FISCAL YEAR 2021 STEWARDSHIP REPORT

Ivy Brain Tumor Center



The new headquarters for the Ivy Brain Tumor Center will encompass 75,000 square feet, making it the largest translational research center dedicated to brain tumor drug development in the world.

ORE THAN 138,000 PEOPLE in the United States, and over 1.4 million people worldwide, are struggling with malignant brain tumors. For the most common malignant brain tumor—glioblastoma multiforme (GBM)—nine out of ten people diagnosed will lose their battle with the disease within five years.

The Ivy Brain Tumor Center at Barrow Neurological Institute, led by Nader Sanai, MD, is home to the largest Phase O clinical trials program in the world, and the first of its kind for neuro-oncology. Specialists at the Ivy Center know that time is a brain tumor patient's most important commodity, which is why Ivy Phase O clinical trials match patients with first-in-class drug combinations and confirm drug effects within days. If the drug combination has the intended effect on the tumor, the patient moves on to the next phase of the trial. If the drug combination has no effect on the tumor, the patient can enroll in another trial without losing too much time.



in-human trial of sonodynamic therapy in the world launched

patients screened for clinical trials since 2018

active clinical trials

BARROW NEUROLOGICAL INSTITUTE BY THE NUMBERS





CLINICAL IMPACT

77,600+ number of patie

total number of patients seen at Barrow annually

22,200+ telemedicine visits

5,700+ brain and spine surgeries



GLOBAL IMPACT

11

research fellows and visiting scholars from Brazil, Columbia, India, Ireland, Pakistan, Russia, Thailand, and Turkey

PROGRAM ACCOMPLISHMENTS

Since opening in 2018, the Ivy Center has grown to employ 44 full-time staff members, has screened over 1,000 patients for clinical trials, has opened 11 new clinical trials, and has formed partnerships with over 25 biopharma companies. Despite the challenges presented by COVID-19, the Ivy Center was able to continue enrolling patients for ongoing studies and even launched new studies, including the groundbreaking sonodynamic therapy.

Patient Impact – Patricia Levy's Story

After suffering a seizure while on vacation abroad with her husband, Ken Levy, Patricia Levy was rushed to a hospital in Florence, Italy, where she found out that she had a brain tumor. The couple returned stateside immediately and went directly to the Ivy Brain Tumor Center at Barrow. Exactly one week later, Patricia underwent her first brain surgery, learning that her tumor was indeed glioblastoma. Patricia fought hard, but when the standard treatment for glioblastoma was no longer working, she turned to the Phase O clinical trials program at the Ivy Center. She enrolled in one trial and the results seemed promising at first, but the glioblastoma eventually returned, prompting Patricia to begin a new trial with a different drug combination. Throughout her journey, Patricia has stayed hopeful knowing that she's in the care of the best and brightest in brain tumor research and treatment at the Ivy Center. Today, Patricia continues to be a beacon of resilience as she participates in the Ivy Center's first-in-human clinical trial of sonodynamic therapy.



Ivy Brain Tumor Center Phase O clinical trial patient Patricia Levy with her family.

RESEARCH ADVANCES

In spring 2021, the Ivy Center initiated the first in-human clinical trial of sonodynamic therapy in the world. Sonodynamic therapy combines the use of a focused ultrasound device and a proprietary formulation of 5-aminolevulinic acid. The groundbreaking study aims to develop a noninvasive treatment option for patients with recurrent glioblastoma and other high-grade gliomas.

Patients enrolled in the clinical trial of sonodynamic therapy will have the 5-aminolevulinic acid (SONALA-001) administered intravenously, allowing the drug to travel straight to the brain tumor, where it is metabolized selectively by tumor cells. The drug remains inert until it comes into contact with targeted ultrasound waves emitted from a specialized helmet worn by the patient. These ultrasound waves activate the drug's byproduct to become a lethal form that kills tumor cells, while sparing the surrounding normal brain tissue. This novel drug-and-device combination therapy overcomes the most challenging part of treating brain cancer, breaking through the protective shell around the brain, called the blood-brain barrier.

The initial results of the study are positive, indicating that sonodynamic therapy rapidly leads to targeted oxidative stress and cell death in human glioblastoma tissue. It was also well-tolerated in all patients. Addressing participants at a conference for the European Society for Medical Oncology Congress, Dr. Sanai speaks to the initial results, stating, "Sonodynamic therapy has tremendous potential to become a new nonsurgical therapeutic modality to treat brain tumors. We found that MR-guided focused ultrasound combined with SONALA-001 demonstrated rapid and selective cell death in the patients' tumors, an encouraging discovery of this new noninvasive treatment option."

ON THE HORIZON

The Ivy Center has announced plans to build a new 75,000-square-foot headquarters. The five-story building will be the largest translational research center dedicated to brain tumor drug development in the world.

The new, state-of-the-art headquarters for the Ivy Center will encompass 30,000 square feet of wet laboratory space, 14,000 square feet for trial infrastructure, 7,000 square feet for multidisciplinary clinical consultation, an MR-guided ultrasound suite, and a video teleconference auditorium. Construction of the new headquarters is expected to be completed in 2023.

The continued growth and success of the Ivy Center's novel clinical trials program is made possible through the unwavering leadership of the Ben & Catherine Ivy Foundation, and support from Barrow Neurological Foundation, Barrow Neurological Institute, and Dignity Health.

BARROW NEUROLOGICAL INSTITUTE BY THE NUMBERS



RESEARCH

320+ tive researce

active research studies

791 patients enrolled in clinical trials

\$11.7 MILLION in federal research grant support



DONOR IMPACT

\$28 MILLION
total distributed to Barrow
Neurological Institute,
including:

\$21 MILLION

designated to specific centers/programs

\$5 MILLION

for basic, clinical, and translational research

\$1.7 MILLION

for endowed research chairs



THANK YOU FOR YOUR SUPPORT

We rely on generous donors to investigate new treatments for brain cancer. Not only are we committed to extending the lives of patients with malignant brain tumors, we also want to improve their quality of life. The only way we can contribute to finding a cure within this decade is to continue investigating new drug combinations and quickly identify safe and effective therapies.

On behalf of the entire team at the Ivy Brain Tumor Center, we thank you for helping us make a difference for people everywhere inflicted with this horrible disease.

With Gratitude,

Nader Sanai, MD Director, Ivy Brain Tumor Center ↑ Dr. Nader Sanai, director of the Ivy Brain Tumor Center, is an internationally-recognized neurosurgical oncologist with clinical and research expertise in the treatment of all brain tumors.

The mission of Barrow Neurological Foundation is simple: to be the catalyst of our donors' passion for transformation by providing the resources for Barrow Neurological Institute to achieve its mission of saving human lives through innovative treatment, groundbreaking research, and by educating the next generation of the world's leading neuroclinicians.

