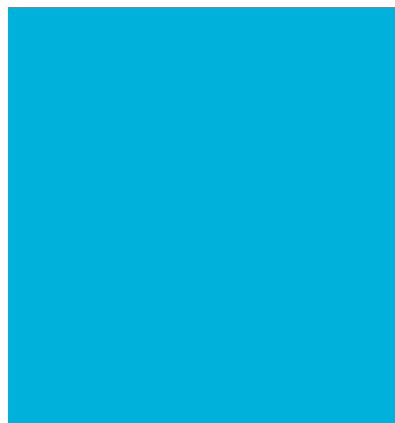
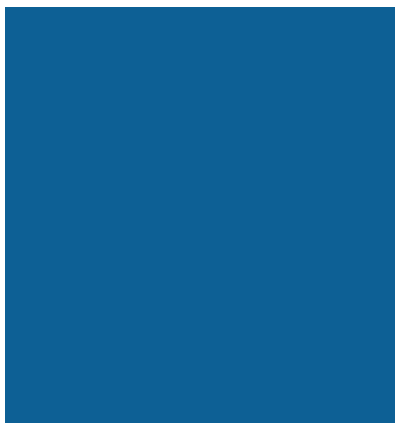
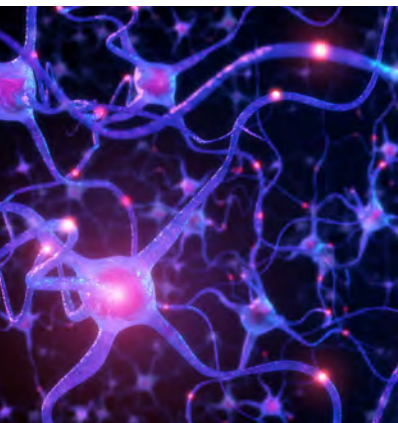
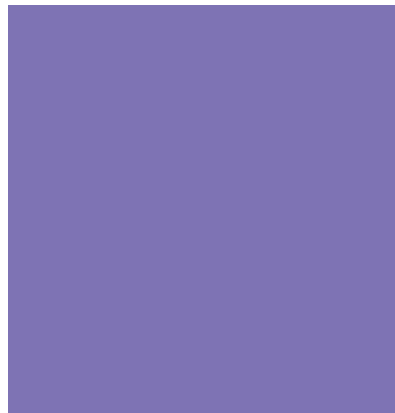
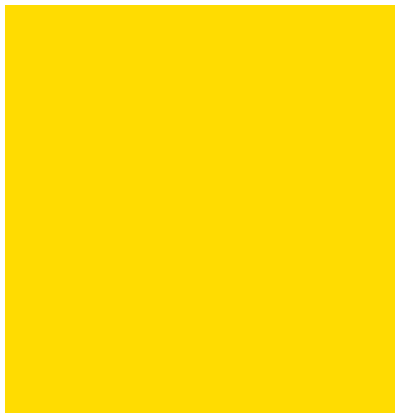
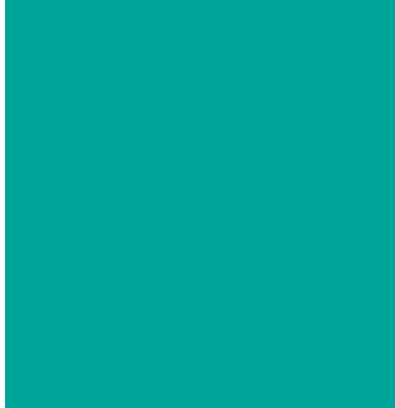
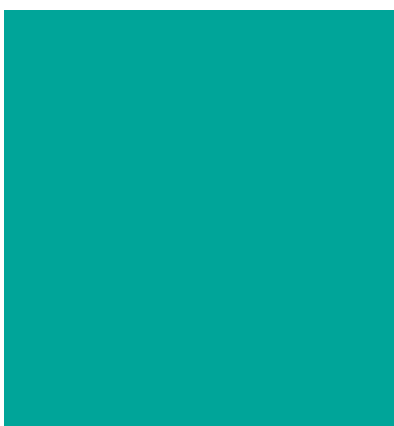
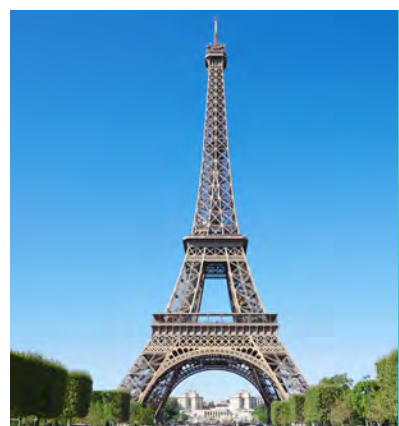
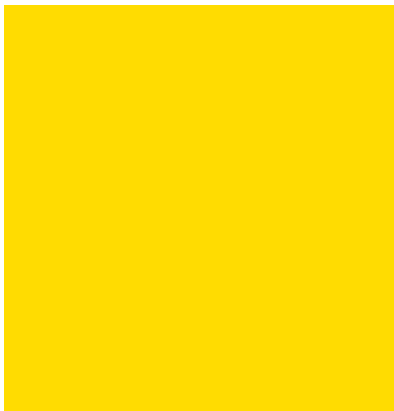
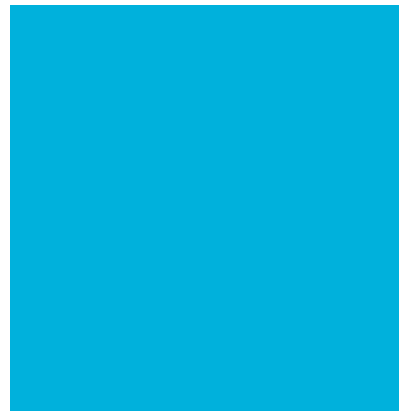




Focused Ultrasound Foundation

2022
Year in Review





5 Elements of success

While 2022 brought increased uncertainty and instability in the world, progress in the field of focused ultrasound has continued and is accelerating at a remarkable pace.

At the Foundation, our work is more important than ever as we strive to speed the development and adoption of focused ultrasound as a global standard of care and improve the lives of millions of people worldwide.

This year our report is divided into the five elements needed to drive focused ultrasound into the mainstream: evidence, awareness, capital, partnerships, and businesses. Content highlights the remarkable progress in the field including updates on clinical trials, Foundation initiatives, reimbursement wins, and major advances in raising awareness via international media coverage, including National Geographic and CNN. And as always, everything we do is about the patients—advancing the technology in the shortest time possible, saving lives.

Each of these pursuits is made possible by the generous support of our donors, Board, Council, and extensive medical community. We thank you for your continued support.

Be well. Be happy.

Neal F. Kassell, MD

evidence research milestones ◀

Advancing research

The Foundation builds evidence for focused ultrasound by funding world-class research around the globe. In 2022, we leveraged our donor investments by supporting clinical trials for glioblastoma (GBM), Parkinson's disease, Alzheimer's disease, and many types of cancer. ■

Projects funded

36
projects initiated

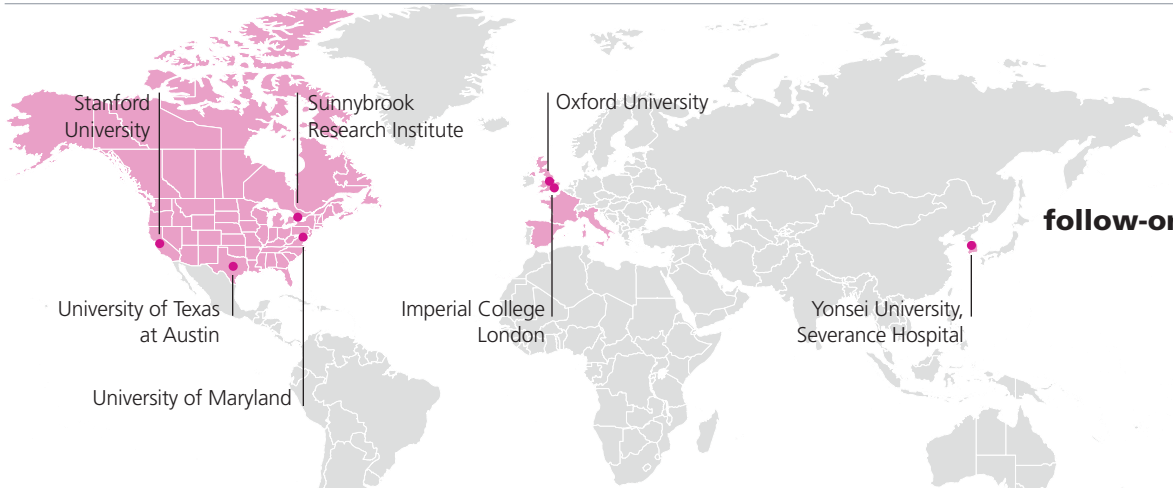
9
projects completed

Locations

24
institutions and organizations

7
countries

7
projects with
follow-on or co-funding



- Sites with follow-on or co-funding
- Countries with research sites

2022

evidence research milestones ◀

By the numbers

131

projects completed

117

projects with
results presented at
scientific meetings

101

projects with
results published

45

projects with
follow-on or co-funding

By the dollars

\$14.9_m

funding provided for
completed projects

\$73.9_m

follow-on or co-funding

5_x

return on investment

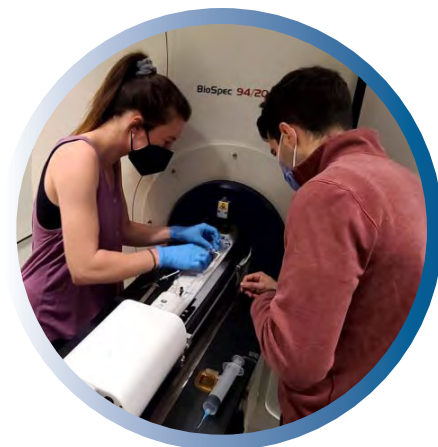
factor by which
the Foundation leverages
donor contributions

cumulative



Providing opportunity

Together with the University of Virginia, the Foundation opened the world's first center dedicated exclusively to cancer immunotherapy and focused ultrasound research, the **Focused Ultrasound Cancer Immunotherapy Center**. ■



Top photograph by Sanjay Suchak, UVA Communications

glioblastoma

BBB Opening

An early-stage clinical trial assessing focused ultrasound-induced blood-brain barrier (BBB) opening to delay or prevent brain tumor recurrence began in Milan.

Researchers are using focused ultrasound to disrupt the BBB in participants with GBM undergoing maintenance chemotherapy after the initial removal of the tumor. The trial, taking place at the **Istituto Neurologico Carlo Besta**, is led by Francesco DiMeco MD, and Francesco Prada MD.

Similar studies are ongoing in the US, Canada, and Korea. ■




Sonodynamic therapy

A clinical trial investigating the safety and feasibility of using sonodynamic therapy (SDT) in patients with newly diagnosed GBM also began enrolling participants at **Istituto Neurologico Carlo Besta**.

SDT uses focused ultrasound to activate 5-ALA, an agent that accumulates in

tumor cells and causes cell death when activated. Up to 10 participants will undergo surgery to remove the tumor approximately two weeks after focused ultrasound and will then continue with traditional medical therapy. ■



 This icon represents projects that are partially or fully funded by the Foundation.

Above: Istituto Neurologico Carlo Besta
Photograph by Arbalet, Wikipedia Commons

parkinson's disease

Dementia

People living with Parkinson's disease sometimes develop memory loss, forgetfulness, trouble concentrating, and eventually dementia. Prof. José Obeso MD PhD, and his team used focused ultrasound to address this devastating complication. Participants underwent BBB opening twice, two to four weeks apart.

In June, results from the group's first-in-human study to open the BBB in a new region of the brain (the striatum) were published in the journal *Movement Disorders*. ■



▶ Prof. José Obeso MD PhD
Centro Integral de Neurociencias
(HM CINAC), Madrid

Delivering therapeutics

Researchers from **Sunnybrook Health Sciences Centre** and **University Health Network in Toronto** used focused ultrasound to disrupt the BBB in patients with early-stage Parkinson's disease to deliver an enzyme replacement therapy called imiglucerase—or Cerezyme®. Participants received three doses of Cerezyme plus focused ultrasound every two weeks to the side of the brain most affected by the disease.

The promising results were published in *Movement Disorders*, and a larger Phase I/II study is planned. ■



▶ Insightec's Exablate Neuro device

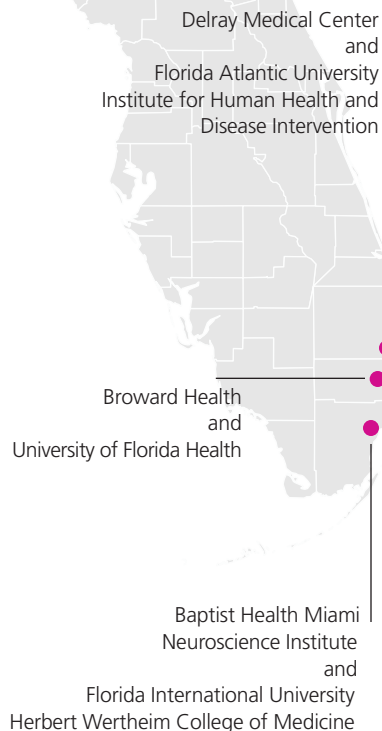
alzheimer's disease

Gathering proof

Data from multiple centers have now shown that using focused ultrasound to open or disrupt the BBB is safe in patients with Alzheimer's disease. The field has reached an inflection point where the next step is to combine focused ultrasound BBB opening with therapeutics and expand the number of centers that are gathering evidence. ■

New Florida initiative

In March, Insightec launched the "Brain State Initiative" to promote Alzheimer's disease research in Florida. Six leading clinical and academic research centers joined forces to create a network of providers who will use the Exablate device to advance novel therapies and understanding of Alzheimer's and other neurologic diseases. ■



Clinical trial data

Interim data from the first ten participants in the US clinical trial investigating focused ultrasound-induced BBB opening for Alzheimer's disease were published in the *Journal of Neurosurgery*.

The trial, which is using Insightec's Exablate Neuro device, is taking place at **West Virginia University's Rockefeller Neuroscience Institute, Weill Cornell Medicine**, and other sites. Importantly, these participants experienced no worsening of cognitive function when compared with a control group. ■



cancer immunotherapy

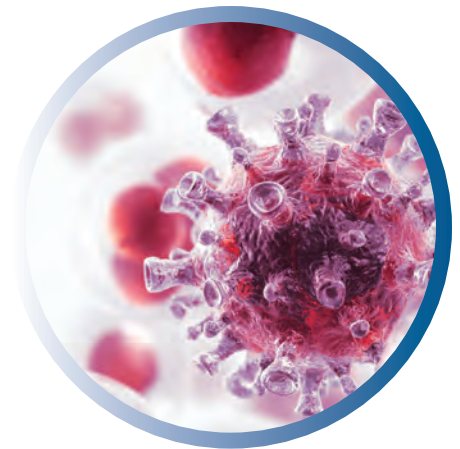
Fighting with new tools

Immunotherapy is the most important breakthrough in cancer treatment in decades. In May, UVA Health and the Foundation launched the **Focused Ultrasound Cancer Immunotherapy Center** which will conduct research to revolutionize 21st-century cancer care. Combining immunotherapy with focused ultrasound has been found to overcome existing limitations of immunotherapy and may open new fronts in the war against many types of cancer. ■

Research

funded by the Foundation

Primary research site	Project title
Georgia Institute of Technology	Closed-loop MRgFUS controlled activation of CAR T cells in brain tumors
Inserm LabTAU	Focused ultrasound stimulation of the immune response in cancer models
University of Michigan	Multimodal analysis of immune response post-FUS in two tumor models
University of Virginia Health System	Improving of bioeffects during FUS-microbubble treatments Spatial interrogation of the immune cell co-localization associated with high intensity focused ultrasound-induced lesions Development of MRI-FUS-PET Focused ultrasound delivery of miR-142-3p
Virginia-Maryland College of Veterinary Medicine	Investigating the immunotherapeutic effects of histotripsy ablation in osteosarcoma



Metastatic lung cancer

Four sites across the US and Canada launched a focused ultrasound plus immunotherapy clinical trial to treat non-small cell lung cancer that has spread to the brain. Researchers predict that using focused ultrasound to open the BBB in these participants will enable higher concentrations of the immunotherapy drug pembrolizumab—known as Keytruda®—to enter the brain tumor tissue. ■



pediatrics

Focusing on children

Focused ultrasound could make a difference for children with benign and malignant brain tumors and for women with high-risk pregnancies. ■

Benign brain tumors

Results published in March 2022 in the *Journal of Neurosurgery* suggest that focused ultrasound ablation is safe for benign pediatric brain tumors.

Four children with hypothalamic hamartoma and one with tuberous sclerosis harboring a subependymal giant cell astrocytoma were treated at Nicklaus Children's Hospital in Miami. The procedure was well tolerated with no procedure-related complications. Ablation was successful in the four participants with hypothalamic hamartomas and led to improved seizure control and decreased hyperphagia. ■



Malignant brain tumor

A Foundation consensus paper described how focused ultrasound is being explored to treat diffuse midline gliomas. The paper provides a comprehensive overview of preclinical and clinical work, most of which use the technology for BBB opening to allow therapeutics to reach the devastating brain tumors. Four manufacturers are currently in clinical trials. ■



Neurofibromatosis

Children's National Hospital successfully performed the first-ever high-intensity focused ultrasound (HIFU) surgery on a pediatric patient with neurofibromatosis. This is the youngest patient in the world to undergo HIFU treatment. ■



Twin-twin transfusion syndrome

Twin-twin transfusion syndrome (TTTS) is a rare placental condition that causes imbalanced blood exchange between twins in utero. Ultrasound-guided HIFU has the potential to provide a safer therapeutic option compared to currently available treatments.

Professor Christoph Lees MD FRCOG is leading a clinical trial in the UK that has treated five women with early onset TTTS, using a research system developed by the Institute of Cancer Research. In all cases, there has been successful and safe ablation of the targeted placental vessels. Pregnancy outcome data is not yet available. ■



diabetes



GE Research partnership

A large, multicenter team of researchers partnered with **GE Research** to study the use of focused ultrasound neuromodulation for the treatment or prevention of Type 2 diabetes. Results from the study were published in *Nature Biomedical Engineering*.

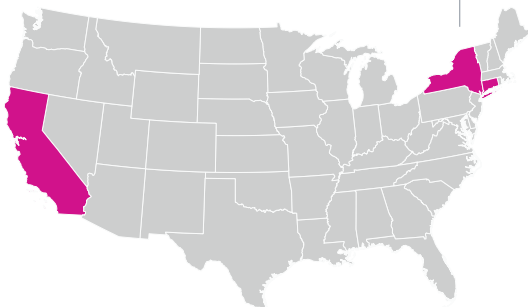
The scientists used focused ultrasound to stimulate the nerves controlling the veins that return blood from the

digestive system to the liver and spleen. The stimulation positively impacted communication between the digestive organs and the brain, neurotransmitter concentrations, and glucose tolerance and utilization in three preclinical models. Human feasibility studies are now underway. ■



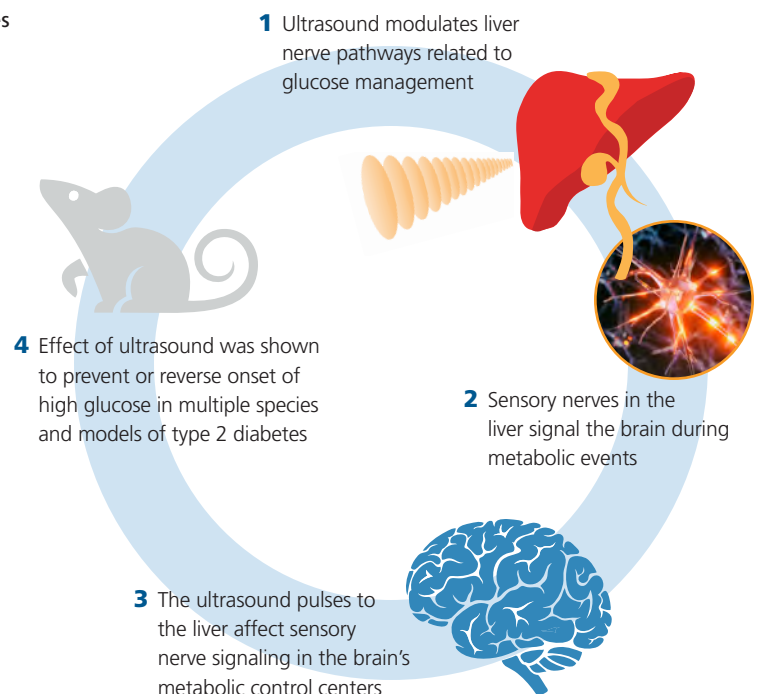
▲ Stimulation of the hepatoportal nerve plexus with focused ultrasound restored glucose homeostasis in diabetic mice, rats, and swine. Cotero, V., Graf, J., Miwa, H. et al. Volume 6 Issue 6, June 2022

▼ The GE Research team includes GE scientists and laboratories at Feinstein Institutes for Medical Research (New York), UCLA Samueli School of Engineering, Yale School of Medicine, and Albany Medical College.



Focused ultrasound neuromodulation

▶ in diabetes



veterinary

Treating companion animals

The goal of the Foundation's veterinary program is to offer innovative care to pets while also collecting data that can be beneficial for humans. Focused ultrasound veterinary research is being conducted at ten institutions across the globe. ■

Solid tumor ablation

A Foundation-funded clinical trial determined that HIFU can safely ablate subcutaneous solid tumors in dogs. The veterinary research group, based at Virginia-Maryland College of Veterinary Medicine, also found HIFU to induce anti-cancer immune system changes in the treated animals.

This was the first trial funded by the **Foundation's Veterinary Program**.

The trial enrolled 20 dogs; most had soft tissue sarcomas, three had mast cell tumors, one had an osteosarcoma, and

one had thyroid carcinoma. The HIFU procedure was performed with Theracision's Echopulse device, which is also approved for human use. It was generally well-tolerated by the dogs. After three to six days post-treatment, the dogs underwent surgical removal of the treated tumors, which were also collected for immune analyses.

The study was published in the *International Journal of Hyperthermia*. ■



Bone tumor histotripsy

A team at the **Virginia-Maryland College of Veterinary Medicine** published the results of a clinical trial to address osteosarcomas in dogs. Osteosarcomas are aggressive bone tumors that affect both humans and dogs.

The team found that histotripsy safely and effectively treated the targeted volumes within the tumors with no significant adverse events. Four dogs with osteosarcoma and one with chondrosarcoma were treated. When the team assessed whether the histotripsy triggered an immune response in the subjects, results were inconclusive, likely due to the short time frame between treatment and resection. ■



media coverage



DJ Steve Aoki

Grammy-nominated DJ, producer, and philanthropist Steve Aoki released a video illustrating how **West Virginia University's Rockefeller Neuroscience Institute** is using focused ultrasound to treat conditions like essential tremor, Alzheimer's disease, and addiction. ■

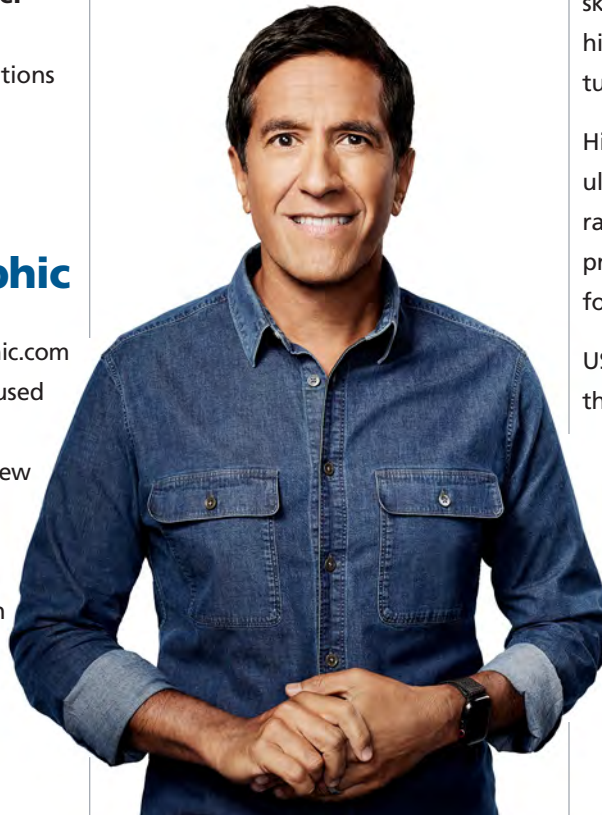
National Geographic

A lead story on NationalGeographic.com included a detailed profile of focused ultrasound for drug delivery and BBB opening, as well as an interview with Foundation Chairman and Founder Neal Kassell MD.

The outlet has more than 27 million followers on Twitter. ■

CNN *Vital Signs*

A successful focused ultrasound treatment of an essential tremor patient in December 2022 was featured in a lead article on CNN's homepage and a related half-hour program with CNN's **Dr. Sanjay Gupta** called "Vital Signs." Both included interviews with Neal Kassell MD. ■



BBC *Click*

A BBC story in the UK followed Peter, a Guinness World Record-holding skateboarder, who underwent histotripsy treatment for neuroendocrine tumors on his liver.

Histotripsy is a mechanism of focused ultrasound that, unlike heat- and radiation-based treatments, is more precise, making it an appealing option for smaller and widespread tumors.

US-based firm Histosonics is running the trial. ■

symposium

Gathering a hybrid audience

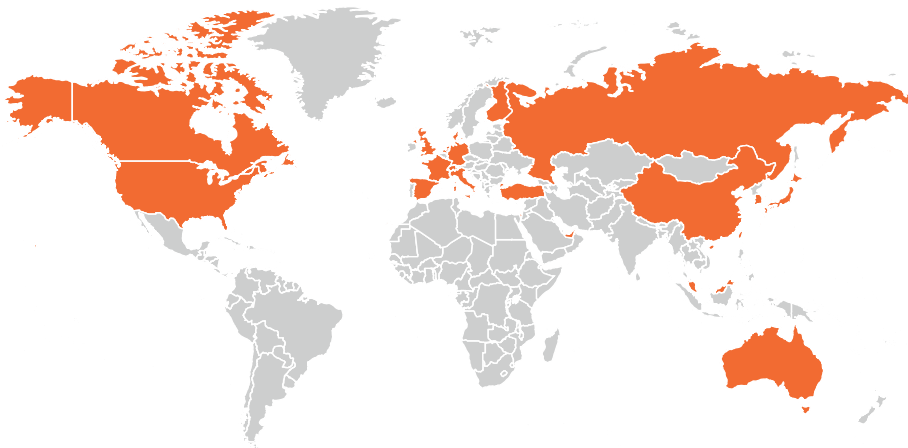
The Foundation was delighted to see so many people both face-to-face and virtually after three years of primarily virtual meetings. The main objectives of the symposium are to: create knowledge by sharing data and information, foster collaboration and innovation through personal relationships, and have fun. ■

Engaging the community

617 participants

22 countries represented

In October, the Foundation's **8th International Symposium on Focused Ultrasound** showcased the tremendous progress in the field. The four-day meeting featured panel discussions, keynote speakers, and special lectures, as well as an increased spotlight on many commercialization topics. ■



▲ **Elisa Konofagou PhD** was the meeting's honorary president.

2 keynote speakers

- **Geoff Martha**
Chairman and CEO, Medtronic
- **Bob Smith**
Senior Vice President, Global Gene Therapy Business, Pfizer

5 special lectures

- **Reimbursement Through the Eyes of CMS**
Thomas Scully
Former Administrator, Centers for Medicare and Medicaid Services
- **Evidence Development for Medical Devices**
Jill Hagenkord MD
Chief Medical Officer, Optum Genomics
- **FUS for Thyroid**
Brian Lang MS MBBS FACS
University of Hong Kong
- **FUS for Diabetes**
Chris Puleo PhD
GE Global Research
- **Addressing Disparities in Clinical Trials**
Freda Lewis-Hall MD DFAPA MFPM

symposium

highlights

25+

panel discussions

200+

prerecorded
presentations

6

commercialization
sessions

22

sponsors &
exhibitors



◀ Fireside Chats

Left
Laurie Clarke and Harold
Stowe of TSG Consulting
discuss regulatory strategies

Right
Sumit Mukherjee, Bank of
America Merrill Lynch, speaks
on capital markets

20 young
investigators
awards



information

Lockhart award

Yutong Guo PhD was awarded the 2022 Andrew J. Lockhart Postdoctoral Fellowship in Focused Ultrasound and Immuno-Oncology, a one-year fellowship designed for early-career researchers. A recent PhD graduate at the Georgia Institute of Technology, Dr. Guo plans to study in Katherine Ferrara's laboratory at Stanford University. Her work centers on how focused ultrasound can be combined with CAR T cell therapy to treat aggressive brain tumors, such as glioblastoma. ■



Covering the globe

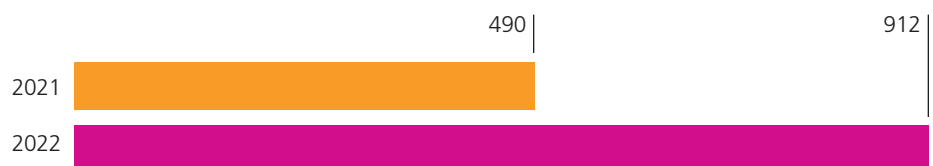
The Foundation launched a new tool to help patients, scientists, and other stakeholders locate focused ultrasound treatment and research sites around the world, aiding access and awareness of the technology. The interactive site map simulates a globe with more

than 1,000 pinpoints, which indicate focused ultrasound sites for commercial treatment, and both clinical and preclinical research. The idea for the map came from musician Peter Gabriel, who is also a member of the Foundation's Council. ■



Disseminating knowledge

Focused ultrasound related abstracts presented at scientific meetings



webinars

Hot topics

More than 10,000 people were reached by five Foundation-sponsored webinars on topics ranging from open science to aging and longevity. ■

10,000+

▶ Watch on YouTube



Launched in 2022

Title	Presenters
1 The future of Medicine, Aging and Longevity in a Post-COVID World	Ken Dychtwald, PhD Age Wave
2 LabTAU's Focused Ultrasound Center of Excellence <i>A Five-Year Perspective</i>	Cyril Lafon, PhD; W. Apoutou N'DJIN, PhD; & Anne-Gaëlle Chaux, PhD, DDS LabTAU
3 The Foundation's Open Science Program	David Mellor, PhD Center for Open Science Holly Smith, MBA, PMP & Jon McDunn, PhD Project Data Sphere
4 Focused Ultrasound and Alzheimer's Disease <i>Using Sound to Deliver Drugs to the Brain</i>	Sandra Black, OC, O.Ont., MD, FRSC & Nir Lipsman, MD, PhD Sunnybrook Arjun (JJ) Desai, MD Insightec
5 New Approaches with Immunotherapies and Breast Cancer	David R. Brenin, MD University of Virginia Scott Abrams, PhD & Michael Nemeth, PhD Roswell Park Comprehensive Cancer Center

Alzheimer's disease

On World Alzheimer's Day, the **Global Alzheimer's Platform Foundation** and **USAagainstAlzheimer's** partnered with the Foundation to host a webinar. Focused ultrasound is a novel approach to noninvasively opening the BBB in the hopes of clearing amyloid plaques and tau proteins. It may also provide a method to facilitate the delivery of medications across the BBB to the brain. ■

September 21
**WORLD
ALZHEIMER'S
DAY**



coverage

Increasing affordability

Global coverage for focused ultrasound-based procedures increased by an incredible 48.8 million people in 2022. ■

Expanding global coverage

In 2022, global coverage for focused ultrasound-based procedures increased by an incredible 48.8 million people.

The Danish healthcare system granted coverage for the treatment of **essential tremor**, making it the fifth European country to do so, and adding more than 52,000 potential patients. Progardia Healthcare is treating patients with essential tremor in Denmark.

In the US, Anthem Blue Cross Blue Shield agreed to cover **essential tremor** treatment for approximately 36 million beneficiaries in 44 states. Providence

Health Plan, which insures more than 600,000 patients in five states, agreed to cover focused ultrasound treatment of **prostate cancer**, pain palliation for **bone metastases**, and **essential tremor**. Wisconsin Physicians Service Government Health Administrators agreed to cover 6.3 million patients with **Parkinson's tremor**.

There is now coverage for focused ultrasound procedures in 17 countries. ■



US beneficiaries

In 2022, US private insurers and Medicare provided coverage for 206.1 million people for focused ultrasound procedures. Because several insurers covered more than one indication, the total number covered is not the same as the total for the indications listed below. ■



184.6M Essential tremor

115.6M Bone metastases

64.5M Prostate cancer

30.7M Parkinson's tremor

367,000 Uterine fibroids

reimbursement

Advocacy

Foundation staff, Council, and Board members tirelessly advocate for increasing reimbursement for focused ultrasound. ■

Expertise

Informative presentations captured some of these efforts at the Foundation's 8th International Symposium on Focused Ultrasound. ■

Overview on the Status of Reimbursement

Mike Broad PhD

Reimbursement Through the Eyes of CMS

Thomas Scully

The Cost of Care Calculator

Mark Carol MD



Watch the presentations on YouTube

"Why it Takes So Long"

A Foundation senior consultant, Mark Carol MD, is writing a series of blogs addressing the processes, trials, and tribulations involved in bringing a new medical technology to market. The series will continue in 2023. ■

Part 1

The Complex Ecosystem of a Medical Device Startup

Part 2

Novel Technology Development

Part 3

Regulatory Authorization

Part 4

Reimbursement

Part 5

Physicians

Part 6

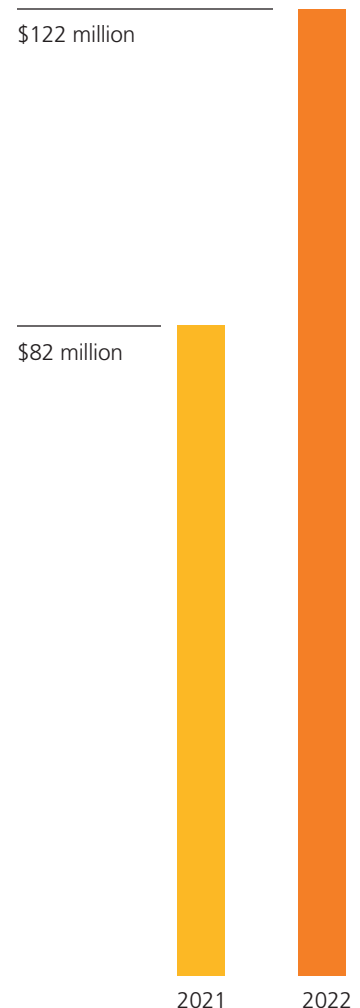
Patients



Read blog posts online

Government investment

Agencies invested \$122 million in focused ultrasound research in 2022, an increase from \$82 million in 2021. ■



international

Foundations abroad

Sister organizations in Hong Kong and the UK are continuing to advance the use of focused ultrasound throughout the world. Both organizations work closely with the US Foundation and share common goals and resources to achieve our mission of reaching millions worldwide with focused ultrasound in the shortest time possible. ■

UK FUSF

The **UK Focused Ultrasound Foundation** (UK FUSF), dedicated to advancing the development and adoption of focused ultrasound in the UK, was formally launched in January 2023 with an event held at the House of Lords. UK FUSF will apply donations directly to laboratory research and clinical trials in the UK, with the hope of significantly increasing accessibility to focused ultrasound-based treatments.

Specific areas of focus for the UK FUSF include cancer immunotherapy, brain diseases, pancreatic cancer, prostate cancer, and pediatric applications. ■

FUSHK

The **Focused Ultrasound Hong Kong Foundation** (FUSHK) was established in 2020 to improve the lives of people with serious medical disorders by promoting the development and adoption of focused ultrasound throughout Asia. FUSHK has gained momentum in the past two years by raising funds and increasing awareness for this technology.

In June, FUSHK partnered with the US Foundation to host an inaugural virtual awareness event for researchers, clinicians, investors, manufacturers, and philanthropists to highlight the rapid expansion of focused ultrasound in the region. More virtual events will be held to spotlight specific focused ultrasound researchers and manufacturers. ■

FUSF



collaborations

Collectively advancing the field

No single entity can drive the acceleration of focused ultrasound. To rapidly scale the technology, the Foundation recognizes the value of strong partnerships—including the US FDA and NIH, disease-specific foundations, advocacy and trade organizations, pharmaceutical manufacturers, medical and scientific societies, financial institutions, academic institutions, and commercial insurance companies. ■



Improving treatment

The Foundation and **The Michael J. Fox Foundation for Parkinson's Research** have partnered to explore how focused ultrasound can improve the treatment of Parkinson's disease. Focused ultrasound has been used since 2018 as a therapy for this debilitating condition.

A new collaboration will fund a clinical trial to disrupt the BBB and study whether proteins related to Parkinson's disease will escape the brain and be detected in peripheral blood. If successful, this could lead to easier diagnosis, monitoring, and development of therapies. ■



Children's Tumor Foundation

The Foundation and the **Children's Tumor Foundation** are working to advance noninvasive treatments for pediatric patients.

Together, we are co-funding a laboratory study to investigate the role of focused ultrasound in treating neurofibromatosis type 2 (NF2). The study, led by Tyrone Porter PhD, will deliver a commonly used lung cancer drug to a preclinical model of NF2 using focused ultrasound and special liposome packaging. The goal is to determine whether the packaging will reduce the drug's systemic side effects, thereby increasing its effectiveness in treating NF2. ■



collaborations



BloodPAC

BloodPAC is a nonprofit organization dedicated to accelerating the development of liquid biopsy assays to improve patient outcomes. Partnering with the Foundation and **C2i Genomics**, BloodPAC hosted a virtual workshop, “New Frontiers in Liquid Biopsy: Personalized Medicine for Brain Cancer in Adults and Children,” to collaborate and create a roadmap to improve care for patients with brain cancer. The workshop included discussion of research on the use of focused ultrasound to open the BBB, allowing for the detection of biomarkers in the bloodstream. ■



MITA

In March, the Foundation and **MITA** partnered for the third time to host a Congressional fly-in event to educate policymakers about focused ultrasound.

Patients, physicians, and industry leaders participated in 11 virtual meetings with US Representatives and their staff from nine states to increase awareness of focused ultrasound and address barriers to widespread adoption. Two focused ultrasound patients shared their stories, including prostate cancer patient Michael and essential tremor patient Tom. ■

scholars

Future leaders

The Foundation launched the **ACCESS FUS Scholars Program** to provide educational and research opportunities to underrepresented and underserved students. The program aims to create a more diverse and inclusive community of focused ultrasound leaders, increasing representation in the field and strengthening the technology. ■



Global interns

Focused ultrasound global interns **Matteo Gionso** and **Nicoletta Corradino** successfully defended their medical degree dissertations.

Both conducted research on the use of focused ultrasound to treat brain tumors. Gionso studied opening the BBB, and Corradino studied fluorescein-mediated SDT in an intracranial malignant glioma mouse model.

They received their degrees with honors and were mentored by Francesco Prada MD, a neurosurgeon and former FUSF Merkin Scholar. ■

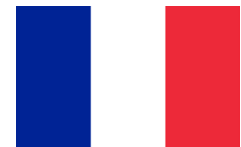
Foundation interns

Over the summer, the Foundation hosted interns from five universities.

Four technical interns completed projects related to transducer design, ultrasound wave simulation, and pediatric brain tumor research. Three students assisted the IT department, managed symposium outreach, and handled social media initiatives.

The Foundation continued partnerships with Xavier University of Louisiana and the Economic Club of Washington's Urban Alliance Summer Internship Program and added a new partnership with Virginia Bio's STEM2VA program.

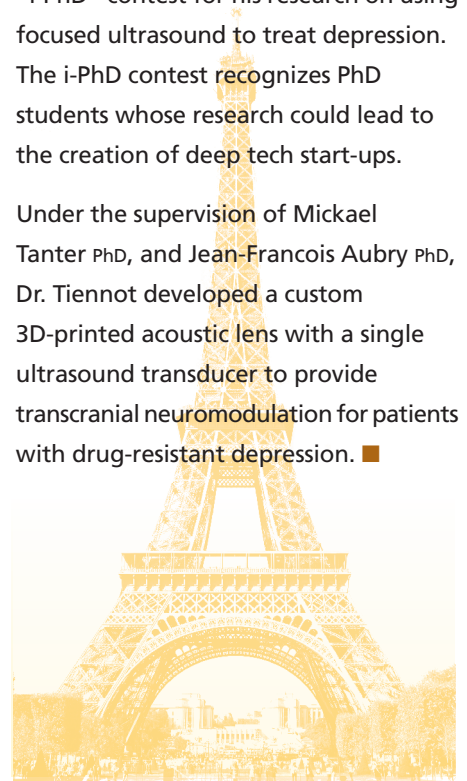
Fall intern **Imogen Hequet** explored machine learning and its intersection with focused ultrasound. ■



French grand prize

Thomas Tiennot, a PhD student at Physics for Medicine Paris, won a Grand Prize in the French Government's "i-PhD" contest for his research on using focused ultrasound to treat depression. The i-PhD contest recognizes PhD students whose research could lead to the creation of deep tech start-ups.

Under the supervision of Mickael Tanter PhD, and Jean-Francois Aubry PhD, Dr. Tiennot developed a custom 3D-printed acoustic lens with a single ultrasound transducer to provide transcranial neuromodulation for patients with drug-resistant depression. ■



commercialization

Start-up partnerships

Large medical device companies are continuing to show strong interest in partnering with start-ups in the field, helping to move the needle on widespread adoption. In October, manufacturer NaviFUS signed an early-stage cooperation agreement with Brainlab, a global leader in surgical imaging and navigation, enabling the companies to combine focused ultrasound and surgical guidance technologies and identify methods to accelerate the clinical integration of these approaches. ■



EDISON AWARDS

Award winning system

NaviFUS Corporation won a 2022 **Edison Award** in the Science & Medical Outpatient Treatment category for their "NaviFUS Focused Ultrasound System." This win marks an important step for the company toward gaining global recognition and validates the technology's potential to transform the care of many brain disorders.

The product uses optical (infrared) guidance, which is noninvasive and provides an alternative to MRI guidance in terms of cost, time, availability, and scalability. ■

Breakthrough device designation

Carthera's Sonocloud-9 device received **Breakthrough Device Designation** from the US FDA. This program offers device manufacturers the opportunity to receive expedited review and approval of novel devices while preserving FDA standards.

The device uses ultrasound to temporarily disrupt the BBB, allowing higher concentrations of therapeutic agents to enter the brain. Results from a pilot trial with a first-generation device showed promise, with the data currently being prepared for publication. This designation is a step toward providing more effective treatments for GBM patients. ■

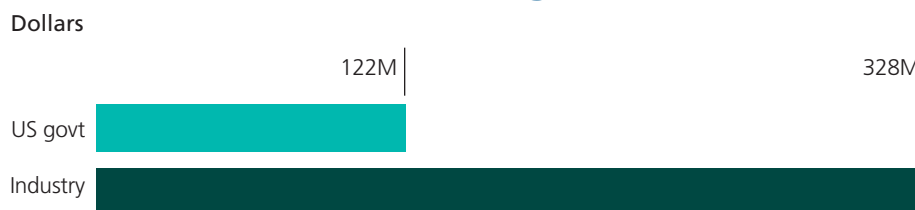


commercialization

Investment and patents

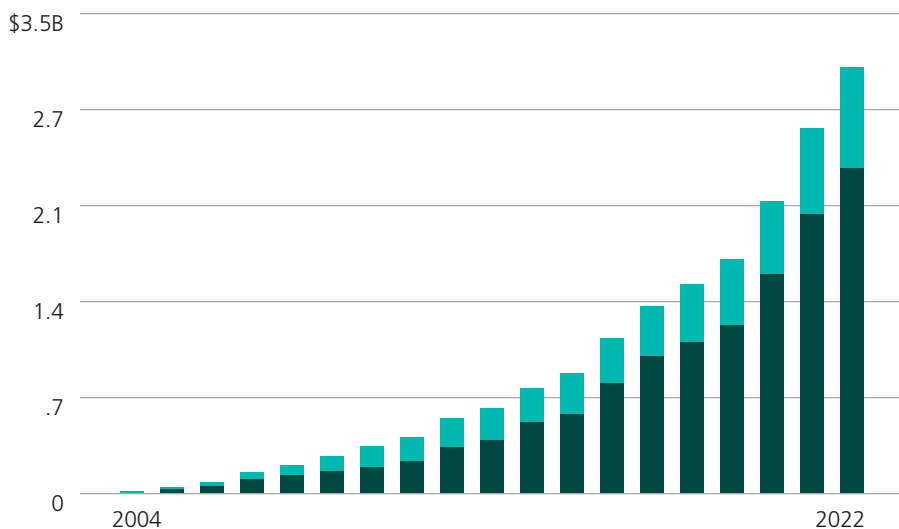
There has been a large increase in both government and private investment in focused ultrasound in the last two decades. In 18 years, investment has grown from 7 million to more than 450 million in 2022. Resulting in more than 3 billion in total funding. Additionally, the number of patents issued in both the US and abroad has increased dramatically indicating a shift from research to commercialization. ■

2022 unrivaled for funding



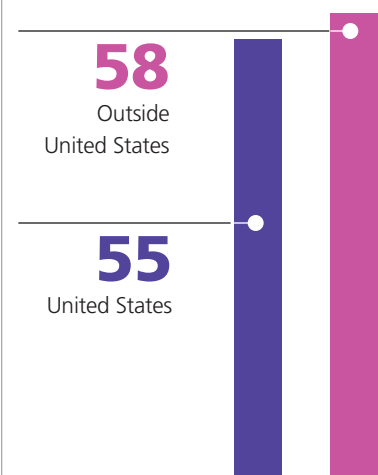
3+ billion

cumulative investment dollars ■ industry investments ■ government grants



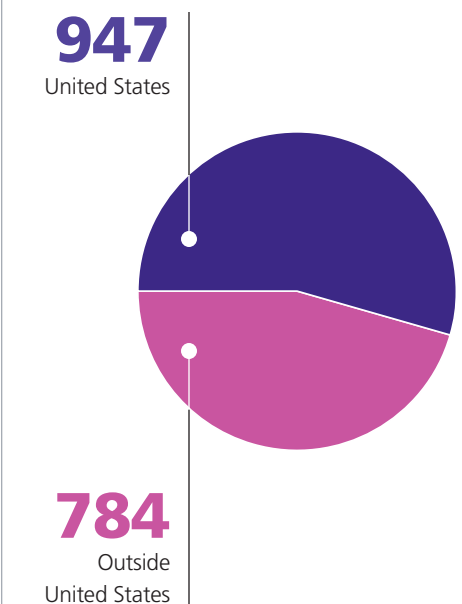
Yearly patents

FUS patents issued in 2022



Cumulative patents

FUS patents issued 1995–2022



advocates



“This technology is so cutting edge that I would actually feel remiss if I didn’t try to keep up with it.

I love the idea of people whose hearts and souls are devoted to making people better. I asked how I could help, and they told me I could join their Council—so here I am!”

— Whoopi Goldberg

New Council members

The Foundation’s Council is a group of passionate, enthusiastic advocates who partner with us to connect the Foundation to the greater community, share our story, and promote our mission. These goodwill ambassadors work closely with the Foundation’s Chairman, Board of Directors, and team to provide counsel and advice and assist with raising funds and awareness. ■

6 We welcomed six new members

■ **Garry Choy** MD MBA

Senior Vice President and Deputy Chief Medical Officer of Clinical Systems in the Office of Medical Affairs at UnitedHealth Group

■ **Whoopi Goldberg**

EGOT-winning artist, prolific producer, and entrepreneur who is well known around the world for her many humanitarian endeavors

■ **Molly Hardie** MD

Co-chair of the private family investment company, H7 Holdings, LLC, and longtime supporter of focused ultrasound research

■ **Mo KC Pritzker**

Serial entrepreneur with successful ventures in influencer marketing, food and dining, and neuroplasticity

■ **Thomas A. Scully**

General partner with the most active US private equity investor in healthcare, and former administrator of the Centers for Medicare & Medicaid Services

■ **Stefan Vilsmeier**

Founder and CEO of Brainlab, a global medical software and hardware company improving access to and consistency of medical treatments

experts

New Board members

The Foundation has added two new members to the Board, who share a passion for advancing transformational technologies and are facilitating the Foundation's efforts to shorten the time for focused ultrasound to become a global standard of care. ■

Healthcare and industry leader



Freda Lewis-Hall MD DFAPA MFPM, who has been a member of the Foundation's Council since 2021, was recently elected to the Board of Directors. With more than 40 years on the frontlines of healthcare as a clinician, researcher, and leader in the biopharmaceutical and life sciences industries, Dr. Lewis-Hall is a pioneer in medicine whose experience and passion for patient advocacy are unparalleled.

Her special lecture at the 8th International Symposium on Focused Ultrasound addressed the importance of reducing disparities in clinical trials, particularly the need to increase racial diversity among those enrolled. ■

“I am passionate about advancing the development, delivery, and deployment of transformational technology with the potential to save lives.”

— Freda Lewis-Hall

Patient turned advocate

Tom Ryder was elected to the Foundation's Board of Directors in March 2022. He has served as Chairman and CEO of the Reader's Digest Association and on numerous boards, including Amazon.

Tom brings his unsurpassed skills and experience to the Foundation's leadership team and is also an essential tremor patient who underwent focused ultrasound treatment. ■



our campaigns

Saving Time, Saving Lives.

Donors who support the Foundation's mission are changing lives worldwide. Your gifts enable the rapid advancement of focused ultrasound and help ensure the availability of the technology in the shortest time possible. ■

\$10M

Neurodegenerative
Campaign goal

\$10M

Cancer Immunotherapy
Campaign goal

\$4M

Veterinary Program
Campaign goal

\$2.2M

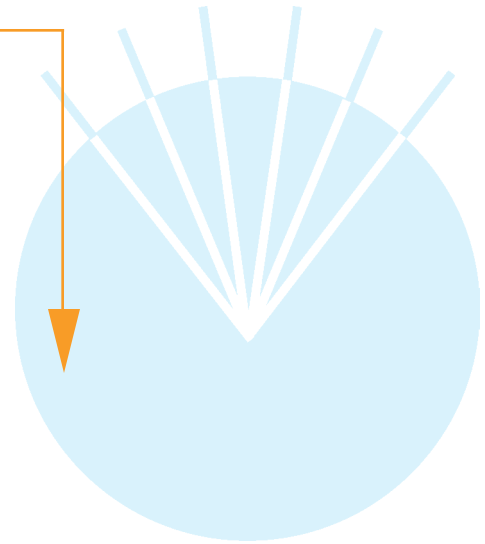
Diffuse Midline Glioma
Campaign goal

At a glance

The Foundation continues to secure support toward key strategic campaigns in neurodegenerative diseases, cancer immunotherapy, our veterinary program, and Diffuse Midline Glioma—a rare, fast-growing brain tumor that occurs mostly in children.

Our \$10 million **neurodegenerative campaign** is advancing focused ultrasound for a wide variety of disorders including Alzheimer's disease, Parkinson's disease, essential tremor, and more. In 2022, our generous donors succeeded in fulfilling a matching gift challenge—raising \$5.5 million to support a pipeline of more than 20 focused ultrasound projects.

The Foundation's \$10 million **Cancer Immunotherapy Campaign** is supporting next-level focused ultrasound research. Our rapidly expanding research pipeline boasts more than 32 projects at a cost of nearly \$5 million, and the Focused Ultrasound Cancer Immunotherapy Center is the first such institute in the world. The campaign will catalyze new discoveries in glioblastoma, pancreatic cancer, breast cancer, and melanoma. ■



donor spotlight

Rick & Susan Goings

Long-time Foundation donors Rick and Susan Goings reflected on the three challenging years of the COVID-19 pandemic as they considered their approach to holiday gift giving.

"We wanted to do something meaningful in the field of medicine, in honor of those we care most about, by contributing in their names to a medical technology that is having an incredible and growing impact,"

Rick said.

The Goingses elected to donate to the Foundation in the names of their friends and family, which they provided to the Foundation. Then, the Foundation team issued elegant electronic and printed acknowledgements notifying honorees

of the Goingses gift, which included information about the technology and the Foundation.

"Susan and I believe this gift matters more than chocolates that would be gone or flowers that would die.

We hope that it will bring more awareness and financial support to focused ultrasound and its potential for the future,"

Rick stated. ■



▶ To learn more about tribute giving, please contact

Jessica Lukens, Managing Director
jlukens@fusfoundation.org



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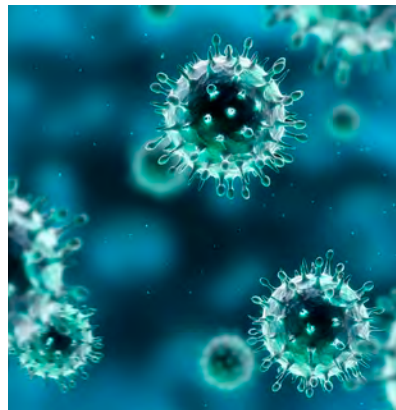
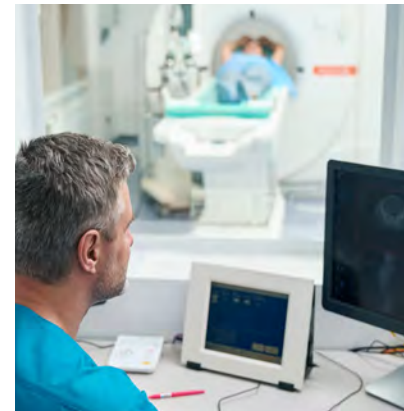
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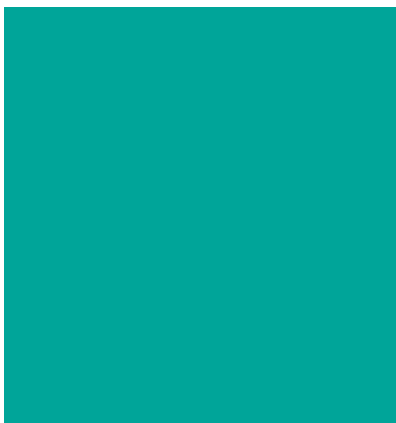
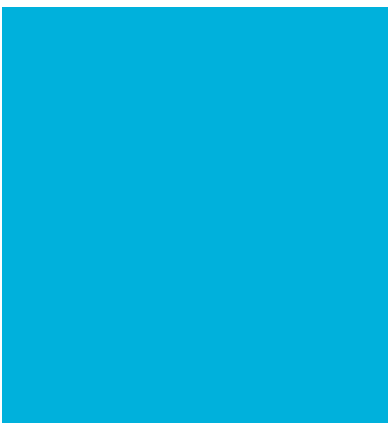
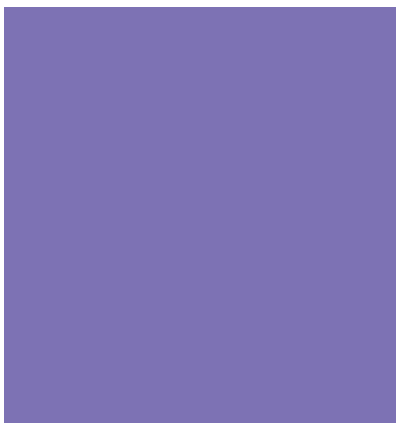
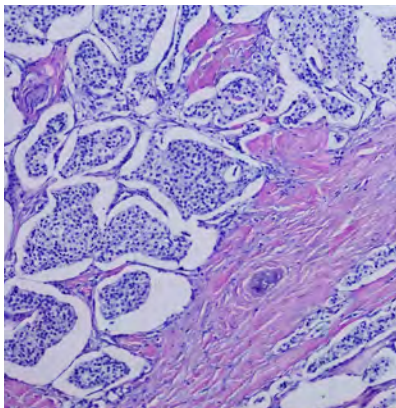
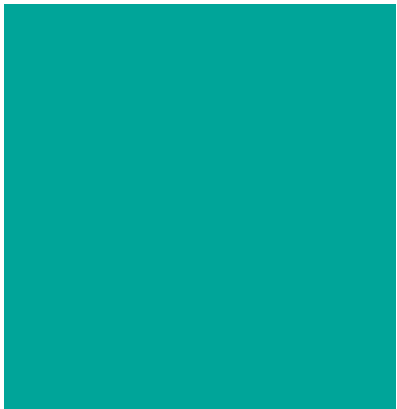
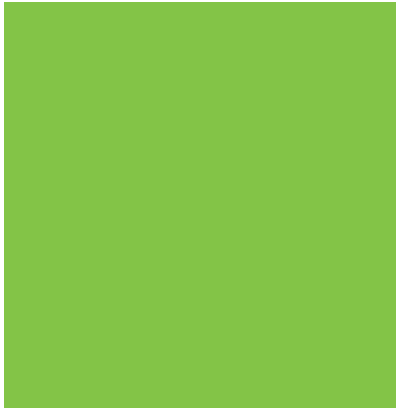
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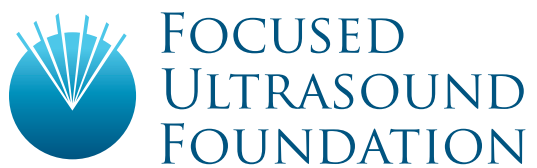
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