Focused Ultrasound Foundation

2024

Year in Review

One million+ patients treated

For the field of focused ultrasound, 2024 was a year of remarkable progress, driven by the dedication of researchers, clinicians, industry leaders, and donors like you. Nearly 151,000 patients were treated with 2,300 focused ultrasound devices worldwide, totaling more than 1,000,000 patient treatments to date. Evolution of the technology continues to accelerate, with over 180 clinical indications in various stages of development and more than 30 regulatory approvals globally—9 in the US.

New clinical trials explored applications for glioblastoma, psychiatric conditions, back pain, cerebral palsy, and tumors of the pancreas, kidney, and more. A *60 Minutes* feature highlighting focused ultrasound's potential for treating Alzheimer's disease and addiction skyrocketed national awareness.

A generous donor pledged $15 million to be matched one-for-one, doubling the impact of contributions to accelerate research and expand clinical adoption.

We remain committed to closing the gap between focused ultrasound's potential and its reach. Every advancement strengthens our resolve to make this a mainstream treatment and impact countless lives.

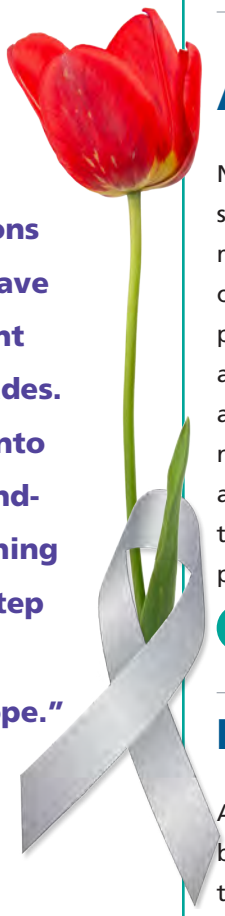
Be well. Be happy.

Neal F. Kassell, MD, on behalf of the Foundation team

neurodegenerative

Revolutionizing brain health

The Foundation is on a mission to transform the treatment of neurodegenerative diseases and is funding a pipeline of 14 active clinical trials with a total budget exceeding $4.1M. We expect this pipeline of pioneering projects to accelerate in 2025. ■



> **“Therapeutic options for Alzheimer’s have remained stagnant over several decades. Recent research into focused ultrasound-induced BBB opening is an important step toward offering these patients hope.”**
>
> — **Neal F. Kassell,** MD
> Foundation Chairman

Alzheimer’s disease

New published clinical data in Korea showed that focused ultrasound–mediated blood-brain barrier (BBB) opening in Alzheimer’s disease (AD) patients decreased amyloid plaques—a hallmark of AD—in some patients and showed improvement in one neuropsychiatric test. More of the amyloid in the brain was exposed to focused ultrasound than in any previous study worldwide. ■

A research team at Columbia University led by Elisa Konofagou, PhD, published final data from their clinical trial using **focused ultrasound + microbubbles** to open the BBB in patients with AD. Researchers identified several positive relationships between BBB opening and levels of serum-derived AD biomarkers. ■

Parkinson’s disease

A neuromodulation study was funded by the Foundation in British Columbia to explore the use of low-intensity focused ultrasound (LIFU) in treating Parkinson’s disease (PD) tremors. This research builds on the Foundation’s growing movement disorder portfolio and patient treatments began in 2025. ■

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

psychiatric disorders

Healing the mind

Focused ultrasound has emerged as a promising therapeutic option for many psychiatric disorders including depression, obsessive-compulsive disorder (OCD), and opioid addiction. ■

Suzanne LeBlang, MD
Director of Clinical Relationships, Focused Ultrasound Foundation

Podcast spotlight

On Episode 24 of the Foundation's *Curing with Sound* podcast, Suzanne LeBlang, MD, discusses how the technology has expanded to address many different psychiatric conditions in clinical trials—including depression, anxiety, and addiction—with promising results. **Podcast episodes** are accessible via our website and all popular podcast platforms. ■

Obsessive-compulsive disorder

A research team at Sunnybrook Health Sciences Centre in Toronto led by Nir Lipsman, MD, PhD, published long-term positive results from early-phase clinical trials testing the use of MR-guided focused ultrasound (MRgFUS) to perform a capsulotomy in participants with OCD and major depressive disorder. Results after one year of follow-up showed the treatment to be particularly effective for OCD. ■

Ten-year results from Jin Woo Chang, MD, PhD, who pioneered modern focused ultrasound psychiatric treatments in Korea, demonstrated it is safe and effective in patients with OCD; participants reported significant improvements in function and significantly reduced symptoms. ■

Sunnybrook Health Sciences Centre, Toronto

neuromodulation

“We’ve been blown away by the positive results so far. After just a single 40-minute stimulation session, patients [in the depression study] showed immediate, clinically substantial improvements in symptoms.”

— **Thomas Riis,** PhD
Postdoctoral researcher
Department of Biomedical Engineering
University of Utah

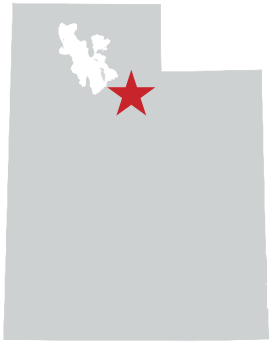
John and Marcia Price College of Engineering, University of Utah
Photograph Wikipedia

Precision therapy

Focused ultrasound neuromodulatory effects may enable a range of therapeutic benefits, including verifying targets in the brain prior to ablative procedures, suppressing epileptic seizures or symptoms of psychiatric disorders, and temporarily blocking nerves to treat pain. ■

Chronic **pain**

Researchers at **Virginia Tech** conducted two clinical trials that demonstrated the potential of LIFU neuromodulation as a noninvasive pain treatment method. One study targeted the insula, finding that LIFU reduced pain perception and affected heart rate variability. The second study focused on the dorsal anterior cingulate cortex, showing that LIFU decreased acute pain perception and altered autonomic responses. ■



Pain & **depression**

A **University of Utah** team conducted two clinical trials using Spire’s Diadem device to apply LIFU neuromodulation to treat chronic pain and depression. In the chronic pain study, stimulation of the anterior cingulate cortex resulted in rapid and lasting pain reduction, with some participants experiencing over 50% pain relief. The depression study, which targeted the subcallosal cingulate, showed immediate mood improvements and confirmed neuromodulatory effects on brain activity. ■

cancer immunotherapy

Breast cancer + CI **webinar**

For Breast Cancer Awareness Month in October, the Foundation and the **Breast Cancer Alliance** hosted a webinar on the potential impact of CI for the treatment of breast cancer. Four distinguished researchers presented their work. ■

Histotripsy + CI **podcast**

Clifford Cho, MD, a surgical oncologist from the **University of Michigan**, discussed the revolutionary intersection of histotripsy and CI on Episode 9 of the *Curing with Sound* podcast—including how histotripsy may boost the body's immune response to cancer and alter tumor blood vessel architecture and oxygen levels, potentially making cancers more vulnerable to treatment. ■

Boosting immune response

Important research continues to investigate the powerful anti-tumor immune response initiated by focused ultrasound. Studies aim to address the limitations of current cancer immunotherapy (CI) treatments—which are only effective in 20–40% of patients—for a variety of deadly cancers. ■

Histotripsy + CI trial

A clinical trial in the Netherlands began investigating focused ultrasound histotripsy + immune checkpoint inhibitors to treat metastatic or unresectable cancers that do not typically respond to immunotherapy alone.

The iFOCUS trial at **UMC Utrecht** is using Profound Medical's Sonalleve® MR-HIFU device to mechanically destroy tumors without heat, potentially enhancing immune recognition. ■

Melanoma + CI trial

UVA Health, led by surgical oncologist Lynn Dengel, MD, is conducting a clinical trial to evaluate the potential of focused ultrasound to enhance the immune response to immunotherapy in melanoma patients. The study aims to determine whether focused sound waves can modify the tumor microenvironment, improve immunotherapy effectiveness, and ultimately lead to better treatment outcomes for advanced melanoma. ■

UMC Utrecht

mechanism milestones

Surge in MOAs

Mechanisms of action (MOA) refer to the different ways a medical treatment works in the body. Researchers have identified more than 30 ways focused ultrasound can affect tissue. As of April 2024, three MOAs are being used in approved treatments, while others continue to be explored in research and clinical trials. ■

3

Thermal ablation

Heat treatment. Occurs when high-power ultrasound waves are applied to tissue. This is the most clinically advanced bioeffect of focused ultrasound. Like a magnifying glass focusing sunlight, ultrasound waves heat and destroy unwanted tissue. ■

A

Histotripsy

Bubble breakdown. Short, high-pressure focused ultrasound pulses are used to create tiny bubbles that act like mini jackhammers, breaking apart targeted tissue without heat. ■

A

Neuromodulation

Brain/nerve adjustment. Precisely targeted gentle ultrasound waves act like a remote control, adjusting nerve activity without damage to the brain or nervous system. ■

A

Drug delivery

Medicine release. Focused ultrasound acts as a key, allowing access through obstacles like the blood-brain barrier so medicine can reach hard-to-access areas. ■

Immunomodulation

Immune system boost. Focused ultrasound stresses tumor cells which flags them for attack, and helps the immune system better recognize and fight disease. ■

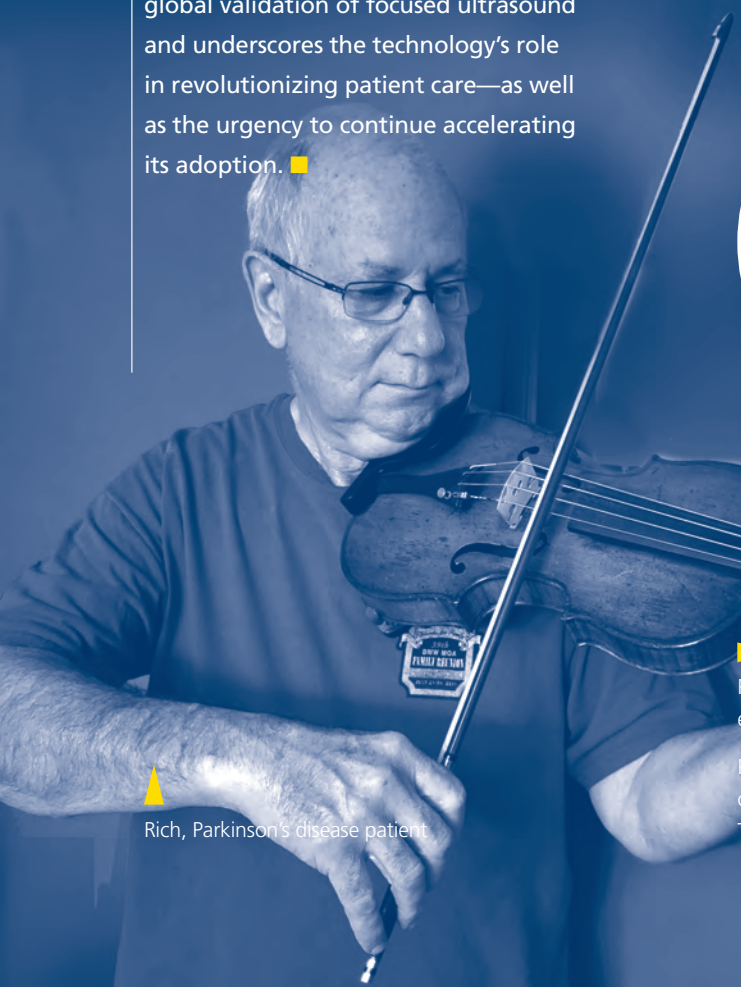
A This icon represents MOAs used in approved focused ultrasound treatments.

patients treated

1,000,000+

It's all about the patients. In 2024, the field of focused ultrasound hit a milestone with over **1 million** total patients treated worldwide.

This achievement reflects the increasing global validation of focused ultrasound and underscores the technology's role in revolutionizing patient care—as well as the urgency to continue accelerating its adoption.



Rich, Parkinson's disease patient

Patients, center top to bottom: Beverly, essential tremor; and Robert, prostate cancer

Patients, right top to bottom: Jack, osteoid osteoma; Tammy, neuropathic pain; and Thomas, prostate cancer

evidence research milestones

414
Projects funded
to date

Research is the cornerstone of the Foundation's programs and consumes approximately 50% of the organization's budget. The strategic focus of our research program is the rapid development of new indications of focused ultrasound to fulfill unmet clinical needs and benefit patients worldwide in the shortest time possible—saving time, saving lives.

Research projects include technical initiatives, preclinical studies, and clinical trials. The in-human clinical trials have three phases: safety, effectiveness, and large-scale testing. ■

By the numbers

135
active projects

169
projects
completed

130
projects with
results published

55
projects with
follow-on or co-funding

By the dollars

$17.9M
funding provided for completed projects

$80.3M
follow-on or co-funding

4.5x
return on investment
for completed projects

cumulative

evidence research milestones

Accelerating **research**

Streamlining activities applied to the Foundation's research and funding program in 2024 resulted in a 50% increase in funded projects. ■

Projects funded

36
projects initiated

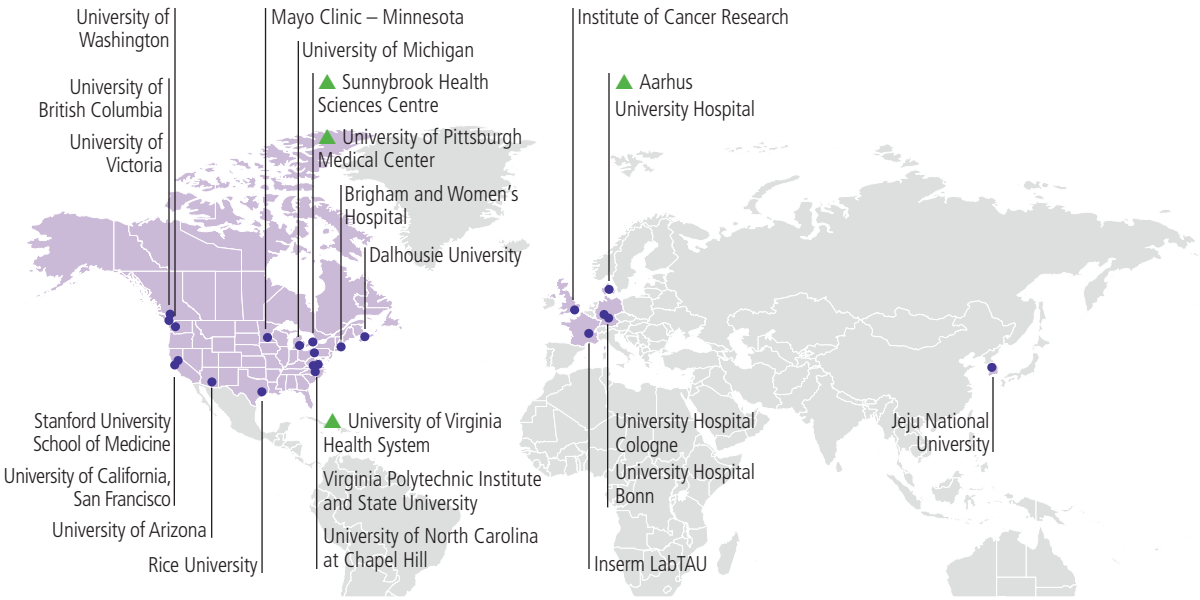
26
projects completed

Locations

22
institutions and organizations

7
countries

4
projects with **co-funding**

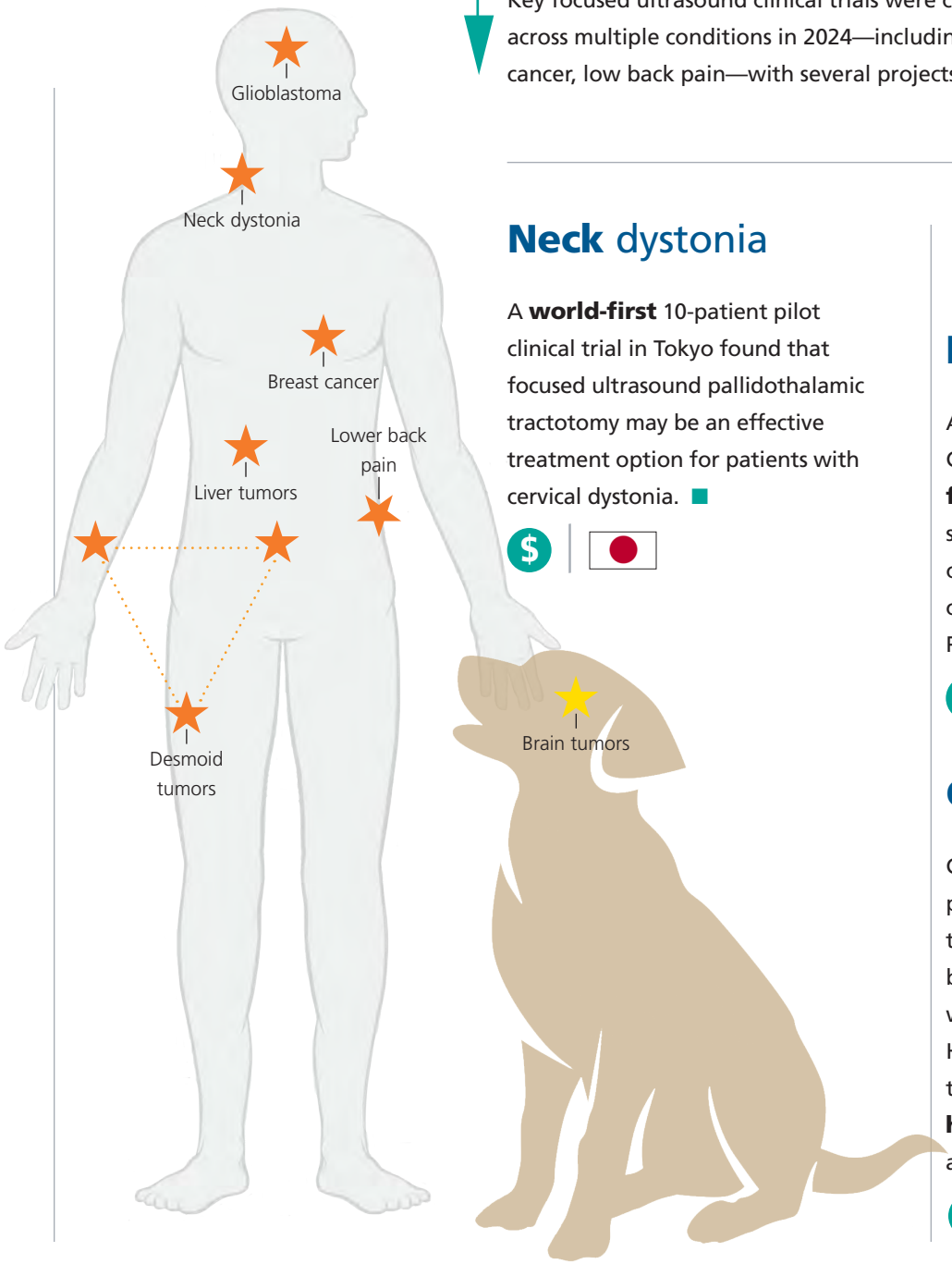


2024

clinical trials

Global adoption

Key focused ultrasound clinical trials were completed and/or data were published across multiple conditions in 2024—including neck dystonia, advanced breast cancer, low back pain—with several projects receiving Foundation support. ■



Neck dystonia

A **world-first** 10-patient pilot clinical trial in Tokyo found that focused ultrasound pallidothalamic tractotomy may be an effective treatment option for patients with cervical dystonia. ■

Breast cancer

A Phase I clinical trial led by Gregory Czarnota, MD, PhD, demonstrated that **focused ultrasound + microbubbles** significantly enhanced the effectiveness of radiotherapy for advanced breast cancer. This work has now progressed to Phase II trials. ■

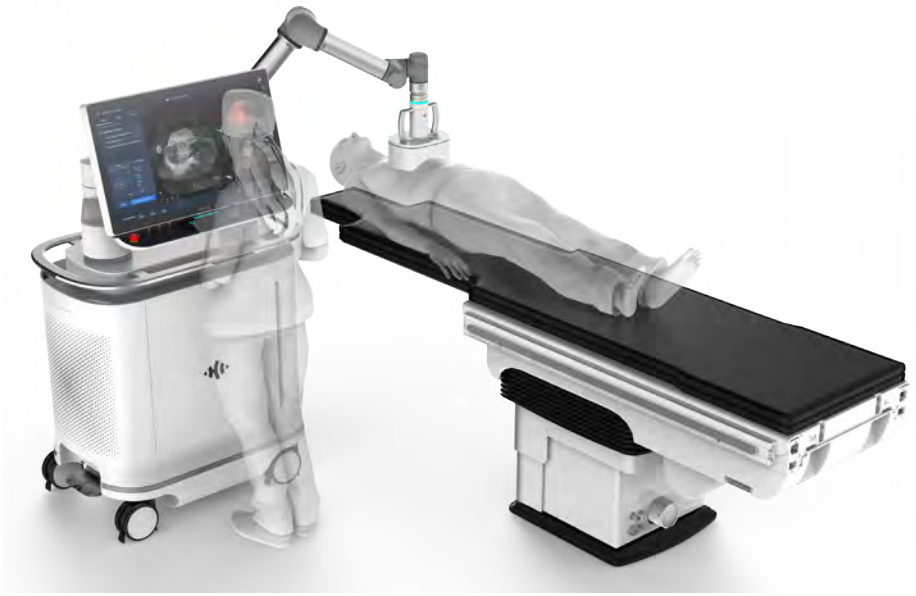
Canine brain tumors

Clinical trial results in pet dogs published in December demonstrated the safety and feasibility of treating brain tumors with histotripsy. Co-funded with the American Kennel Club's Canine Health Foundation, this study supports the development of **transcranial histotripsy** systems for both human and canine patients. ■

clinical trials

Desmoid tumors

A retrospective study of 105 patients found that focused ultrasound effectively reduced desmoid tumor volume, alleviated pain, and improved quality of life. The first author of the study is Daniel M. Düx, MD, a research fellow funded by the Foundation who completed his fellowship at **Stanford University**'s Minimally Invasive MRI-Guided Interventional Center. ■



HistoSonics' Edison® Histotripsy System

Lower back **pain**

FUSMobile recently published positive clinical trial results using focused ultrasound to treat low back pain; responses were comparable with radiofrequency ablation. ■

Liver tumors

The #HOPE4LIVER clinical trial results were published in *Radiology* in September and showed a 95% success rate in ablating liver tumors. This trial led to the FDA's October 2023 clearance of **HistoSonics'** Edison® Histotripsy System for liver tumor treatment.

Focused ultrasound for liver cancer is available at 20 US sites and one in the UAE, with more locations being added. ■

Glioblastoma

Final results from **Carthera's** international Phase I/II clinical trial in patients with recurrent glioblastoma (GBM) were published in *Nature Communications*. Focused ultrasound provided 90% BBB disruption in a larger volume around the treatment area. The median overall survival rate was higher in the group that received the chemotherapy drug carboplatin before BBB disruption. ■

collaborations

Unified efforts

The Foundation collaborates with dozens of organizations through fundraising, in-kind contributions, strategic guidance, awareness efforts, and research advancement. Each partnership aims to expand focused ultrasound's reach to new communities while jointly funding and advancing critical research initiatives. ■

Exploring ALS treatment

The Foundation and **The ALS Association** partnered in 2024 to fund a new study exploring whether focused ultrasound can open the BBB to enhance the delivery of a promising new ALS treatment, JRMS-22, which may help prevent toxic protein buildup in neurons. The study is led by Agessandro Abrahao, MD, at the University of Toronto. ■

Dementia research

The UK Focused Ultrasound Foundation and **Race Against Dementia** recently partnered to fund a world-first clinical trial exploring the use of LIFU to improve cognition in patients with Lewy body dementia (LBD). Led by Ashwini Oswal, MD, at the University of Oxford, this study will use focused ultrasound neuromodulation for LBD, testing its impact on brain activity and memory in 30 participants. ■

Expanding access

In May, the Foundation was selected as a "spoke organization" in the ARPANET-H Customer Experience Hub, a nationwide health innovation network led by the **Advanced Research Projects Agency for Health** (ARPA-H).

As part of this initiative, the Foundation will help diversify clinical trials and promote patient-centric approaches to improve healthcare outcomes while advancing equitable access to focused ultrasound treatments. ■

patient spotlight

Rima Youssef

For Rima, the symptoms of obsessive-compulsive disorder (OCD) began in early childhood. By age 12, her compulsions led to anxiety and depression, and she was forced to leave school to undergo treatment. Despite years of therapy and medication, her symptoms continued to worsen, and she was unable to work or engage in daily life. In 2021, she participated in a clinical trial at Sunnybrook using focused ultrasound to target areas of the brain linked to OCD.

In the following months, she noticed small but meaningful changes. Before treatment, OCD dictated nearly every aspect of her life—she couldn't touch door handles, hug her family, or even pet her dog. But gradually, she started reclaiming control. A year and a half later, she was able to return to work and is now thriving.

"I feel like it's day and night. I am gaining back who I lost to OCD and for the first time ever in my life, OCD is not at the forefront. It doesn't control what I do, doesn't control where I go, what I say."

Rima is grateful and hopes others will have the same opportunity.

"You can get your life back, you can go to work, you can contribute to society like everyone else. And it makes a difference." ■

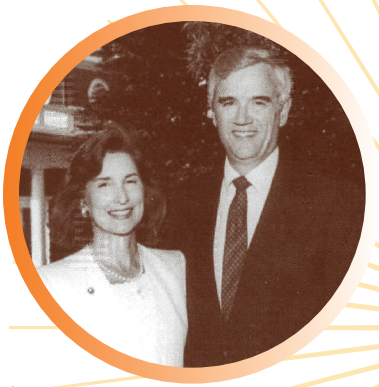
Rima Youssef

Sunnybrook is now offering focused ultrasound treatment for OCD to international patients.

home

Cultivating the next generation

Now in its 13th year, the summer internship program provided hands-on opportunities at our Charlottesville headquarters for eight interns, many of whom furthered their contributions to our mission during the fall and spring semesters. ■



Lou and Dan Jordan

Honoring leadership

In March, the program became the **Dan and Lou Jordan Focused Ultrasound Internship Program**—honoring the Jordans' deep commitment to education, their belief in nurturing future focused ultrasound researchers and clinicians, and the Foundation's gratitude for their enduring support and vision for the next generations. ■

2024 **Foundation interns**

Asad Faqirzada
Data Automation for Advocacy and Outreach

Beyzanur Gokce Ak
Immuno-Oncology Research on the Abscopal Effect

Grace Gawrylowicz
Functional Analysis of Foundation Activities

Ian Hamilton
UK Development and Funding Application Research

Sophie Kemprecos
Analysis of AI for Literature Reviews

Vaibhav Khare
Incubators/Accelerators for Medical Devices

Nate Owen
Generative AI Applications

Evan Stewart
Research Data Analysis

Avery Wilkerson
Generative AI Applications

2024 **leaders**

FUSF interns **9**

Global interns **15**

abroad

2024 **Global interns**

Max Au-Yeung
University College London

Alexander Aviles Cruz
North Carolina Agricultural & Technical State University

Aditya Baishnob
Inserm LabTAU

Eli Hines
Brigham and Women's Hospital

Daegan Kee
Sungkyunkwan University

Milea Koster
Brigham Young University

Carrington Lea
North Carolina Agricultural & Technical State University

Qiyixing (Ethan) Liu
Imperial College London

Thomas Lu
University of Michigan

Varshini Packiyathasan
Imperial College London

Edena Park
Jeju National University

Isabel Quintana
Virginia Polytechnic Institute and State University

Talia Sachs
Columbia University

Jang Sanghyeok
Jeju National University

Nicolo Zaia
Fondazione IRCCS Istituto Neurologico Carlo Besta

Lockhart **fellowship**

Chulyong Kim, PhD, was awarded the 2024 Andrew J. Lockhart Postdoctoral Fellowship in Focused Ultrasound and Immuno-Oncology, a one-year fellowship to support early-career researchers. Dr. Kim is a postdoctoral researcher at Georgia Institute of Technology exploring the use of focused ultrasound to advance cancer immunotherapy. His work aims to enhance therapeutic strategies for solid tumors—especially brain tumors—while addressing key limitations in current immunotherapies. ■

Chulyong Kim, PhD

utilizing platforms

Spreading the word

The Foundation continues to raise global awareness about focused ultrasound through a multifaceted approach, including widespread media coverage, educational webinars, a new podcast, and more. ■

2024 **media reach**

Foundation presence*

138% **Media engagements**

226% **Social media posts**
5,000

31% **Social media followers**
18,000

44% **Social media impressions**
1,276,800

16% **Newsletter engagement**
41,168

24% **Website visits**
402,000

* Increases over 2023

Stay on top of focused ultrasound news and advancements through our Newsletter and News Digest emails.

Sign up at **fusfoundation.org/connect**

> **"What we're talking about here is a revolutionary change—a quantum leap forward in technology."**
>
> — ***The Globe and Mail***
> **Nir Lipsman, MD, PhD**
> Sunnybrook Research Institute

Worldwide **press coverage**

Focused ultrasound was prominently featured in 20 major national and international news outlets in 2024, including *Bloomberg Businessweek*, *The New York Times*, *The Wall Street Journal*, *The Washington Post*, STAT, *The Globe and Mail*, and *South China Morning Post*. ■

Expert **insights**

The Foundation's **Seminar Series** returned with a presentation by John Lukens, PhD, who shared how advances in our understanding of brain health are paving the way for focused ultrasound treatments. ■

John Lukens, PhD, Professor of Neuroscience, University of Virginia

utilizing platforms

5
Webinars

600 registrants
3,200 YouTube views
3,800 total reach

Foundation **webinars**

These events give experts in the field opportunities to present on areas of emerging interest or promising research. They are shared with the broader community to keep them informed of the latest advances. ■

2024 on-demand **episodes**

Without a Scalpel™
Advances in Minimally Invasive Liver Tumor Treatments

Future of Healthcare
Navigating AI Integration in Medical Devices

Advancing the Frontier
Novel Immunotherapies for Breast Cancer Treatment

FUS Transforming Women's Health

FUS Therapy
Powerful Platform Technology Transforming Patients' Lives

Podcast
Curing with Sound

The *Curing with Sound* podcast was launched in March, to showcase the power of focused ultrasound through interviews with top researchers, medical experts, influential advocates, and patients. Episodes are now available on major streaming platforms including Apple Podcasts, Spotify, Amazon Music, and YouTube Music. ■

20+
Podcast episodes

4,000 downloads
5,000 views

Generative **AI**

The Foundation continued its integration of artificial intelligence (AI) throughout 2024, implementing a comprehensive AI strategy to enhance operations and facilitate attention to advancing the technology.

This commitment extended to our summer internship program, where eight bright minds applied AI tools to elevate their research projects. ■

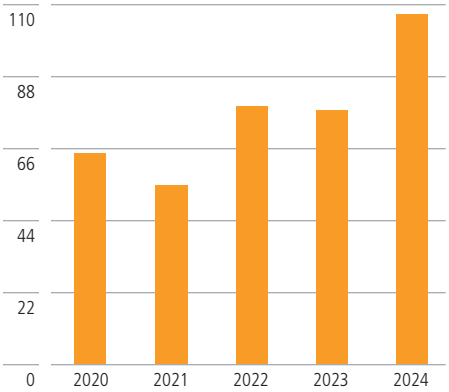
"From the onset, *Curing with Sound* has amplified the voices of researchers, patients, and clinicians—becoming a powerful platform for insight and connection, and deepening engagement with listeners." — **Allison Preston-Smith,** Host of *Curing with Sound*

Above
Allison Preston-Smith

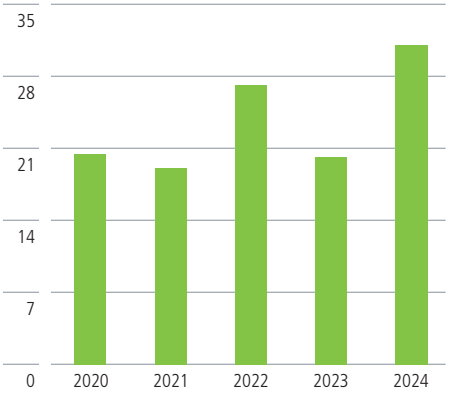
outreach

Foundation presence **at meetings**

Foundation attendees



Foundation presentations



Scientific community engagement

Representatives of the Foundation attended medical and scientific professional meetings around the globe to advance awareness and collaboration within the focused ultrasound community. Meeting attendance in 2024 was at an all-time high, as were presentations given by staff. ■

2024 **Award recipients**

The Foundation honored four leaders in focused ultrasound at the ISTU meeting in Taiwan for their important contributions to the field.

Elisa Konofagou, PhD, received the Visionary Award for pioneering research in BBB opening, neuromodulation, and cancer treatments.

Wladyslaw Gedroyc, MD, earned the Clinical Adoption Award for treating over 800 patients and advocating for reimbursement in the UK.

Rosie Xing, PhD, received the Commercialization Pathfinder Award for expanding global access to focused ultrasound through Chongqing Haifu Medical Technology.

Chrit Moonen, PhD, was honored with the Lifetime Achievement Award for his three decades of research, leadership in clinical trials, and role in advancing focused ultrasound therapy worldwide.


Elisa Konofagou, PhD


Wladyslaw Gedroyc, MD


Rosie Xing, PhD


Chrit Moonen, PhD

workshops

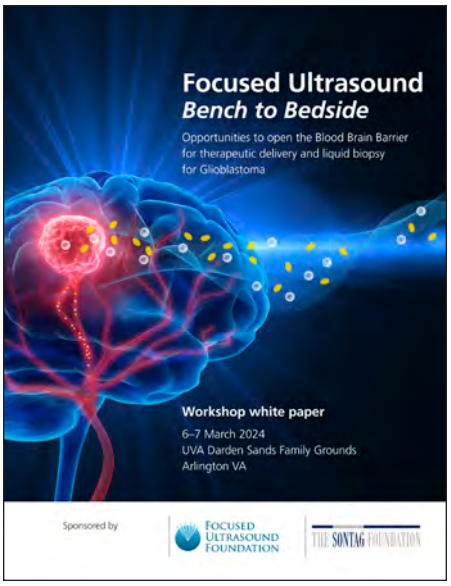
5 Workshops

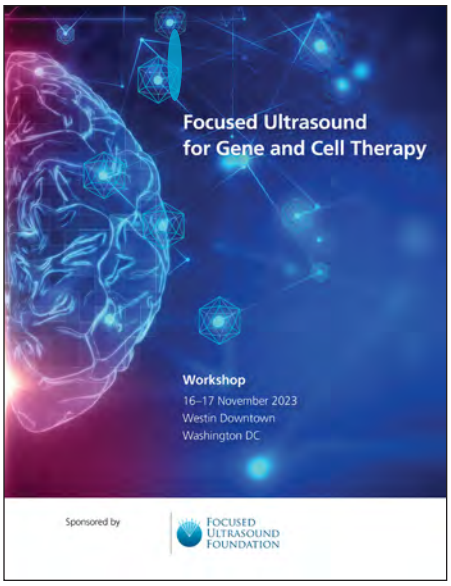
The Foundation hosts or co-funds workshops to produce roadmaps of research needed to lay the groundwork for collaborations between manufacturers, research laboratories, industry, and academia.

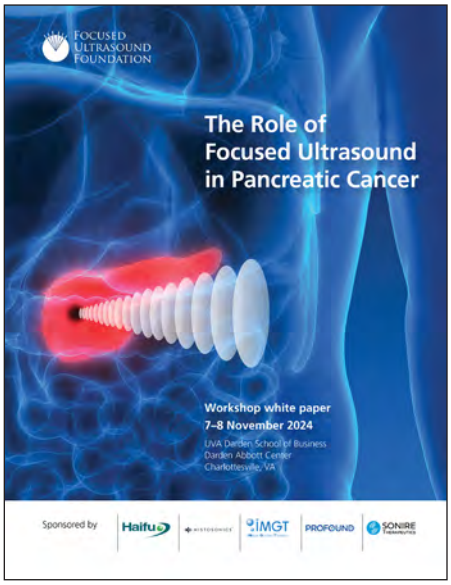
These events gather experts in the field from around the world to evaluate crucial topics. The following areas were recently covered: **glioblastoma**, **pancreatic cancer**, **gene and cell therapy**, **essential tremor**, and **psychiatry**. ■

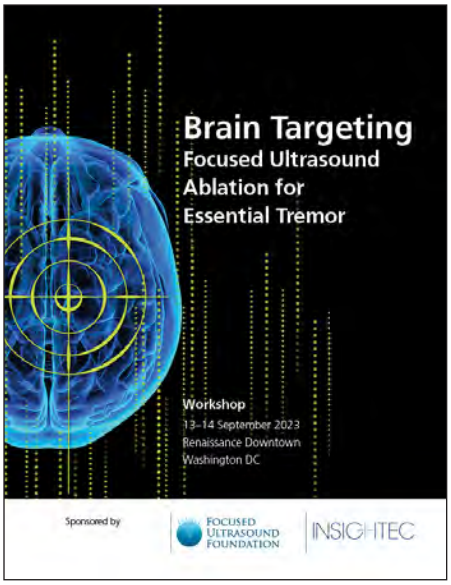
3 Mini-workshops

Several mini-workshops and virtual roundtables took place this year to advance focused ultrasound for key indications. Topics included: **microbubbles**, **benign prostatic hyperplasia**, and **navigating AI integration in medical devices**. ■









The 2024 white papers summarizing Foundation-sponsored workshop findings can be found on our **website**.

advocacy

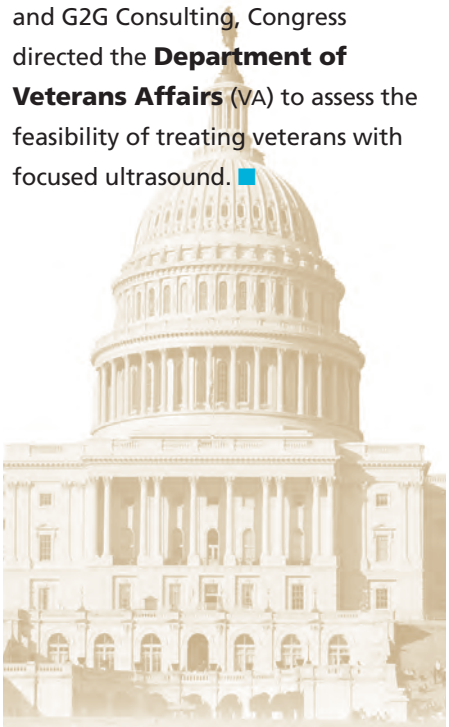
Driving impact

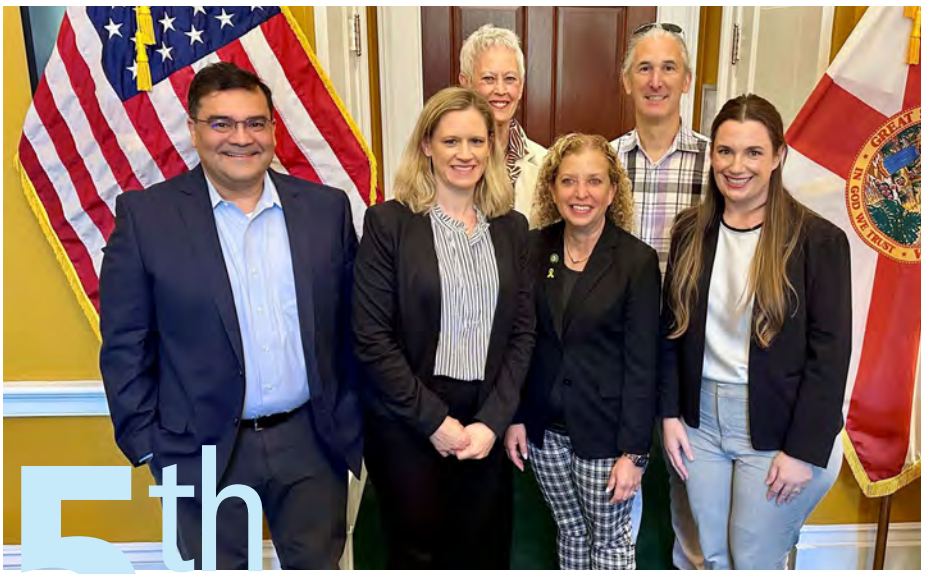
In recent years, advocacy has begun playing a much bigger role in how the Foundation—a medical research, education, and advocacy organization—advances the field. Advocacy efforts focus on addressing regulatory, reimbursement, and awareness barriers to expanding focused ultrasound adoption, as well as working with trade associations, policymakers, and consultants to advance funding and policy changes. ■

Congressional recognition

The **US Senate Appropriations** subcommittee recently recognized focused ultrasound's potential in a budget hearing, where senators and NIH directors discussed its role in treating Alzheimer's and addiction.

With advocacy from the Foundation and G2G Consulting, Congress directed the **Department of Veterans Affairs** (VA) to assess the feasibility of treating veterans with focused ultrasound. ■





Capitol Hill meeting with Congresswoman Debbie Wasserman Schultz from Florida

5th Congressional "Fly-in"

The Foundation's fifth annual Capitol Hill "fly-in" took place in July and brought together patients, physicians, and industry representatives to advocate for focused ultrasound funding, legislation, and cross-agency collaboration during 22 meetings.

Key priorities included Medicare coverage for breakthrough devices (HR 1691), expanding access to focused ultrasound for veterans, and enhancing NIH research coordination. ■

advocacy

Securing support

Jessica Foley, PhD, the Foundation's Chief Scientific Officer and Managing Director of Government Affairs, presented to the **Virginia House Appropriations Higher Education Subcommittee** to highlight the technology's global impact and economic benefits and advocate for continued state funding of focused ultrasound research at UVA and Virginia Tech.

The full funding request for the 2024–2026 biennium was secured in early 2024. ■

Senator Mark Warner

Virtual Congressional briefing

In April, the Foundation and G2G Consulting hosted a congressional briefing featuring **Senator Mark Warner** and expert speakers to educate policymakers on the medical potential of focused ultrasound, including its role in treating neuropathic pain, childhood brain tumors, and mental health conditions.

With over 150 attendees, the event was part of the Foundation's advocacy efforts to increase research funding and improve patient access through policy support and reimbursement initiatives.

The briefing can be viewed on the Foundation's **website**. ■

sister organizations

United Kingdom

The UK Focused Ultrasound Foundation (UKFUSF) continues to build momentum and increase awareness of focused ultrasound throughout the UK.

In November, UKFUSF hosted an awareness event at the Cavalry and Guards Club in London to advance focused ultrasound research for critically ill infants and children. Attendees gained valuable insights on important clinical trials for pediatric indications, including childhood liver failure and Twin-Twin Transfusion Syndrome. ■

Above, left to right
Gail ter Haar, PhD; Brian Davidson, MD; and Nader Saffari, PhD

UK Focused Ultrasound Foundation

EU Focused Ultrasound Foundation

Focused Ultrasound Hong Kong Foundation
香港聚焦超聲波基金會

European Union

The Foundation expanded its reach in 2024, establishing the European Union Focused Ultrasound Foundation (EUFUSF) to accelerate the adoption of focused ultrasound and raise funds to support groundbreaking research at leading sites across Europe.

In December, the EUFUSF secured a €1,620,000 donation to co-fund a study at UMC Utrecht combining histotripsy with immunotherapy. ■

Hong Kong

Focused Ultrasound Hong Kong Foundation Limited (FUSHK) leaders Jessica Che-yi Chao, Oliver Weisberg, and Carolyn Yeh organized awareness events with Goldman Sachs and Blue Pool Capital, and FUSHK Board member Shirley Lin hosted events in Taipei in collaboration with YPO Taiwan and FUSF. Focused ultrasound and the Foundation were also featured in a *South China Morning Post* article about the expanding availability of histotripsy in Asia. ■

international

> **"The growth in the number of treatments, clinical trials, and research sites, and the fact that equipment manufacturers are getting investments from strategic investors and major financial institutions, are indications that focused ultrasound is scaling up in Asia."**
>
> — *South China Morning Post*
> **Neal F. Kassell, MD**
> Foundation Chairman

India

In April, the Foundation launched its **India Program**, an effort to support the country's application and development of focused ultrasound technology.

More than 10 centers in India use focused ultrasound for research, clinical trials, and commercial treatments. ■

New
Centers of Excellence

The Foundation established two new Centers of Excellence (COE) in 2024. The COEs serve as hubs for collaboration, bringing together academia, industry, and the Foundation to champion therapeutic ultrasound technology in innovative ways.

- **Virginia Tech**
- **Chongqing Haifu Hospital**

reimbursement

Insuring treatments

By 2024, reimbursement for all existing focused ultrasound indications stabilized. Several newly approved applications—including treatments for liver tumors, kidney stones, facetogenic arthritis, and various dermatological conditions—are expected to secure insurance coverage in the coming years. ■

Australian **ET coverage**

Insightec's MRgFUS treatment for medication-refractory ET received a positive recommendation from Australia's Medical Services Advisory Committee, paving the way for potential government subsidies and nationwide patient access.

There are 22 million covered enrollees in their Medicare program, with a projected 200,000 eligible. ■

Parkinson's dyskinesia

In 2024, **Anthem Blue Cross Blue Shield** expanded coverage for focused ultrasound treatment of Parkinson's dyskinesia. The company is the first US insurer to cover focused ultrasound pallidotomy for Parkinson's disease. ■

Reimbursement codes

Focused ultrasound treatments for **ET** and **prostate cancer** now have permanent CPT codes in the US.

After nearly nine years under a temporary Class III designation, **Insightec**'s MRgFUS treatment for ET transitioned to a Class I CPT code on January 1, 2025, signifying its recognition as a well-established medical procedure for reimbursement. ■

reimbursement

US **coverage**

In the US, coverage is provided by state through private or public insurers.

115.6M Bone metastases

229.3M Essential tremor

33.1M Parkinson's disease, tremor

33.4M Parkinson's disease, dyskinesia

65.4M Prostate tumors

0.4M Uterine fibroids

Regulatory **authorizations**

A dozen new regulatory authorizations were granted for focused ultrasound in 2024, including six approvals for uterine fibroids, two for facetogenic arthritis, and one each for kidney stones, actinic keratosis, basal cell carcinoma, and neurofibromatosis. There are now **39 focused ultrasound indications worldwide** authorized for 22 manufacturers across 46 regulatory agencies. ■

Regulatory **wins**

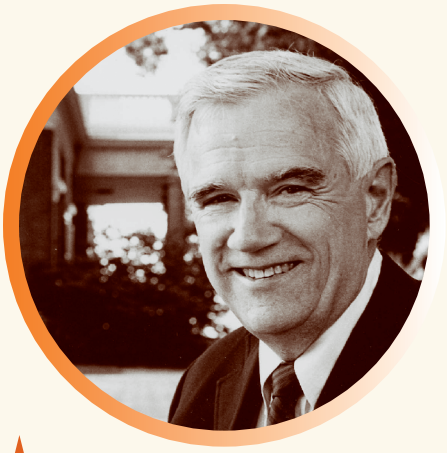
New regulatory authorizations were awarded in 2024 to four focused ultrasound companies, and an additional manufacturer was authorized for three new non-aesthetic indications. ■

2024 new approvals

Approval	Indication	Company
	Uterine fibroids	Arrayus Technologies INC
	Arthritis, facetogenic; Back pain	FUSMobile INC
	Kidney stones*	SonoMotion INC
	Actinic keratosis*, Basal cell carcinoma*, and Neurofibromatosis*	TOOsonix A/S
	Uterine fibroids	Zhonghui Medical (Sinoways)

* Indications with a first approval

in memorium



Daniel P. Jordan, PhD

Daniel P. Jordan tribute

The Foundation lost a true friend, and the world lost a transformational leader when Dan Jordan, PhD—a founding member of our Board of Directors—passed away in March 2024.

His distinguished 23-year tenure as president of the Thomas Jefferson Foundation included the creation of a more than $200-million endowment and the building of the Thomas Jefferson library. Following his retirement in 2008, Dan became a founding partner of Bryan and Jordan Consulting, LLC, a Richmond, Virginia-based firm.

Dan also held academic roles at the University of Virginia and Virginia Commonwealth University and public service roles with the Gilder Lehrman Institute of American History, the National Trust for Historic Preservation, and the National Park Service Advisory Board. He was awarded the U.S. Department of the Interior's Public Service Award and the Commonwealth's "Outstanding Virginian" award in 2006.

Dan is survived by his wife of over 60 years, Lou, their three children, and six grandchildren. In honor of their longstanding support for focused ultrasound, the Foundation named its internship program the Dan and Lou Jordan Focused Ultrasound Internship Program, ensuring Dan's legacy will continue to inspire future healthcare innovators. ■

"Dan was an immeasurable source of advice, guidance, and inspiration to the entire community. The success of the Foundation is in large part a result of his efforts, and his memory will continue to be the guiding light for all of the lives he touched."

— **Neal F. Kassell, MD**
Foundation Chairman

Dan with his wife, Lou

advocates

Our Council members

We welcomed three new members to our Council: **Kevin Passarello**, **Mary Harrison Keevil**, and **Marjorie Harrison Webb**. The Council is a dedicated group of goodwill ambassadors who work closely with the Board of Directors and staff to provide advice and assist with raising funds and building awareness. ■

3

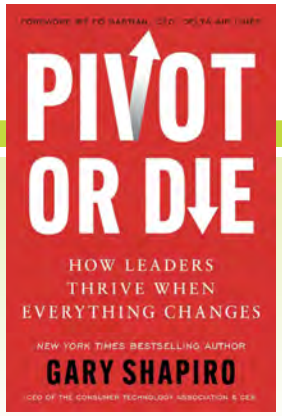
Focused Ultrasound **highlighted**

"It is breathtaking, the number of disorders… that might be impacted by the groundbreaking, innovative use of this technology."

— **Juju Chang**
ABC News *Nightline* co-anchor

At the Lake Nona Impact Forum, Emmy Award-winning co-anchor of **ABC News' *Nightline***, Juju Chang, moderated a panel discussion highlighting focused ultrasound's transformative potential.

The event featured Board member John Grisham, Neal F. Kassell, MD, and a patient, Beverly, who shared her life-changing experience with focused ultrasound for ET. ■



Focused Ultrasound **featured**

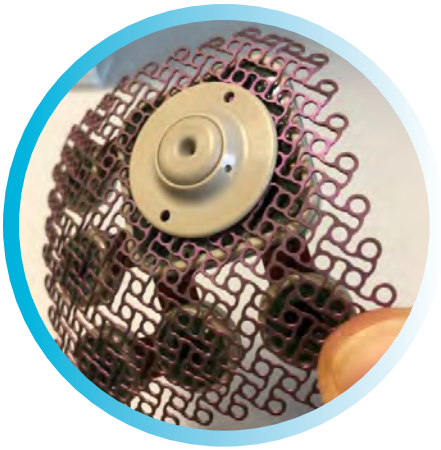
A new book, *Pivot or Die*, by Gary Shapiro—Board member and CEO & Vice Chair of the Consumer Technology Association—distills 40+ years of tech innovation into a practical guide on adaptability and leadership. It includes a section on how the Foundation has advanced focused ultrasound under the leadership of Neal F. Kassell, MD. ■

Left to right
Juju Chang, Neal Kassell, MD, John Grisham, and Beverly

commercialization

Business advancement

Later-stage focused ultrasound companies saw strong support from investors and strategic partners in 2024, while earlier-stage financings continued to be limited, in line with the medical device industry in recent years. Early-stage companies also found creative paths to continue developing the data needed to commercialize focused ultrasound treatments for patients in the future. ■



Carthera's SonoCloud-9® device

Orphan drug designation

Carthera's SonoCloud-9® device—in combination with carboplatin—received Orphan Drug Designation by both the **US FDA** and the **European Medicines Agency** to treat malignant glioma. This special status for treating rare diseases includes financial incentives, expedited review, and market exclusivity to encourage development. ■

$**100**M+ financings

Two major focused ultrasound manufacturers, **Insightec** and **HistoSonics**, each raised over $100 million this year, with Insightec closing a $150 million Series F round and HistoSonics securing a $102 million Series D round. ■

Treatment for **veterans**

Within 18 months of FDA clearance of its Edison® Histotripsy System for liver cancer, **HistoSonics** was awarded a $90 million exclusive contract with the **Veterans Affairs** hospitals, the largest integrated healthcare system in the US. ■

Strategic partner **interest**

Profound Medical announced a partnership with **Siemens Healthineers** for the treatment of prostate cancer, and **Exact Therapeutics** announced a strategic collaboration with **GE HealthCare**, which included a $13 million investment to support the development of Exact's Acoustic Cluster Therapy to treat pancreatic cancer. ■

donor spotlight

Kissick Family Foundation

The Kissick Family Foundation is committed to catalyzing change through bold and dynamic philanthropy, providing early support for leaders, researchers, and entrepreneurs tackling urgent challenges. It invests in scientific research and awareness-building efforts for neurodegenerative diseases, with a particular focus on frontotemporal dementia (FTD).

The Kissick family learned about the Focused Ultrasound Foundation through Board member Michael Milken and Council member Lorraine Spurge, whose advocacy for medical innovation encouraged them to get involved. The family's connection to focused ultrasound is personal—John Kissick, the family foundation's founding president, lived with both FTD and essential tremor. Their interest in focused ultrasound deepened as they learned that essential tremor is one of the first FDA-approved clinical applications for the technology, and as they witnessed its impact on patients. The family shared:

"What stands out is the potential for focused ultrasound to provide noninvasive treatment options for conditions that currently have few effective solutions.

We encourage others to look at the impact focused ultrasound is already having for conditions like tremors, prostate cancer, fibroids, and more.

Supporting the Focused Ultrasound Foundation helps move these innovations forward."

Kissick family

To support the Focused Ultrasound Foundation visit the **website** or contact:

Jessica Lukens
jlukens@fusfoundation.org

our campaigns

Saving Time, Saving Lives

The Foundation is actively securing support for critical focused ultrasound initiatives, including Alzheimer's disease, Parkinson's disease, ALS, cancer immunotherapy, OCD, and depression.

Three-year campaigns

$20M

Cancer

Cancer immunotherapy

$15M

Brain indications

Neurodegenerative and psychiatric

One-for-one match

A generous anonymous donor pledged a $15 million gift in 2024 to be matched one-for-one. The Foundation is currently funding more than 110 projects with a total budget of approximately $20 million.

When fulfilled, this $30 million infusion will accelerate vital research and advance focused ultrasound technologies to clinical application.

Awareness events

Awareness events take place globally throughout the year to educate others about the promise and potential of focused ultrasound.

Platinum Transparency 2024 Candid.

Charity Navigator FOUR-STAR

Did you know?

Focused ultrasound may transform treatment for more than 180 serious medical conditions, ultimately improving the quality of life and longevity for millions of people around the world. But much more work remains.

Did you know?

Your investment will help desperately ill patients by making this noninvasive, life-changing treatment available in the shortest time possible.

Join the revolution, help us make the future now. ■

Ways to **give**

Please give to the Focused Ultrasound Foundation by taking advantage of one of the following options:

By Mail

Make check payable to Focused Ultrasound Foundation
Mail to 1230 Cedars Court, Suite 206, Charlottesville, VA 22903

Donor-Advised Funds

Give from your donor-advised fund, by recommending to your financial institution how much and how often you want to contribute.

Gifts of Stock

Donating stock is highly tax efficient. Effectively, you can often give 20%+ more than by gifting cash.

IRA Distributions

If you are 70½ or older, you can make a charitable gift directly from your IRA as a qualified charitable distribution up to $100,000.

Gifts in Tribute

Honor friends, family members, and valued health care professionals by making gifts in honor or memory of individuals.

Online

Visit **fusfoundation.org/donate**

Contact Jessica Lukens at jlukens@fusfoundation.org or 434.326.0924 to learn how you can support our mission.

The Foundation is a unique 501(c)3 medical research, education, and advocacy organization.

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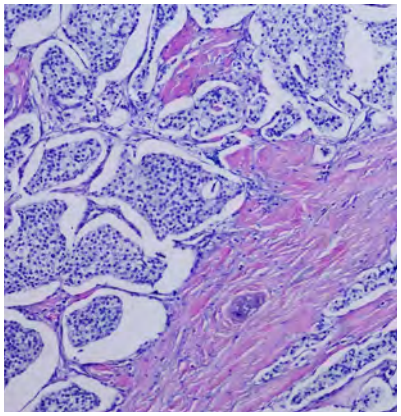

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