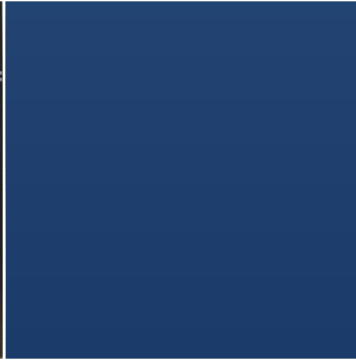
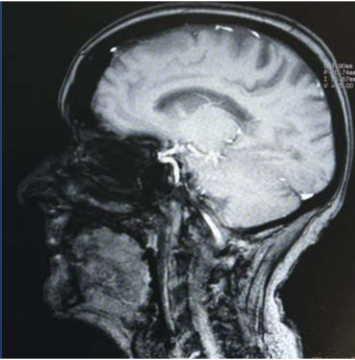
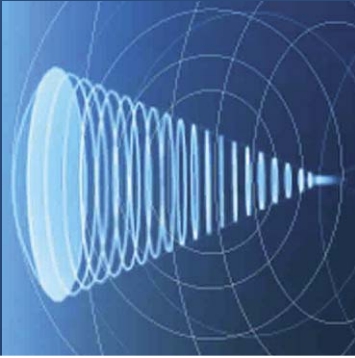


Focused Ultrasound Foundation

Progress Report



the revolution has begun



it's all about the patients

The Focused Ultrasound Foundation's mission is to improve the lives of millions of people worldwide by accelerating the development and adoption of focused ultrasound, a revolutionary, noninvasive therapeutic technology that is early stage, but with additional research and development could potentially transform the treatment of a variety of serious medical disorders.

the revolution has begun

The Focused Ultrasound Foundation was created to revolutionize the treatment of a variety of serious medical disorders and, thereby, improve the lives of millions of people worldwide by funding research, raising awareness and accelerating the global adoption of focused ultrasound.

In 2011 the revolution began in earnest as judged by a palpable increase in the enthusiasm and interest of stakeholders in the focused ultrasound community, including physicians, scientists, manufacturers, patients, regulatory agencies, investors, payers and the media.

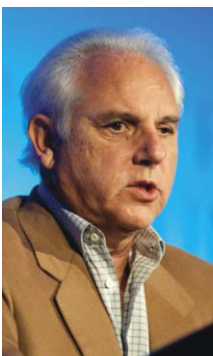
The spark that ignited the revolution was the essential tremor clinical trial organized by the Foundation and conducted in partnership with the University of Virginia and InSightec, the manufacturer of the focused ultrasound device used in the trial.

Capitalizing on years of hard work, innovation and risk-taking by many pioneers in industry and academia, the essential tremor trial demonstrated the enormous potential of the technology. If focused ultrasound can be used to safely reverse a long-standing neurological disability and improve quality of life by noninvasively treating an area deep in the brain through the intact scalp and skull with extreme precision and accuracy in a fully awake patient, we believe it's also potentially capable of successfully and safely treating less sensitive tissues such as breast, liver, prostate and bone.

The dialogue has shifted from “*if* this technology truly can have a transformational role in therapy” to “*when* will this technology be widely available?” And, because of our activities and programs—including funding research and training, fostering collaboration and partnerships, disseminating information and coordinating stakeholders efforts—the Focused Ultrasound Foundation has become generally recognized as the compass or guiding light for the field.

We are at a tipping point and can see the day when focused ultrasound will no longer be one of “medicine’s best kept secrets.” Towards this end, we were thrilled that the prestigious conference TEDMED included focused ultrasound on its 2011 agenda and that *TIME* Magazine recognized focused ultrasound as one of the “50 Best Inventions of 2011.”

The generous support and encouragement of our donors has made these accomplishments possible. The challenge now is to continue building on the momentum we have gained. With a steadfast commitment to the disciplined, entrepreneurial approach that distinguishes this organization, we will act decisively to ensure that 2012 is another successful year for the field and, even more importantly, for the patients.



Neal F. Kassell, MD

A handwritten signature in blue ink that reads "Kassell".

Neal F. Kassell, M.D.

Chairman



highlights

- World's first patient treated for essential tremor with focused ultrasound
- Brain Workshop drives research breakthroughs
- *TIME* Magazine recognizes focused ultrasound as a top invention of 2011
- Liver and Pancreas Program launched
- European focused ultrasound community strengthens ties
- Focused ultrasound "wows" audience at TEDMED
- Foundation research funding exceeds \$4 million mark



it's all about patients

With additional research and development, focused ultrasound could potentially transform the treatment of a variety of serious medical disorders.

Focused Ultrasound could be—

- A breakthrough in noninvasive surgery
- A replacement for or complement to radiation therapy
- A way to deliver chemotherapeutics and other drugs at higher concentrations to precise targets with less toxicity
- The means to dissolve blood clots and restore circulation in blocked vessels

Focused Ultrasound could be used to—

- Eradicate tumors of the brain, breast, prostate, liver and other organs
- Convert metastatic cancer from a lethal condition to a chronic, controllable disorder
- Reverse neurological deficits from stroke
- Alleviate the symptoms of Parkinson's disease, essential tremor and epilepsy

Focused Ultrasound could fulfill unmet patient needs and provide superior treatments that—

- Require no general anesthesia or incisions
- Can be performed on an outpatient basis, usually in a single session
- Cause less pain and discomfort
- Allow for more rapid recovery
- Result in fewer complications, like infections or blood clots
- Avoid the toxic side effects of drug and radiation therapies
- Are safer and more effective
- Cost less
- Produce an immediate and verifiable effect

Research is underway to further explore the enormous potential of this early-stage technology.

impact

first in the world essential tremor trial

The Foundation helped make medical history in 2011. For the first time, focused ultrasound was used to treat essential tremor, a debilitating neurological condition that affects 10 million people in the United States and millions more worldwide.

In February 2011, the world's first patient was treated for essential tremor with focused ultrasound. With the goal of reducing the uncontrollable shaking in the patient's hand, W. Jeffrey Elias, M.D., Director of Stereotactic and Functional Neurosurgery at the University of Virginia, and his team ablated, or destroyed, the tremor-causing cells deep within the patient's brain by heating and thereby burning away the abnormal cells with focused ultrasound energy. The procedure was completely noninvasive (no surgery) and the patient, 74-year old Mr. Billy Williams, was wide-awake during the procedure (no anesthesia).

A total of 15 patients were treated in this pilot study, which was organized and funded by the Foundation thanks to the generous support of our donors. The interim results of this study, as presented at the Congress of Neurological Surgeons Annual Meeting in October 2011, are encouraging. Based on a standardized rating scale, the patients have essentially no residual disabilities in daily activities following treatment. For the patients and their families who have suffered with the debilitating condition for years, the treatment has been "life-changing."

The trial represents a potential quantum leap for the field as it demonstrates that focused ultrasound may offer patients a better alternative to invasive surgery or complicated drug therapies. In addition, it lays the groundwork for new clinical trials for other neurological disorders, like Parkinson's disease, brain tumors and epilepsy, and opens the door to studying focused ultrasound therapy to treat targets more easily reached in the body, such as in the breast, prostate or spine.

pilot project



Before the procedure, Billy R. Williams could not write legibly or drink and eat normally. Immediately after treatment, the tremor almost completely subsided and he walked outside for this photo with the essential tremor clinical trial team.

The leadership of W. Jeffrey Elias, MD, Diane Huss, PT, DPT, NCS and the University of Virginia team has been critical in advancing this groundbreaking research in partnership with the Foundation.



before...

& after treatment





pre & post treatment

Pre-treatment

This is my handwriting
Phyllis Walker
7-22-11

*Phyllis Walker
7-22-11*

Post-treatment

This is my handwriting
Phyllis Walker
7-22-11

*This is my handwriting
Phyllis Walker
7-22-11 pm*



impact

fast-tracking the technology through collaboration

The groundbreaking essential tremor trial was conducted in 2011 because of the Foundation's leadership and vision. This initiative demonstrates the Foundation's ability to help patients while driving the field forward.

At the Foundation's initial Brain Workshop in 2009, 45 physicians, scientists, government officials and industry leaders gathered to discuss how best to safely and efficiently fast-track use of focused ultrasound therapy. It was at this meeting that Dr. Jeff Elias championed the idea of using focused ultrasound as a noninvasive treatment for Parkinson's disease and other movement disorders. He suggested that the first step on the roadmap should be a clinical trial to treat patients with essential tremor. Essential tremor was considered an ideal subject because the target of treatment in the thalamus, a structure deep in the brain, is well established. This idea was enthusiastically discussed and endorsed.

Following the meeting, the Foundation assembled an internationally recognized group of physicians as the Movement Disorders Steering Committee with Dr. Elias leading the research as the principal investigator. In collaboration with the Foundation and the device manufacturer InSightec, Dr. Elias began developing the regulatory protocol. Once the FDA approved the study, the Foundation worked with the University of Virginia and InSightec to initiate the trial and secured the financial resources needed to fund patient treatments.

The essential tremor trial illustrates the Foundation's ability to forge partnerships between industry and academia, as well as the Foundation's insistence on tightly managing donor funds to ensure that meaningful projects that accelerate the field and improve life for the patients are achieved.

Before treatment Phyllis Walker's handwriting was illegible. After the treatment, her handwriting vastly improved, allowing her to once again write letters to her grandsons serving in Iraq and Afghanistan.

ABC NEWS featured the Foundation-funded essential tremor clinical trial and the encouraging preliminary results of the study.



in the news



impact

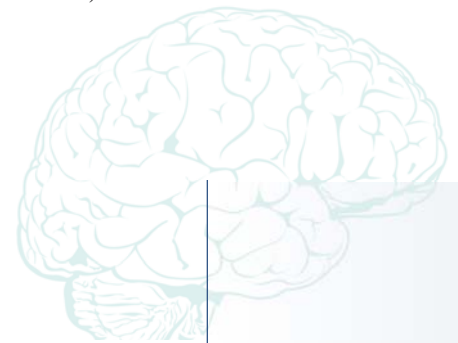
more work to be done

While the first step is complete, more work must be done before the treatment is widely available to patients.

As with most new medical devices and particularly in the case of a device using an early-stage technology like focused ultrasound, government regulatory authorities typically require a series of patient studies. If the initial study is successful in showing the treatment to be feasible and safe, then one may opt to move onto a larger study to prove the treatment's clinical effectiveness, with the goal of ultimately gaining full regulatory approval.

For essential tremor, the next step forward is to advance this promising treatment option by organizing a larger patient study in the United States with the goal of achieving FDA approval for the treatment of essential tremor with the InSightec device. Toward this end, the Foundation is exploring partnership opportunities to ensure the continued acceleration of focused ultrasound treatment options for essential tremor patients. We are also gathering data related to the cost of focused ultrasound treatment versus current standard of care alternatives to pave the way for reimbursement from insurance providers.

The Foundation is forging ahead and making plans to continue this research with the goal of establishing a new, noninvasive treatment for Parkinson's disease and epilepsy. Until focused ultrasound treatments are widely available to patients suffering from movement disorders, this work is not done.



John Watterson, the fifth person treated in the essential tremor clinical trial, and his wife, Yvonne, described the procedure as "marvelous" and exclaimed "it was one of the happiest days of our lives."



“is it still surgery if you don't cut anything?”

The “greatest minds in health and medicine” uttered a collective “Wow!” at TEDMED2011 when InSightec Vice President and Chief Systems Architect Yoav Medan described the outcomes of the essential tremor clinical trial. The inclusion of focused ultrasound on TEDMED’s agenda places it among an elite set of breakthroughs shared with a world-class audience.



vision + collaboration + programs = results

accelerate

strategic vision

Everything we do begins and ends with the patient in mind. If you or a loved one is sick, soon is not fast enough.

Moving a medical device from research bench to patient bedside is a slow, complex process that can consume decades while patients continue to suffer. Because focused ultrasound has such enormous potential to save lives and reduce suffering, this delay is unacceptable.

The Foundation was created to streamline the process and bring this revolutionary technology to patients in the shortest time possible. We began by analyzing the medical device development process from concept to worldwide standard of care, pinpointing chokepoints and identifying opportunities to accelerate progress.

Then we built an organization designed to break through these chokepoints and catalyze cooperation among stakeholders, concentrating on high-priority areas where we have the greatest ability to affect change. Our programs are designed to provide an adrenaline rush in the field and achieve progress faster. We work to clear the path to global adoption of focused ultrasound by coordinating research activities, creating effective partnerships, fostering collaboration and building awareness of “medicine’s best kept secret.”

We are dedicated to exploring the potential of focused ultrasound as a mainstream therapy for cancer, brain tumors, Parkinson’s disease, epilepsy, stroke and other life-threatening conditions within years, not decades. To do so, we have become the:

- Largest nongovernmental funder of focused ultrasound research
- Worldwide network for researchers and treatment sites devoted to focused ultrasound
- Foremost authority on focused ultrasound technology
- Leader in developing disease-specific roadmaps designed to bring focused ultrasound treatments to patients in the shortest time possible
- Global clearinghouse for information on the latest advances in the field
- Most trusted source for patients
- Compass, influencing and setting direction for the field

Much like an adrenaline rush, the Foundation’s programs provide energy needed to speed-up the global adoption of focused ultrasound and make this revolutionary medical technology available to patients in the shortest time possible.

The philanthropic support of our donors, who recognize the urgent needs of patients, the potential of focused ultrasound therapies and the value of our disciplined, entrepreneurial approach, makes this work possible.

innovate

advancing research to help patients

For thousands of people struggling with deadly diseases and debilitating conditions, few if any treatment options exist. Others must settle for treatments requiring invasive procedures which may permanently diminish their quality of life.

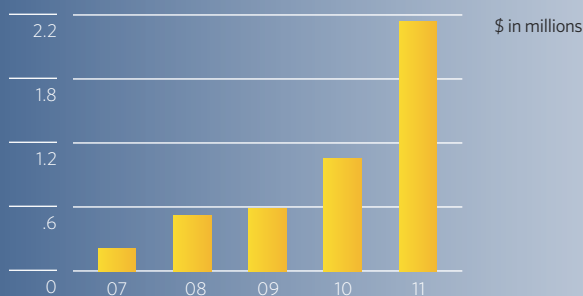
Patients deserve better. To help them, the Foundation devotes the majority of its resources to research.

Research Strategy

The Foundation funds research projects with the greatest potential of leading to the rapid development of new, reimbursable focused ultrasound treatments for unmet patient needs or that are superior to current therapies. We also support high-risk, early-stage, proof-of-concept projects that are unlikely to receive funding from other sources and could have a profound impact on the adoption of focused ultrasound.

Our funding enables researchers to compile the preliminary data needed to apply for follow-on funding—from government agencies, industry leaders or other philanthropic groups—that they can use to move their work closer to clinical reality. Furthermore, we use our funding powers to encourage changes in the research paradigm to make it more efficient and more patient-focused.

foundation research commitments



The Foundation is continually increasing its investment in high-priority research projects that may lead to new treatments for unmet patient needs, are superior to current therapies or could accelerate the adoption of focused ultrasound.



research that moves the dial

Foundation-funded research awards have led to follow-on funding from others in excess of \$10 million, a 1,000 percent return on investment. By targeting research that could have a profound impact and has the potential to receive additional funding, the Foundation is leveraging its financial investment.



Brain Workshop 2011

To foster collaboration among the diverse leaders engaged in the field, the Foundation convened its third annual Brain Workshop in October 2011. Seventy-seven leading scientists, researchers, physicians, public health officials and industry executives from 12 countries and 30 different institutions attended.

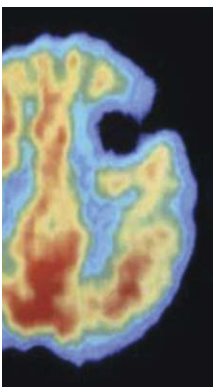
The Brain Program

The essential tremor clinical trial of 2011 was a major milestone for the Foundation’s Brain Program. Encouraged by its promising results, we are pushing the envelope of discovery further and making plans to treat patients suffering from Parkinson’s disease and epilepsy.

At the same time, we are initiating new studies to help patients with brain tumors. Focused ultrasound could offer an alternative to invasive brain surgery, a complement or replacement to radiation therapy or a treatment option where none is available.

Another area of keen interest relates to exploring the use of focused ultrasound to improve the delivery of chemotherapy drugs, antibodies, growth hormones and other pharmacological agents to the brain. Laboratory studies have shown that focused ultrasound in combination with microbubbles can safely create a temporary breach in the blood-brain barrier, a tightly formed membrane which protects the brain from everyday exposure to mundane ailments like the common cold but which makes it difficult to deliver helpful drugs and other agents to the brain. This research could open the possibility of treating not just brain cancer, but a whole range of neurological diseases.

In addition to funding clinical trials, the Brain Program is advancing a variety of preclinical laboratory studies, as well as select technical research projects. The research results are made available to the community, thus not for the exclusive benefit of any one device manufacturer, academic institution or research scientist.



The Foundation identified the brain as a watershed target for focused ultrasound and established the Brain Program in 2009 with the goal of driving innovation in this area.

brain applications



Liver and Pancreas Program

To advance focused ultrasound therapies for two of the most deadly, prevalent and difficult-to-treat cancers, the Foundation launched the Liver and Pancreas Program in 2011. This decision was an important outcome of the Focal Drug Delivery Workshop held in March 2011. The workshop attracted 63 participants from 36 institutions in 10 countries and identified liver and pancreas cancer as a primary research interest.

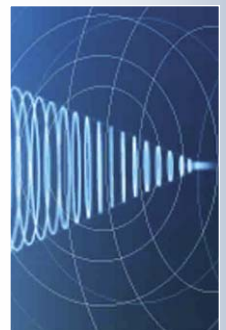
Two approaches are being explored. The first is to ablate the tumor by heating and destroying the tissue with focused ultrasound, thus avoiding surgery. Ablation may also provide a replacement or complement to radiation therapy. The second approach is to use focused ultrasound to enhance the delivery of chemotherapeutics to the tumor site. Focused ultrasound may offer a way to deliver powerful chemotherapy drugs in higher concentrations than possible through traditional methods while reducing toxic side-effects.

The Foundation is now organizing a world-class working group to develop research roadmaps for liver cancer. In addition, laboratory studies to evaluate the combination of focused ultrasound and chemotherapy in the treatment of pancreatic cancer are underway.



Joo Ha Hwang MD, PhD
University of Washington

Working with the Foundation, Dr. Joo Ha Hwang is advancing research aimed at improving the treatment of pancreatic cancer by using focused ultrasound to enhance drug delivery into the tumor. Estimates indicate focused ultrasound could benefit as many as 161,000 patients suffering from pancreatic cancer worldwide each year.



Research Awards Program

The Research Awards Program is geared toward funding investigator-initiated projects and gives the Foundation an avenue to encourage new ideas for treatments addressing a broad spectrum of diseases and conditions ranging from breast and prostate cancer to diabetes, functional brain disorders and chronic back pain. With research funding from government agencies and industry declining, the Foundation's support is more critical than ever.

In 2011, the Foundation received 35 abstracts from individual investigators, a record number and a 67 percent increase from the previous year. The Foundation provided awards to six researchers working in the United States and abroad. Awards are typically \$100,000 over a 12-month period.

The Foundation's Research Advisory Committee guides our selection through a peer-review process. The committee consists of academic, industry and government thought leaders with expertise in such fields as focused ultrasound, magnetic resonance imaging, cancer treatment and focal drug delivery.

Since 2007, the Foundation has received 108 abstracts, invited 95 proposals and disbursed \$2.4 million to fund 23 projects. Of these, 11 projects are complete. These projects have generated 16 papers and 47 presentations, and have led to follow-on funding in excess of \$10 million, a 1,000 percent return on investment.



Nathan McDannold, PhD
Bringham & Women's
Hospital



Natalya Rapoport, PhD, DSc
University of Utah



Bijan J. Borah, PhD
Mayo Clinic

2011 FUSF-funded institutions

Brigham & Women's Hospital, Harvard University
Imperial College and Saint Mary's Hospital, United Kingdom
Institute Langevin, France
Mayo Clinic
University of Arkansas
University of California San Diego
University of Toronto
University of Utah
Universtiy of Virginia

building community

and achieving better results through collaboration

Collaboration is much more than a word to us, and we realize that it is not easy to achieve. But collaboration leads to diverse teams that produce better results; therefore, it is a “must have” in the world of focused ultrasound.

Collaborative Research Network

As a trusted, independent third party that is unbiased and does not stand to achieve financial gain, the Foundation has the unique ability to play the role of global connector and link all stakeholders engaged in the international focused ultrasound field, including individual investigators, research and treatment sites, government agencies and industry leaders. Through our Collaborative Research Network (CRN), we do just that. By bringing together people from different backgrounds, disciplines, cultures and generations, the Foundation can leverage all they have to offer and use their talents to drive innovation.

The Foundation encourages both online and interpersonal interactions among its CRN members. Foundation staff maintain ongoing contact with sites and researchers, resulting in the CRN as the most comprehensive and up-to-date source of information about the dynamic, ever-changing field of focused ultrasound. Through the CRN’s online portal, working groups, such as the Brain Cancer Working Group or the University of Virginia Research Group, can collaborate and share research developments in real time, avoiding common pitfalls that slow progress, such as redundant studies or individual achievement trumping collaborative teamwork.

researchers by region

67	Asia/Pacific
144	Europe
31	Canada
241	United States



483

Through its Collaborative Research Network, the Foundation plays the role of global connector and links the stakeholders engaged in the focused ultrasound community.

The number of research sites worldwide continues to increase, reflecting the scientific and medical community’s growing interest in this dynamic field.



research sites by region

- 22 Asia/Pacific
- 59 Europe
- 11 Canada
- 72 United States



164



First European Symposium

Alessandro Napoli, MD, PhD, and his colleagues at Sapienza University of Rome organized the First European Symposium and are driving forces for the European focused ultrasound community.



Symposia and Meetings

The Foundation sponsors and participates in conferences that are important to advancing the focused ultrasound field. By supporting and participating at such meetings, the Foundation forges relationships with leading investigators worldwide.

In 2011, the Foundation helped the European research community organize its First European Symposium on Focused Ultrasound Therapy. Held in Rome in September 2011, the symposium attracted more than 200 people. Foundation chairman Neal Kassell, M.D. served as its co-president. The event galvanized the European research community and resulted in the formation of a European Working Group dedicated to fostering collaboration among investigators and sites in those countries.

As a way to encourage and support the inclusion of focused ultrasound on the program agenda of relevant professional meetings, the Foundation sponsors, attends and often presents at related conferences. To further capitalize on conference opportunities, the Foundation hosts informal meetings and events for the focused ultrasound community during such events. In 2011 Foundation board director David Heller and his wife Diane graciously hosted a dinner for nearly 75 members of the research community who were attending the Radiological Society of North America's annual meeting in Chicago.

By forging collaborations and partnerships, the Foundation is building a strong focused ultrasound community and making great strides on a global scale.



Wladyslaw Gedroyc, MD

2012 **s y m p o s i u m**

In 2012, the Foundation will host the Third Biannual International Symposium on Focused Ultrasound Therapy. Wladyslaw Gedroyc, MD of Imperial College and Saint Mary's Hospital in London will be the honorary president.

educating the next generation

fellowship support

The future of focused ultrasound depends on imaginative, well-trained, dedicated physicians and scientists entering this rapidly-changing field. To help them help patients, the Foundation funds educational fellowships.

To accelerate breakthroughs and encourage bold new ideas, the Foundation provides today's best young scientists and clinicians with funds to pursue training and research opportunities. These funds enable those with the greatest potential for advancing and promoting the field to work with luminaries at leading focused ultrasound treatment and research sites.

Fellowships allow rising young physicians to gain the experience needed to bring focused ultrasound therapies into their own medical practices. For young scientists, fellowships give them opportunities to pursue focused ultrasound research and accelerate the translation of scientific discoveries into new treatments for cancer, movement disorders and other debilitating conditions.

In our first five years, the Foundation has awarded nine young physicians fellowships, enabling them to work at sites in the United States and abroad. Three of these awards were made in 2011 to fellows working at Methodist Hospital Research Institute, Houston, University of California, Los Angeles, and University of Dundee, Scotland. With additional funding, we will continue this program in future years with a focus on young scientists.



Sarfraz Ahmad, PhD, MRCS, University of Dundee

Having witnessed the suffering of patients with metastatic prostate cancer, Dr. Sarfraz Ahmad became interested in focused ultrasound as a potentially superior treatment for this disease. The Foundation is providing a fellowship for him to pursue his goals of offering focused ultrasound therapies to patients.

establishing best practices

centers of excellence

To ensure patient care and research of the highest quality, the Foundation establishes Centers of Excellence at institutions with global reputations for both research and clinical care.

Through its Centers of Excellence Program, the Foundation is establishing a template for how research, training, and patient care can be combined to drive the adoption of focused ultrasound therapies. These centers are highly collaborative, bringing together researchers and clinicians from a variety of disciplines and involving contributions from academia, industry and government.

The Foundation's first Center of Excellence, located at the University of Virginia, is a case in point. Dedicated in September 2009, the Focused Ultrasound Center represents a partnership between the University of Virginia, the Commonwealth of Virginia, the Foundation, Insightec and General Electric. It draws on expertise from 10 departments at the University and the work of more than 40 clinicians and scientists.

In 2011, the UVA Center was the site of the essential tremor trial, which attracted global attention and made medical history. This trial is just one element of an ambitious research agenda fostered at UVA where 20 studies related to focused ultrasound therapy are planned or underway. In celebration of its second anniversary, UVA held a mini-symposium in September 2011, which featured leading preclinical and clinical research, as well as a presentation on focal drug delivery from representatives of the U.S. National Institutes of Health.



Recognizing Virginia's leadership in the field, Governor Bob McDonnell toured the UVA Center in 2011. Also during the year, investigators from China, France and South Korea traveled to Charlottesville to learn from research and patient treatments taking place there.



Virginia Governor Bob McDonnell touring with UVA leaders Helen Dragas and Leonard Sandridge.

increasing awareness

& building momentum

To increase awareness of “medicine’s best kept secret” and provide information about the latest advances in the field, the Foundation directs communications and patient support programs.

Communications

The Foundation has earned a reputation as the most trusted source of timely and authoritative information about focused ultrasound. During 2011, our communications and public relations efforts produced a steady stream of press releases and cultivated media interest, which resulted in focused ultrasound features in *TIME* Magazine, *CBS Weekend Evening News*, *ABC World News*, National Public Radio, *Richmond Times-Dispatch*, as well as in *Albemarle Magazine* and other local news outlets. In addition, medical media coverage included articles in *Medscape*, *Medgadget* and *MedTech Insight*.

At our website, www.fusfoundation.org, visitors can find up-to-date information about treatment sites, clinical trials, research funding, equipment manufacturers and more. In 2011, website traffic increased by 33 percent from 2010.

In addition, our monthly online newsletter is attracting a growing audience, as evidenced by the number of subscribers, which increased by 34 percent from the prior year. Our social media program, including Facebook, Twitter and YouTube, also experienced explosive growth in 2011.

in the news

The logo for TIME magazine, featuring the word "TIME" in a bold, red, serif font.The logo for CBS, featuring the letters "CBS" in a bold, black, sans-serif font next to the CBS eye symbol.The logo for NPR, featuring the letters "n", "p", and "r" in a bold, sans-serif font, each in a different color (red, black, and blue respectively).

Media attention reached an all-time high in 2011 and is helping us shift the dialogue from “if this technology truly can have a transformational role in therapy” to “when will this technology be widely available?”

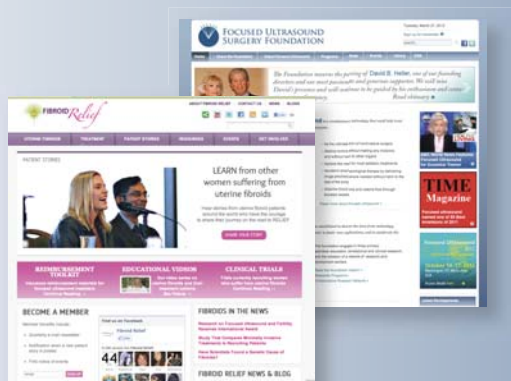
Patient Support

More than 600,000 women have a hysterectomy each year in the United States alone and it is estimated that approximately half of these are the result of uterine fibroids. Focused ultrasound could provide a noninvasive treatment option for many women in the U.S. and around the world who want to avoid major surgery and the lengthy recovery time associated with other treatment options.

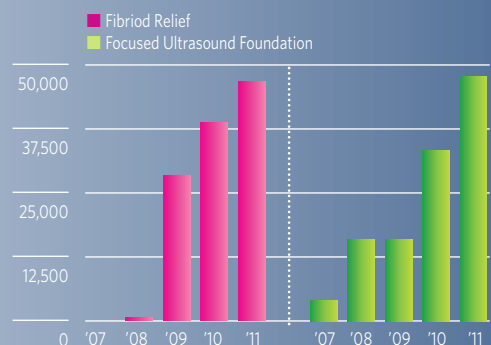
The U.S. FDA approved a focused ultrasound treatment for uterine fibroids in 2004, and focused ultrasound treatments have since been approved by regulatory authorities across the globe, including in Europe, Korea, Japan, India and Australia. Despite these achievements, access to and awareness of the technology remains limited. Lack of widespread insurance reimbursement poses a major barrier in the U.S. and several other countries, discouraging hospitals and physicians from recommending focused ultrasound as a treatment option.

The Foundation established the patient support program Fibroid Relief as a resource for women seeking information about uterine fibroids and alternative treatment options. We have reached nearly 100,000 women through our website (www.fibroidrelief.org), Facebook page, and a series of educational events in the United States and United Kingdom. In addition, hundreds of women annually access our Focused Ultrasound Insurance Toolkit to help them navigate the payment process. During 2011, visitors to the Fibroid Relief website increased by 20 percent over the previous year. We continue to engage women around the world, with more than 6,500 Facebook fans—an increase of 86 percent over 2010.

Through both the Fibroid Relief website and the Foundation's website, we are increasingly a "go to" resource for patients interested in learning about focused ultrasound treatments and research.



web traffic



improving access

reimbursement

Because widespread adoption depends on reimbursement from insurance providers, the Foundation establishes collaborative programs to examine the value proposition of focused ultrasound therapy, build evidence and advocate for patients.

Lack of reimbursement slows patient access to focused ultrasound therapy. Until insurance companies are willing to pay for focused ultrasound therapy, hospitals will not offer it and patients will have limited access to these treatment alternatives.

The Foundation is establishing collaborations and developing methods to heighten the likelihood of new applications being considered commercially viable and reimbursable. As new clinical trials are designed, the Foundation is consulting with researchers to ensure that studies are designed from the start not only to demonstrate safety and efficacy, but also to meet insurers' requirements for data demonstrating superior long-term benefits, quality of life and cost-effectiveness.

To improve patient access to focused ultrasound therapy for uterine fibroids, in 2011 the Foundation organized a Reimbursement Working Group as a partnership between Philips Healthcare, InSightec and the Foundation. This working group funded a study assessing the views of clinicians and private payers about the use of focused ultrasound for fibroids, and commissioned a comprehensive review of the published literature and the development of a value dossier.

In addition, the Foundation joined with clinicians and industry to advocate for a change in United Kingdom policy, resulting in the UK's National Institute for Health and Clinical Excellence (NICE) declaring that focused ultrasound is safe and effective for normal use. NICE's endorsement will help build support for reimbursement from private payers in the UK, as well as in the United States and other critical markets.

advocating for patients

Thanks in part to the Foundation's efforts, the UK's National Health Service's National Institute for Health and Clinical Excellence (NICE) declared that focused ultrasound is safe and effective for normal use in the treatment of fibroids.



bridges, not barriers

regulatory affairs

In 2011 the U.S. FDA for the first time officially recognized the field of focused ultrasound and its potential as “a leading-edge technology to perform surgery without incisions.”

A key aim of the Foundation’s Regulatory Affairs Program is to facilitate dialog with U.S. Food and Drug Administration officials and provide them with data required to advance focused ultrasound patient studies. In doing so, the Foundation supports researchers in developing clinical study protocols that adhere to FDA standards.

Thanks to the working relationship between the Foundation and the FDA, focused ultrasound therapy gained traction with this important regulatory agency in 2011. In addition to recognizing its potential to “reduce the number of invasive surgeries that patients need,” the FDA acknowledged that existing methods to test focused ultrasound systems have been complicated and often unreliable. To move the field forward, the FDA developed test methods for focused ultrasound products and is evaluating tests developed by others.

In addition, Foundation representatives work with regulatory agencies to establish pathways for new indications. As part of these efforts, the Foundation helped facilitate regulatory approval for the essential tremor trial and continues to work with the FDA on studies related to tumors of the brain, breast and prostate, as well as Parkinson’s disease.

The Foundation helped facilitate regulatory approval for the essential tremor trial and is now working to obtain regulatory approval for studies related to Parkinson’s disease and tumors of the brain, breast and prostate.

advancing the field



venture philanthropy in action

making progress and saving lives

We are at a magic moment in the development of focused ultrasound and the actions we take now have the potential to improve millions of lives.

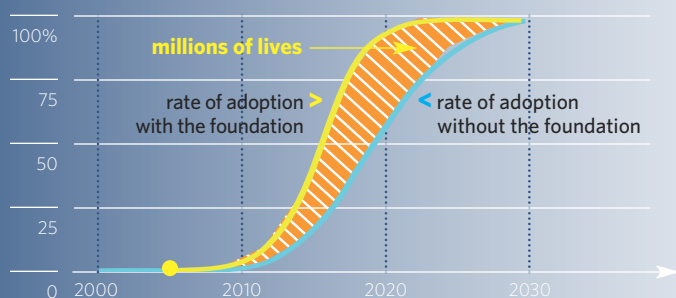
The Foundation is extraordinarily grateful for the generosity and vision of its supporters, who exemplify how venture philanthropy can advance medical research and embody the entrepreneurial spirit of the Foundation and of the pioneering researchers, manufacturers, physicians and others in the focused ultrasound community.

In the last five years, donors have committed more than \$35 million. Individual donors have contributed 70 percent of these gifts, and the balance has come from corporations and organizations. These funds have been successfully invested in high-potential research projects and programs, and are helping to fill the funding gap between early-stage research and commercialization, a space sometimes called “the valley of death” in which life-saving ideas like focused ultrasound technology can languish. Eighty cents of every dollar contributed to the Foundation supports research and programs, a healthy margin by traditional nonprofit standards.

In 2011, our generous supporters made new gifts totaling more than \$6.1 million. These contributions include leadership gifts of \$1 million or more from Diane and David Heller, and an anonymous supporter. Overall, the Foundation’s donor base increased by 75 percent. The Foundation values every dollar and every donor, and thanks all of its supporters for making 2011 a successful year.

saving time, saving lives

Cumulative rate of adoption



Accelerating Progress
and Saving Lives...

We are at a point
in the lifecycle of this
technology where
small investments
can have outsized
impacts.



patients don't have patience

Our donors are motivated by the realization that every day without access to focused ultrasound treatments is a day of needless death, disability, and suffering for countless patients. Join us and help make focused ultrasound therapies available to patients in the shortest time possible.



the focused ultrasound community lost its most passionate and generous supporter on March 11, 2012, when David Heller succumbed to lung cancer at the age of 80. Always a force to be reckoned with, David was extraordinarily successful financially; however, his greatest pleasure was not in making money but in giving it away.

He and his wife Diane have generously supported numerous causes, but in his last months as it became apparent that the end was in sight, David repeatedly stated that the most important activity in which they were involved was the Focused Ultrasound Foundation and that he considered his legacy to be the patients who were going to benefit from the advances in the field resulting from his time, energy and philanthropic support.

David was the ultimate venture philanthropist, and as one of the Foundation's founding directors, we have benefited tremendously from his efforts and contagious sense of urgency. While his presence will be missed, the enthusiasm encompassed in his spirit will continue to guide us.



Diane and David Heller

supporters

October 2006 – February 2012

The Focused Ultrasound Surgery Foundation is pleased to recognize the following individuals, foundations and corporations for their generous support.

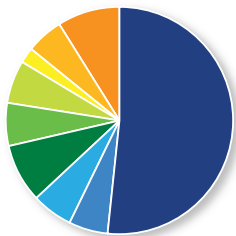
Anonymous (4)	Herndon Foundation	Joy Marie Polefrone
Abbott Laboratories	Fred and Mary Buford Hitz	Prince Charitable Trusts
John B. Adams, Jr.	Ulrike Hoffmann-Burchardi	Dr. M.G. Pat Robertson
Aimee and Frank Batten Jr. Foundation	and Dirk Willes	The Robertson Foundation
D.N. Batten Foundation	Horton Foundation Fund in CACF	Wyndham Robertson
Frank* and Jane Batten	Mr. and Mrs. Robert M. Huff	Felicia W. Rogan
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Anson and Debra Beard	Imasonic	St. Luke's Hospital
Dr. and Mrs. S. Morry Blumenfeld	Chad D. Inman	Valerie Beth Schwartz Foundation
Birdsall Family Fund	InSightec, Ltd	Mr. and Mrs. Charles H. Seilheimer, Jr.
Rich and Roxanne Booth	International Society of	Rick and Sherry Sharp,
Charles R. Bronfman	Therapeutic Ultrasound (ISTU)	The Community Foundation Serving
Edgar M. Bronfman and Jan Aronson	JJA Instruments	Richmond and Central Virginia
Phebe Cambata	Dean Johnson	Alice H. Siegel
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Roy R. Charles Charitable Trust	Lou and Dan Jordan	Jane-Ashley and Peter Skinner
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The Christian Broadcasting	Ms. Marcia A. Kean	Charles Fund of The Community
Network, Inc.	The Kellogg Organization, Inc.	Foundation Serving Richmond
Moffett and Dupre Cochran	Mr. and Mrs. Donald A. King, Jr.	and Central Virginia
Cooley, Godward and Kronish LLP	Mr. and Mrs. Fritz R. Kundrun	Robert H. Smith Family Foundation
Crutchfield Corporation	John L. Lewis IV	Virginia and John Syer
Mr. and Mrs. Victor M. Dandridge, Jr.	Mr. and Mrs. Harvey L. Lindsay, Jr.	Supersonic Imagine
Mr. and Mrs. Terrence D. Daniels	Terry J. Lockhart	Fay Davis Taylor in memory of
Mr. and Mrs. John Stewart Darrell	Mr. and Mrs. John Lucey	Bertrand L. Taylor III
Mrs. Margareta C.H. Douglas*	John and Dudley Macfarlane	Theraclion
Mrs. Frances Dulaney	Paul and Diane Manning	Sandra Thomas
EDAP	Jill Kiersky and Andrew Marcus	Jane Tolleson
Elbit Medical Imaging	Mr. and Mrs. Donald Mazzoni	Sarah Beck and Wojtek Uzdelewicz
Elekta	Janice McArdle Cancer Research	Eleanor Cameron Van Clief Foundation
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Bruce D. Fisher	Methodist Hospital	Sheri Waddell
GE Healthcare	Microsoft Corporation	Mark Warner and Lisa Collis
Struthers and Frederick Gignoux	Milken Family Foundation	The Watterson Foundation
Mark and Judy Giles	Mitford Children's Foundation	R. Ted and Sheila Weschler
Richard and Leslie Gilliam	Thos. Nelson Jr. Initiative Fund of	Custis Westham Fund of
Marge and Joe Grills	The Community Foundation Serving	The Community Foundation Serving
Mr. and Mrs. Eugene R. Hack, Jr.	Richmond and Central Virginia	Richmond and Central Virginia
Jim and Sue Haden	Paula and Rob Newcomb	
The John A. Hartford Foundation Inc.	Dick and Judy Nunley	
Matching Grants Program	Ogilvy Public Relations Worldwide	
David* and Diane Heller	Philips Healthcare	

*Denotes those donors who are now deceased

Leadership & staff

The Foundation was founded five years ago as a small, tax-exempt organization with a big idea—to improve the lives of millions of people. Thanks to the generosity of our donors and the leadership of our Board and Council, progress is being made.

2011 Allocated Funds

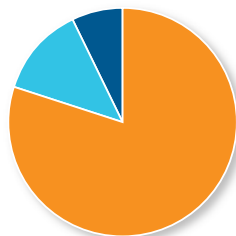


■	\$2,941,141	Research
■	322,825	Collaborative Research Network/Symposia, Meetings
■	330,615	Fellowships
■	472,769	Communications
■	350,746	Reimbursement
■	338,756	Fibroid Relief
■	121,702	Regulatory
■	306,255	Centers of Excellence
■	499,332	Development

\$5,684,141 Total

Key Ratios

% of budget



■	80%	Research/Programs
■	13%	Administration
■	7%	Development

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Chairman, Founder
Focused Ultrasound Foundation
Distinguished Professor of Neurosurgery
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Vice Chairman
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Kobi Vortman, Ph.D.
Founder, President & CEO
InSightec

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Charlottesville, VA

Charles H. Seilheimer
Orange, VA

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John Snell, Ph.D.
Technical Director, Brain Program



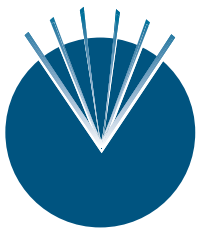
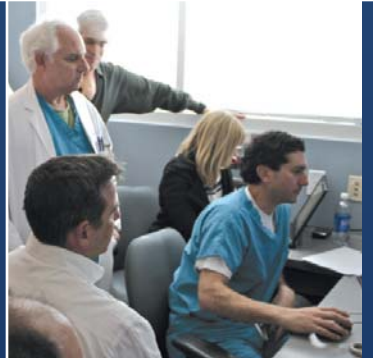
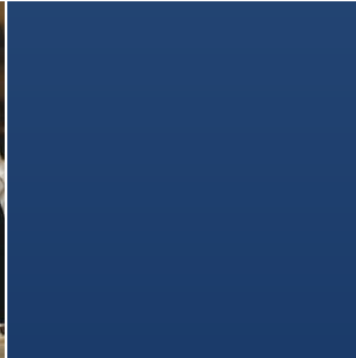
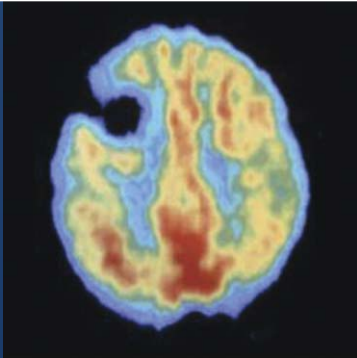
for more information

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www.fusfoundation.org



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