



FOCUSED ULTRASOUND FOUNDATION

PROGRESS REPORT FALL 2016

Dear Friends,

Over the last several months, the Foundation and the field have experienced major achievements. In July, the US Food and Drug Administration approved focused ultrasound to treat essential tremor, and Medicare has agreed to reimburse the treatment. Regulatory approval and insurance coverage are important stepping stones to widespread utilization.

Just weeks after the FDA's announcement, the 5th International Symposium convened a record number of attendees to hear more than 200 presentations and foster relationships.

Meanwhile, other areas of research are driving progress as the first trial for epilepsy has begun, and the Foundation's immunotherapy initiative continues to build momentum. The Centers of Excellence program has also grown with the addition of three new sites this year.

The Foundation's effectiveness was enhanced throughout the year as we welcomed a number of new team members and two new Board members - Former President of Virginia Tech, Charles Steger, PhD, and Bill Hawkins, former CEO of Medtronic.



Creating Knowledge: Research Milestones

WORLD'S FIRST FUS CLINICAL TRIAL FOR EPILEPSY BEGINS

Researchers at the University of Virginia are starting the first clinical trial using focused ultrasound to treat patients with [epilepsy](#). The [15-patient study](#), supported by the Focused Ultrasound Foundation in collaboration with the Epilepsy Foundation, will assess the feasibility, safety and initial effectiveness of focused ultrasound to non-invasively destroy (ablate) diseased brain tissue that causes seizures. [Read more >](#)

PARKINSON'S RESEARCH UPDATES

The pilot trial using focused ultrasound to treat the symptoms of tremor-dominant [Parkinson's disease](#) has been completed. The promising results were presented at the Symposium in August and have been submitted for publication.

A similar [study](#) investigating the feasibility and safety of treating the dyskinesia associated with Parkinson's disease is underway at a number of sites in the US, Canada and Korea. Overall, the study has enrolled over two-thirds of its 31 patients.

The clinical trials to date have tackled treating the debilitating symptoms of Parkinson's disease, but new pre-clinical research is underway into treating the underlying disease. Early results are encouraging.

BRAIN TUMOR CONSORTIUM INVESTIGATING IMMUNOTHERAPY

Recent pre-clinical and clinical research has demonstrated that immunotherapies can have beneficial effects in glioblastoma multiforme (GBM) – an aggressive and fatal brain tumor. The Foundation has created a multi-site consortium to streamline efforts and accelerate progress in using FUS to increase the body's anti-tumor immune response. The first major project brings together seven research sites in North America to investigate the effects of different FUS modalities on the immune system, each using the same animal model of GBM. [Read more >](#)



Research Program Update

The Foundation funded a new pre-clinical neuromodulation research project at Brigham and Women's Hospital this fall.

Of the 53 research projects funded by this program:

- 37 have been completed
- 80% have been published in peer-reviewed journals
- Nearly all have been presented at scientific meetings

For every Foundation dollar spent, the projects have earned \$7 in follow-on funding from NIH & foundations.

FIELD REPORT ADVANCES IN THE FOCUSED ULTRASOUND COMMUNITY

- **Insightec's Exablate Neuro system was FDA approved for essential tremor and reimbursed by Medicare. Study results were published in the *New England Journal of Medicine*.**
- **With the Children's Research Institute and NIH, Celsion will explore treating pediatric solid tumors using targeted drug delivery.**
- **The first patient has been treated in Profound Medical's pivotal trial for prostate cancer.**
- **The US FDA approved Theraclion to begin a 100-patient study for breast fibroadenoma.**

Convening the Community

SYMPOSIUM DRAWS RECORD ATTENDANCE, KEY DATA SHARED

Every two years, the Foundation hosts an international Symposium where the leading minds in focused ultrasound gather to discuss their research findings and clinical progress. In August, our Symposium brought together over 400 attendees to share the latest in treating the brain and many cancers, as well as hypertension, arthritis, and other disorders.

[Watch presentation videos >](#)

[Read the meeting summary >](#)



NEW SITES NAMED CENTERS OF EXCELLENCE

Established in 2009, the Foundation's [Centers of Excellence](#) program 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. This year, three new sites have joined the ranks.



Stanford University focuses on a number of clinical, pre-clinical and technical projects, including trials using FUS to treat bone metastases, uterine fibroids, essential tremor, prostate cancer, soft tissue tumors, and arthritis. [Read more >](#)



Several University of Maryland departments are collaborating to study the treatment of movement disorders, chronic neuropathic pain, brain tumors, and the use of enhanced drug delivery and immunomodulation. [Read more >](#)



Sunnybrook Health Sciences Centre in Toronto is conducting research for focused ultrasound in neurology, neurosurgery, urology, orthopedics, gynecology, radiation oncology, and biomedical engineering and have studies planned in the near future for Alzheimer's, obsessive-compulsive disorder, depression, and others. [Read more >](#)

WEBINAR ON FUS FOR PARKINSON'S

In July, we hosted a webinar by Paul Fishman, MD, Professor of Neurology at the University of Maryland, on current therapies for Parkinson's disease. He covered the state of the field for this disease, treatment gaps, and the potential of focused ultrasound to become a treatment option.

[Watch Now >](#)



Fostering Collaboration

FOCUSED ULTRASOUND FOUNDATION JOINS THE MOONSHOT

President Obama's [Cancer Moonshot](#) is an initiative to accelerate cancer research in part by breaking down silos in order to promote collaboration and data sharing. The Foundation's Chairman Dr. Neal Kassell serves on the [Cancer Moonshot Blue Ribbon Panel](#).

We believe that focused ultrasound has the potential to transform treatment and improve outcomes for cancer patients. We recently wrote an article detailing how focused ultrasound fits into the Moonshot. [Read the article >](#)

We also invited Greg Simon, Executive Director of the Moonshot Task Force, to address the Symposium crowd. [Watch his presentation >](#)



FUS IMMUNOTHERAPY SUMMIT BUILDS ON MOMENTUM

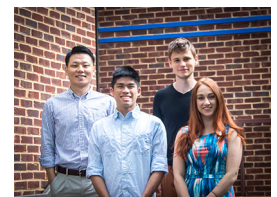
More than 40 experts from around the world gathered for the Focused Ultrasound and Immunotherapy Summit, held in partnership with the Cancer Research Institute on October 14. The group met to evaluate the current body of evidence, assess ongoing work, and create a roadmap of projects to address any gaps or questions. Its ultimate goal is to reduce the time it takes for FUS and immunotherapy combination treatments to reach clinical adoption. [Read more >](#)



Cultivating the Next Generation

SUMMER INTERNS CONTRIBUTE TO THE FIELD

Two returning students were met by a couple of new faces to round out our talented group of summer interns. One team employed 3D printing techniques to develop a therapeutic ultrasound system, which will be used in a Foundation-funded sonodynamic therapy research project at the University of Virginia. The others worked to develop new software and study techniques to improve safety and functionality. [Read more >](#)



LEADING FRENCH RESEARCHER JOINS FOUNDATION AS MERKIN FELLOW

Dr. Cyril Lafon, Director of LabTAU, a research laboratory of the French National Institutes of Health, joins the Foundation as the 2016-2017 Richard Merkin Fellow.

Cyril will study ultrasound-induced immunological responses in breast cancer in collaboration with researchers at the University of Virginia. He will also join the Foundation's brain technical program scientists to study cranial thermal ablation for essential tremor and brain tumors. [Read his profile >](#)

Last year, Cyril gave a webinar about research on conformal treatments for prostate and brain. [Watch now >](#)

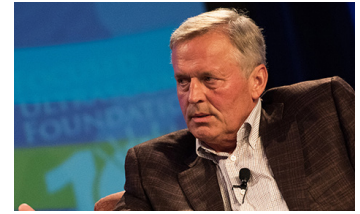




Increasing Awareness

GRISHAM ON HIS CONNECTION TO FOCUSED ULTRASOUND

Bestselling author John Grisham sat down with CBS's Chip Reid at the Symposium to discuss his personal connection to the technology and how he's helping to spread the word. His book, *The Tumor* was released in November 2015, and nearly 700,000 copies have been distributed to date. [Watch now >](#)



VIRGINIA GOVERNOR TERRY MCAULIFFE VISITS FOUNDATION

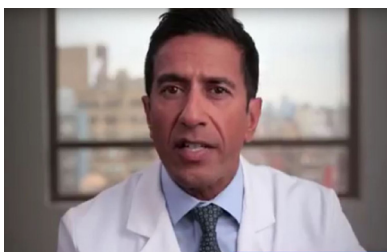
On August 22, Virginia Governor Terry McAuliffe visited the Foundation's offices and met with members of the team, Board, Council, and leaders from the University of Virginia Health System. They discussed the importance of Foundation-initiated activities to the Commonwealth and the way in which state support has contributed to the development of the entire field. [Read more >](#)



I want Virginia to be known as the Brain State. These are the jobs of the future. We have invested tremendously in bio. We have gone from the back of the heap to the front for our country on bio. Virginia can take it to the next level.

DR. SANJAY GUPTA ASKS IF FUS IS THE NEXT BIG THING

Reporting for Everyday Health, Dr. Sanjay Gupta follows Kimberly, whose Parkinson's symptoms were reduced following the experimental procedure. He explains the technology and describes how focused ultrasound was used to improve Kimberly's quality of life. [Watch now >](#)



Biking is my true love. It's like a new lease on life being able to ride my bike again. It's like nothing was wrong with me. It's incredible.



READERSHIP AT ALL-TIME HIGH

The Foundation's communication channels bring our audience - including researchers, clinicians, industry, and patients - abreast of happenings in the field. This fall, our [website](#) viewership hit record numbers of views and is on track to see more than 400,000 visits this year. Meanwhile, our [newsletter](#) now reaches nearly 9,000 people each month.



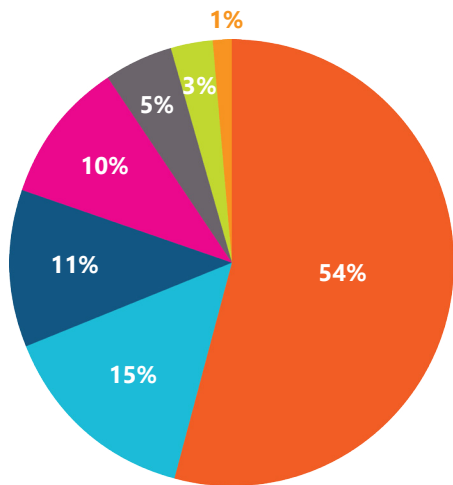
The Foundation hosted four awareness events this fall. These gatherings allow us to spread the word about the technology and our work.



Finances

ALLOCATION OF FUNDS

2016 YEAR TO DATE THROUGH SEPTEMBER 30: \$5,128,225



	<u>ACTUAL YTD</u>
RESEARCH	\$2,781,933
COMMUNICATIONS	\$754,213
SYMPOSIA/MEETINGS	\$582,140
FUNDRAISING	\$536,023
EXTERNAL RELATIONS	\$248,444
SCHOLARS PROGRAM/FELLOWSHIPS	\$155,986
REIMBURSEMENT/FIBROID RELIEF	\$69,486

DOUBLE YOUR IMPACT TODAY

Our donors play a critical role in enabling us to fulfill our mission of advancing the field of focused ultrasound to help as many patients as possible in the shortest amount of time.

We have had the good fortune to have received two \$1 million pledges of unrestricted funds to be matched 1:1. One of the matches has been fulfilled, and we have \$500,000 to raise to fulfill the second match. We hope you will help us meet this challenge, appreciating that the impact of your contribution will be doubled.

FOUNDATION EARNS TOP CHARITY RANKINGS

Our work depends on generous donors who, like us, believe in the potential of focused ultrasound to change the lives of millions of patients. Our commitment to these donors is paramount, and we are proud to say we hold the highest ratings by [GuideStar](#) and [Charity Navigator](#) - leading online tools that assess non-profits' financial and organizational transparency.



FOUNDATION RECOGNIZED FOR CANCER THERAPY EFFORTS

The [CEO Roundtable on Cancer](#) has accredited the Foundation with the [CEO Cancer Gold Standard](#), recognizing our efforts to reduce the risk of cancer for our employees and covered family members.

The Roundtable, a nonprofit organization of CEOs, founded by former President George H.W. Bush, developed and administers the Gold Standard, a workplace accreditation program which encourages and recognizes the commitment of organizations that take concrete actions to address cancer in their workplaces. Nearly 200 private, nonprofit and government employers in a wide range of occupational categories have earned Gold Standard accreditation, including the National Cancer Institute (NCI) and a number of NCI-designated cancer centers.



The Foundation's 2015 Audited Financial Reports are available on the website.

If you would like additional information or want to discuss how you can support our mission, please contact:

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