

# Clinical Trials | Neuro-Oncology

Several clinical trials are open for patients with glioma, meningioma, CNS lymphoma or NCSLC brain metastases.

Two of these trials were initiated by UVA investigators. Please note that chemoradiation may be administered at the patient's local facilities for these trials. However, prompt referrals are essential for enrollment due to the timeline requirements of the trials.

Also, please note that several neuro-oncology trials not mentioned below are in the process of opening at UVA, including the **INSIGHt trial** (NCT02977780) and a trial testing a mutant IDH1 inhibitor in participants with gliomas. You may consult with our providers at any time for an update on available trials.

## Newly Diagnosed Glioblastoma

**ICT-107-301** is a randomized phase III immunotherapy trial investigating maintenance temozolomide plus study drug, which consists of peptide pulsed dendritic cells, ICT-107, or a control made from autologous monocyte-enriched peripheral blood mononuclear cells (PBMC). Participants will need to be consented immediately after surgery to allow time for central HLA testing, pathology analysis and MRI review. These items will be checked during the trial screening phase and only HLA-A2+ participants will qualify. Following these tests and prior to radiation, subjects will undergo apheresis to isolate PBMCs, which will be used for synthesis of their study drug. After chemoradiation, eligible candidates will initiate study therapy, consisting of a four-week induction phase followed by a maintenance phase. More information on this trial can be found at [clinicaltrials.gov](https://clinicaltrials.gov) using the identifier NCT02546102.

UVA Principal Investigator | Camilo Fadul, MD  
Phone : **434.982.4415**

**Alliance A071102** is a randomized phase II/III trial studying how well temozolomide and the PARP inhibitor veliparib compare to temozolomide alone in treating participants with newly diagnosed glioblastoma. Subjects enrolled in the experimental arm will receive temozolomide PO OD on days 1-5 and veliparib PO BID on days 1-7 of every 28-day cycle. The study therapy does not begin until participants have concluded radiation therapy, which can be administered in the local community. More information on this trial can be found at [clinicaltrials.gov](https://clinicaltrials.gov) using the identifier NCT02152982. Please note this study is not currently enrolling, but is expected to reopen shortly.

UVA Principal Investigator | David Schiff, MD  
Phone: **434.982.4415**  
Email: [ds4jd@virginia.edu](mailto:ds4jd@virginia.edu)

## Recurrent Glioblastoma or Anaplastic Glioma

**CLEE011XUS01T** is a UVA investigator-initiated pilot study examining the Novartis CDK4/6 inhibitor Ribociclib (LEE011) in participants with recurrent GBM or anaplastic glioma requiring surgical resection. Prior treatment with bevacizumab is allowed. This study will investigate the ability of the study drug to cross the blood-tumor barrier and inhibit CDK4/CDK6/Rb/E2F signaling in the tumor. Secondary outcomes include progression-free and overall survival. Study subjects will take Ribociclib for one to three weeks prior to their resection, so must enroll pre-operatively. Participants with retinoblastoma protein positive (Rb+) tumors will continue taking Ribociclib postoperatively until progression or study discontinuation. More information on this trial can be found at [clinicaltrials.gov](https://clinicaltrials.gov) using the identifier NCT02345824.

UVA Principal Investigator | Camilo Fadul, MD  
Phone : **434.982.4415**

## Brain Metastases from Non-Small Cell Lung Cancer (NSCLC)

**Novocure EF-25 METIS** is a pivotal, open-label randomized study of radiosurgery with or without Tumor Treating Fields for 1-10 brain metastases from NSCLC. The device being tested in the investigational treatment arm is very similar to the Novocure Optune device that is approved for GBMs. More information on this trial can be found at [clinicaltrials.gov](https://clinicaltrials.gov) using the identifier NCT02831959.

UVA Principal Investigator | Jason Sheehan, MD, PhD  
Phone: **434.982.4415**  
Email: [jps2f@virginia.edu](mailto:jps2f@virginia.edu)

## Progressive Meningioma

**ALLIANCE A071401** is a phase II trial investigating targeted therapies for treatment of qualifying progressive meningiomas. Pathology will be tested centrally for mutations that could indicate sensitivity to SMO or NF2 inhibitors. Participants with SMO positive tumors will receive the sonic hedgehog pathway inhibitor Vismodegib. Participants with NF2 positive tumors will receive the FAK inhibitor GSK2256098. Vismodegib and GSK2256098 may stop the growth of tumor cells by blocking some of the signaling pathways needed for cell growth. More information on this trial can be found at [clinicaltrials.gov](https://clinicaltrials.gov) using the identifier NCT02523014.

UVA Principal Investigator | David Schiff, MD  
Phone: **434.982.4415**  
Email: [ds4jd@virginia.edu](mailto:ds4jd@virginia.edu)

## Recurrent CNS Lymphoma

**MC1281** is a phase I study of Pomalidomide and dexamethasone for treatment of relapsed/refractory primary central nervous system lymphoma and newly diagnosed or relapsed/refractory intraocular lymphoma. It is a phase I trial that aims to find the maximal tolerated dose and side effects of pomalidomide in this population. The study is also designed to determine the efficacy and survival related to pomalidomide therapy in the maximum tolerated dose (MTD) cohort. More information on this trial can be found at [clinicaltrials.gov](https://clinicaltrials.gov) using the identifier NCT01722305.

UVA Principal Investigator | David Schiff, MD  
Phone: **434.982.4415**  
Email: [ds4jd@virginia.edu](mailto:ds4jd@virginia.edu)

### Neuro-Oncology Center

#### UVA Cancer Center

Emily Couric Clinical Cancer Center  
1240 Lee St.  
Charlottesville, VA 22903

Refer a patient: **800.552.3723**

Transfer a patient: **844.XFERUVA (933.7882)**

Learn more about the UVA Neurosciences and Behavioral Health Center:

[neurosciences.uvahealth.com](https://neurosciences.uvahealth.com)