Our Critical Mission

The Foundation’s mission to shorten the time it takes for focused ultrasound to become a global standard of care has never been more important. While much has been accomplished, it is increasingly apparent that there is greater potential for the technology than anyone anticipated; accordingly, there is much more work to be done.

The Foundation continues to thrive as a unique medical research, education, and advocacy organization. The litmus test of every action we take and every dollar we spend continues to be, “Will it help a patient?” We are pleased that the Foundation is funding a record 26 focused ultrasound projects in seven countries this year alone, for conditions such as Alzheimer’s; tumors of the brain, breast, and pancreas; and twin-to-twin transfusion syndrome.

The fuel for the Foundation’s success—and of the field in general—is the generous support of an incredible group of donors who have become our friends and our partners in this journey to revolutionize therapy to decrease death, disability, and suffering for countless people. On behalf of the entire Focused Ultrasound Foundation and the patients who will ultimately benefit, thank you.

Be well.

Neal F. Kassell, MD
Numerous patients worldwide have been treated with focused ultrasound this year in trials funded by the Foundation, leveraging co-funding support from our partners.

**Research highlights**

A record-setting number of projects were funded in the first half of the year, surpassing the 12-month totals of both 2020 and 2021. The total Foundation spend on these 26 projects is nearly $3.8 million.

- **15+ distinct clinical indications** in 2022 Foundation funded clinical trials, including—
  - Gastrointestinal
    - Colorectal cancer
    - Pancreatic cancer
  - Musculoskeletal
    - Soft tissue cancer
  - Neurological
    - Alzheimer’s disease
    - ALS
    - Brain metastasis
    - Dystonia
    - Epilepsy
    - Neuropathic pain
    - Pediatric brain tumors
  - Women's health
    - Breast tumors

- **7 countries** have ongoing Foundation funded clinical trials—
  - Canada
  - Japan
  - Korea
  - The Netherlands
  - Taiwan
  - United Kingdom
  - United States

- **26 Foundation funded projects** January – June 2022

- **8 clinical projects**

- **+18 preclinical projects**

- **$3.8M**
Neuropathic pain
Terri’s story

Terri was diagnosed in 2016 with neuropathic pain, which forced her to quit her job and made simple tasks—like sitting, driving, and holding her grandchild—“unbearable.”

Terri underwent multiple surgeries and tried various pain medications, all of which provided no relief. “The pain just overtook everything,” she says. “It was awful.”

Eventually, however, Terri found a focused ultrasound trial* at the University of Maryland Medical Center, and Dheeraj Gandhi, MD, and his team successfully treated Terri’s pain with focused ultrasound in fall 2020. The treatment “was like a miracle,” she says. “I felt like a kid getting Christmas presents. I simply could not believe that focused ultrasound took all my pain away.”

Two years later, Terri continues to feel well and is active and grateful.

Chronic neuropathic pain is a debilitating condition that involves dysfunction and disease of nerves within the brain, spinal cord, and appendages. The pain is often described as burning, pins and needles, numbness, and/or itching. Focused ultrasound can noninvasively destroy tissue in the brain where chronic pain signals originate, thereby decreasing or completely eliminating pain.

“This was my last hope, and it worked,” says Terri. “Focused ultrasound truly gave me my life back, and I’m ‘me’ again. I’m so very thankful.”

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Read Terri’s full story on the Foundation’s [website](#).

* This trial has completed enrollment.
The world’s first focused ultrasound cancer immunotherapy center has been launched, helping advance cancer immunotherapy treatment.

**new center**

**Advancing cancer treatment**

The world’s first center dedicated to advancing a focused ultrasound and cancer immunotherapy treatment approach that could revolutionize 21st-century cancer care was launched in the spring. The Focused Ultrasound Cancer Immunotherapy Center at the University of Virginia (UVA) in Charlottesville, VA, aims to better understand focused ultrasound’s ability to improve a patient’s immune response to their cancer. The center’s goals include:

- **understanding** how to optimize the antitumor effect of focused ultrasound
- **developing** new focused ultrasound technologies
- **improving** quality of life and survival while enhancing access to cutting-edge care and reducing costs

“Focused ultrasound is proving to enhance the effectiveness of cancer immunotherapy throughout the cancer immunity cycle in a variety of ways,” said Neal F. Kassell, MD, Founder and Chairman of the Foundation, which funds focused ultrasound cancer immunotherapy research around the world. “It can stimulate the body’s immune response to convert immunologically ‘cold’ tumors into ‘hot’ tumors, making more patients responders; enhance the delivery of immunotherapeutics to tumors; and augment the effectiveness of immunotherapeutics to enable more robust and prolonged response to drugs and decrease the doses needed.”

The $8 million combined initial investment from UVA, the Commonwealth of Virginia, and the Foundation will fund cutting-edge research, launch clinical trials, and create jobs.
Focused Ultrasound Foundation | 2022 Midyear Highlights

Center's co-directors

1. Craig Slingluff, MD
   Joseph Helms Farrow Professor of Surgery
   Director of UVA Cancer Center's Human Immune Therapy Center

2. David R. Brenin, MD
   M.C. Wilhelm Professor in Diseases of the Breast
   Division Chief of Breast and Melanoma Surgery, UVA Health

3. Richard Price, PhD
   Lawrence R. Quarles Professor of Biomedical Engineering at UVA

Cancer immunotherapy

CI is the stimulation of the immune system to treat cancer, improving on the body’s natural ability to fight the disease.

Research trials

The multi-disciplinary team of investigators at the UVA Focused Ultrasound Cancer Immunotherapy Center has developed a robust preclinical and clinical research program, including three groundbreaking cancer trials that are currently active. Two trials are pairing focused ultrasound with an immunotherapy drug in patients with metastatic breast cancer or solid tumors. A third trial is using focused ultrasound plus chemotherapy to activate the immune response in patients with early-stage breast cancers.

More information, including how to enroll, can be found at: bit.ly/UVA-CI-clinical-trials.

Updates will be shared at the Foundation's biennial symposium.

Please direct any questions about the new center or the Foundation's robust cancer immunotherapy program to: Jessica Foley, PhD
jfoley@fusfoundation.org
In response to the progress of focused ultrasound throughout the world, the Foundation is expanding.

### International Expansion

**UK Foundation**

Meet the **Chairman**

Philip C. Keevil is the Chairman of the newly formed UK Focused Ultrasound Foundation, and an advisor to the US Foundation. An investment banker with more than 40 years of merger advisory experience, he has also advised many nonprofit entities.

Mr. Keevil is focused on advancing UK research by increasing local support for leading researchers and clinicians, establishing partnerships with UK-based disease-specific charities, and increasing awareness.

A dual British and American citizen, Mr. Keevil was the Vice Chairman of the British American Chamber of Commerce, a founding member of the Business Advisory Forum of Oxford’s Said Business School, and a director of Americans for Oxford. He holds an MA from Oxford and an MBA from Harvard.

“The UK Foundation provides the unrivaled opportunity to move the needle in UK healthcare. We can help advance the treatment of various cancers and brain diseases like Alzheimer’s and Parkinson’s.”

— Philip Keevil

**Asia Updates**

This June, the US Focused Ultrasound Foundation and Focused Ultrasound Hong Kong Foundation co-hosted an inaugural virtual event in Asia which highlighted the rapid expansion of focused ultrasound in the region.

- The US Foundation is currently supporting **11 research projects** in Japan, South Korea, and Taiwan.
- As of 2021 in the region, there were **25 device manufacturers** and **394 treatment sites**.
- **29 focused ultrasound indications**— currently have regulatory approval in Asia.
cultivating the next generation

future leaders

New scholars initiative

The Foundation launched the ACCESS FUS Scholars Initiative in 2022 to provide educational and research opportunities to undergraduate and early-career scholars from underrepresented and underserved backgrounds.

As part of our mission to cultivate the next generation of focused ultrasound leaders, the program will help create a focused ultrasound community that is more diverse and inclusive and create career paths for those who would not otherwise have the opportunity. The goal is to ensure the best and brightest choose careers in focused ultrasound, thereby strengthening our entire field.

Building upon current internship initiatives, the Foundation will also establish a new postdoctoral fellowship position.

ACCESS FUS is supported by a dedicated fund, and the first gift was generously made by Gladstone Jones, former Vice Chair of the Xavier University of Louisiana Board of Trustees.

Interested in supporting or partnering with this initiative? Contact: Jessica Foley, PhD at jfoley@fusfoundation.org

Summer interns’ projects

1. Ella Taylor
   Duke University
   Simulating and Building Low-Cost Ultrasound Transducers

2. Abey Babu
   Virginia Tech
   Assisting in the Information Technology (IT) Program

3. Adeoluwa Adedeji
   Xavier University of Louisiana
   Acoustic Lens Design

4. Leticia Banda
   American University
   Focused Ultrasound Symposium Sponsorship and Senior Executive Shadowing

5. Erick Lassair, Jr.
   Xavier University of Louisiana
   Analysis of Focal Point and Peak Negative Pressure due to Transducer Fabrication Error

6. Kavya Parekh
   University of Virginia
   A Comprehensive Review of Focused Ultrasound for Diffuse Intrinsic Pontine Glioma (DIPG)

7. Velan Shanmuganathan
   University of Virginia
   Focused Ultrasound Indication Scripts for Social Media
State of the Field Report helps predict important trends in focused ultrasound for key audiences—patients, clinicians, investors, manufacturers, and donors.

**Why collect and publish data**

The State of the Field (SOTF) Report is a major endeavor, produced annually to inform all stakeholders in the focused ultrasound ecosystem of the progress in the field. It provides highlights of the past year as well as trend data over several years to forecast where the field may be headed next and help speed the time to widespread approval and access. The Report’s highlights and trends cover the full spectrum of preclinical proof-of-concept to clinical trials—as well as regulatory and reimbursement status, which are critical components of the pathway to increased patient access to the technology. Commercialization efforts are also included as successful companies are critical to bringing focused ultrasound to patients as quickly as possible.

**2022 highlights**

The 2022 State of the Field Report features an in-depth look at patient treatments, a spotlight on global sites investigating the various mechanisms of action, and detailed case reports on osteosarcomas, breast cancer, and reimbursement in Italy. The report also contains data related to investments in the field by region, a historical analysis of the time it takes to achieve FDA approval, and intellectual property trends.

The 2022 State of the Field Report is available on the Foundation’s website.

**Report highlights**

- $393m invested in FUS companies
- 11 new indications identified
- 21 new regulatory approvals
- +92k patient treatments
- 13 new companies
- 96 new commercial treatment sites
The Foundation’s hardworking team facilitates programs, publications, workshops, and research.

New team members

Rick Hamilton has joined the Foundation as Chief Technology Officer. Rick is the one of the world’s most prolific inventors with more than 1,040 patents, just behind Thomas Edison. He is an expert in cloud computing, artificial intelligence, machine learning, and blockchain.

Eliza Vellines Phillips is the Foundation’s new Managing Director of Development, leading efforts in fundraising, advancement operations, and increasing awareness.

8th Symposium
23–27 October 2022

Targeted to scientists, clinicians, and other stakeholders, the 8th International Symposium on Focused Ultrasound to be held in October in Bethesda, MD, offers a multifaceted exploration of focused ultrasound.

The live event consists of 25+ moderated expert panel discussions, keynote speakers, and special lectures, and more than 200 prerecorded scientific presentations will be accessible up to one week prior to the live event, with opportunities to interact virtually with presenters.

+25
LIVE panel discussions, keynote speakers, and lectures

+200
PRERECORDED scientific presentations accessible prior to live event with virtual interaction

join us virtually or in person!
reaching our goals

Supporting our mission

Donors who support the Foundation are improving lives worldwide by making focused ultrasound available in the shortest time possible. Thank you for your generous gifts to advance the Foundation’s mission.

Ways to give

We hope you will include the Foundation in your giving plans by taking advantage of one of the following options:

- **Online**
  Online at fusfoundation.org/donate

- **By mail**
  Make payable to Focused Ultrasound Foundation
  Mail to 1230 Cedars Court, Suite 206 Charlottesville, VA 22903

- **Gifts in Tribute**
  Honor friends, family members, and valued health care professionals by making gifts in honor or memory of individuals. Please indicate your choice in the memo line of your check.

- **Gifts of Stock**
  Donating stock is highly tax efficient. Effectively, you can often give 20+% more than by gifting cash. Visit Gifts of Stock on our website to learn more.

- **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.

Double your impact

The Foundation has launched a $10 million campaign to support research of focused ultrasound treatment for neurodegenerative disorders.

Thanks to a generous anonymous challenge, campaign gifts will be matched, 1-for-1, up to $2.75 million.

To learn more contact:
Eliza Phillips
ephillips@fusfoundation.org
434.326.9838
Sharon McBay

Sharon McBay says she has been blessed with many supportive friends and family, including her late husband Wilbur and their children and grandchildren; her Ski Chalet family, a business she and Wilbur started together back in 1969; and the Parkinson’s community, among many others.

It was Wilbur’s experience with Parkinson’s that helped lead Sharon to focused ultrasound many years ago. She attended a focused ultrasound seminar with friends in 2015, and soon after traveled to Charlottesville to tour the Foundation and the Focused Ultrasound Center of Excellence at the University of Virginia.

“I was hooked,” she says. “I vividly remember thinking this life-saving treatment could have saved Wilbur’s life, instead of the deep brain stimulation treatment he had and the resulting infection that ended his life just 10 days later.”

In the time since Sharon began supporting the Foundation, the US FDA has approved focused ultrasound for both tremor-dominant Parkinson’s disease and Parkinson’s dyskinesia, which she says has been particularly encouraging for her.

“Focused ultrasound is saving lives and giving hope,” she adds. “It can help those with serious diseases, including Parkinson’s. The potential is here now in actual practice, trials, and research at key sites worldwide, which need our support.

Over the past seven years, I have seen the Foundation use donations like mine to fund research, build awareness, and make meaningful progress to advance the technology. I believe in the work of Dr. Kassell and the goals of his amazing team. I encourage all to step up to the plate big time and put your money in the best investment you can make—for yourself and your family.”
Board

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Former Co-chair of Neurosurgery, University of Virginia

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