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
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
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

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### 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.
Focused ultrasound treatments have 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 update**

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

- 195 projects
- 55 institutions
- 13 countries

### 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

### Currently

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

North America
- Canada
- United States

Europe
- France
- Germany
- Italy
- Spain
- Switzerland
- The Netherlands
- United Kingdom

Asia
- Israel
- Japan
- South Korea
- Taiwan

North America
- Canada
- United States

Europe
- France
- Germany
- Italy
- Spain
- Switzerland
- The Netherlands
- United Kingdom

Asia
- Israel
- Japan
- South Korea
- Taiwan
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.

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.

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.

- 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.

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

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

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.
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.

**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.

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.
2 researchers receive Lockhart Memorial Prize

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.

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.

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.

**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.

**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
  - Sunnybrook Health Sciences Centre
    - Toronto, Canada

- **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.
convening the community

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.

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.

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.

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.
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.
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.

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

- Bone metastases
- Essential tremor
- Prostate cancer
- Parkinson’s disease, tremor dominant

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

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.

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.

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.

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.

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.

**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

2020 LOCKHART PRIZE WINNERS—RESEARCH HIGHLIGHTS
Matthew Bucknor and Pejman Ghanouni

1927 First reported bioeffects of focused ultrasound
1942 Report of tissue ablation used in brain studies
1960 Fry brothers describe a four transducer system, diagram on left
1968 Focused ultrasound guidance device used to treat brain cancer
1990s Ultrasound guidance successfully treats bladder tumors
1998 Chinese HAIFU device used to treat malignant bone tumors
2005-07 MR-guided system built and refined for treatment of brain disorders
2012 Number of prostate treatments rises to 30,000
2006 Foundation founded

Access the webinar on our YouTube channel.

Focused Ultrasound Foundation | 2020 Year in Review
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.

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
New indications 9
New indications in clinical trials 7
Indications with new regulatory approval 2
Commercial treatment sites 528
Clinical research sites 208
Veterinary program sites 6

Indications with regulatory approvals 32
Indications with US reimbursement 4
Insured for bone metastases in US 120m
Insured for prostate in US 22.8m
Clinical device manufacturers 50+
FUS industry investment $112m
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 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

"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

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

— Kat Imhoff

"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

"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.
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’ 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.

“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

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

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

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
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**
**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
Focused Ultrasound Foundation | 2020 Year in Review

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Claude Wasserstein

384 presentations at our 2020 symposium

4 indications with US insurance reimbursement

58 countries represented by 2020 symposium participants
2020 distribution of John Grisham’s *The Tumor*

50+
Clinical device manufacturers

+10,000
webinar viewers
cumulative

+1.25 million
2020 combined reach of Twitter, Facebook & LinkedIn

9
new indications
in 2020