## Developmental Therapies Protocol List



## July 2021

BMT developmental therapy treatment protocols					
Disease type	Study	Clinical trial name	Phase	Age	
GvHD	Autologous MSCs for GvHD	A Phase I Study of Mesen chymal Stromal Cells for the Treatment of Acute and Chronic Graft versus Host Disease <u>https://clinicaltrials.gov/ct2/show/NCT02359929</u>	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 $\beta$ -thalassemia (TDT)	1/11	<u>≥</u> 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	1/11	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 <u>https://clinicaltrials.gov/ct2/show/NCT02445222</u>	NA	any age (received anti- CD19 directed CART therapy)	
CNS developr	nental therapy treatmen	t 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 <u>https://clinicaltrials.gov/ct2/show/NCT02644460</u>	I	≥2 to <u>&lt;</u> 25 yr	
	AflacST1901 – Peds WP1066	AflacST1901: A Phase I Study of WP1066 in Children with Refractory and Progressive or Recurrent Malignant Brain Tumors <u>https://clinicaltrials.gov/ct2/show/NCT04334863</u>	I	<u>&gt;</u> 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 <u>https://clinicaltrials.gov/ct2/show/NCT02323880</u>	I	≥12 mo to <u>&lt;</u> 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 <u>&lt;</u> 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 <u>https://clinicaltrials.gov/ct2/show/NCT03709680</u>	L	<u>&gt;</u> 2 to <21 yr
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 <u>https://clinicaltrials.gov/ct2/show/NCT03611595</u>	L	<u>≥</u> 2 to <u>≤</u> 26 yr
LOXO-EXT-17005	LOXO-EXT-17005: A Phase 1/2 Study of the TRK In hibitor LOXO-195 in Adult and Pediatric Subjects with Previously Treated NTRK Fusion Cancers <u>https://clinicaltrials.gov/ct2/show/NCT02650401</u>	1/11	<u>≥</u> 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, Med ullo-blastoma and Hypermutated Brain Tumors <u>https://clinicaltrials.gov/ct2/show/NCT02359565</u>	I	≥1 to <u>≤</u> 18 yr
PBTC-048	PBTC-048: Feasibility Trial of Optune for Children with Recurrentor Progressive Supratentorial High- grade Glioma and Ependymoma	I	<u>≥</u> 5 to <u>&lt;</u> 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 <u>https://clinicaltrials.gov/ct2/show/NCT03389802</u>	I	≥1 to <u>&lt;</u> 21 yr
PBTC-053	A Pediatric Brain Tumor Consortium Phase I/II and Surgical Study of CX-4945 in Patients with Recurrent SHH Med ulloblastoma <u>https://clinicaltrials.gov/ct2/show/NCT03904862</u>	1/11	<u>≥</u> 3 to <u>≤</u> 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 <u>https://clinicaltrials.gov/ct2/show/NCT04201457</u>	1/11	<u>≥</u> 1 to <u>≤</u> 30 yr
ONC014	ONC201 in Newly Diagnosed Diffuse Intrinsic Pontine Glioma and Recurrent Pediatric H3 K27M Gliomas https://clinicaltrials.gov/ct2/show/NCT03416530	I	<u>≥</u> 2 to <19 yr
lgnyta 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 <u>https://clinicaltrials.gov/ct2/show/NCT02650401</u>	l/lb	<u>&gt;</u> 2 to <22 yr
COG APEC1621D <sup>REQ</sup>	APEC1621D NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)—Phase 2 Subprotocol of LY3023414 in Patients with Solid Tumors <u>https://clinicaltrials.gov/ct2/show/NCT03213678</u>	II	≥12 mo to <u>&lt;</u> 21 yr
COG APEC1621H <sup>REQ</sup>	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 <u>https://clinicaltrials.gov/ct2/show/NCT03233204</u>	II	≥12 mo to <u>&lt;</u> 21 yr
COG APEC1621J <sup>REQ</sup>	APEC1621J NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)—Phase 2 Subprotocol of BVD-523FB (Ulixertinib) in Patients with Tumors Harboring Activating MAPK Path way Mutations https://clinicaltrials.gov/ct2/show/NCT03698994	11	≥12 mo to <u>&lt;</u> 21 yr

	COG APEC1621K <sup>REQ</sup> COG ADVL1823	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 ADVL1823, Larotrectinib (LOXO-101, NSC# 788607, IND# 141824) for Previously Untreated TRK Fusion Pediatric Solid Tumors and TRK Fusion Relapsed Pediatric Acute Leukemias	11	≥12 mo to ≤21 yr ≤30 yr
	Aflac ST1502 CHOANOME II	https://clinicaltrials.gov/ct2/show/NCT03834961 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 <u>&lt;</u> 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 Rh abdoid 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	<u>≤</u> 21 yr
Leukemia dev	elopmental therapy trea	tment 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	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 <sup>®</sup> ) in Combination with UK ALL R3 Induction Chemotherapy for Children, Adolescents, and Young Adults with Relapse of Acute Lymphoblastic Leukemia <u>https://clinicaltrials.gov/ct2/show/NCT02879643</u>	Pilot	<u>≥</u> 1 to <u>≤</u> 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 <u>https://clinicaltrials.gov/ct2/show/NCT03817320</u>	1/11	<u>≤</u> 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 <u>https://clinicaltrials.gov/ct2/show/NCT02303821</u>	lb/ll	<u>≤</u> 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 <u>https://clinicaltrials.gov/ct2/show/NCT03793478</u>	1/11	<u>≥</u> 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)	1/11	>1 to <u>&lt;</u> 30 yr
ALL	COG AALL1521 [Incyte]	INCB 18424-269: A Phase 2 Study of JAK1/JAK2 In hibitor Ruxolitinib with Chemotherapy in Children with <i>De Novo</i> High-Risk CRLF2-rearranged and/or JAK Path way-mutant Acute Lymphoblastic Leukemia <u>https://clinicaltrials.gov/ct2/show/NCT02723994</u>	II	>1 to <u>≤</u> 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 <u>https://clinicaltrials.gov/ct2/show/NCT03384654</u>	II	≥1 to <u>≤</u> 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 <u>https://clinicaltrials.gov/ct2/show/NCT03190915</u>	II	<u>&gt;</u> 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 <u>https://clinicaltrials.gov/ct2/show/NCT03834961</u>	II	<u>≤</u> 30 yr

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	1	>12 mo to ≤30 yr
Lymphoma de	evelopmental therapy tre	atment protocols		
Disease type	Study	Clinical trial name	Phase	Age
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 <u>&lt;</u> 21 yr
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 <u>https://clinicaltrials.gov/ct2/show/NCT03458728</u>	1/11	<u>&gt;</u> 6 mo to <u>&lt;</u> 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	I	≥1 to <u>&lt;</u> 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 <u>&lt;</u> 21 yr
NHL	COG APEC1621D <sup>REQ</sup>	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 <u>&lt;</u> 21 yr

NHL	COG APEC1621H <sup>REQ</sup>	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 <u>https://clinicaltrials.gov/ct2/show/NCT03233204</u>	II	≥12 mo to <u>&lt;</u> 21 yr
NHL	COG APEC1621J <sup>REQ</sup>	APEC1621J NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)—Phase 2 Subprotocol of BVD-523FB (Ulixertinib) in Patients with Tumors Harboring Activating MAPK Path way Mutations <u>https://clinicaltrials.gov/ct2/show/NCT03698994</u>	II	≥12 mo to <u>&lt;</u> 21 yr
NHL	COG APEC1621K <sup>REQ</sup>	APEC1621K NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)—Phase 2 Subprotocol of AG-120 (Ivosidenib) in Patients with Tumors Harboring IDH1 Mutations <u>https://clinicaltrials.gov/ct2/show/NCT04195555</u>	II	≥12 mo to <u>&lt;</u> 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 <u>https://clinicaltrials.gov/ct2/show/NCT03236857</u>	I	<25 yr
Neuroblaston	na developmental therap	y treatment protocols		
	Study	Clinical trial name	Phase	Age
	APEC1621SC	APEC1621SC: NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) Screening Protocol <u>https://clinicaltrials.gov/ct2/show/NCT03155620</u>	NA	≥12 mo to <u>&lt;</u> 21 yr
	APEC1621SC AflacST1501	(Molecular Analysis for Therapy Choice) Screening Protocol	NA	
		(Molecular Analysis for Therapy Choice) Screening Protocol <u>https://clinicaltrials.gov/ct2/show/NCT03155620</u> 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	NA I	yr ≥2 to

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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 <u>https://clinicaltrials.gov/ct2/show/NCT03611595</u>	I	≥2 to ≤26 yr
lgnyta 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 <u>https://clinicaltrials.gov/ct2/show/NCT02650401</u>	l/lb	<u>&gt;</u> 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 <u>https://clinicaltrials.gov/ct2/show/NCT02975882</u>	I	≥12 mo to <u>&lt;</u> 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 <u>https://clinicaltrials.gov/ct2/show/NCT03709680</u>	I	<u>≥</u> 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 <u>https://clinicaltrials.gov/ct2/show/NCT03458728</u>	1/11	<u>≥</u> 6 mo to <u>&lt;</u> 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 <u>https://clinicaltrials.gov/ct2/show/NCT02650401</u>	1/11	<u>≥</u> 1 mo
COG APEC1621D <sup>REQ</sup>	APEC1621D NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) – Phase 2 Subprotocol of LY3023414 in Patients with Solid Tumors <u>https://clinicaltrials.gov/ct2/show/NCT03213678</u>	II	≥12 mo to <u>&lt;</u> 21 yr
COG APEC1621H <sup>REQ</sup>	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 <u>https://clinicaltrials.gov/ct2/show/NCT03233204</u>	II	≥12 mo to <u>&lt;</u> 21 yr
COG APEC1621J <sup>REQ</sup>	APEC1621J NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)—Phase 2 Subprotocol of BVD-523FB (Ulixertinib) in Patients with Tumors Harboring Activating MAPK Path way Mutations <u>https://clinicaltrials.gov/ct2/show/NCT03698994</u>	II	≥12 mo to <u>&lt;</u> 21 yr

COG APEC1621K <sup>REQ</sup>	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 <u>https://clinicaltrials.gov/ct2/show/NCT02574728</u>	II	>12 mo to <u>&lt;</u> 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 <u>https://clinicaltrials.gov/ct2/show/NCT03834961</u>	11	<u>≤</u> 30 yr
NANT 2013-01	NANT 2013-01: A Phase I Dose Escalation Study of Autologous Expanded Natural Killer (NK) Cells for Immun otherapy of Relapsed Refractory Neuroblastoma with Dinutuximab +/- Len alidomide <u>https://clinicaltrials.gov/ct2/show/NCT02573896</u>	I	<u>≤</u> 30 yr
NANT 2015-02 <sup>REQ</sup>	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 <u>https://clinicaltrials.gov/ct2/show/NCT03107988</u>	I	<u>&gt;</u> 12 mo
NANT 2017-01 <sup>REQ</sup>	NANT 2017-01: A Phase I Study of <sup>131</sup> I-MIBG with Dinutuximab for Relapsed/Refractory Neuroblastoma (IND# 137554) <u>https://clinicaltrials.gov/ct2/show/NCT03332667</u>	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	<u>&gt;</u> 31 days
MIBG Access	An Open Label, Expanded Access Protocol Using <sup>131</sup> I-Metaiodobenzylguanidine( <sup>131</sup> I-MIBG) Therapy in Patients with Refractory Neuroblastoma, Pheochromocytoma, or Paragangioma	Access to MIBG therapy	<u>≥</u> 12 mo
AflacST17B1	AflacST17B1: Immun ophenotyping and Cytokine Profiling of Patients Receiving Therapeutic 131I- MIBG for Relapsed/Refractory Neuroblastoma	Biology	≥1 to <u>&lt;</u> 30 yr

	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	<u>&gt;</u> 2 to <u>&lt;</u> 21
Solid tumor d	levelopmental therapy tr	eatment 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 <u>&lt;</u> 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 <u>https://clinicaltrials.gov/ct2/show/NCT02644460</u>	I	≥2 to <u>&lt;</u> 25 yr
	AflacST1603 GemAbrax	AflacST1603: A Phase 1 Study Using Nab-paclitaxel (Abraxane®) in Combination with Gemcitabine for Pediatric Relapsed and Refractory Solid Tumors <u>https://clinicaltrials.gov/ct2/show/NCT03507491</u>	I	<u>&gt;</u> 6 mo to <u>&lt;</u> 30 yr
	AbbVie M13-833	A Phase 1 Study of the Safety and Pharmacokinetics of Veneto clax in Pediatric and Young Ad ult Patients with Relapsed or Refractory Malignancies <u>https://clinicaltrials.gov/ct2/show/NCT03236857</u>	I	<25 yr
	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 <u>https://clinicaltrials.gov/ct2/show/NCT03611595</u>	I	<u>≥</u> 2 to <u>&lt;</u> 26 yr
	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 <u>https://clinicaltrials.gov/ct2/show/NCT03900793</u>	l/lb	10 to 40 yr
	lgnyta 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 <u>https://clinicaltrials.gov/ct2/show/NCT02650401</u>	l/lb	<u>≥</u> 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 <u>https://clinicaltrials.gov/ct2/show/NCT02650401</u>	1/11	<u>≥</u> 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 <u>https://clinicaltrials.gov/ct2/show/NCT02323880</u>	I	≥12 mo to <u>&lt;</u> 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 <u>https://clinicaltrials.gov/ct2/show/NCT02975882</u>	I	≥12 mo to <u>&lt;</u> 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 <u>https://clinicaltrials.gov/ct2/show/NCT03709680</u>	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 <u>https://clinicaltrials.gov/ct2/show/NCT03458728</u>	1/11	<u>≥</u> 6 mo to <u>&lt;</u> 21 yr
COG APEC1621D <sup>REQ</sup>	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 <u>&lt;</u> 21 yr
COG APEC1621H <sup>REQ</sup>	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 <u>https://clinicaltrials.gov/ct2/show/NCT03233204</u>	11	≥12 mo to <u>&lt;</u> 21 yr
COG APEC1621J <sup>REQ</sup>	APEC1621J NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)—Phase 2 Subprotocol of BVD-523FB (Ulixertinib) in Patients with Tumors Harboring Activating MAPK Path way Mutations <u>https://clinicaltrials.gov/ct2/show/NCT03698994</u>	II	≥12 mo to <u>&lt;</u> 21 yr

COG APEC1621K <sup>REQ</sup>	APEC1621K NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice)—Phase 2 Subprotocol of AG-120 (Ivosidenib) in Patients with Tumors Harboring IDH1 Mutations <u>https://clinicaltrials.gov/ct2/show/NCT04195555</u>	II	≥12 mo to <u>&lt;</u> 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 <u>https://clinicaltrials.gov/ct2/show/NCT02574728</u>	Ш	>12 mo to <u>&lt;</u> 30 yr
COG ADVL1823	ADVL1823, Laro trectinib (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	<u></u> ≤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 <u>https://clinicaltrials.gov/ct2/show/NCT04195399</u>	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