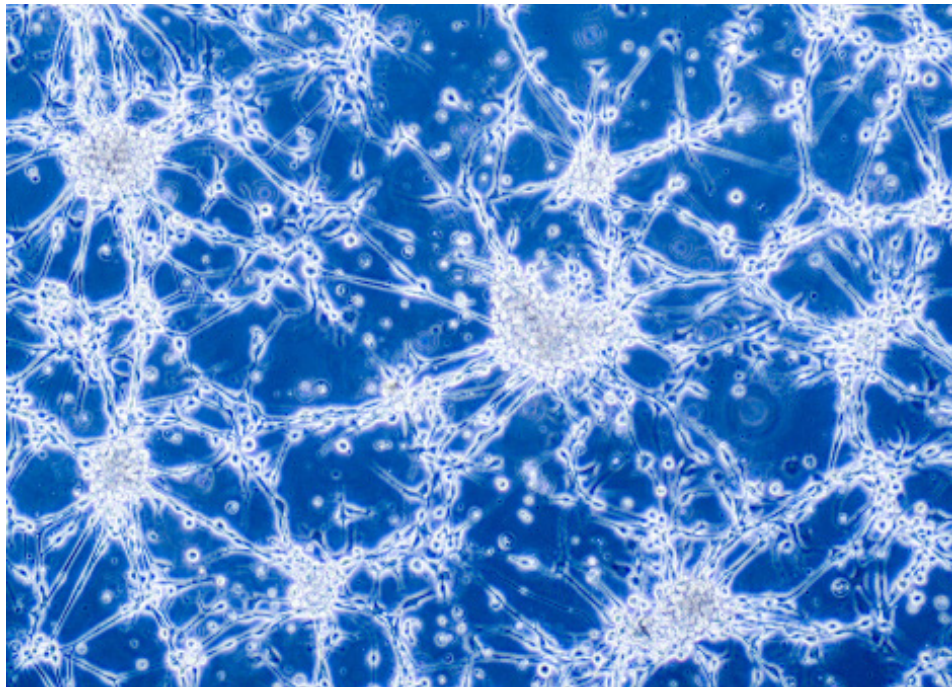


# UCSF Brain Tumor Center

Summer 2022



## Message from the Neuro-Oncology Division Chief

It is an incredible honor to join the University of California, San Francisco Neuro-Oncology program as the Division Chief. The UCSF brain tumor program is the premier Neuro-Oncology program in the world. This position is a once-in-a-lifetime opportunity to join the exceptional team advancing clinical and translational programs that bring new therapies to patients.

As a neurologist specializing in neuro-oncology, I bring a new perspective to clinical research at UCSF after spending nearly twenty years in translational and clinical research at the University of Texas, MD Anderson Cancer Center. A broad clinical and laboratory experience has given me a unique perspective on the translation of novel therapies into the clinic for the treatment of patients with primary brain tumors. Throughout my career, I have significantly contributed to the clinical development and led clinical trials of antiangiogenic, molecularly targeted, and immunotherapy treatments for glioblastoma and regularly advise companies on such agents in development.

Our adult multidisciplinary team from Neuro-Oncology, Neurosurgery, Neuropathology, Neuroradiology and Radiation Oncology collaboratively develop and provide the most advanced treatment options. Multiple novel clinical trials are open for accrual, and this trial portfolio is constantly growing. Cellular immunotherapies, precision medicine approaches,

and new technologies such as the implementation of focused ultrasound to disrupt the blood-brain barrier for improved therapy delivery are all rapidly advancing treatments for our patients. I believe we are on the cusp of realizing major improvements in outcomes for brain tumor patients.

In addition to clinical trials, the success of our program includes many existing resources to support patients with brain tumors and their families. The Sheri Sobrato Brisson Brain Cancer Survivorship Program; Gordon Murray Neuro-Oncology Caregiver Program, Social Work Program; NeuroCognitive Clinic; and Palliative Care Program are all available to support the emotional, cognitive, social, and symptom management challenges for both the patient and their caregivers.

I look forward to connecting with you and offering the best treatments for our patients. Please contact me directly if I can be of assistance.

Sincerely,

A handwritten signature in black ink, appearing to read "John de Groot, MD". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

**John de Groot, MD**  
**Professor in Residence, Neurology**  
**Division Chief of Neuro-Oncology**  
**Department of Neurological Surgery**

# New clinical trial brings adaptive study design to treating glioblastoma

A clinical trial for people with newly diagnosed and recurrent glioblastoma (GBM) is now open for enrollment at the UCSF Brain Tumor Center. GBM AGILE, a global Phase II/III trial, is evaluating several different therapies in multiple treatment arms.

By using a statistical method called Bayesian adaptive randomization, scientists use real-time data during the trial to randomize patients into treatment arms that are statistically more effective. This increases enrollment of patients onto treatment arms that are more promising.

“Our goal in this trial is to rapidly identify effective therapies for GBM,” said chief of Neuro-Oncology, John de Groot, MD. “This would greatly expand the treatment armamentarium for our patients.”

The most established biomarker for GBM is called O-6 methyl guanine methyltransferase (MGMT). When MGMT is not modified by the cellular process called methylation, cancer patients tend to not respond well to standard treatments. Clinical trials for MGMT unmethylated GBM are designed to include novel agents in the place of temozolomide. GBM AGILE is evaluating multiple therapies to replace temozolomide in patients with newly diagnosed GBM with both methylated and unmethylated MGMT.

Scientists are aggressively developing new therapies including immunotherapies designed to enhance the immune system’s targeting of tumors, cell-signaling-pathway inhibitors to block tumor growth, and cytotoxic chemotherapies that directly kill cancer cells. These novel therapies need to be evaluated in the clinical setting with

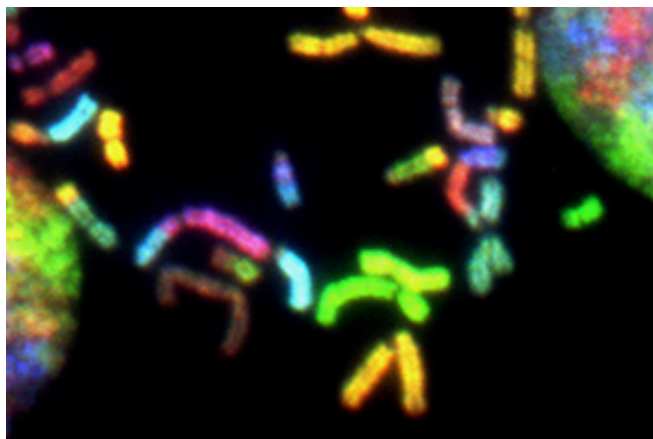
a contemporary control arm to compare outcomes with standard approaches.

The multi-national trial UCSF is participating in, sponsored by the Global Coalition for Adaptive Research, takes an alternative approach to testing new treatments for GBM. Traditionally, researchers use a two-armed randomized and controlled clinical trial to evaluate a new therapy’s efficacy. However, this process is slow and only evaluates one new treatment at a time.

“The importance of a contemporary control arm cannot be over emphasized,” de Groot said. “Many therapies have been advanced into late-stage clinical trials after being inappropriately compared to older historical controls that do not accurately depict the real-life outcomes of patients.”

de Groot is the principal investigator for one of the treatment arms of the trial that involves a drug called VAL-083 that directly kills brain tumor cells. UCSF neuro-oncologist Nicholas Butowski, MD, is the UCSF principal investigator for the trial, which will recruit newly diagnosed and recurrent GBM patients at UCSF Medical Center.

de Groot also sits on the Agent Selection Committee, which determines whether an experimental therapy is eligible to be incorporated into a future clinical trial arm. He hopes the adaptive study design will help scientists more quickly understand whether a treatment is helping patients.



Chromosomes prepared from a malignant glioblastoma visualized by spectral karyotyping reveal an enormous degree of chromosomal instability — a hallmark of cancer. Photo by the National Cancer Institute on Unsplash.

## Precision medicine trial for adults with glioblastoma

The results from previous clinical trials for recurrent GBM don’t clearly identify a superior standard of care. A major challenge in treating these malignant brain tumors is that they are genetically heterogeneous between patients, as well as within different regions of an individual tumor.

A UCSF-sponsored phase I clinical trial — led by UCSF neuro-oncologist Jennifer Clarke, MD, MPH — is evaluating blood and tumor samples from patients with surgically resectable recurrent GBM with the UCSF500 Gene Panel. This open trial is assessing the feasibility of designing individualized drug regimens based on the genetic profile of each person’s tumor.

# Clinical trials

The UCSF Brain Tumor Center has one of the largest clinical trials portfolios in the nation and is part of several national clinical trials consortia. Our involvement in national cooperative clinical trials ensures that our patients have access to the latest techniques and the newest concepts for treatment of brain tumors.

Select Trials for Adults	
NCT03970447	A trial to evaluate multiple regimens in newly diagnosed and recurrent glioblastoma (GBM AGILE)
NCT03776071	A randomized, double-blind, placebo-controlled phase 3 study of enzastaurin added to temozolomide during and following radiation therapy in newly diagnosed glioblastoma patients who possess the novel genomic biomarker DGM1
NCT03681028	Feasibility of individualized therapy for recurrent GBM
NCT047620	A Study of berubicin in adult subjects with recurrent glioblastoma multiforme
NCT02428712	A phase 1/2a study to assess the safety, pharmacokinetics, and pharmacodynamics of PLX8394 in patients with advanced, unresectable solid tumors
NCT04478279	A phase 1-2 dose-escalation and expansion study of ST101 in patients with advanced unresectable and metastatic solid tumors
NCT04659811	A phase II study of stereotactic radiosurgery in conjunction with the PD-1 inhibitor pembrolizumab for the treatment of recurrent meningioma
NCT03295396	ONC201 in adults with recurrent H3 K27M-mutant glioma
NCT03948490	Rehabilitation and longitudinal follow-up of cognition in adult lower grade gliomas
NCT03561207	3D-PREDICT REGISTRY: 3D prediction of patient-specific response using ex vivo interrogation of live cells from tumors
	Impact of cannabis and synthetic cannabinoid use on quality of life of patients with central nervous system tumors (ICANCNS-QOL)
NCT03739411	Pilot study of safety and feasibility of acquiring hyperpolarized imaging in patients with gliomas

## Unique support services

The Brain Tumor Center offers supportive care services, resources and events tailored to meet the needs of brain tumor patients and their caregivers.

For patients:

- Neurocognitive care
- Patient support groups
- Social work and case management services
- The Workout for Wellness exercise program
- Palliative care

For caregivers:

- Personal consultations
- Caregiver support groups
- Peer-to-Peer Connection program
- The Workout for Wellness exercise program
- Social work and case management services

Scan this QR code to learn more about all our adult and pediatric clinical trials



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Request an online  
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**Brain Tumor Workshop 2022**

Course# MNS23001A  
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Silverado Resort in Napa, CA



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