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

| Sponsor ID | Protocol Title | Basic Eligibility | Status |
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| **Radiation Only** | | | |
| COG ACCL2031 | A Phase 3 Randomized, Placebo-Controlled Trial Evaluating **Memantine** (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 **Reduced Therapy** 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 **Dabrafenib with Trametinib** 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 |

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| COG ACNS1821 | A Phase 1/2 Trial of **Selinexor (KPT-330) and Radiation Therapy** in Newly-Diagnosed Pediatric Diffuse Intrinsic Pontine Glioma (DIPG) and High-Grade Glioma (HGG) | Age 1-21; DMG included w/o $BRAF^{V600}$ 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 **CBL0137** in Patients With Relapsed or Refractory Solid Tumors, Including CNS Tumors and Lymphoma | Age 1-21<br>Part A: r/r CNS tumors<br>Part B1: progressive DIPG | Enrollment on HOLD |
| PEPN2121 | **Tiragolumab** and **Atezolizumab** 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 |
| UAB18113 | Phase 1 Trial of Engineered HSV **G207** in Children with Recurrent or Refractory Cerebellar Brain Tumors | ≥ 36 months to < 19 years | Active, Enrolling |

| NF and LGGs | | | |
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| **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 ≥ $1cm_2$; 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 ≥ $1cm^2$; must be able to swallow capsule; IOP WNL | Active, Enrolling |
| Neurofibromatosis Consortium NF110 | Open-label, Phase 2 Clinical Trial of **Crizotinib** 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 **Poly-ICLC** 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 **Selumetinib or Selumetinib in Combination With Vinblastine** 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 **Trametinib and Everolimus** 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 |