



FOCUSED ULTRASOUND FOUNDATION

2018 SPRING REPORT

Highlights

- **Parkinson's dyskinesia pivotal trial begins**
- **Alzheimer's disease pilot trial completed; results accepted for publication**
- **Focused ultrasound media coverage expands rapidly**
- **Foundation's new veterinary program launches studies of cancer treatment and wound healing**
- **Presentations raise awareness, funds in Hong Kong, Oklahoma City, others**
- **Registration and abstract submissions open for upcoming 6th International Symposium on Focused Ultrasound**

Dear Friends,

Progress in the evolution of focused ultrasound to become a standard of care for a host of medical diseases continues to advance. The key factor driving this growth is the investment of people from various disciplines who have created a community of passionate enthusiasts committed to accelerating the development and adoption of focused ultrasound. We thank all of you for your encouragement and support.

Thank you, and be well.

Neal F. Kassell, MD





Creating Knowledge: Research Milestones

EXTERNAL RESEARCH AWARDS PROGRAM

In this program, the Foundation funded four projects: “MR-gFUS Gene Delivery for Neuroprotection in Parkinson’s Disease” (Michael Gordon Kaplitt, MD, PhD, Cornell University); “Efficient Transcranial Ultrasound Delivery Using Lamb Waves” (Pierre Khuri-Yakub, PhD, Stanford University); “Therapeutic Efficacy and Safety of Ceramide Nanoliposomes in Combination with FUS for Treating Breast Cancer” (Rich Price, PhD, University of Virginia); and “Functional Neuroimaging Feedback for FUS Thalamotomy for Tremor Surgery” (Vibhor Krishna, MD, Ohio State University).

The total number of funded projects to date is 67. Twenty-eight percent of reviewed proposals have been funded, and 45 projects have been completed. 98% of completed projects have been presented at scientific meetings and 70% of those have been published. For every dollar invested in our external research awards program, more than eight dollars of follow-on or co-funding have been secured. Our ratio of return on investment for donors continues to climb.

Completed external projects, cumulative



\$4.5M

Funding provided for completed projects



\$36.3M

Follow-on funding



x8

Factor by which the Foundation leverages donors' contributions

BRAIN PROGRAM

Preclinical Laboratory Studies

New brain preclinical studies have been initiated related to the use of focused ultrasound for the following: tumor ablation using microvascular obstruction with microbubbles; malignant tumors of the brain (glioblastoma) and benign tumors of the brain (cavernoma) using microvascular occlusion and sonodynamic therapy; and two ischemic stroke studies using focused ultrasound to open the blood-brain barrier to aid recovery of neurological function (one with stem cells and one with mitochondria).

Clinical Trials

Parkinson’s Disease – Dyskinesia

Results of a study using focused ultrasound to treat dyskinesia in 10 patients at Yonsei University Medical Center in Seoul, Korea, will be published in the *Journal of Neurosurgery*. The target treatment area in this study is the globus pallidus, an area in the center of the brain.

A **study of Parkinson’s dyskinesia** was started at Clinical Universitaria in Pamplona, Spain, and nine of 40 patients have been treated. The target treatment area in this study is the subthalamic nucleus.

In a **tractotomy study of Parkinson’s dyskinesia** at Tokyo Women’s Medical University in Japan, the first patient has been treated. This study is treating the nerve pathways that carry undesired nerve signals; the target treatment area in this study is the pallido-thalamic tract.



Creating Knowledge: Research Milestones

BRAIN PROGRAM (CONT.)/Clinical Trials (Cont.)

Depression

A four-patient pilot study of focused ultrasound to treat medication-refractory severe depression has been completed at Yonsei University Medical Center in Seoul, Korea. The target treatment area in this study was the cingulate gyrus, a portion of the brain linked to depression. The results are being reviewed for possible publication.

Another study using focused ultrasound to treat medication-refractory severe depression has been initiated at Sunnybrook Health Sciences Centre in Canada, and the first two patients have been treated. This study is treating the anterior limb of the internal capsule in the brain.

Obsessive-Compulsive Disorder (OCD)

A two-year follow-up of 11 patients who received focused ultrasound to treat medical therapy-refractory OCD at Yonsei University Medical Center in Seoul, Korea, has been published in the *Journal of Psychiatry & Neuroscience*.

In a similar study, five out of 10 patients have been treated so far at Sunnybrook Health Sciences Centre in Canada.

Neuropathic Pain

Two studies have been initiated for the investigation of focused ultrasound to treat neuropathic pain. The University of Maryland is using focused ultrasound to treat medication-refractory neuropathic pain, and the University of Virginia is investigating focused ultrasound to treat chronic craniofacial neuropathic pain. Both studies are now open and enrolling patients.

Alzheimer's Disease

A pilot clinical trial of focused ultrasound to treat Alzheimer's disease in six patients by temporarily opening the blood-brain barrier (BBB) has been completed at Sunnybrook Health Sciences Centre in Canada. The results have been accepted for publication in *Nature Communications* for release this summer.

Amyotrophic Lateral Sclerosis (ALS)

A pilot study of the feasibility and efficacy of using focused ultrasound to treat ALS by opening the BBB in the region of the motor cortex has treated the first patient at Sunnybrook Health Sciences Centre.



The first patient in a pilot clinical trial of FUS to treat Alzheimer's disease being treated at Sunnybrook Health Sciences Centre in Canada.

BODY PROGRAM

In a clinical trial comparing focused ultrasound to radiofrequency ablation in treating osteoid osteomas (painful, benign tumors of the bone) at the University of California, San Francisco and Stanford University, two additional patients have been treated, bringing the total number of patients treated to date to four.

In a clinical trial of focused ultrasound to treat facetogenic low back pain at McGill University in Canada, a total of three patients have been treated.

A 20-patient clinical trial of focused ultrasound to treat osteoarthritis of the knee at Kochi Medical University Hospital in Japan has been completed. The findings were presented at the International Society for Therapeutic Ultrasound meeting in Nashville, and the results have been submitted for publication.



Creating Knowledge: Research Milestones

CANCER IMMUNOTHERAPY PROGRAM

In a first-of-its-kind pilot trial combining focused ultrasound with a cancer immunotherapy drug to treat Stage 4 metastatic breast cancer at the University of Virginia, two additional patients have been treated, bringing the total number of patients treated to four out of 15.

VETERINARY PROGRAM

A study to treat sarcomas and mast cell tumors in dogs is underway at the Virginia-Maryland College of Veterinary Medicine (VMCVM) at Virginia Tech in Blacksburg, Virginia. In the **Foundation-funded trial**, researchers are investigating to use of focused ultrasound to noninvasively destroy tumors and stimulate the dogs' immune systems to fight the cancer. Two patients have been treated.

In **another study** to treat soft tissue tumors in dogs and cats at the Oklahoma State University Center for Veterinary Health Sciences (CVHS), five patients have been treated.



Maddie Lynn
VMCVM patient



Oreo
CVHS patient

In a second study investigating focused ultrasound to speed wound healing at the Oklahoma State University Center for Veterinary Health Sciences, two patients have been treated. In this study focused ultrasound is enhancing delivery of an antimicrobial agent (or drug) to the tissue to treat hygromas (a condition where repeated pressure on a bony joint produces significant swelling).

Convening the Community

2018 SYMPOSIUM



Registration and abstract submissions are open for the **6th International Symposium on Focused Ultrasound**, to be held October 21-25 in Reston, Virginia. The Foundation welcomes abstracts related to the use of image-guided focused ultrasound in preclinical research, clinical research, or technology development; all abstracts must be submitted online

before June 18. More information on registration and abstract submissions can be found on the **Foundation website**.

Gary Shapiro, President and CEO of the Consumer Technology Association (CTA) – which annually produces CES, the largest global innovation and technology conference in the world – has been **confirmed as a keynote speaker** on Tuesday, October 23. Shapiro will discuss the importance of innovation at the intersection of technology, business, and healthcare.



Gary Shapiro, CEO CTA

Increasing Awareness

PRESENTATIONS

Foundation Chairman Neal F. Kassell, MD, and Board member John Grisham spoke with nearly 200 people at three events in Oklahoma City including the Young Presidents' Organization (YPO), the boards of American Fidelity Assurance Company and First Fidelity Bank, and guests at the Oklahoma City Golf and Country Club. The day was organized by brothers and Foundation supporters Mark and Greg Allen.

Neal F. Kassell, MD, presented to nearly 100 people at various events in Hong Kong including the Harvard Club and Yale Club, American Chamber of Commerce, Gleneagles Hospital leadership, and private events at the Hong Kong Club and Foreign Correspondents Club. These opportunities were coordinated by Council member Shirley Lin and Foundation supporters Bernice Szeto and Rosa Ling. Media interviews were also conducted with reporters from South China Morning Post and S&P Global.

Foundation Chief Medical Officer Tim Meakem, MD, also presented to 85 people at the Military Officers Association in Charlottesville, Virginia, and Chief Scientific Officer Jessica Foley, PhD, spoke to 150 people at the Peninsula Engineers Council in Hampton, Virginia.



CES (CONSUMER ELECTRONICS SHOW)



In January the Foundation participated in **CES® 2018** – known as the “Global Stage for Innovation” – in Las Vegas, Nevada, to raise awareness of focused ultrasound technology among an unprecedented audience of tens of thousands of fellow global innovators, technology-minded consumers, and journalists. Foundation Board member and best-selling author John Grisham and Chairman Neal F. Kassell, MD – joined by Foundation staff – participated in a wide variety of strategic outreach activities including: two exhibitor booths on the convention floor; “Unveiled” media event; **“Gary’s Book Club” interview**

discussing Grisham’s *The Tumor*; **“Let’s Go Humans” panel** discussion focusing on organizations using technology to better the world; and on-site media interviews and additional media coverage post-CES resulting in a potential audience reach of more than 100 million. CES is produced annually by the Consumer Technology Association (CTA); more than 180,000 people attend the event.

MEDIA PLACEMENTS

Focused ultrasound was featured prominently by several major national and global news outlets, achieving our largest media reach to date, primarily due to the Foundation’s participation at CES 2018. The combined potential reach of our first quarter media hits exceeds 100 million. Highlights include: CNBC, NBC News, WIRED, Forbes, Huffington Post, NPR, Toronto Star and CBC/Radio-Canada. Links to these articles can be found our website.

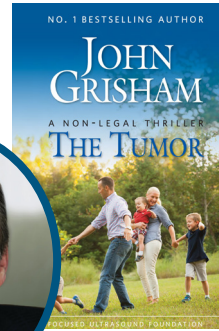
Read More Below:



Increasing Awareness

JOHN GRISHAM'S "THE TUMOR"

Distribution of Foundation Board of Directors member John Grisham's popular **e-book discussing focused ultrasound** continues to climb, with nearly 920,000 hardcopy and electronic books distributed to date. A new audiobook version of the book featuring an introduction from Grisham will be available in June.



Aggregating and Sharing Knowledge

SOCIAL MEDIA AND WEBSITE

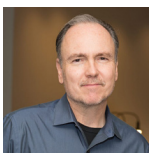
The Foundation's social media and online presence continues to grow, with targeted outreach efforts continuing to attract a steady stream of followers. Web traffic was up nearly 30% in the first quarter of 2018. We have also seen website increases this year in visitors from outside the US, mobile versus desktop viewing, and time spent on the site. On social media we have seen increases in Facebook likes as well as followers on Twitter, YouTube, LinkedIn and Instagram. Please be sure to follow us on these social media platforms.



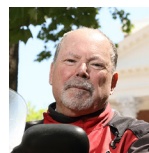
SEMINAR SERIES

The Foundation hosted a webinar with Optum's Rick Hamilton entitled, "Blockchain: A Healthcare-Focused Introduction." Blockchains are an application of cryptography used to construct distributed, immutable records; webinar participants learned where blockchain opportunities exist and gained a basic understanding of the technology and its major platforms. A Distinguished Engineer with Optum, Rick Hamilton works broadly across strategic imperatives, including machine learning, genomics, blockchain, IoT, and cybersecurity to help people live healthier lives and make healthcare work better.

A second webinar was led by Philip Bourne, PhD, Stephenson Chair of Data Science and Director of the Data Science Institute at the University of Virginia, entitled, "Data Science in Biomedicine – How Much Value Versus How Much Hype?" Dr. Bourne explored some of the questions relating to data science in biomedicine including successes and failures, whether or not developments in the category point to a paradigm shift, and what organizations and individual researchers should be doing to hedge their bets.



Rick Hamilton
[Watch Now >](#)

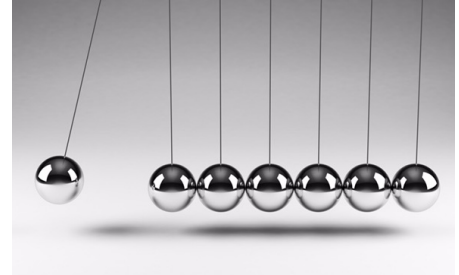


Philip Bourne, PhD
[Watch Now >](#)

FUNDRAISING

The Foundation raised \$2 million in new cash and \$500,000 in pledges from January 1st to May 17th. This is a strong start to the year, as we work to meet our goal of \$5 million in cash and \$5 million in pledges to be paid in 2019.

In July of 2017, we had the good fortune to receive a **\$10 million pledge** of unrestricted funds that need to be matched one for one. According to the terms of this “MegaMatch” pledge agreement, this generous donor will match any gift to the Foundation dollar-for-dollar up to \$10 million by 2022. To date (May 17), we have raised approximately \$5.4 million against the match and hope to meet the match by the end of 2018. We hope you will consider helping us to meet this goal, appreciating that your gift will be doubled.



FINANCES

Compared to budget for the first quarter, the Program and Indirect Expenses are running 17% below budget and Program Awards are 69% below budget, with timing being a significant factor. Revenues for the same period are 117% above budget due to the one-time Mega Match (which effectively contributes 108% of the 117% because it doubles everything we receive).

FOUNDATION ORGANIZATION



Charles Steger, PhD

Board of Directors

We are saddened to share that we have lost one of the Foundation’s most effective members of the Board of Directors, Charles Steger, PhD. Dr. Steger led one of the longest and most impactful terms as the 15th president of Virginia Polytechnic Institute and State University (Virginia Tech). He joined the Foundation’s Board of Directors in 2016 to “make a difference in improving the human condition.” Dr. Steger died on May 6 at the age of 70. We are honored to **name the Foundation’s internship program** in his memory.

Foundation Team

Our internal team was strengthened with the addition of two information technology specialists, Tony D’Alessio and Deborah Heishman. Mike Broad was also hired as a Project Manager/Manufacturer Relationships Coordinator. We are continuing to grow our team in response to the ever-changing field of focused ultrasound.



Tony D’Alessio



Deborah Heishman



Mike Broad



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

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