

# Trametinib and Everolimus for Treatment of Pediatric and Young Adult Patients With Recurrent Gliomas (PNOC021)

NCT04485559

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<b>Status</b>	RECRUITING
<b>Phase</b>	Phase 1
<b>Sponsor</b>	University of California, San Francisco
<b>Enrollment</b>	50 participants

## Key Eligibility Criteria

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### Inclusion (41)

- Participants must have histologically confirmed diagnosis of an LGG (WHO grade I-II) that is recurrent or progressive after prior treatment (biologic, chemotherapy or radiation therapy) or must have a histologically confirmed diagnosis of a high grade glioma (HGG) (WHO grade III-VI)
- Participants with LGG who have had surgery alone are not eligible.
- Participants with neurofibromatosis type 1 (NF-1) are eligible but must have available tissue per study requirements neurofibromatosis (NF) status will be collected
- Participants with spinal cord primaries or disseminated disease are eligible
- For enrollment, snap frozen tissue (150 mg) or 10 unstained 10 um formalin-fixed, paraffin-embedded (FFPE) slides for comprehensive genomic testing or results of prior testing is required

... and 36 more (see full listing online)

### Exclusion (14)

- Participants who are receiving any other investigational agent for treatment of their tumor
- History of allergic reactions attributed to compounds of similar chemical or biologic composition to everolimus or trametinib
- Participants without available tissue from prior surgery. (If clinical comprehensive testing has already been performed, the requirement for submission of tissue may be waived after discussion and review of results with study chairs)
- Participant is receiving any of the following medications within 7 days prior to enrollment (If participants require (re)initiation of these agents after enrollment and prior to start of therapy they will not be eligible to initiate study therapy):
- Known strong inducers or inhibitors of CYP3A4/5, including enzyme inducing anti-convulsant drugs (EIACDs), grapefruit, grapefruit hybrids, pomelos, starfruit, and Seville oranges

... and 9 more (see full listing online)

## Locations (17 total)

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University of Alabama at Birmingham, Children's of Alabama, Birmingham, Alabama, United States  
Children's Hospital Los Angeles, Los Angeles, California, United States  
University of California, San Diego Rady Children's Hospital, San Diego, California, United States

... and 14 more locations

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<https://clinicaltrials.gov/study/NCT04485559>

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