AflacDevTReferral@choa.org
	<u>COG APEC1621H^{REQ}</u>	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	II	≥12 mo to ≤21 yr	Dolly Aguilera, MD AflacDevTReferral@choa.org
	<u>COG APEC1621J^{REQ}</u>	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	Jason Fangusaro, MD AflacDevTReferral@choa.org
	<u>COG APEC1621K^{REQ}</u>	APEC1621K NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)—Phase 2 Subprotocol of AG-120 (Ivosidenib) in Patients with Tumors Harboring IDH1 Mutations	II	≥12 mo to ≤21 yr	Tobey MacDonald, MD AflacDevTReferral@choa.org
	<u>COG ADVL1823</u>	ADVL1823, Larotrectinib (LOXO-101, NSC# 788607, IND# 141824) for Previously Untreated TRK Fusion Pediatric Solid Tumors and TRK Fusion Relapsed Pediatric Acute Leukemias	II	≤30 yr	Jason Fangusaro, MD AflacDevTReferral@choa.org

	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	II	>12 mo to ≤30 yr	Thomas Cash, MD AflacDevTReferral@choa.org
	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)	II	<22 yr	Dolly Aguilera, MD AflacDevTReferral@choa.org

Leukemia developmental therapy treatment protocols					
Disease type	Study	Clinical trial name	Phase	Age	Local PI
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	Jason Fangusaro, MD AflacDevTReferral@choa.org
ALL	AflacLL1602 ENCERT	ENCERT: A Phase 1 Trial using Everolimus in combination with Nelarabine, Cyclophosphamide and Etoposide in Relapsed T cell Lymphoblastic Leukemia/ Lymphoma	I	>1 to <30 yr	Himalee Sabnis, MD AflacDevTReferral@choa.org
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	Pilot	≥1 to ≤21 yr	Himalee Sabnis, MD AflacDevTReferral@choa.org
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	I/II	≤21 yr	Himalee Sabnis, MD AflacDevTReferral@choa.org
ALL	20140106 (formerly ONYX CFZ008)	Phase 1b Study of Carfilzomib in Combination with Induction Chemotherapy in Children with Relapsed or Refractory Acute Lymphoblastic Leukemia	Ib/II	≤18 yr	Himalee Sabnis, MD AflacDevTReferral@choa.org

AML	AC220-A-U202 (ADVL1822)	A Phase 1/2, Multi-center, Dose-escalating Study to Evaluate the Safety, Pharmacokinetics, Pharmacodynamics, 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	I/II	≥1 mo to <21 yr	Himalee Sabnis, MD AflacDevTReferral@choa.org
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	Himalee Sabnis, MD AflacDevTReferral@choa.org
ALL	COG AALL1521 [Incyte]	INCB 18424-269: A Phase 2 Study of JAK1/JAK2 Inhibitor Ruxolitinib with Chemotherapy in Children with <i>De Novo</i> High-Risk CRLF2-rearranged and/or JAK Pathway-mutant Acute Lymphoblastic Leukemia	II	>1 to ≤21 yr	Melinda Pauly, MD AflacDevTReferral@choa.org
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	II	≥1 to ≤30 yr	Melinda Pauly, MD AflacDevTReferral@choa.org
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	II	≥2 to <22 yr	Himalee Sabnis, MD AflacDevTReferral@choa.org
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	II	≤30 yr	Jason Fangusaro, MD AflacDevTReferral@choa.org
ALL/CML	DFCI 18-328	Phase I Trial of Ribociclib in Combination with Everolimus and Dexamethasone in Children and Young Adults with Relapsed Acute Lymphoblastic Leukemia	I	>12 mo to ≤30 yr	Himalee Sabnis, MD AflacDevTReferral@choa.org

Lymphoma developmental therapy treatment protocols					
Disease type	Study	Clinical trial name	Phase	Age	Local PI
Lymphoma	AflacLL1602 ENCERT	ENCERT: A Phase 1 Trial using Everolimus in combination with Nelarabine, Cyclophosphamide and Etoposide in Relapsed T cell Lymphoblastic Leukemia/ Lymphoma	I	>1 to <30 yr	Himalee Sabnis, MD AflacDevTReferral@choa.org
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	I	≥12 mo to ≤21 yr	Jason Fangusaro, MD AflacDevTReferral@choa.org
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	I/II	≥6 mo to ≤21 yr	Thomas Cash, MD AflacDevTReferral@choa.org
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	II	≥1 to ≤30 yr	Melinda Pauly, MD AflacDevTReferral@choa.org
NHL	APEC1621SC	APEC1621SC: NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	NA	≥12 mo to ≤21 yr	Thomas Cash, MD AflacDevTReferral@choa.org
NHL	COG APEC1621D^{REQ}	APEC1621D NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) – Phase 2 Subprotocol of LY3023414 in Patients with Solid Tumors	II	≥12 mo to ≤21 yr	Himalee Sabnis, MD AflacDevTReferral@choa.org

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	II	≥12 mo to ≤21 yr	Dolly Aguilera, MD AflacDevTReferral@choa.org
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	II	≥12 mo to ≤21 yr	Jason Fangusaro, MD AflacDevTReferral@choa.org
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	II	≥12 mo to ≤21 yr	Tobey MacDonald, MD AflacDevTReferral@choa.org
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	I	<25 yr	Kelly Goldsmith, MD AflacDevTReferral@choa.org

Neuroblastoma developmental therapy treatment protocols

Study	Clinical trial name	Phase	Age	Local PI
APEC1621SC	APEC1621SC: NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	NA	≥12 mo to ≤21 yr	Thomas Cash, MD AflacDevTReferral@choa.org
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	I	≥2 to ≤25 yr	Thomas Cash, MD AflacDevTReferral@choa.org
AflacST1603 GemAbrax	AflacST1603: A Phase 1 Study Using Nab-paclitaxel (Abraxane®) in Combination with Gemcitabine for Pediatric Relapsed and Refractory Solid Tumors	I	≥6 mo to ≤30 yr	Thomas Cash, MD AflacDevTReferral@choa.org
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	I	<25 yr	Kelly Goldsmith, MD AflacDevTReferral@choa.org

	<u>UCSD Cabozantinib cisRA</u>	A National Phase I Study of Cabozantinib in Combination with 13-cis-Retinoic Acid in Children with Relapsed or Refractory Solid Tumors	I	≥2 to ≤26 yr	Dolly Aguilera, MD AflacDevTReferral@choa.org
	<u>Ignitya RXDX-101-03</u>	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	I/Ib	≥2 to <22 yr	Thomas Cash, MD AflacDevTReferral@choa.org
	<u>COG ADVL1514</u>	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	I	≥12 mo to ≤21 yr	Jason Fangusaro, MD AflacDevTReferral@choa.org
	<u>COG ADVL1921</u>	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	I	≥2 to <21 yr	Thomas Cash, MD AflacDevTReferral@choa.org
	<u>COG ADVL1721</u>	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	I/II	≥ 6 mo to ≤21 yr	Thomas Cash, MD AflacDevTReferral@choa.org
	<u>COG APEC1621D^{REQ}</u>	APEC1621D NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) – Phase 2 Subprotocol of LY3023414 in Patients with Solid Tumors	II	≥12 mo to ≤21 yr	Himalee Sabnis, MD AflacDevTReferral@choa.org
	<u>COG APEC1621H^{REQ}</u>	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	II	≥12 mo to ≤21 yr	Dolly Aguilera, MD AflacDevTReferral@choa.org
	<u>COG APEC1621J^{REQ}</u>	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	Jason Fangusaro, MD AflacDevTReferral@choa.org

	<u>COG APEC1621K^{REQ}</u>	APEC1621K NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)—Phase 2 Subprotocol of AG-120 (Ivonesidenib) in Patients with Tumors Harboring IDH1 Mutations	II	≥12 mo to ≤21 yr	Tobey MacDonald, MD AflacDevTReferral@choa.org
	<u>Aflac ST1502 CHOANOME II</u>	AflacST1502: A Phase II Study of Sirolimus in Combination with Metronomic Chemotherapy in Children with Recurrent and/or Refractory Solid and CNS Tumors	II	>12 mo to ≤30 yr	Thomas Cash, MD AflacDevTReferral@choa.org
	<u>COG ADVL1823</u>	ADVL1823, Larotrectinib (LOXO-101, NSC# 788607, IND# 141824) for Previously Untreated TRK Fusion Pediatric Solid Tumors and TRK Fusion Relapsed Pediatric Acute Leukemias	II	≤30 yr	Jason Fangusaro, MD AflacDevTReferral@choa.org
	<u>NANT 2013-01</u>	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	I	≤30 yr	Kelly Goldsmith, MD AflacDevTReferral@choa.org
	<u>NANT 2015-02^{REQ}</u>	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	I	≥12 mo	Kelly Goldsmith, MD AflacDevTReferral@choa.org
	<u>NANT 2017-01^{REQ}</u>	NANT 2017-01: A Phase I Study of ¹³¹ I-MIBG with Dinutuximab for Relapsed/Refractory Neuroblastoma (IND# 137554)	I	≥1 to <30 yr	Kelly Goldsmith, MD AflacDevTReferral@choa.org
	<u>MIBG Access</u>	An Open Label, Expanded Access Protocol Using ¹³¹ I-Metaiodobenzylguanidine (¹³¹ I-MIBG) Therapy in Patients with Refractory Neuroblastoma, Pheochromocytoma, or Paraganglioma	Access to MIBG therapy	≥12 mo	Kelly Goldsmith, MD AflacDevTReferral@choa.org

	Lilly J10-MC-JZHD	A Phase 1 Study of Aurora Kinase A Inhibitor LY3295668 erbumine as a Single Agent and in Combination in Patients with Relapsed/Refractory Neuroblastoma	I	≥2 to ≤21	Kelly Goldsmith, MD AflacDevTReferral@choa.org
Solid tumor developmental therapy treatment protocols					
Disease type	Study	Clinical trial name	Phase	Age	Local PI
	APEC1621SC	APEC1621SC: NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol	NA	≥12 mo to ≤21 yr	Thomas Cash, MD AflacDevTReferral@choa.org
	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	I	≥2 to ≤25 yr	Thomas Cash, MD AflacDevTReferral@choa.org
	AflacST1603 GemAbrax	AflacST1603: A Phase 1 Study Using Nab-paclitaxel (Abraxane®) in Combination with Gemcitabine for Pediatric Relapsed and Refractory Solid Tumors	I	≥6 mo to ≤30 yr	Thomas Cash, MD AflacDevTReferral@choa.org
	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	I	<25 yr	Kelly Goldsmith, MD AflacDevTReferral@choa.org
	UCSD Cabozantinib cisRA	A National Phase I Study of Cabozantinib in Combination with 13-cis-Retinoic Acid in Children with Relapsed or Refractory Solid Tumors	I	≥2 to ≤26 yr	Dolly Aguilera, MD AflacDevTReferral@choa.org
	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	I/Ib	10 to 40 yr	Thomas Cash, MD AflacDevTReferral@choa.org
	Ignyta RXDX-101-03	A Phase 1/Ib, 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	I/Ib	≥2 to <22 yr	Thomas Cash, MD AflacDevTReferral@choa.org

	<u>COG ADVL1414</u>	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	I	≥12 mo to ≤21 yr	Jason Fangusaro, MD AflacDevTReferral@choa.org
	<u>COG ADVL1514</u>	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	I	≥12 mo to ≤21 yr	Jason Fangusaro, MD AflacDevTReferral@choa.org
	<u>COG ADVL1921</u>	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	I	≥2 to <21 yr	Thomas Cash, MD AflacDevTReferral@choa.org
	<u>COG ADVL1721</u>	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	I/II	≥ 6 mo to ≤21 yr	Thomas Cash, MD AflacDevTReferral@choa.org
	<u>COG APEC1621D^{REQ}</u>	APEC1621D NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) – Phase 2 Subprotocol of LY3023414 in Patients with Solid Tumors	II	≥12 mo to ≤21 yr	Himalee Sabnis, MD AflacDevTReferral@choa.org
	<u>COG APEC1621H^{REQ}</u>	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	II	≥12 mo to ≤21 yr	Dolly Aguilera, MD AflacDevTReferral@choa.org
	<u>COG APEC1621J^{REQ}</u>	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	Jason Fangusaro, MD AflacDevTReferral@choa.org

	<u>COG APEC1621K^{REQ}</u>	APEC1621K NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)—Phase 2 Subprotocol of AG-120 (Ivosidenib) in Patients with Tumors Harboring IDH1 Mutations	II	≥12 mo to ≤21 yr	Tobey MacDonald, MD AflacDevTReferral@choa.org
	<u>Aflac ST1502 CHOANOME II</u>	AflacST1502: A Phase II Study of Sirolimus in Combination with Metronomic Chemotherapy in Children with Recurrent and/or Refractory Solid and CNS Tumors	II	>12 mo to ≤30 yr	Thomas Cash, MD AflacDevTReferral@choa.org
	<u>COG ADVL1823</u>	ADVL1823, Larotrectinib (LOXO-101, NSC# 788607, IND# 141824) for Previously Untreated TRK Fusion Pediatric Solid Tumors and TRK Fusion Relapsed Pediatric Acute Leukemias	II	≤30 yr	Jason Fangusaro, MD AflacDevTReferral@choa.org
	<u>COG ADVL1921</u>	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	II	>12 mo to <18 yr	Thomas Cash, MD AflacDevTReferral@choa.org
	<u>SJATRT</u>	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)	II	<22 yr	Dolly Aguilera, MD AflacDevTReferral@choa.org