

A stylized circular graphic on the right side of the page. It features a large dark blue circle with several lighter blue, wedge-shaped segments extending from its right edge, resembling a pie chart. Two white curved arrows are positioned around the circle: one at the top pointing right, and one at the bottom pointing left, suggesting a clockwise cycle.

Focused Ultrasound Foundation

2020

Year in Review

fusfoundation.org

195

research projects funded
cumulative

12

webinars

7

new partnerships

214

interns, global scholars,
and fellows
cumulative

10

Centers of Excellence

+70%

increase in views on
YouTube
in 2020





7th

International Symposium

November 2020

Progress Despite Challenges, Reason for Hope

It was a good year for focused ultrasound, in spite of many challenges in 2020 including COVID-19. With your support, the Foundation was able to thrive, and major progress was made in the field.

We saw many groundbreaking discoveries in the technology’s mechanisms of action and clinical indications, successes in regulatory approvals and reimbursement, and the technology’s sixth US FDA approval for the treatment of osteoid osteoma.

A highlight was the 7th International Symposium on Focused Ultrasound, with its virtual format enabling a record number of people—more than 1,800 from 58 countries—to participate.

As we have said before, fields like highly disruptive therapeutic technologies evolve exponentially, from laboratory research to widespread utilization as a mainstream standard of care. And significantly, we have just recently passed the inflection point of the adoption curve, where the dialogue has clearly shifted to “when”—not “if”—focused ultrasound will have an important role to play in the therapeutic armamentarium. We’re now at the very beginning of the transition from a primarily research environment to one of patient- and commercial-treatment.

Maintaining focus in this rapidly exploding ecosystem continues to be a challenge, including determining which mechanisms of action are most likely to translate into new indications and which indications are most likely to provide unique value for patients.

We are also pleased to have a new US president—Joseph R. Biden, who attended our Symposium in 2014—whose longstanding commitment to fact-based policy and science will help expedite the advancement of focused ultrasound for patients worldwide.

Thank you for your continued interest and support of focused ultrasound.

Be happy. Be well.

Neal F. Kassell, MD

32

indications

with regulatory approvals
worldwide



COVID-19 adaptation and resilience

7th International Symposium on Focused Ultrasound

The community has been busier than ever with increased participation:

384 presentations


1,800 attendees

The dissemination of key results at the meeting and in subsequent publications will continue to propel the field toward new and improved therapies for patients. Read the full details of the November symposium on page 12.

The COVID-19 pandemic has had a dramatic impact on all our lives—our homes, our families, our businesses, and our health have all been affected. The focused ultrasound community is no exception, but as we begin 2021, we are awed by this entire community's resilience despite the unpredictable nature of the past year.

In early 2020, focused ultrasound laboratories around the world shut down, clinical trials were halted, and employees moved to remote work. Because most focused ultrasound procedures were deemed “elective,” for many months most patients were unable to access focused ultrasound treatments for essential tremor, pain, or even cancer.

With the shuttering of laboratories have come delays in critical research and a costly loss in time that will push back advances in the field. The pause in clinical trials and commercial



focused ultrasound treatments has also threatened companies and hospitals at the forefront of the field that are pioneering new therapies.

Yet the community's ingenuity and spirit have remained strong: lab meetings, patient consults, and business development meetings have been moved online; awareness and educational webinars have grown our community; and laboratory and manufacturing resources have been directed to meet critical need.

The field response

In the latter half of 2020, we have seen laboratories resuming work, important clinical trials restarting, and some workers returning to offices.

Focused ultrasound is well positioned to help address the challenges of our "new normal" as our healthcare system seeks to rebuild. Treatments are noninvasive, with less risk of infection than the alternatives, and are also typically outpatient procedures, not taking up much-needed hospital beds; also, with no ionizing radiation and no systemic toxicity, focused ultrasound is less likely to impair a patient's immune system, which could make them more susceptible to SARS-CoV-2 or other pathogens. Patients considering focused ultrasound treatment should feel confident that they can maintain their treatment plan without additional risk.

Optimism in our "new normal"

Of course, there is reason for optimism with the first vaccines now available, and their development in record time shines a light on how public-private investments, unprecedented

collaboration, and a collective sense of urgency can accelerate the timelines for critical biomedical advances. These principles guide the Foundation in our own efforts to bring life-changing and life-saving technology to patients as quickly as possible.

Although this global health and economic crisis is far from over, the focused ultrasound community has demonstrated great resilience over the past year, and we will all continue to rise to the challenges ahead because we know that patients are counting on us. The Foundation is proud to stand with and support our community as we all strive to continue saving time and saving lives. ■

▶ **Groundbreaking discoveries were achieved** this year in focused ultrasound's mechanisms of action and clinical indications, despite the temporary slowing down of research worldwide due to COVID-19.

Research programs and indications

The Foundation's **research program** is the cornerstone of all our activities and includes:

- external rewards
- brain
- body
- immunotherapy/immuno-oncology
- veterinary
- pediatrics

Nearly 40 **clinical indications** are being studied, including:

- benign and malignant tumors
- brain and CNS disorders
- OCD
- depression
- epilepsy

New indications in areas related to:

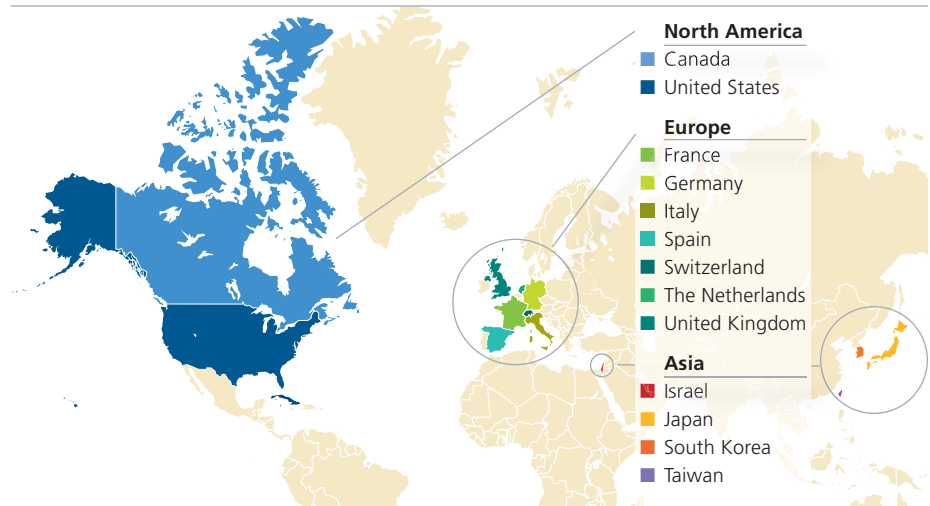
- Parkinson's disease
- glioblastoma
- essential tremor

Research update

195 To date, we have funded 195 research projects at a variety of institutions across the globe:

55 • institutions

13 • countries



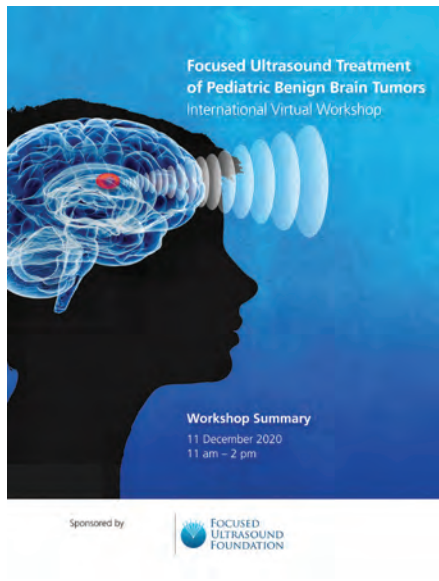
72 Currently, we are managing a portfolio of 72 funded projects on a variety topics, including:

- blood-brain barrier opening • drug delivery • gene therapy •
- histotripsy • immunomodulation • mechanical cell disruption •
- neuromodulation • radiosensitization • sonogenetic therapy •
- tissue destruction •

Pediatrics program

Ignited by two major Foundation milestones, the Pediatrics Program was revitalized in 2020.

- In September, Children’s National Hospital in Washington, DC, became the first pediatric **Focused Ultrasound Center of Excellence**. As such, the team of pediatric physicians who are leading the Center will be well supported to explore pediatric oncologic applications of focused ultrasound.
- In November, focused ultrasound treatment for **osteoid osteoma**—a condition that primarily affects the pediatric population—received FDA approval through the Humanitarian Device Exemption, HDE, Program.

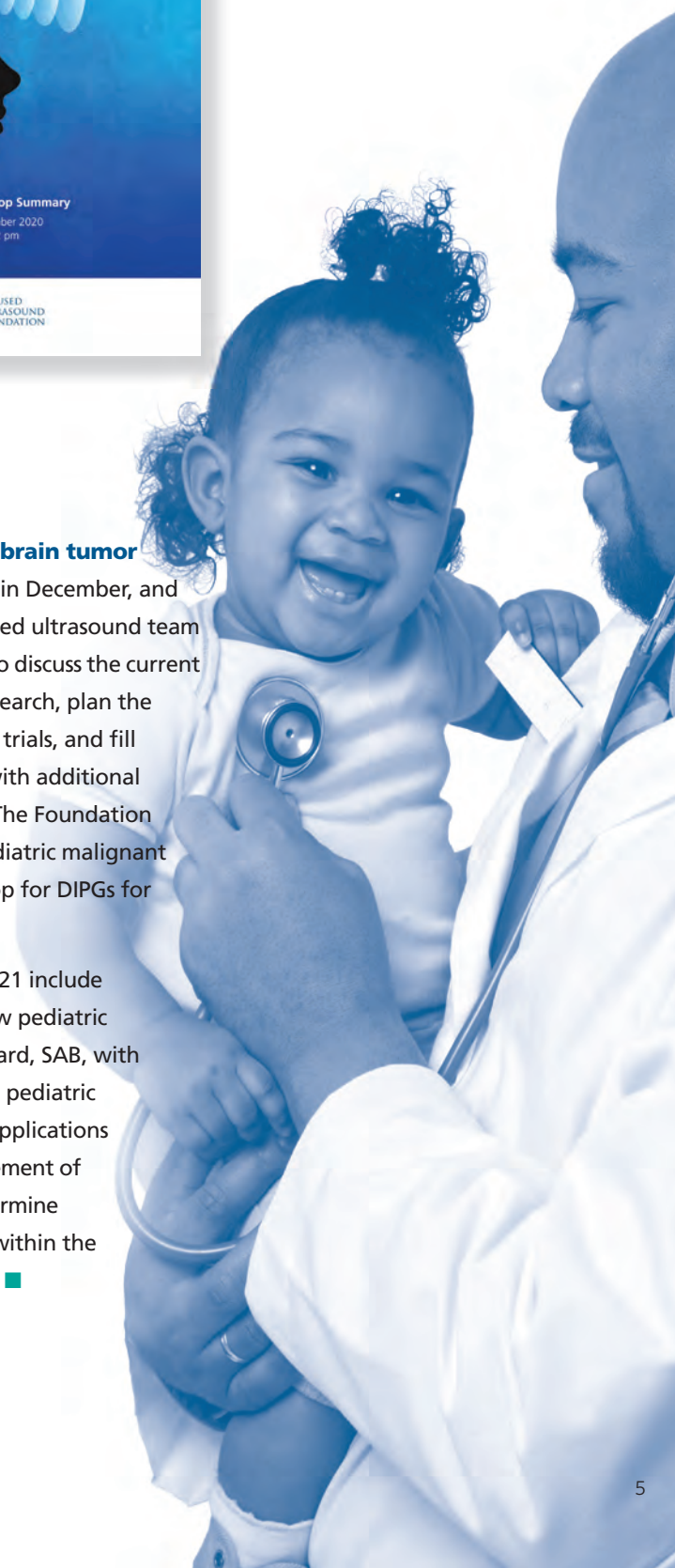


◀ Workshop white paper available online

Pediatrics workshop

A **pediatric benign brain tumor workshop** was held in December, and a committee of focused ultrasound team members convened to discuss the current status of ongoing research, plan the next steps for clinical trials, and fill in knowledge gaps with additional preclinical research. The Foundation is also planning a pediatric malignant brain tumor workshop for DIPGs for the summer of 2021.

Program goals for 2021 include the assembly of a new pediatric scientific advisory board, SAB, with experts to oversee all pediatric focused ultrasound applications as well as the engagement of a focus group to determine critical unmet needs within the pediatric population. ■



► Strategic partnerships in cancer immunotherapy educate thousands about the technology's promising role in this critically important field.



To date, the webinar featuring Jill O'Donnell-Tormey has reached more than 1,000 people.

\$5m

The Foundation has launched a \$5 million, five-year campaign to support research of focused ultrasound's role in cancer immunotherapy.

Cancer Immunotherapy

The Foundation recognizes that the intersection of focused ultrasound and cancer immunotherapy offers a highly promising opportunity for combination approaches to treat a variety of cancers. Through our **Cancer Immunotherapy Program**, launched in 2015, and in collaboration with our partners and the research community, we aim to explore and assess the full potential of focused ultrasound to turn this promise into reality in the shortest time possible.

In recognition of this year's 8th annual **Cancer Immunotherapy Month™** in June, the Foundation coordinated with the Cancer Research Institute, CRI,—a leader in the field of cancer immunotherapy and an important partner to the Foundation—throughout the month to help raise awareness of immunotherapy for all types of cancer and to emphasize the role of focused ultrasound.

Awareness activities conducted for Cancer Immunotherapy Month™ included the following:

- A **webinar** featuring Cancer Research Institute CEO, Jill O'Donnell-Tormey, PhD, and the Foundation's chief scientific officer, Jessica Foley, PhD, discussing the lifesaving potential

of cancer immunotherapy and the ways that CRI and the Foundation are working together to advance exciting research, through the lens of the new COVID-19 environment.

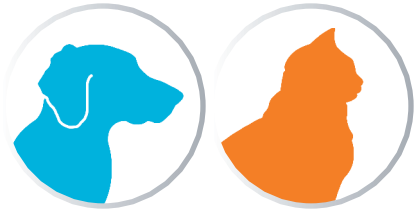
- A **Cancer Immunotherapy Focus Feature** highlighting important progress that has been made in the field and key Foundation activities in our flagship program.

- A dedicated **web page**, "Cancer Immunotherapy at a Glance," providing videos, workshop summaries, helpful links, and periodic updates on the Foundation's efforts to accelerate the powerful intersection of focused ultrasound and cancer immunotherapy.

- The launch of a five-year, **\$5 million campaign** supporting research on focused ultrasound's role in cancer immunotherapy.

- The Foundation's demonstration of commitment by joining together in wearing white for CRI's **Wear White Day** on June 12.

- The Foundation's sharing of key cancer immunotherapy moments in the field of focused ultrasound throughout June across our **social media channels**, which reached more than 35,000 people.



Virginia Tech's **three clinical trials**

Veterinary trials make new innovative therapies available for family pets, while simultaneously collecting data that can be used to advance human medicine. The Foundation's veterinary program now includes three active clinical trials at Virginia Tech, exploring the areas of brain tumors, histotripsy for soft tissue tumors, and histotripsy for osteosarcoma in canines. Notably, Virginia Tech's state-of-the-art Animal Cancer Care and Research Center also opened in November and is devoted to researching noninvasive treatment options, including focused ultrasound for dogs and cats. ■



OSU's **studies and trials**

Additional vet studies continue at Oklahoma State University, including a clinical trial funded by the Foundation for oral melanoma (thermal ablation + immunostimulatory aspect) in dogs. With the FDA approval of nanoparticles + focused ultrasound to treat canines, OSU has also begun commercially treating canine patients, including the use of focused ultrasound to deliver chemotherapeutic nanoparticles to soft tissue tumors. ■



SABs for **equine and pets**

NEW

For more information on the Foundation's vet program, including the newly established Equine scientific advisory board, SAB, or our small animal SAB, please contact Kelsie Timbie, PhD at ktimbie@fusfoundation.org.



veterinary program

▶ Our research programs are the cornerstone of our activities and are rapidly paving the way to transforming treatment across a wide array of indications and body systems.

2020

saw major advances in research for treating the brain. Clinical trials focused on opening the blood-brain barrier to deliver drugs, targeting new areas of the brain to treat Parkinson's disease, bilateral treatments for essential tremor, and many others.

Brain program

▶ Glioblastoma

The first patient was treated in CarThera's "SoniMel" clinical trial at St. Louis Hospital in Paris, which is using focused ultrasound to treat brain metastases, or secondary tumors, by delivering immunotherapeutic drugs directly to the brain.

The first patient was enrolled in a new NaviFUS trial at Linkou Chang Gung Memorial Hospital in Taiwan to evaluate using focused ultrasound to open the blood-brain barrier and facilitate the delivery of the chemotherapy drug bevacizumab in patients with recurrent glioblastoma. ■

▶ Essential tremor

A team of researchers in Madrid, Spain, and another team in Toronto, Canada, were the first in the world to use focused ultrasound to open the blood-brain barrier in a new area of the brain—the striatum—in patients with Parkinson's disease to potentially curb, or even reverse, its progression. In the Toronto trial, patients were also administered the drug Cerezyme. ■

▶ Alzheimer's disease

Two clinical trials at multiple locations in the US are seeking to open the blood-brain barrier in an attempt to delay the progression of Alzheimer's disease. Additionally, a preclinical study at Sunnybrook Research Institute in Canada was published demonstrating that focused ultrasound plus microbubbles improved the delivery of intravenous immunoglobulin to the brain, which can reduce the plaques associated with Alzheimer's disease. ■

2 researchers receive **Lockhart Memorial Prize**

Body program

▶ Prostate

A study at the University of Southern California's Keck School of Medicine represents the first published data on patients treated in the United States, demonstrating that focal image-guided focused ultrasound ablation of prostate cancer is an effective alternative to prostatectomy or radiation therapy and has fewer side effects. ■

▶ Liver

Minnesota-based HistoSonics received [Investigational Device Exemption approval](#) from the FDA to begin its first clinical trial in the US, called #HOPE4LIVER, to investigate the use of histotripsy to noninvasively and mechanically destroy liver tumors. ■

Matthew Bucknor, MD, associate professor of radiology at the University of California, San Francisco, and **Pejman Ghanouni**, MD, PhD, assistant professor of radiology at Stanford University, were awarded the [2020 Andrew J. Lockhart Memorial Prize](#), which recognizes outstanding contributions in advancing cancer treatment using focused ultrasound, and the potential for continued achievements in the field.

In a break from tradition, the Foundation awarded two prizes this year. "Dr. Bucknor and Dr. Ghanouni's active collaboration and passion for the treatment of intractable cancers—coupled with their interest in immune-based focused ultrasound treatments—made them equally deserving of the award," said Jessica Foley, PhD, the Foundation's chief scientific officer. ■



Matthew Bucknor, MD



Pejman Ghanouni, MD, PhD



Andrew J. Lockhart

Post-doctoral fellowship established

Through the generosity of the Lockhart family, the Foundation has created a one-year fellowship—the [Andrew J. Lockhart Postdoctoral Fellowship in Focused Ultrasound and Immuno-Oncology](#)—pairing focused ultrasound investigators with

immunology laboratories, and/or immuno-oncology investigators with focused ultrasound laboratories, to continue identifying and cultivating the best minds in the field, both in the US and abroad. The first award recipient will be announced in 2021. ■

► List of luminary sites grows to 10 worldwide, with the addition of new Centers of Excellence in Washington, DC, and the Netherlands.

The Centers of Excellence program was established in 2009 and brings together the best people and technical resources at luminary sites. The Centers are created through partnerships of academia, industry, and the Foundation to showcase the technology and serve as hubs for collaboration.



9

Children's National Hospital

In September, Children's National Hospital, CNH, in Washington, DC, became the first pediatric medical center to be named a [Focused Ultrasound Foundation Center of Excellence](#), and the ninth Center of Excellence worldwide.

The Center is led by Karun Sharma, MD, PhD, director of interventional radiology and associate director of clinical translation at the Sheikh Zayed Institute for Pediatric Surgical Innovation at CNH, and AeRang Kim, MD, PhD, associate professor of pediatrics and a member of CNH's solid tumor faculty. In this effort, Drs. Sharma and Kim will work with a multidisciplinary team of clinicians and investigators from radiology, oncology, surgery, orthopedics, neurosurgery, and urology. ■



10

University Medical Center Utrecht

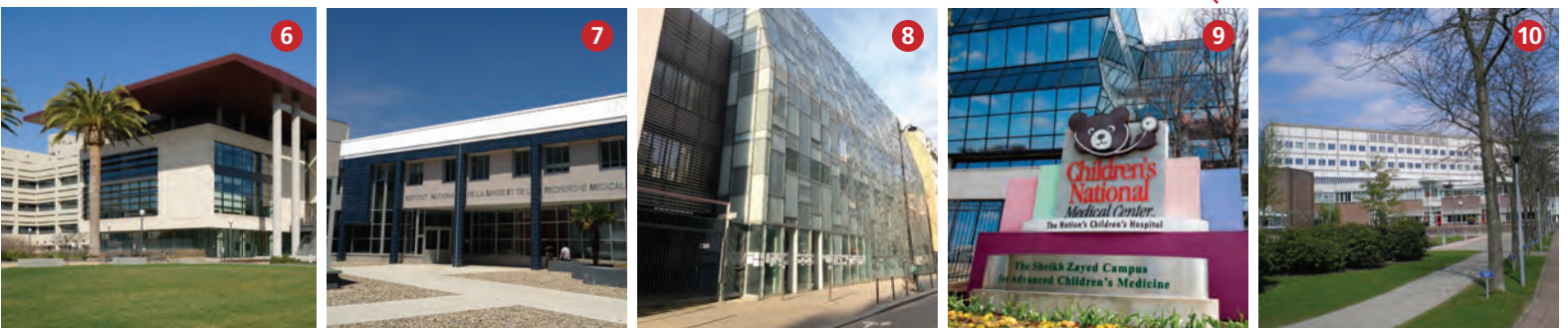
The Foundation has named University Medical Center Utrecht (UMC Utrecht), in the Netherlands, as the latest [Focused Ultrasound Foundation Center of Excellence](#). UMC Utrecht is the fourth European Center of Excellence and the tenth worldwide.

UMC Utrecht has been recognized for their innovative vision and for increasing the synergy among image-guided therapies—incorporating focused ultrasound, nuclear medicine, radiotherapy, radiology, and oncology into a single division. ■

Centers of Excellence

- 2019
Physics for Medicine Paris
Paris, France 2019
- 2017
Inserm - LabTAU
Lyon, France
- 2016
Stanford University School of Medicine
Stanford, CA
- 2016
Sunnybrook Health Sciences Centre
Toronto, Canada
- 2016
University of Maryland School of Medicine
Baltimore, MD
- 2015
Brigham and Women's Hospital
Boston, MA
- 2013
The Institute of Cancer Research and The Royal Marsden
London, England
- 2009
University of Virginia Health System
Charlottesville, VA

creating knowledge research milestones ◀



▶ **Record-breaking attendance**, keynotes from esteemed experts in the field, and hundreds of scientific presentations featured at virtual Symposium.

Expanded **audience**

In November, the Foundation hosted the **7th International Symposium on Focused Ultrasound**, the world's leading forum for sharing the latest translational and clinical advances in focused ultrasound. Targeted to scientists, clinicians, and other stakeholders, the conference offered a multifaceted exploration of focused ultrasound and showcased the tremendous progress in the field.

The virtual format of last year's meeting, due to the COVID pandemic, facilitated the sharing of information and knowledge and drastically increased participation of every kind.

Attendance increased by 300%

1,800

Global participation nearly doubled

58 countries

Presentations totaled

384

There was also an enormous increase in content shared, including keynote addresses and special lectures, scientific presentations, panels, fireside chats, and roundtable discussions. The meeting was extended by an extra day and a half, and included parallel tracks on the final day, due to expanded content.

Presentation videos are archived on the Symposium YouTube channel.



Symposium proceedings can be found on our [website](#).

virtual symposium



1



2



3

Special lectures

Chetan Bettegowda, MD, PhD, Professor of Neurosurgery at Johns Hopkins Medicine, and **Graeme Woodworth, MD**, Professor of Neurosurgery at the University of Maryland School of Medicine, discussed liquid biopsy.

Merit Cudkowicz, MD, Chief of Neurology at Massachusetts General Hospital, Dr. Cudkowicz presented clinical trial ideas for therapeutics in neurodegenerative disorders.

Renana Eitan, MD, From the Functional Neuroimaging Lab of Brigham & Women's Hospital and Harvard Medical School, Dr. Eitan discussed FUS for psychiatric disorders.

Howard R. Soule, PhD, Executive VP and Chief Science Officer of the Prostate Cancer Foundation (PCF), Dr. Soule discussed PCF's achievements in advancing the field.

Keynote speakers

1

▶ **James P. Allison, PhD**
Nobel Laureate and Chair of Immunology at MD Anderson Cancer Center, Dr. Allison shared his experience studying cancer immunotherapies.



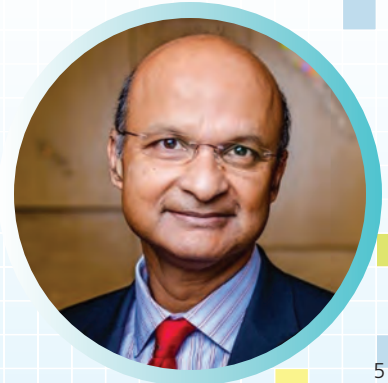
4

2

▶ **Clifton Leaf**
Editor-in-Chief of FORTUNE, Mr. Leaf presented, "Want To Go To the Moon? Build a Road."

3

▶ **Michael Milken**
As Milken Institute Chairman, Mr. Milken discussed his personal journey to the frontiers of medical science.



5

4

▶ **Ralph Northam, MD**
The Governor of Virginia, and pediatric neurologist at Children's Hospital of the King's Daughters, addressed focused ultrasound's impact in the state.

5

▶ **Omar Ishrak, PhD**
Chairman of the Board at Medtronic and Intel, Mr. Ishrak presented, "The Role of MedTech in Driving Patient Outcomes."

 Strategic partnerships explore shared goals with a variety of like-minded organizations to improve health and wellness around the world by aiming to advance focused ultrasound.

A new partnership



The Foundation joined forces with the **Blood Profiling Atlas in Cancer**, BloodPAC—a nonprofit consortium dedicated to accelerating the development, validation, and clinical use of liquid biopsy assays—to explore focused ultrasound’s potential in this burgeoning field.

Similar to the Foundation, BloodPAC has an extensive collaborative infrastructure that enables sharing of information between stakeholders in academia, industry, and regulatory agencies. Several Foundation team members will join BloodPAC working groups—on topics including reimbursement, sustainability, and patient context variables—and attend quarterly meetings. ■

BloodPAC

8 Additional partnerships

Partnership activity this year included work with the Children’s Tumor Foundation; the Breast Cancer Alliance; the Society for Neuro-Oncology; the American Institute of Ultrasound in Medicine; Pancreatic Cancer UK; cancer immunotherapy outreach with the Cancer Research Institute; the second annual “fly-in” event on Capitol Hill in Washington, DC, with the Medical Imaging and Technology Alliance, MITA; and co-hosting a reimbursement workshop with AdvaMed. ■



BREAST CANCER ALLIANCE






World leaders awareness

For the first time, two sitting world leaders—the presidents of the United States and France—are aware of focused ultrasound technology and its potential to transform medicine. Newly elected **US President Joe Biden**—who attended the Foundation’s symposium in 2014 when he was vice president—has a longstanding commitment to fact-based

policy and decision-making, science, and healthcare, which will serve to expedite the advancement of focused ultrasound worldwide. The president also recently elevated the Office of Science and Technology Policy (OSTP) director to a cabinet-level position for the first time in US history; the Foundation’s work fits within the mandate of OSTP, which in part advises the Executive Office on scientific and technological aspects of health.


In France, **President Emmanuel Macron** visited Physics for Medicine Paris—a Focused Ultrasound Center of Excellence—in December to kick off a major project aimed at making France a world leader in digital health. President Macron met with director Mickael Tanter, scientific director Jean-Francois Aubry, and others to discuss the technology’s potential. ■



 **Regulatory and reimbursement “firsts”** to benefit pediatric and prostate patients seeking focused ultrasound treatment in the US; comprehensive Foundation report released detailing complex reimbursement landscape.

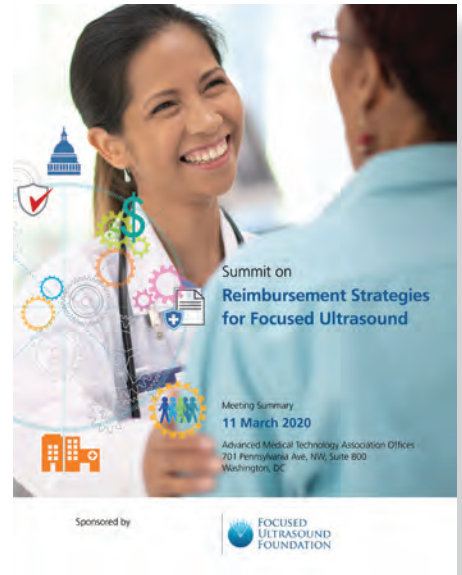
Osteoid osteoma treatment approved

In November the **US FDA** announced the approval of Profound Medical’s Sonalleve MR-guided High Intensity Focused Ultrasound system for the treatment of osteoid osteoma in the extremities. This marks the first focused ultrasound regulatory approval that will directly impact pediatric patients and the sixth indication to earn approval in the US. Osteoid osteomas are painful bone tumors that comprise about 10 percent of all benign bone tumors. ■

Visit our website to learn about reimbursement from the perspective of patients, providers, and medical device companies. 

CPT billing code established

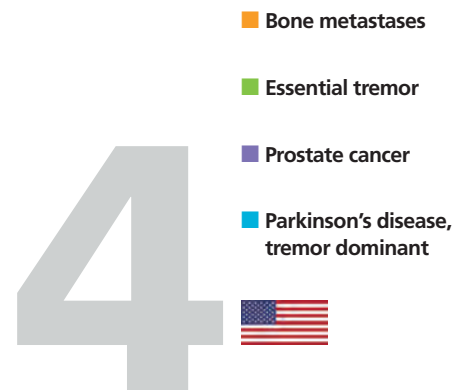
The American Medical Association established for the first time a **Category I CPT® billing code** to facilitate reimbursement for the use of focused ultrasound to treat malignant prostate cancer. The code, described as “ablation of malignant prostate tissue, transrectal, with high intensity focused ultrasound including ultrasound guidance,” went into effect January 1, 2021. ■



Reimbursement report released

The Foundation released a report on the complexities of **reimbursement**, especially as it pertains to innovative treatments like focused ultrasound. ■

Indications with regulatory approvals by region 



Indications with reimbursement in the US 

▶ **More than 80,000 patients worldwide** were treated with focused ultrasound in 2020. Here is one woman's story about obtaining treatment for her father's essential tremor.

Patient spotlight **Essential tremor**

In 2013, Perry Payne Millner was living in Charlottesville, VA, when she learned of a focused ultrasound clinical trial for essential tremor, ET. Her father, Dan Payne, had suffered with tremors since 1993, when he was 55 years old. He had stopped playing golf because he couldn't control the club like he used to, and the ET progressed every year.

Unfortunately for Dan, this particular trial was closed, and since the procedure would cost \$30,000 out-of-pocket, he and Perry decided to wait until Medicare approved the treatment.

Six years later, in January 2019, the approvals came through, and Medicare said they would ultimately cover all but \$7,500. Dan also had private insurance which would cover up to \$15,000, but getting that coverage would prove cumbersome. Dan was treated in July 2019, approximately four months after his private insurance approvals came through.

Regarding the reimbursement process, Perry said, "Older patients need someone to advocate for them. They need help with the paperwork, the technology, the insurance. My dad's generation has such respect and reverence for physicians;

they don't want to rock the boat or seem pushy. But somebody has to get past the red tape and through the bureaucracy." Thankfully for Dan, now 82, his story ended happily. "At lunch on the way to UVA for his treatment, I watched my dad try to cut into an éclair—his tremor sent the plate flying across the table," said Perry. But now, "he can go to a cocktail party and hold both drink and plate. It's a happy ending for sure." Overall, Dan's quality of life is much improved, and his private insurance ultimately covered all or nearly all the expenses. ■



▶ Read Millner's full story on the Foundation's [website](#).

Communications and connections via virtual platforms became the norm in 2020, enabling unique opportunities for widespread audience reach via online channels and social media.


Chase Koch and Neal Kassell sat down in the spring via a Zoom meeting, resulting in a podcast and three-part blog series. They discussed the field and how the Foundation and Koch Disruptive Technologies are working together to revolutionize health care.



Amplifying our story

Foundation Chairman Neal F. Kassell, MD, and Board member and best-selling author John Grisham, were interviewed virtually in 2020 by influentials to amplify the focused ultrasound story and continue educating a broad range of audiences totaling in the thousands.




 This summer, David Rubenstein—a former financial analyst, lawyer, and philanthropist who is well-known for his thoughtful interviews with “influential people” on his program, **The David Rubenstein Show: Peer to Peer Conversations**—interviewed Neal and John via Zoom; it was widely distributed via YouTube and social media.




 Additionally, medical research activist, philanthropist, and financier Mike Milken interviewed Neal and John about the potential of focused ultrasound to address today’s most vexing health conditions as part of the **Milken Institute’s 2020 Future of Health Summit**.

The annual Summit “convenes the best minds in the world to confront the most significant health challenges by matching human, financial, scientific, and educational resources with innovative and impactful ideas.” The conversation was also repurposed by the Institute as a podcast and shared widely on social media. ■



 YouTube views increased from **51,200 to 86,600** in 2020.

 Additional content is available on the Foundation’s website as podcasts, transcripts, and PDFs:

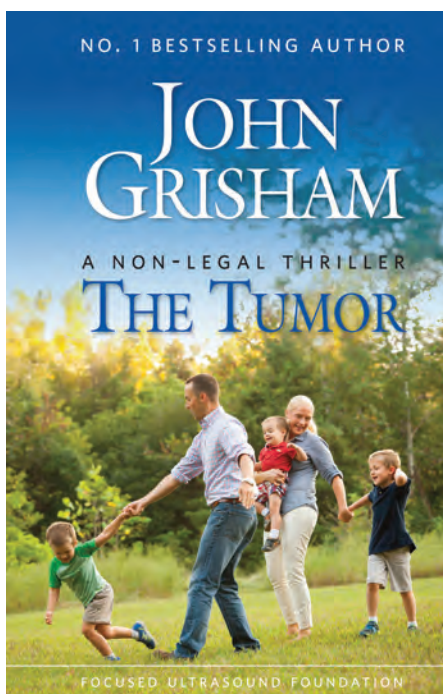


NEO.LIFE highlights the Foundation

NEO.LIFE recently published an article about the Focused Ultrasound Foundation and founder Neal F. Kassell, MD. The article notes:

“It’s hard to talk about promoting focused ultrasound without talking about the Foundation—and impossible to do so without focusing on Kassell, who has emerged over the last dozen years as something of an evangelist-in-chief for the technology. To listen to him talk is to hear hope vocalized—hope for the thousands and thousands of people whose lives, he says, will be saved by focused ultrasound in what he calls a coming ‘revolution in therapy.’”

▶ NEO.LIFE founder Jane Metcalfe recently joined the Foundation’s Council after becoming excited about the technology while interviewing Neal for her publication. ■



▶ Access the e-book or audio book from our website.

85,000

▶ Distribution of *The Tumor* went from just under 40K in 2019 to almost 85K in 2020, pushing our total distribution to

1,050,000+



1.25M

▶ Our 2020 combined reach of **Twitter**, **Facebook**, and **LinkedIn**.

“Once I realized the potential of this noninvasive surgical procedure to save countless lives and improve the healthcare of millions of people, I realized how important this work is.”

— John Grisham



▶ Packaging relevant, shareable information via educational webinars and reports is moving the needle toward widespread awareness of focused ultrasound.



History of Focused Ultrasound

A “who’s who” in the development of focused ultrasound was presented by Gail ter Haar, PhD, from the Institute of Cancer Research, ICR, London, in December. “History of Focused Ultrasound,” the webinar was part of the International Society for Therapeutic Ultrasound’s “ISTU On-Air” series. Said Foundation Chairman Neal F. Kassell, MD, “Professor ter Haar’s webinar is by far the best piece to date on the subject. Anyone with an interest in focused ultrasound must watch it.” ■

Access the webinar on ▶ our [YouTube channel](#).

Webinars’ reach multiplies

Virtual meetings and webinars were the go-to format for sharing information in 2020 due to the COVID pandemic. The Foundation’s webinar series covered a wide variety of topics from gene therapy to patent strategy for business leaders. The webinar series reached:

10,000+
people

1,500+
live participants

9,000+
recorded views

IMMUNOTHERAPY FOR BRAIN TUMORS

Michael Lim

HISTOTRIPSY FOR THE TREATMENT OF CANCER AND NEUROLOGICAL DISEASES

Zhen Xu

CURING WITH SOUND

Neal Kassell

FOCUSED ULTRASOUND THERAPIES FOR PARKINSON’S DISEASE IN PRECLINICAL MODELS

Elisa Konofagou

BREAKING BARRIERS WITH SOUND:

THE FUTURE OF PARKINSON’S DISEASE THERAPY WITH FUS
Nir Lipsman

LIQUID BIOPSY FOR BRAIN TUMORS: RECENT ADVANCES AND FUTURE DIRECTIONS

Stephen Bagley

CANCER IMMUNOTHERAPY TREATMENT AND RESEARCH IN A COVID-19 WORLD

Jill O’Donnell-Tormey and Jessica Foley

FOCUSED ULTRASOUND AND ITS POTENTIAL ROLE IN NEUROFIBROMATOSIS TREATMENT

Michel Kalamarides, Nathan McDannold, Tyrone Porter, and AeRang Kim

FOCUSED ULTRASOUND FOR GENE THERAPY: AN OVERVIEW

Natasha Sheybani

ULTRASOUND BLOOD-BRAIN BARRIER DISRUPTION IN NEURO-ONCOLOGY

John de Groot, Kullervo Hynynen, Nir Lipsman, Kuo-Chen Wei, and Adam Sonabend

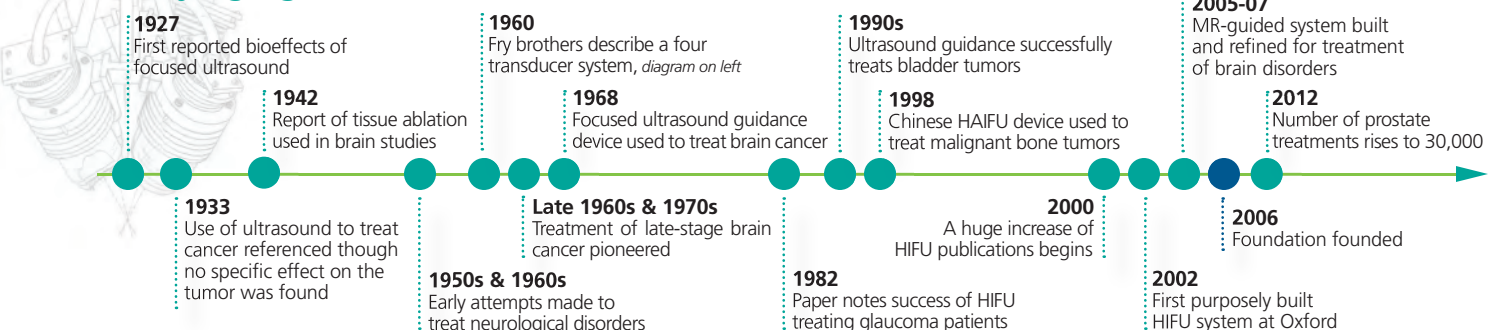
PATENT STRATEGY FOR BUSINESS LEADERS

Rick Hamilton

2020 LOCKHART PRIZE WINNERS—RESEARCH HIGHLIGHTS

Matthew Bucknor and Pejman Ghanouni

History highlights | Read the history essay on our [website](#)



2020 State of the Field Report available

Each year, the Foundation team surveys stakeholders to assess the field of focused ultrasound around the world. The *2020 State of the Field Report* documents the progress that is only possible through the hard work, time, and resources of everyone in our community. This year's report provides a more in-depth analysis of key areas of research—including transducer design and image guidance in technical research—and mechanisms of action, as well as commercialization figures and a detailed look at the state of global regulatory approvals by geographic region. ■



The *2020 State of the Field Report* is available on the Foundation's [website](#).

Foundation team **community support**

At the Foundation, people come first—whether it is the patients in the clinical trials we support, or those in need right here in Charlottesville who have suffered greatly due to COVID-19.

In March, the Foundation initiated a voluntary tithing program in which team members were asked to personally contribute to individuals and organizations adversely affected by the pandemic. As a group—including members of the Board, Council, and local donors—we supported [No Kid Hungry](#), the [Blue Ridge Area Food Bank](#), and the [Cedars Healthcare Center](#), a long-term care facility located adjacent to the Foundation that experienced a severe COVID-19 outbreak. We were able to provide Cedars with more than \$20,000 in gifts and support, including fulfilling the “Santa’s wish lists” of more than 50 residents. ■

Highlights

Distinct indications	136	Indications with regulatory approvals	32
New indications	9	Indications with US reimbursement	4
New indications in clinical trials	7	Insured for bone metastases in US	120m
Indications with new regulatory approval	2	Insured for prostate in US	22.8m
Commercial treatment sites	528	Clinical device manufacturers	50+
Clinical research sites	208	FUS industry investment	\$112m
Veterinary program sites	6	Companies with regulatory approvals	16

▶ Four iconic leaders of industry joined the Foundation's Board of Directors, and the Council grew by seven, to better achieve our shared mission of saving time, saving lives.

Foundation Board expands

Michael Milken, Chairman of the Milken Institute, and **Gary Shapiro**, president and CEO of the Consumer Technology Association, CTA, were elected to the Foundation's Board in August. Their expertise will broaden the effectiveness of the Board, as it works to expand the use of focused ultrasound for a wide variety of serious medical disorders.

Mike Milken has been recognized as "The Man Who Changed Medicine" by Fortune magazine and has dedicated nearly half a century to accelerating medical solutions and advancing public health. He founded the Milken Institute, a nonprofit, nonpartisan think tank whose scholars lead an international dialogue on solutions in economics, health, aging, human capital, philanthropy, and capital markets.

Gary Shapiro leads CTA, North America's largest technology trade association. CTA owns and produces CES®—the most influential technology event in the world. Shapiro is a vocal advocate for innovation and technology in Washington, DC, having testified before Congress dozens of times. Shapiro has been named a top lobbyist by *The Hill*, one of the 100 most influential people in Washington by *Washington Life* magazine, and a Tech Titan by *Washingtonian* magazine.

Additionally, the Foundation appointed two leading executives to the Board earlier this year: **Scott Beardsley**, dean of the University of Virginia Darden School of Business, and **Mike Lincoln**, global business department chair at the international law firm Cooley LLP. ■

Right, top to bottom
Michael Milken, Gary Shapiro, Scott Beardsley,
and Mike Lincoln



Goodwill Ambassadors Join Council

The Council is a group of passionate, enthusiastic advocates who connect us to the greater community, share our story, and promote our mission.

Peter Gabriel

Musician

David R. Goode

Former Chairman and CEO,
Norfolk Southern

Alice W. Handy

Founder, former President, and CEO,
Investure

Robert J. Hugin

Former Chairman and CEO,
Celgene Corporation

Kat Imhoff


Senior Conservation Fellow
Piedmont Environmental Council (PEC)

Jane Metcalfe

Founder and CEO, NEO.LIFE

Claude Wasserstein

Founder and CEO, Fine Day Ventures

 **Focused ultrasound shows great promise for improving patients' lives, and I am particularly committed to technologies that may transform treatment for cancer."**


— Robert J. Hugin

 **I'm amazed at the potential of focused ultrasound to transform how diseases are treated and managed, thereby improving the quality of life of so many patients. This field is full of possibilities, and I am excited to be involved."**


— David R. Goode

 **The technology is so promising for treating patients noninvasively and cost effectively with focused ultrasound. It's exciting to see how much research activity there is around the world, and I look forward to supporting the effort."**


— Jane Metcalfe

 **I'm excited about the transformative reach that focused ultrasound could have when made more affordable and accessible. Currently focused ultrasound requires costly equipment and precise environments, but it has the long-term potential to be digitized, miniaturized, and augmented with artificial intelligence."**

— Peter Gabriel

 **In looking for new ways to combat serious disease and improve quality of life, the Foundation is a source of inspiration."**

— Kat Imhoff

 **It's a rare thing to help advance a revolution in medical therapy, and I'm delighted to be serving on the Council."**

— Alice W. Handy

▶ **New industry relationships** and the establishment of international affiliates strengthened the Foundation's global reach in 2020.

FUS Partners expands

The Foundation's **FUS Partners Program** expanded its activities this year by taking a more holistic approach toward the ever-adjusting needs of key stakeholders in the focused ultrasound community, identifying key bottlenecks and removing them through coordinated efforts and targeted solutions. Program activities include fostering relationships and developing critical resources to aid the focused ultrasound community with regulatory and reimbursement efforts, corporate financing, training and credentialing, employee recruiting, strategic partnerships, technology transfer, industry advocacy, and intellectual property. The program continues to serve as a galvanizing force in facilitating the rapid success of the commercial stakeholder segment of the focused ultrasound ecosystem. ■

Hong Kong and London affiliates

We are pleased to share that Focused Ultrasound Hong Kong Foundation, FUSHK, received its inaugural gift from a generous donor, in memory of Stacey Kuo. Contributions from Hong Kong- and Asia-based philanthropists to FUSHK will support preclinical and clinical projects throughout Asia, where a tremendous amount of groundbreaking research activity is ongoing. FUSHK founding members are Syaru Shirley Lin and Carolyn Yeh; Jessica Che-yi Chao and Bernice Szeto are directors.



Additionally, plans are underway to establish the London-based UK Focused Ultrasound Foundation to support our ongoing research, preclinical and clinical efforts in the United Kingdom. The trustees include Foundation Chairman Neal F. Kassell, MD; Foundation advisor Philip Keevil; Lord Aberdare, a member of the UK House of Lords; John Bowis, a former UK Minister of Health and Member of the European Parliament; and Sir Ivor Roberts, former UK ambassador to Ireland and Italy and President of Trinity College, Oxford University. ■



香港



▶ Clinicians' and scientists' growth was fostered by the Foundation through fellowships, internships, and online learning.



Meet the 2020 STAT Wunderkinds

Dr. Natasha Sheybani, a Postdoctoral Research Fellow at Stanford University, was recently included in *STAT News*'s small group of up-and-coming scientists and researchers known as "Wunderkinds," the next generation of scientific superstars.

She serves as a Senior Scientist at the Focused Ultrasound Foundation, where her role involves supporting research programs in glioblastoma, gene therapy, and cancer immunotherapy.

▶ Glioblastoma patients are in need of better treatment. Worldwide scientists like Dr. Sheybani are exploring ways of attacking these deadly tumors with the help of focused ultrasound. ■

Glioblastoma research

At Foundation's Centers of Excellence

7 Preclinical research

Brigham and Women's Hospital
ICR and The Royal Marsden
Inserm - LabTAU
Sunnybrook Health Sciences Centre
Stanford University School of Medicine
University of Maryland School of Medicine
University of Virginia Health System

4 Clinical research

Brigham and Women's Hospital
Inserm - LabTAU
Sunnybrook Health Sciences Centre
University of Maryland School of Medicine

“Sheybani is passionate about using focused ultrasound—a non-invasive way to heat tissue using sound waves—to treat cancer.”

— STAT News, November 16, 2020

“I consider it such an honor to have received this recognition. It is incredibly inspiring and motivating to be in the company of such remarkable early career scientists who share a desire to bear meaningful impact on patient lives through research. I owe a great deal to the many mentors who have championed my ambition to bring focused ultrasound and imaging to the forefront of immuno-oncology.”

— Natasha Sheybani, PhD

4

Next generation joins the Foundation

Four recent college graduates joined the Foundation this year, to assist in efforts ranging from website to data analysis and research:

- **Camille Favero**
Darden Focused Ultrasound Fellow,
FUS Partners strategic consulting and development support
- **Jordan Krupp**
Website Developer,
website management and coding
- **Charlie Manning**
Open Science Manager, *contracting pipeline analysis, medical device financing*
- **Natasha Sheybani, PhD**
Senior Scientist, *glioblastoma, gene therapy & cancer immunotherapy research programs*

MOOC reaches hundreds


In 2018 our first Massive Online Open Course, MOOC, was launched in collaboration with the Laboratory of Therapeutic Applications of Ultrasound, LabTAU, as part of their Center of Excellence, and the University of Lyon.

This MOOC is a free online course targeted toward physicians, students, and patients who are interested in learning about research in the field of therapeutic ultrasound, and features world renowned experts covering topics such as technical explanations of FUS applications and clinical case presentations.

2020 has seen an upsurge in viewing of our MOOC. To date the course has had:

591

global participants

More about this MOOC  is available on our [website](#).

Courses

- 1 Neurological disorders treated by HIFU
- 2 Generation and propagation of ultrasound
- 3 Ultrasound-induced bio effects
- 4 HIFU for treating prostate cancer
- 5 Ultrasonic imaging for high-intensity focused ultrasound treatment
- 6 Drug delivery by ultrasound
- 7 What is cavitation?
- 8 Opening the BBB by ultrasound
- 9 MRI for guiding HIFU treatment
- 10 MR-guided high intensity focused ultrasound: A pediatric application
- 11 Application of HIFU in oncology
- 12 HIFU for treating glaucoma

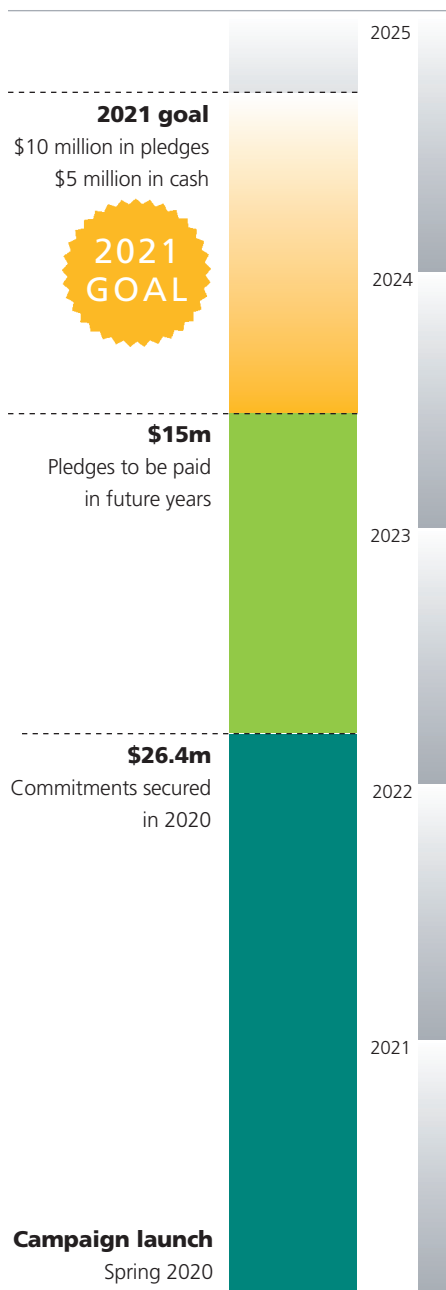
FUSF Internship Program | Since 2012

87 local interns
from **12 institutions**

121 global scholars
from **9 countries**
and **37 institutions**

6 fellows
from **4 countries**

\$60 million
5 years of support for research & activities



Fundraising 2021

The Foundation’s budget for 2021 is \$14 million, of which over 65% is dedicated to research.

To support the Foundation’s activities for 2021, our annual fundraising goal is to raise \$5 million in cash and \$10 million in multiyear pledges. ■

Campaign

In Spring 2020, we launched a campaign to raise \$60 million to support research and activities for the next five years. As the field advances and the Foundation commits to more lengthy clinical trials, the campaign will create long term funding stability that will enable us to achieve our strategic priorities in neurological conditions, psychiatric disorders, and cancer and cancer immunotherapy.

To date, building on \$26.4 in new commitments secured in 2020, our five-year campaign total has reached \$45 million, thanks to an additional \$15 million in gifts to be paid in future years. ■

Donate

The progress outlined in this report is made possible by our supporters, and we are thankful. We need your continued support to fulfill our mission by accelerating the adoption and development of focused ultrasound. Together we can improve the lives of millions of people with serious medical disorders.

Foundation donors may contribute unrestricted funds to advance the field or dedicate their gifts to a particular disease area.

► For more information, please contact Nora Seilheimer at 434.326.9830 or nseilheimer@fusfoundation.org



384

presentations
at our 2020 symposium

Board

Neal F. Kassell, MD
Chairman, Focused Ultrasound Foundation
Former Co-chair of Neurosurgery,
University of Virginia

Scott Beardsley, PhD
Dean, University of Virginia
Darden School of Business

Eugene V. Fife
Founding Principal, Vawter Capital, LLC
Former Chairman,
Goldman Sachs International

John R. Grisham
Author

William A. Hawkins III
Senior Advisor, EW Healthcare Partners
Retired Chairman & CEO, Medtronic

Daniel P. Jordan, PhD
President Emeritus,
Thomas Jefferson Foundation

Syaru Shirley Lin, PhD
Adjunct Professor,
Chinese University of Hong Kong
Director, Goldman Sachs Asia Bank

Michael R. Lincoln
Global Business Department Chair,
Cooley LLP

Michael Milken, MBA
Chairman, Milken Institute

Edward D. Miller, MD
Former CEO, Johns Hopkins Medicine

Frederic H. Moll, MD
Chief Development Officer,
J&J Medical Devices
Co-founder, Auris Health & Intuitive Surgical

Charles "Wick" Moorman IV
Former Chairman & CEO, Norfolk Southern
Former CEO, Amtrak

Steve H. Rusckowski
Chairman, President, and CEO,
Quest Diagnostics Inc.
Former CEO, Philips Healthcare

Gary Shapiro
President & CEO, Consumer Technology
Association (CTA)

Carl P. Zeithaml, PhD
Dean and F. S. Cornell Professor of
Free Enterprise, McIntire School
of Commerce, University of Virginia

Council

Co-chairs

Jane P. Batten
Charles H. Seilheimer Jr.

.....

John B. Adams Jr.
Dorothy N. Batten
Ellen H. Block
Amanda Brown
Deborah Caldwell
Jessica Che-yi Chao
Nancy Jones Chewning
Thomas N. Chewning
Marguerite Davis
Norwood H. Davis Jr.

Peter Gabriel
David R. Goode
Rick Hamilton
Alice W. Handy

Diane Heller
Robert J. Hugin
Kat Imhoff

Dean L. Kamen
Ann Kingston
Harry Lester
Jonna Hiestand Mendez
Jane Metcalfe

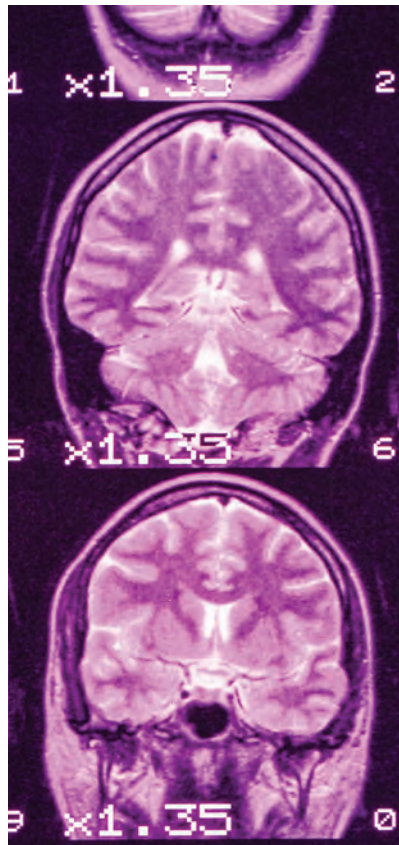
Paula F. Newcomb
Marc Onetto
Wyndham G. Robertson
Mary Lou Seilheimer
Alice H. Siegel
Allan C. Stam, PhD
Aaron Stern, MD, PhD
Fredericka Stevenson
Howard H. Stevenson
Bernice Szeto

Andrew C. von Eschenbach, MD
Claude Wasserstein



4

indications with US
insurance reimbursement

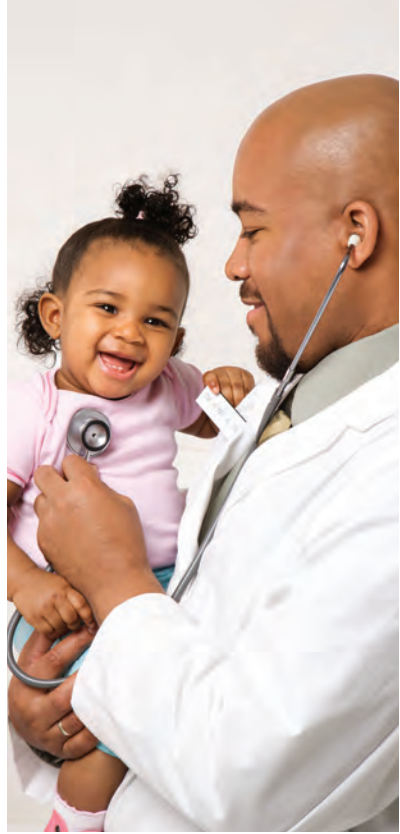


58

countries
represented by 2020
symposium participants

85_k

2020 distribution of
John Grisham's *The Tumor*



+10_k

webinar viewers
cumulative



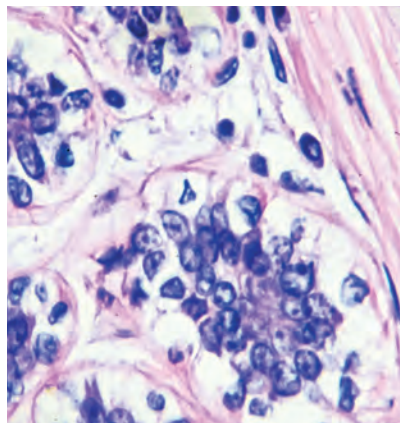
50₊

**Clinical
device manufacturers**



+1.25_m

2020 combined reach of
Twitter, Facebook & LinkedIn



9

new indications
in 2020





FOCUSED
ULTRASOUND
FOUNDATION

1230 Cedars Court, Suite 206
Charlottesville, VA 22903
434.220.4993 main line

fusfoundation.org