FOCUSED ULTRASOUND FOUNDATION: WHAT WE DO

**CULTIVATE THE NEXT GENERATION**
- 41 Interns
- 11 Fellows

**CREATE KNOWLEDGE**
- 328 Patients treated in 23 clinical trials
- $4.8M spent on completed projects
- $25M earned in follow-on funding

**AGGREGATE & SHARE KNOWLEDGE**
- 7,500 Newsletter Subscribers
- 90,000 Annual Website Visits

**OVERCOME BARRIERS**
- 3 Reimbursement Workshops
- 16 Working Groups

**FOSTER COLLABORATION**
- 15 Communities
- 3 International Databases

**CONVENE THE COMMUNITY**
- 4 Symposia
- 12 Workshops
- 49 External Meetings

**INCORPORATE AWARENESS**
- 232 Media Placements
- 74 Events
Focused Ultrasound Foundation: What We Do

I. Elevator Speech
II. Foundation Overview
III. Fostering Collaboration
IV. Creating Knowledge
V. Overcoming Barriers
VI. Aggregating and Sharing Knowledge
VII. Cultivating the Next Generation
VIII. Convening the Community
IX. Increasing Awareness
The Focused Ultrasound Foundation was created to improve the lives of millions of patients by transforming the treatment of a variety of serious medical disorders using focused ultrasound – an early-stage, revolutionary, non-invasive therapeutic technology.

Focused ultrasound has the potential to improve outcomes and decrease costs by serving as an alternative or complement to surgery, radiation therapy and drug delivery.

A unique, entrepreneurial medical research, education, and advocacy organization, the Foundation is the catalyst to accelerate the development and adoption of focused ultrasound. We work to ensure that this technology finds its place as a mainstream therapy within years, not decades.
Imagine treating cancer, Parkinson’s disease, epilepsy and brain tumors using sound.

For many patients struggling with life-threatening and debilitating diseases, few if any treatment options exist. Numerous others must settle for current therapies, like surgery, radiation and chemotherapy, which may diminish their quality of life.

We strive to provide a better option.

**Focused Ultrasound**

Focused ultrasound is an early-stage, disruptive, noninvasive therapeutic technology with the potential to transform the treatment of a variety of disorders, improve outcomes, and decrease the cost of care. It could eventually be an alternative or complement for traditional surgery, radiation therapy and drug delivery.

Focused ultrasound utilizes multiple intersecting beams of high-frequency sound concentrated accurately and precisely on tissue deep in the body, much like light passing through a magnifying glass can be focused to burn a hole in a leaf. At the point where the beams converge, the ultrasound energy induces a variety of biological effects while avoiding damage to surrounding normal structures. Magnetic resonance or ultrasound imaging is used to identify, guide and control the treatment in real time.

**The Problem**

Unfortunately, it often takes decades for a new therapeutic technology to become mainstream. Every year we shave off that process could reduce death, disability and suffering for countless people.

**The Focused Ultrasound Foundation**

The Focused Ultrasound Foundation is a unique medical research, education and advocacy organization, created to shorten the time from laboratory research to widespread patient treatment. As an entrepreneurial, tax-exempt, 501(c)(3), we act as stewards of our donors’ contributions to maximize our impact on the field.

The Foundation is the catalyst to accelerate the development and adoption of focused ultrasound, clearing the path to global utilization as a standard of care with an approach that is market-driven and results-oriented. To do so, we:

- Influence the direction of the field by setting priorities and defining areas of clinical benefit
- Foster collaboration and stimulate innovation
- Provide resources, both financial and human capital

Major initiatives include:

- Creating knowledge by organizing, conducting and funding research
- Aggregating and sharing knowledge through our website, newsletter, social media and online Journal
- Overcoming barriers, including regulatory and reimbursement challenges
- Cultivating the next generation of clinicians and scientists by supporting internships and fellowships
- Convening the community through symposia and workshops
- Increasing awareness through events and media outreach

The philanthropic support of our donors, who recognize the urgent needs of patients, the potential of focused ultrasound and the value of the Foundation’s disciplined, entrepreneurial approach make this work possible.
This chart portrays the global status of focused ultrasound. The number of indications in various states of development is increasing rapidly, but most are in the early stages of evolution.
The Focused Ultrasound Foundation works to foster collaboration among stakeholders in the focused ultrasound ecosystem in order to rapidly achieve a critical mass of knowledge, effort and results. Collaboration is a catalyst for innovation and a force multiplier for intellectual capital. When people share experience, information, and ideas they can coordinate activities to avoid duplication and enhance their impact.

**Engaging Stakeholders**

Our scientific team maintains contact with more than 40 disease-specific organizations, patient support groups, advocacy networks, trade organizations, councils, and government bodies; 225 research laboratories and 391 treatment sites, in order to facilitate dialogue and provide information about focused ultrasound. In 2014 alone we established relationships with key representatives from the Cancer Research Institute, FDA urology, and the Medical Device Innovation Consortium MDIC, among others.

**Building Communities**

We convene individuals in topic-specific communities to facilitate sharing of information, collaboration, and innovation, through meetings, workshops and symposia (see: *Convening the Community* document). We supplement in-person interaction with online communication tools.

To date this includes groups with interests in:

- Blood Brain Barrier
- Brain Technical
- Brain Technical (FUSF only)
- Brain Technical -- Simulations
- Brain Thermal Dose
- Brain Treatment Envelope
- Cancer Immunotherapy
- Essential Tremor Reimbursement
- Histotripsy
- Neuromodulation
- Osteoid Osteoma
- Pediatrics
- Sonodynamic Therapy
- Targeted Drug Delivery
- Uterine Fibroid Reimbursement

**Maintaining Databases for Patients, Researchers and Manufacturers**

The Foundation provides up-to-date information on research sites, treatment sites, and manufacturers around the world through searchable, online databases. These resources are available on our website at [www.fusfoundation.org](http://www.fusfoundation.org). They are also summarized in a comprehensive report, “*Focused Ultrasound: A Global Perspective,*” produced biannually.
The Focused Ultrasound Foundation’s research program has had an outsized impact on the development of the body of knowledge about focused ultrasound. Since its inception in 2006, the Foundation has funded 76 research projects led by 65 principal investigators at 36 institutions in 10 countries. Of these, 48 have been completed. The Foundation’s investment of $4.8 million into completed projects has resulted in follow-on funding of over $25 million.

Below is a summary of the Foundation supported research to date. Some projects are listed under more than one indication because they served more than one primary research purpose. A more detailed list is available on our website: fusfoundation.org/for-researchers/research.

### Brain

#### Brain Tumors

**Blood brain barrier disruption and delivery of doxorubicin to treat glioblastomas and metastatic brain tumors**: pilot clinical trial.

**Focused ultrasound thermal ablation of metastatic brain tumors and glioblastomas**: pilot clinical trial.

**Sonodynamic therapy for treatment of brain tumors**: pre-clinical study.

**Focused ultrasound cavitation induced ablation of brain tissue**: pre-clinical study.

**Controlled-release nanoparticles to treat brain tumors**: pre-clinical study.

**Microbubble-enhanced ablation by focused ultrasound**: pre-clinical study.

**The effect of focused ultrasound ablation on adjacent nerve function**: pre-clinical study.

#### Essential Tremor

**Treatment of Essential Tremor**: pilot clinical trial.

**Treatment of Essential Tremor**: pivotal clinical trial.

**Treatment of chronic functional brain disorders (thalamocortical dysrhythmia) using transcranial MR-guided focused ultrasound**: pilot clinical trial.
**Parkinson’s Disease**

Treatment of Parkinson’s Disease Dyskinesia: pilot clinical trial.

Treatment of tremor-dominant Parkinson’s Disease: pilot clinical trial.

Focused ultrasound lesioning in the setting of deep brain stimulation: pre-clinical study.

Alzheimer’s and Parkinson’s disease treated by opening the blood brain barrier to facilitate drug delivery: pre-clinical study.

**Alzheimer’s Disease**

Alzheimer’s and Parkinson’s disease treated by opening the blood brain barrier to facilitate drug delivery: pre-clinical study.

**Stroke**

Intracerebral and intraventricular hemorrhage treated with focused ultrasound thrombolysis: pre-clinical study.

**Multiple Sclerosis**

Treatment of de-myelinating axons in multiple sclerosis lesions: pre-clinical study.

**Pyschiatric Disorders**

Treatment of severe medical refractory depression: pilot clinical trial.

**Neuropathic Pain**

Treatment for neuropathic pain: pilot clinical trial.

**Neuromodulation**

Reversible modulation of region specific brain function: pre-clinical study.

Targeted neuromodulation and functional imaging: pre-clinical study.

**Dystonia**

Ablation of the Ventrooralis (Vo) Nucleus of the Thalamus for the Treatment of Focal Hand Dystonia: clinical trial.
Miscellaneous Brain

Pediatrics skull characterization for focused ultrasound: technical.

Optimization of MR imaging sequences for focused ultrasound planning, treatment, and evaluation: technical.

Enhancement of FUS mediated delivery of stem cells to the brain: pre-clinical study.

Measurement of focused ultrasound treatment envelope in a cadaver: pre-clinical study.

Enhanced MR imaging using a custom-built brain coil: technical.

Detection and characterization of intracranial cavitation during focused ultrasound treatment: technical.

Non-thermal treatment using MR-ARFI: technical.

Transcranial sound field characterization using high intensity focused ultrasound: technical.

Study of standing waves and secondary focal spots in transcranial focused ultrasound treatment: technical.

MR bone imaging: technical.

3D volumetric thermometry using MR imaging: technical.

Measurement of treatment envelope created by the 220 kHz and 60 kHz focused ultrasound transducers: technical.

Custom-molded thermal MRgFUS brain phantom: technical.

A radiographic and histologic comparison between radiofrequency, gamma knife radiosurgery, and focused ultrasound lesions in brain: pre-clinical study.

Oncology

Lung Cancer

Treatment of lung cancer with saline flooding of the lung: pre-clinical study.

Pancreatic Cancer

Treatment of pancreatic cancer with focused ultrasound enhanced targeted drug delivery: pre-clinical study.
Prostate Cancer

Treatment of prostate cancer with focused ultrasound: pre-clinical study.

Thyroid Cancer

Treatment of papillary thyroid cancer: pilot clinical trial.

Liver Cancer

MRgFUS therapy for breast and liver cancer treatments: technical.

Breast Cancer

MRgFUS therapy for breast and liver cancer treatments: technical.

Induction of immune response to breast cancer with focused ultrasound tumor ablation: pre-clinical study.

Heterogeneity correction for improved breast cancer ablation: technical.

Head and Neck Cancer

Treatment of head and neck cancer with focused ultrasound: pilot clinical trial.

Pelvic Cancer

Induction of focal hyperthermia for pelvic cancers: technical.

Miscellaneous Cancer

Amplification and localization of cancer biomarkers induced by focused ultrasound: pre-clinical study.

Induction of focal hyperthermia for pelvic cancers: technical.

Tumor radio-sensitization using deep penetrating triggered release nanoparticles: pre-clinical study.

Focal delivery of chemotherapy using ultrasound activated perfluorocarbon nano-emulsions: pre-clinical study.

Guidance of radiotherapy and other therapies for tumors using tattooing creating by focused ultrasound: technical.

Hypoxia-directed magnetic resonance-guided focused ultrasound therapy: technical.

Immunotherapy

Determination of immunomodulation signal profile consequent to focused ultrasound tumor ablation: pre-clinical study.

Induction of immune response to breast cancer with focused ultrasound tumor ablation: pre-clinical study.
**Musculoskeletal**

Osteoid osteoma in children: pilot clinical trial.

Pain alleviation of medial compartment knee osteoarthritis: pilot clinical trial.

Low back pain related to sacrolitis: pilot clinical trial.

Low back pain related to facet arthritis: pilot clinical trial.

Hand and hip osteoarthritis: pilot clinical trial.

**Uterine Fibroids**

Updated costs of uterine fibroid treatments including focused ultrasound surgery: technical.

Fibroid vascular ablation for faster treatment: pilot clinical trial.

Microbubble-enhanced FUS for more efficient therapy for uterine fibroids: pre-clinical study.


**Focal Drug Delivery**

Focal delivery of chemotherapy using ultrasound activated perfluorocarbon nanoemulsions: pre-clinical study.

Creation and validation of a clinically-relevant ultrasound-enhanced drug delivery strategy: pre-clinical study.

Blood-brain barrier disruption and delivery of doxorubicin to treat glioblastomas and metastatic brain tumors: pilot clinical trial.

MRI-guided localized delivery of chemotherapy using paramagnetic temperature-sensitive liposomes and focused ultrasound: technical.

Alzheimer’s and Parkinson’s disease treated by opening the blood brain barrier to facilitate drug delivery: pre-clinical study.

Delivery of DNA particles intranasally: pre-clinical study.

**Other Indications**

**Deep Vein Thrombosis**

Treatment of deep vein thrombolysis using histotripsy: pre-clinical study.

**Diabetes**

Treatment for metabolic syndrome and diabetes by ultrasound ablation of visceral fat: pre-clinical study.
Technology Development

Pediatrics skull characterization for focused ultrasound: technical.

Creation of an Atlas of MR changes in lot produced by focused ultrasound thrombolysis: technical.

Optimization of MR imaging sequences for focused ultrasound planning, treatment, and evaluation: technical.

Enhanced MR imaging using a custom-built brain coil: technical.

Detection and characterization of intracranial cavitation during focused ultrasound treatment: technical.

Non-thermal targeting treatment using MR-ARFI: technical.

Transcranial Sound Field Characterization Using High Intensity Focused Ultrasound: technical.

Study of standing waves and secondary focal spots in transcranial focused ultrasound treatment: technical.

MR Bone Imaging: technical.

Study of standing waves and secondary focal spots in transcranial focused ultrasound treatment: technical.

3D volumetric thermometry using MR imaging: technical.

Measurement of treatment envelope created by the 220 kHz and 60 kHz focused ultrasound transducers: technical.

MRgFUS therapy for breast and liver cancer treatments: technical.

Heterogeneity correction for improved breast cancer ablation: technical.

Induction of focal hyperthermia for pelvic cancers: technical.

Temperature measurement using MR imaging: technical.

The effects of pulsed high-intensity focused ultrasound using a modified clinical MR guided focused ultrasound device: technical.

Enhanced focused ultrasound ablation using metastable perfluorocarbon nanodroplets: technical.

Microbubble cloud formation from ultrasound contrast agents during histotripsy pulses (FDA Collab.): technical.

White Papers

Focal Drug Delivery Program: Workshop 1," March 2011


These papers are available on our website at fusfoundation.org/publications

### Institutions and Investigators

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<tr>
<th>Institutions</th>
<th>Investigators</th>
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<tbody>
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<td>Brigham and Women’s Hospital, Boston</td>
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<td>Seung-Schik Yoo, Ph.D., M.B.A.</td>
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<td>Cincinnati Children’s Hospital</td>
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<td>Columbia University</td>
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<td>Institut Langevin (ESPCI), Paris</td>
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<td>Bordeaux Segalen University, France</td>
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<td>Mayo Clinic</td>
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The Focused Ultrasound Foundation uses its position as a trusted, independent, unbiased third party to form collaborations between industry, academia, FDA and payers that facilitate achieving regulatory approval and reimbursement for new clinical applications of focused ultrasound.

**Regulatory Requirements**

The Foundation participates in an ongoing dialogue with the FDA and works with them to advance focused ultrasound clinical studies and facilitate the establishment of technical standards for focused ultrasound treatments. We simultaneously support researchers in developing clinical study protocols that adhere to FDA standards, and connect them with regulatory experts for guidance.

A major milestone was achieved in 2011 when the FDA officially recognized the field of focused ultrasound and its potential as “a leading-edge technology to perform surgery without incisions,” and as a way to “reduce the number of invasive procedures that patients need.”

**Reimbursement Requirements**

There is not currently widespread reimbursement from private or government payers for focused ultrasound therapy. Until payers are willing to cover focused ultrasound therapy, patients will have limited access to this non-invasive treatment alternative.

To help make a case for coverage, the Foundation is establishing collaborations and developing methods to heighten the likelihood of new applications being considered commercially viable and reimbursable. As new clinical trials are designed, the Foundation is consulting with researchers to ensure that studies are designed from the start not only to demonstrate safety and efficacy, but also to meet insurers’ requirements for superior long-term benefits, quality of life, and cost-effectiveness.

The Foundation has created a working group of researchers, clinicians, and industry experts to identify needs and develop strategies to generate and capture required data. This group has conducted several projects including creating an evidence dossier on uterine fibroids which pulls together all citations on the safety, efficacy, and durability of treatments. The Foundation also launched a website, Fibroid Relief, which is the leading patient education initiative on current treatment options. The site averages over 60,000 visits a year, and the companion Facebook account is growing with over 7,500 followers.
The Focused Ultrasound Foundation works aggressively to provide up-to-date information on the field of focused ultrasound to stakeholders in the medical community and members of the general public. We aggregate and share knowledge through our website and social media, newsletter, and online journal.

**Website and Social Media**

The Foundation’s website, [www.fusfoundation.org](http://www.fusfoundation.org), is the leading online resource for information on focused ultrasound therapies. The site features technology news, interviews with experts, information on conditions which focused ultrasound has shown potential to treat, and databases of treatment and research locations. The site is visited by over 80,000 visitors annually.

The Foundation’s web presence also continues to grow as we spread our social media footprint. In the past year, we’ve seen a 28% increase in Focused Ultrasound Foundation Twitter followers, and over 15,000 views of informational videos on our YouTube channel.

**Newsletter**

Each month, the Foundation distributes a comprehensive e-newsletter to over 7,000 subscribers. The newsletter highlights Focused Ultrasound Foundation news, top stories in the field of focused ultrasound research, academic articles, recent media coverage, and upcoming focused ultrasound community events.

In addition, the Foundation distributes in-depth, news flashes to recognize major focused ultrasound milestones.

**The Journal of Therapeutic Ultrasound**

The *Journal of Therapeutic Ultrasound* is the official publication of the International Society for Therapeutic Ultrasound (ISTU) and the Focused Ultrasound Foundation. The *Journal* is an open access, peer-reviewed online journal featuring translational and clinical research. The editorial board includes over 30 specialists from more than 20 universities and medical centers in 12 countries. To date the *Journal* has published 35 research articles, all of which are available online.

June 23, 2015
The Focused Ultrasound Foundation works to cultivate the next generation of clinicians and scientists through education initiatives including an annual fellowship program and two annual internship programs—one regional and one international. Visit the Foundation website to learn more about these opportunities, and to read about past intern projects.

**Fellowsips**

The Richard Merkin Visiting Fellowship in Focused Ultrasound, launched in 2015, is an opportunity for a mid-career or senior scientist or clinician to work with the technical and scientific team at the Focused Ultrasound Foundation for one year. The fellow has opportunities to conduct original research and participate in ongoing projects.

Our first Merkin Fellow, Dr. Dong-guk Paeng, joined us this winter from Jeju National University in Korea. His fellowship includes an appointment as Visiting Professor at the University of Virginia Department of Radiation Oncology, and a position within the Foundation’s technical brain program, leading efforts to expand on regions that can be treated with focused ultrasound.

**Internships**

Launched in June 2012, the Foundation’s Local Internship Program enables high school, undergraduate and graduate students to work on intensive research projects in collaboration with the Foundation’s technical and scientific team in Virginia. These internships are designed to foster understanding of focused ultrasound as a clinical tool, empower students to address real-world challenges in medical research, and provide opportunities for them to contribute to the field. To date the Foundation has hosted 36 local interns from 12 institutions.

One of the most important things this internship has given me is a better picture of how engineering and science work. We began with an idea, then modeled it with a computer, then purchased materials and tested it. I learned a lot about ultrasound physics, operated an MR machine and a FUS machine, and enjoyed applying my skills to the thermochromic phantom project.


The Foundation’s Global Internship Program, launched in 2014, is a summertime opportunity for high school, undergraduate and graduate students interested in physical and life sciences to receive funding to participate in focused ultrasound research at recognized focused ultrasound sites around the world. These internships are organized in coordination with an academic researcher or industry mentor who provides space, supplies, and close involvement with the intern’s project. In 2014, the Foundation funded 12 interns at 12 different research sites in France, Germany, England, Cyprus, and the United States.
The Focused Ultrasound Foundation is a trusted, unbiased and independent third party which has the unique ability to act as a global connector, linking stakeholders from industry, academia and government to accelerate the progress of focused ultrasound technology.

As the nexus of the focused ultrasound community, the Foundation organizes and sponsors symposia, workshops and meetings to exchange information, foster collaboration and stimulate innovation.

**Symposia**

On a biennial basis, the Foundation hosts Current and Future Applications of Focused Ultrasound, the world’s largest gathering of experts advancing the field of image-guided focused ultrasound.

Targeted to researchers, clinicians, industry, government and others interested in focused ultrasound, the symposium offers a multifaceted exploration of the field, featuring plenary sessions, panel discussions, poster presentations and technical exhibits.

The next symposium will be held August 28 - September 1, 2016.
The Foundation has organized the following symposia to date:

2014 - 4th Current & Future Applications of Focused Ultrasound, 10/12-10/16
2012 - 3rd Current & Future Applications of Focused Ultrasound, 10/14-10/17
2010 - 2nd Current & Future Applications of Focused Ultrasound, 10/17-10/20
2008 - 1st Current & Future Applications of Focused Ultrasound, 10/6-10/7

Workshops

The Foundation organizes small, invitational workshops to address targeted topics, attended by clinicians, engineers, scientists, and physicists from industry, academia, and government. These workshops produce roadmaps of technical, preclinical, and clinical studies needed to further the development and adoption of focused ultrasound.

The Foundation has organized and planned the following workshops to date:

Blood Brain Barrier & Targeted Drug Delivery (co-sponsor: Kinetics Foundation)
Bone
Brain: Imaging
Brain Treatment Envelope I
Brain Treatment Envelope II: Simulation
Brain Treatment Envelope III: Bio-effects
Brain Workshop #1
Brain Workshop #2
Brain Workshop #3
Brain Workshop #4
Essential Tremor Reimbursement Summit
Focal Drug Delivery
Immunomodulation (co-sponsor: Cancer Research Institute)
Liver
Neuromodulation
Pediatrics
Uterine Fibroid Reimbursement Summit
Foundation Supported Meetings

The Foundation provides organizational assistance and financial support to a variety of meetings.

Below are some of the meetings that the Foundation has assisted with to date:

American Association of Physicists in Medicine
20th International Conference on Brain Tumor Research and Therapy
European Society for Hyperthermic Oncology
European Society of Neurosonology and Cerebral Hemodynamics
European Symposium on Focused Ultrasound Therapy
International Symposium on Therapeutic Ultrasound
Italian Association of Medical Physics
Society for Thermal Medicine
Winter and Summer School on Therapeutic Ultrasound
Increasing Awareness
Awareness Events, Media Coverage, Thought Leadership

To increase global awareness about focused ultrasound technology and to enhance and broaden the focused ultrasound community, the Focused Ultrasound Foundation hosts events, actively cultivate media opportunities to highlight research milestones, and takes advantage of speaking and publication opportunities.

**Awareness Events**

The Foundation hosts events, ranging from a biennial update with hundreds of attendees, to intimate lunches hosted for small groups at the Foundation offices, to one-on-one visits with individuals. The purpose of these events is to inform people who can help to spread the word about focused ultrasound, and prospective donors who have the resources and motivation to invest philanthropic dollars to accelerate the development of this revolutionary therapy.

**Media Coverage**

The Foundation actively cultivates media opportunities building on milestones. Thanks in part to our aggressive efforts, in 2014 there were more than 80 news stories about focused ultrasound. This included Foundation-specific stories in top tier press around the world, including a double-feature in *FORTUNE* and the cover story of the European publication *Health Management*. Below is a partial list of the hundreds of media outlets who have covered focused ultrasound since our founding in 2006.


**Thought Leadership**

The Foundation seeks to take advantage of speaking and publication opportunities and maintains an online database tracking peer reviewed journal articles on clinical applications of focused ultrasound. We also prepare an annual State of the Field Report which provides an overview of the state of focused ultrasound research and development around the world, and white papers to summarize the outcomes of workshops and symposia, and to explain the role of policy and philanthropy in the development of new therapeutic medical technologies.