

PROGRESS REPORT WINTER & SPRING 2015

Dear Friends,

The first half of the year has brought with it groundbreaking new research that could broaden focused ultrasound's impact on the field of medicine. As the technology spreads worldwide, the Foundation has kept a keen eye, knowing that we must sharpen our focus and concentrate our resources on two areas of immense importance: brain disorders and a newcomer, cancer immunotherapy. While progress has been made, we continue to be frustrated by the slow progress of clinical studies. However, we expect these logjams to weaken moving forward.

Highlights

- Foundation Sets its Sights on Cancer Immunotherapy and the Role of Focused Ultrasound
- State of the Field Report Charts Growth
- Chang named Honorary President of Symposium 2016
- Donor Extends Fellowship Opportunity Through 2017



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Creating Knowledge: Research Milestones

FUNDED STUDIES GAIN MOMENTUM

A Foundation-funded study to investigate focused ultrasound's ability to <u>open the blood-brain barrier</u> for drug delivery has earned a multi-million dollar grant from the NIH for further research. The work, being completed by <u>Elisa Konofagou</u> and her team at Columbia University, has also lead to three publications and seven presentations at scientific meetings.

CHARTING A PATH FOR ALZHEIMER'S DISEASE

In March, <u>promising research</u> in Australia confirmed previous data that suggested focused ultrasound may have a role in the treatment of <u>Alzheimer's disease</u>. In response, the Foundation has created an Alzheimer's The Foundation has funded 3 new studies, and 13 projects received follow-on funding totaling \$25 million

Steering Committee. The group, led by experts in the field, is developing a protocol for a pilot clinical trial to assess feasibility and safety of using FUS to treat the neurodegenerative disease.

PARKINSON'S DISEASE TRIAL COMPLETES ENROLLMENT

The pilot trial for tremor-dominant <u>Parkinson's disease</u> has completed enrolling its 27 patients. It now moves to the follow-up phase, where the patients are monitored for one year following treatment.

FOCUSING OUR SIGHTS ON CANCER IMMUNOTHERAPY

Immunotherapy is a transformative approach to amplify the body's natural immune system to fight cancer. Focused ultrasound has the potential to enhance this concept, and the Foundation has made it a major focus, concentrating resources to make the greatest impact. We partnered with the Cancer Research Institute in <u>convening</u> 30 investigators in New York to explore the current status of and future directions for focused ultrasound research and immunotherapy. We have also compiled a working group to promote collaboration and accelerate discoveries.

FIELD REPORT ADVANCES IN THE FOCUSED ULTRASOUND COMMUNITY

• A prostate cancer device is approved by Health Canada.

• Alzheimer's pre-clinical study in Australia confirms earlier findings that FUS may reduce plaques and improve memory. This research serves as a predicate for early clinical studies.

• Breakthroughs in focused ultrasound for uterine fibroids: Canadian Government agency recommends the treatment; the *New England Journal of Medicine* includes FUS as a viable treatment option.

• The first pediatric patients were treated in the US as Children's National Medical Center begins its bone tumor study.

- Reimbursement successes:
 - German insurance provider agrees to reimburse breast fibroadenoma treatment
 - Approvals for bone metastases treatment broaden in the US

Fostering Collaboration and Innovation

REPORT CHARTS FIELD'S GROWTH

As shared in the <u>2015 State of the Field Report</u>, the community is growing, with over 225 research sites and 390 commercial treatments sites worldwide. This report serves as a tool for researchers to identify potential new collaborative partners and for patients to locate treatment sites. The Foundation team will track this progress annually, along with industry statistics, clinical and pre-clinical research, and regulatory advances.

Increasing Awareness

FOCUSED ULTRASOUND HIGHLIGHTED IN MICHAEL J. FOX FOUNDATION WEBINAR

In March, the Foundation participated in a <u>webinar</u> on treatment advances for <u>Parkinson's disease</u> hosted by the Michael J. Fox Foundation. During the broadcast, which reached 1,500 people, we described the potential for focused ultrasound and its current status in clinical trials.

EVENTS BUILD REGIONAL INTEREST

The Foundation has hosted five events this year to build awareness of the technology and its work. Notably, 150 supporters in <u>Charlottesville</u> heard a moving testimonial from the first pediatric patient in North America treated with focused ultrasound. Jack, a 16-year-old from Toronto, spoke about his pioneering decision to participate in a clinical trial to treat his painful bone tumor and his life-changing outcome.

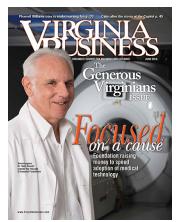
FOUNDATION HOSTS SPRING WEBINARS

This spring, the Foundation began broadcasting webinars, giving experts in the field an opportunity to present on areas of emerging

interest or promising research. We welcomed three speakers on <u>cancer immunotherapy</u>, <u>Alzheimer's disease</u>, and <u>neurodegenerative diseases</u>.

MAKING HEADLINES

The Foundation enjoyed media success during the early part of the year. We were honored to be featured on the cover of *Virginia Business's* Generous Virginians issue. The <u>lead article</u> highlighted the Foundation as a model for success. Chief Scientific Officer, Jessica Foley, PhD, also published an <u>article</u> in *DOTmed's Healthcare Business News* on the variety of clinical applications for the technology.



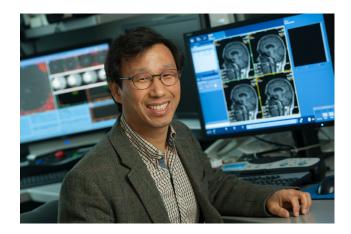


Cultivating the Next Generation

FELLOWSHIP FUNDED THROUGH 2017

The Merkin Fellowship has been renewed through 2017 thanks to a generous donation from Dr. Richard Merkin. The <u>fellowship</u> offers two more scientists the chance to collaborate with the Foundation's scientific and technical teams on research. This year, we are pleased to have Dong-guk Paeng from Korea. Dr. Paeng is studying how focused ultrasound can access broader regions of the brain.

We are now <u>accepting applications</u> for those interested in upcoming fellowships.



A Overcoming Barriers

WORKSHOPS ADDRESS REIMBURSEMENT ROADBLOCKS

The Foundation convened two reimbursement <u>summits</u>, where representatives from industry and various consultants worked to define a path toward reimbursement for essential tremor and uterine fibroids. The <u>essential</u> <u>tremor</u> group devised an action plan for regulatory approval, data publication and generating professional support. The <u>uterine fibroid</u> group discussed evidence and advocacy needs.

Convening the Community

MARK YOUR CALENDAR FOR SYMPOSIUM 2016

The 5th International Symposium on Focused Ultrasound will be held August 28-September 1, 2016 in Bethesda, Maryland. Leading the <u>meeting</u> will be <u>honorary president</u>, Jin-Woo Chang from Korea. Chang has pioneered research in OCD, depression, essential tremor and Parkinson's disease.



WORKSHOP AIMS TO EXPAND BRAIN TREATMENT

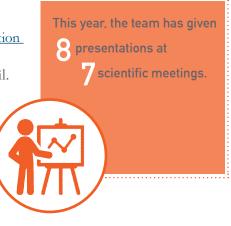
In February, the Foundation hosted a <u>Treatment Envelope</u> <u>& Simulation Workshop</u>, gathering engineers, physicists, and clinicians from 17 organizations to discuss paths toward increasing the treatable area of the brain. The team created a roadmap of projects and a <u>white paper</u> to better define next steps.



Aggregating and Sharing Knowledge

FOUNDATION PRESENTS AT SCIENTIFIC MEETINGS

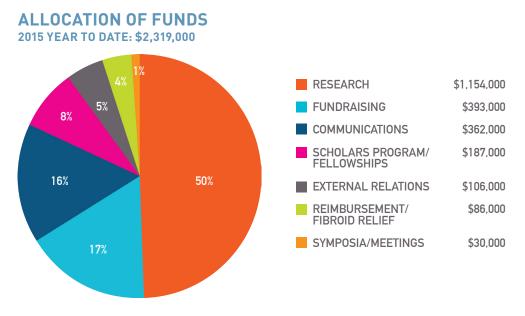
Throughout the year, the Foundation team engages the focused ultrasound community by presenting at key meetings. This year, these included a <u>presentation</u> at Israel BrainTech on the Foundation's collaborative research model and at the <u>annual meeting</u> of the International Society for Therapeutic Ultrasound in April.



🖕 Finances

FOUNDATION FUNDING GOALS ON TRACK

Thanks to our generous donors, the Foundation raised a total of \$3.4 million during the first half of the year. We appreciate your support of our mission to bring this technology to patients in the fastest time possible!



"The Foundation's 2014 Audited Financials are available on the website.

If you would like additional information or want to discuss how you can support our mission, please contact: Mike Cashman, <u>mcashman@fusfoundation.org</u> Nora Seilheimer, <u>nseilheimer@fusfoundation.org</u> (434) 220-4993 www.fusfoundation.org