## Pediatric Clinical Trials Office Research (PCTO) Neuro-Oncology Clinical Trials Portfolio

Sponsor ID	Protocol Title	Basic Eligibility	Status			
Radiation Only						
COG ACCL2031	A Phase 3 Randomized, Placebo-Controlled Trial Evaluating <b>Memantine</b> (IND# 149832) for Neurocognitive Protection in Children Undergoing Cranial Radiotherapy as Part of Treatment for Primary Central Nervous System Tumors	Age 4-17, >15kg, Planned focal, cranial or craniospinal radiation	Active, Enrolling			
	Medulloblastoma, GCTs and HGGs					
Newly diagnosed						
NEXT Consortium Head Start 4	Newly Diagnosed Children With Medulloblastoma And Other Central Nervous System Embryonal Tumors. Clinical And Molecular Risk-Tailored Intensive & Compressed Induction Chemotherapy Followed By Consolidation With Randomization To Either Single-Cycle Or To Three Tandem Cycles Of Marrow-Ablative Chemotherapy With Autologous Hematopoietic Progenitor Cell Rescue	Age <10; no prior radiation or chemo; Open only for high-risk; mandatory tissue submission.	Active, Enrolling; Low-risk strata closed			
COG ACNS1422	A Phase 2 Study of <b>Reduced Therapy</b> for Newly Diagnosed Average-Risk WNT-Driven Medulloblastoma Patients	Age 3-22; rapid central pathology and molecular screen thru PEC; enrolled w/in 36 days after surgery	Active, Enrolling			
COG ACNS1723	A Phase 2 Study of <b>Dabrafenib with Trametinib</b> after Local Irradiation in Newly-Diagnosed BRAFV600-Mutant High-Grade Glioma (HGG)	Age 3-21; rapid central pathology and molecular screen thru PEC; enrolled w/in 31 days of surgery	Active, Enrolling			
ACTION MCC18752	ACTION Trial: Adoptive Cellular Therapy Following Dose-Intensified Temozolomide in Newly-diagnosed Pediatric High-grade Gliomas	Age 3-21; residual post-surgical dz burden <3cm	Slots, case by case			
COG ACNS1821	A Phase 1/2 Trial of <b>Selinexor (KPT-330) and Radiation Therapy</b> in Newly-Diagnosed Pediatric Diffuse Intrinsic Pontine Glioma (DIPG) and High-Grade Glioma (HGG)	Age 1-21; DMG included w/o BRAF <sup>V600</sup> or IDH1, w/o biopsy patients to be start treatment within 31 days of dx; no metastatic disease	Temp. closed to accrual			

PNOC022	A Combination Therapy Trial using an Adaptive Platform Design for Children and Young Adults with Diffuse Midline Gliomas (DMGs) including Diffuse Intrinsic Pontine Gliomas (DIPGs) at Initial Diagnosis, Post-Radiation Therapy and at Time of Progression	Age 2-39, H3K27M, prior use of TMZ allowed, criteria vary per cohort. Excl-H3 wildtype Gr2 diffuse astrocytoma	Active, Cohort 2 enrolling. Cohort 1&3 on HOLD			
ACNS2021	A Phase 2 Trial of Chemotherapy followed by Response-Based Whole Ventricular & Spinal Canal Irradiation (WVSCI) for Patients with Localized Non-Germinomatous Central Nervous System Germ Cell Tumor	Age 3-30, therapy must begin within 31 calendar days of definitive surgery or dx. Required CSF markers	Active, Enrolling			
	Relapsed/Refractory/Recurrent					
PEPN2111	A Phase 1/2 Trial of <b>CBL0137</b> in Patients With Relapsed or Refractory Solid Tumors, Including CNS Tumors and Lymphoma	Age 1-21 Part A: r/r CNS tumors Part B1: progressive DIPG	Enrollment on HOLD			
PEPN2121	<b>Tiragolumab</b> and <b>Atezolizumab</b> for the Treatment of Relapsed or Refractory SMARCB1 or SMARCA4 Deficient Tumors	Age ≥1, r/r OR newly dx'd, ATRT, chordoma, or SMARC deficient tumors; must have measurable dz	Active, Enrolling			
APEC1621SC PedsMatch	NCI-COG Pediatric Match (Molecular Analysis For Therapy Choice) Screening Protocol (Sub-protocol drugs: larotrectinib, erdafitinib, ivosidenib, LY3023414)	Age 1- ≤ 21; r/r CNS tumors. Must have tissue available OR sequencing done	Active, Enrolling			
PNOC019	A Randomized, Double-Blinded, Pilot Trial of Neoadjuvant Checkpoint Inhibition followed by Combination Adjuvant Checkpoint Inhibition in Children and Young Adults with Recurrent or Progressive High-Grade Glioma (HGG)	Age 6 months to 22 years; undergo resection, Performance score ≥ 50, Ex- leptomeningeal dz	Active, IND supply issues			
<u>UAB18113</u>	Phase 1 Trial of Engineered HSV <b>G207</b> in Children with Recurrent or Refractory Cerebellar Brain Tumors	≥ 36 months to < 19 years	Active, Enrolling			
NF and LGGs						
Newly diagnosed, Untreated progressive						
COG ACNS1831	A Phase 3 Randomized Study of Selumetinib versus Carboplatin/Vincristine in Newly Diagnosed or Previously Untreated Neurofibromatosis Type 1 (NF1) Associated Low-Grade Glioma	Age 2-21; measurable dz ≥ 1cm <sub>2</sub> ; must be able to swallow capsule; screen thru PEC; IOP WNL	Active, Enrolling			

COG ACNS1833	A Phase 3 Randomized Non-Inferiority Study of Carboplatin and Vincristine versus Selumetinib in Newly Diagnosed or Previously Untreated Low-Grade Glioma (LGG) not associated with BRAFV600E Mutations or Systemic NF1	Age 2-21; rapid review thru PEC; 2D measurable dz ≥ 1cm²; must be able to swallow capsule; IOP WNL	Active, Enrolling		
Neurofibromatosis Consortium NF110	Open-label, Phase 2 Clinical Trial of <b>Crizotinib</b> for Children and Adults With Neurofibromatosis Type 2 and Progressive Vestibular Schwannomas	Age ≥ 6; measurable dz, radiologic evidence of progression	Enrollment on HOLD		
Relapsed/recurrent, Previously treated progressive					
Neurofibromatosis Consortium NF111	A Phase II Trial of <b>Poly-ICLC</b> for Progressive, Previously Treated Low-Grade Gliomas in Children and Young Adults With Neurofibromatosis Type 1	Age <22; measurable dz; Excluded: prior radiation, malignant glioma; high dose steroids	Active, Enrolling		
COG ACNS1931	A Phase 3 Study of <b>Selumetinib or Selumetinib in Combination With Vinblastine</b> for Non-NF1, Non-TSC Patients With Recurrent or Progressive Low-Grade Gliomas (LGGs) Lacking BRAFV600E or IDH1 Mutations	Age 2-25; BSA ≥ 0.5; Rapid central and molecular screening thru PEC; measurable dz	Active, Enrolling		
PNOC021	A Phase I Trial Evaluating the Combination of <b>Trametinib and Everolimus</b> in Pediatric and Young Adult Patients with Recurrent Low Grade Gliomas	Age 1-25; genomic testing required; Excluded: surgery alone, K27M mutation	Enrollment on HOLD		