

FUSF

chairman's message

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An evolutionary leap is underway in the field of MR-guided focused ultrasound. The number of new manufacturers, investigators and sites engaged in research and clinical treatments is steadily growing. The scope of activity is rapidly expanding, as demonstrated by the many presentations and papers being delivered by investigators around the world. The next generation of patient therapies is now entering the clinical trial pipeline, causing conversations among stakeholders to shift from wondering if treatments can be developed to discussing when they will be available.

In recognition of the field's growing importance, more medical and scientific meetings are featuring focused ultrasound prominently in their programs. Prospects have never been so solid and real for this game-changing technology. Revolutionizing the treatment of a wide variety of serious medical disorders is now within reach and, worldwide, millions of patients stand to benefit.

The Foundation itself grew in strength and breadth in 2010. Our Board of Directors expanded, and our team added several new, highly experienced members. By fostering communication, coordination and collaboration, we confirmed our role as a catalyst for the entire field. Additionally, our financial and informational resources provided the adrenaline needed to step up the pace of progress.

Strategically, the Foundation continued to eliminate "chokepoints" that slow the advancement of focused ultrasound therapies. We funded the development of enabling technologies necessary for preclinical and clinical research and supported translational research and early stage clinical trials. We launched new initiatives to remove regulatory and reimbursement barriers that limit access to focused ultrasound treatments.

The accomplishments of 2010 were made possible by the generous support of our donors and the dedication and spirited collaboration of scientists, clinicians and other stakeholders around the world. I extend my personal appreciation to everyone in our expanding community. Together, we will reduce death and disability and alleviate suffering of countless individuals worldwide.

Sincerely,

Neal F. Kassell, M.D., Chairman









Our Mission

The Focused Ultrasound Surgery Foundation is dedicated to accelerating the development and adoption of patient treatments using one of today's most revolutionary and promising medical technologies: non-invasive Magnetic Resonance-guided Focused Ultrasound (FUS). The Foundation's work is motivated by the belief that FUS treatments could become the ultimate in noninvasive surgery, serve as a viable alternative to radiation therapy and offer a new platform for precise drug delivery—applications with the potential to alleviate suffering, save lives and guicken recovery times for millions of patients worldwide.

ounded in 2006 and based in Charlottesville, Virginia, the Foundation is a high-performance, not-for-profit organization with global reach and an entrepreneurial spirit. We are a crucial advocate and strategic visionary for the field of MR-guided focused ultrasound. Our mission is to accelerate worldwide adoption of this breakthrough technology and gain its acceptance as a mainstream therapy for many serious medical disorders, including benign and malignant tumors, Parkinson's disease, epilepsy and stroke.

To achieve our goals, we organize symposia and workshops, fund research and fellowships, support the establishment of Focused Ultrasound Centers of Excellence, spearhead advocacy and patient support initiatives, and serve as the nexus of a worldwide collaborative research network. Our collaborative community spans medical specialties and brings together clinicians, scientists, government regulatory and funding agencies, pharmaceutical companies, medical device manufacturers, philanthropists, private foundations and venture capitalists.



research programs



2010 Research Award Recipient Nick Todd, Ph.D. University of Utah Salt Lake City, USA

One of the Foundation's six 2010 Research Award recipients, Dr. Todd is developing temperature measuring techniques that accelerate data acquisition in the presence of motion. His work is part of a major collaboration between the University of Utah and the University of Geneva in Switzerland that is developing new, site-specific MR-guided focused ultrasound treatments for breast and liver cancer.

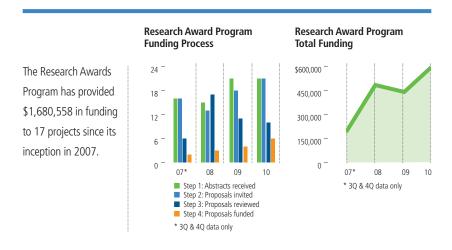
Research is the Foundation's primary area of investment. From early-stage research and fellowships to key technical projects and the Collaborative Research Network, we support activities crucial to the advancement of MR-guided focused ultrasound.

Research Awards. The Foundation's <u>Research Awards Program</u> provides seed funding for investigator-initiated projects involving MR-guided focused ultrasound.

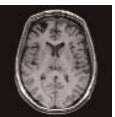
Preference is given to preclinical research projects and pilot clinical trials with the greatest potential to advance new therapeutic uses of this innovative technology.

A primary program aim is to help researchers complete early-stage studies, which are key to qualifying for follow-on funding from other sources—the next step in advancing their work toward clinical reality. Eight of the Foundation's 17 Research Award recipients have completed their projects. Five have received follow-on funding, and two have applications in process.

During 2010, three award recipients completed their projects. The program received 21 new abstract submissions, 20 of which were selected for full proposal development. Ten new proposals and five revised proposals underwent review by the Foundation's independent <u>Research Advisory Committee</u>. Six researchers received funding as indicated on the accompanying chart.













2010 Fellowship RecipientNelly Tan, M.D.,
University of California
Los Angeles, USA

Following a residency in urology at Yale,
Dr. Tan changed her specialty to radiology.
As a postdoctoral fellow in Abdominal
Imaging at UCLA, she is exploring the
commercial and research uses of MR-guided
focused ultrasound. Her key interest is
evaluating this technology in managing
urologic oncologic diseases and in treating
prostate cancer.

Fellowship Awards. To increase the number of physicians who are trained in the use of MR-guided focused ultrasound, the Foundation offers <u>fellowships</u> that combine both clinical and research experience. Since the inception of this program, we have received 25 applications and approved ten fellowships, seven of which were <u>accepted by recipients</u>. Five fellows have completed their training and four have secured positions in focused ultrasound centers.

The Foundation awarded one new fellowship during 2010. The recipient was Nelly Tan, M.D. of the University of California, Los Angeles.

	2010 Research Award Recipients
\$100,000	Nick Todd, Ph.D., University of Utah, USA Robust MR thermometry for MRgHIFU in breast and liver
\$100,000	Gregory Karczmar, Ph.D. , University of Chicago, USA Development and clinical evaluation of MR-guided focused ultrasound for tattooing tumors. (Envisioned indication: breast cancer)
\$100,000	Charles Dumoulin, Ph.D. , Cincinnati Children's Hospital, USA The effect of MR-guided focused ultrasound ablation on visceral fat in obese rats to see if it shifts metabolic activity. (Envisioned indication: Type 2 diabetes and other metabolic diseases in humans.)
\$164,478	W. Jeffrey Elias, M.D., University of Virginia, USA A Radiographic and Histologic Comparison Between Radiofrequency, Gamma Knife Radiosurgery and Focused Ultrasound
\$30,850	A Safety and Feasibility Study of MRgFUS Lesioning in the Setting of Deep Brain Stimulation
\$100,000	Mario Ries, Ph.D., University of Bordeaux, France Heterogeneity correction for improved breast cancer ablation



Brain program researcher Kullervo Hynynen, Ph.D. Sunnybrook Health Sciences Centre Toronto, Canada

A pre-eminent therapeutic ultrasound researcher, Dr. Hynynen has been awarded Foundation funding to address a key technical issue identified by Brain Program participants: will other parts of the brain be damaged when target tissue is sonicated? His preliminary research into this phenomenon—known as remote effects—suggests that MR-guided focused ultrasound can be applied without causing collateral damage within the brain.

Brain Program. The Foundation's <u>Brain Program</u> had significant achievements in 2010. In addition to hosting its second workshop for thought leaders, the program funded key research projects and completed preparations for pilot clinical trials that will begin in 2011.

Brain Workshop. Attended by leading researchers from academia, industry and the NIH, this meeting refined technical roadmaps—developed at the first workshop in 2009—for fast-tracking new treatments. Participants also prepared work statements for several technical projects to address rate limiting issues.

Project Funding. The Brain Program funds technical, preclinical and clinical projects that can accelerate progress in selected brain indications, including intra-cerebral hemorrhage, ischemic stroke and neuromodulation. The chart below describes projects funded during 2010.

Pilot Clinical Trials. In an exciting development, the Brain Program completed preparations in 2010 for pilot clinical trials that will be funded by the Foundation to evaluate the use of MR-guided focused ultrasound in treating essential tremor and brain tumors. Scheduled to launch in 2011, the trials will take place in three countries: the University of Virginia (USA), Sunnybrook Health Sciences Centre (Canada) and the University of Zurich (Switzerland). Each trial has received regulatory approval, and the Brain Program has established supporting infrastructure, including Steering Committees, a Data and Safety Monitoring Board and a Core Imaging Lab.

	2010 Brain Program Contract Award Recipients
\$23,203	Kullervo Hynynen, Ph.D. , Sunnybrook Health Sciences Centre, Canada Study of Standing Waves and Secondary Focal Spots: A Preliminary Feasibility Study (Goal: Rule out the possibility of unintended heating away from targeted tissue.)
\$118,649	Thilo Hoelscher, M.D. , University of California, USA Development of a Skull Database Using an Acoustic Intensity Measurement System (Goal: assess impact of skull thickness, density and shape on the absorption and defocusing of ultrasound waves.)
\$71,077	Jason Sheehan, M.D., Ph.D., University of Virginia, USA "Investigation of the Use of MR-guided Focused Ultrasound to Lyse Intracranial Clot in a Pig Model" (Goal: Determe if MR-guided focused ultrasound can dissolve blood clots within the cranium. Positive findings could lead to the development of new treatments for intracerebral and intraventricular hemorrhage.)
\$11,685	Max Wintermark, M.D., University of Virginia, USA ICH Clot Atlas (Goal: Understand how the appearance of blood changes in MR imaging over time as it clots; select optimal MR pulse sequences for clot imaging before and after sonothrombolysis.)
\$156,362 \$40,666	MR Visualization of Arterial Thrombus/Embolus (Goal: Develop optimal MR imaging protocols for visualizing clotted blood within the lumen of arteries in the brain.) MR Bone Imaging (Goal: Develop MR imaging protocols and post processing to measure the thickness and density of the skull as a substitute for CT in
	MR-guided FUS skull correction.)

Drug Delivery Program. Established in 2009 to explore how the Foundation can support the advancement of focused ultrasound-mediated drug delivery—an area of immense clinical potential—the <u>Drug Delivery program</u> moved into a new stage last year.

Input from core stakeholders in academia, government and industry determined that the Foundation can add unique value to this exciting and expanding field by:

- 1) serving as a nexus for collaboration via working groups, workshops, etc.
- 2) providing seed funding for early stage, proof of concept research.

At a meeting hosted by the Foundation in July 2010, core stakeholders developed research roadmaps for a series of clinical indications and identified five "top priority" applications: pancreatic cancer; blood-brain barrier opening; liver cancer; head and neck cancer; and prostate cancer.

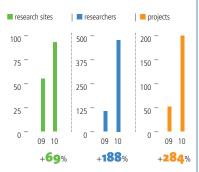
In its next major step, the Drug Delivery Program will convene a thought leader workshop in March 2011.

Collaborative Research Network. The Foundation supports and fosters the worldwide MR-guided focused ultrasound community through its Collaborative Research Network (CRN). Quarterly contact with sites and researchers enables the CRN to maintain the field's most comprehensive and up-to-date community census. At year-end 2010, the CRN census indicated that 478 investigators at 93 sites were engaged in 200 projects related to MR-guided focused ultrasound.

The CRN encourages both online and interpersonal interactions among its members. During 2010, the Foundation launched an online component of the CRN that now hosts eight research groups, has 117 registered members and posts quarterly census information. It also offers sophisticated online collaboration tools and shares information about meetings, funding opportunities and potential projects.

CRN outreach activities during 2010 included the Diane and David Heller Dinner at the Radiologic Society of North America (RSNA) meeting in Chicago and providing sponsorship funding to an expanding number of conferences that are important to the focused ultrasound community.

CRN Census Results



The number of sites and investigators participating in the CRN census grew significantly in 2010.

2010 Meeting Sponsorships

April Society of Thermal Medicine, Clearwater Beach. FL. USA

May Europeon Society of Neruosonology and Cerebral Hemodynamics, Madrid, Spain

June 10th International Symposium on Therapeutic Ultrasound, Tokyo, Japan

July American Association of Physicists in Medicine, Philadelphia, PA, USA

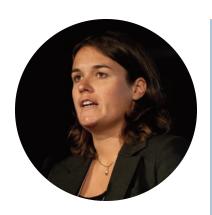








international symposium



2010 Young Investigator Award recipient Marianne Voogt, M.D. University Medical Center Utrecht

Utrecht, Netherlands

One of the Foundation's ten 2010 Young Investigator Award recipients, Dr. Voogt is a Ph.D. candidate in radiology and specializes in minimally invasive treatments for uterine fibroids. With her Utrecht colleagues, she is investigating a new technique that could shorten the time needed to treat fibroids with MR-guided focused ultrasound. Instead of sonicating a fibroid directly, the new approach targets vessels that supply blood to it. Early results are promising and indicate that fast, complete fibroid ablation is possible.

By spotlighting current and future applications of MR-guided focused ultrasound, the Foundation's bi-annual symposium has become a vital source of information and collaboration-building within our nascent and quickly evolving community.

2nd International Symposium on MR-guided Focused Ultrasound.

A tremendous success by all measures, the Foundation's 2nd International Symposium on MR-guided Focused Ultrasound was held from October 17–20, 2010 in Chantilly, Virginia. Essentially every major figure in the field of MR-guided focused ultrasound participated in this landmark program, which drew participants from 22 countries and included 320 clinicians, scientists and engineers from academia, industry and government agencies.

Throughout the symposium, the passion and enthusiasm of participants were palpable and contagious. By sharing information, exchanging ideas and establishing new collaborations, attendees helped define the state-of-the-art and chart the future direction of our quickly evolving field. Supercharging the meeting's atmosphere was the presence of a large contingent of scientists-in-training, ten of whom received funding through the Foundation's new <u>Young Investigator Awards Program</u>.

The symposium program served as a keen indicator of our field's escalating momentum. Included on the program were 130 oral and poster presentations—more than a three-fold increase from the Foundation's first international symposium in 2008. Many presentations addressed new indications under development, including stroke, epilepsy, Parkinson's disease, diabetes, back pain and tumors of the brain, thyroid, breast, liver, prostate, pancreas and bone.

"One of the most amazing meetings I have ever attended...
from a science perspective, this is very energetic, very high quality
because it's truly interdisciplinary. A lot of networks being set
up...you hear accents from France, Europe, North America,
Asia.... This is an example of how a symposium should be done."

Christopher Cheng, M.D.

Singapore General Hospital, Singapore

Centers of Excellence



Center of Excellence clinical researcher W. Jeffrey Elias, M.D. University of Virginia, Charlottesville, USA

A neurosurgeon with clinical interests in movement disorders and epilepsy, Dr. Elias is breaking new ground in developing brain treatments using MR-guided focused ultrasound. The Foundation is funding his next major project: the world's first clinical trial to evaluate the safety and effectiveness of MR-guided focused ultrasound in treating patients with essential tremor.

By partnering with institutions worldwide, the Foundation is establishing standard-setting Centers of Excellence that perform research, training, and patient care at the highest level. As envisioned, these luminary sites will serve as collaboration hubs for interdepartmental, multidisciplinary teams, producing the synergy needed to accelerate research and clinical adoption.

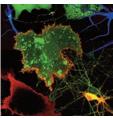
Centers of Excellence Program. The Foundation dedicated its first Focused

Ultrasound Center of Excellence at the University of Virginia in 2009, and
two more sites are set to open in 2011. In addition to Foundation funding,
the expansion of this vitally important program is being supported by the field's
leading manufacturers, InSightec, General Electric and Philips Healthcare.

UVA Center of Excellence Update. During 2010, the UVA center began performing patient treatments for uterine fibroids and conducting clinical trials for both uterine fibroids and pain palliation for bone metastases. It also increased the pace of its research. Preclinical studies investigated potential applications of MR-guided focused ultrasound and ranged from blood-brain barrier opening, brain tumors and ischemic stroke to gene delivery for Crohn's disease and Peripheral Arterial Disease.

The Foundation supported the recruitment and hiring of the newest member of the Center's leadership team—Research Director, <u>Richard J. Price, Ph.D.</u>, a biomedical engineer and an internationally recognized authority on ultrasound-targeted therapies. To expand inter-institutional collaborations, the Foundation also sponsored a seminar series that enabled eight leading focused ultrasound researchers to visit and lecture at UVA.









Richard Price, PhD.

access initiatives



Celebrating motherhood Frances T., FUS patient Atlanta, USA

"What was supposed to be a routine GYN visit in 2007 turned into a very disappointing day in my life as a woman. I was diagnosed with uterine fibroids and told I would not be able to have children unless I had invasive surgery or a hysterectomy. I was very upset because I did not want to have surgery and still wanted to have children. A few days later, my sister found the Fibroid Relief website. I accessed it and was thoroughly impressed by the women's stories—one of whom had conceived after a focused ultrasound procedure. I thought to myself, God is good."

Frances became a first time mother in 2010.

To accelerate approval and use of MR-guided focused ultrasound therapies, the Foundation's access initiatives seek to engage crucial stakeholders, including patients, healthcare providers, government regulators and insurers.

Patient Support. The Foundation's inaugural patient support organization, Fibroid Relief, continued to expand its outreach activities, both online and through highly successful public education events during 2010. Since its inception in 2008, this awareness-building initiative has reached nearly 60,000 women worldwide through its website, social media, education events and other outreach activities.

Online, Fibroid Relief has proven to be a crucial resource for women seeking information about uterine fibroid treatments, especially FDA-approved MR-guided focused ultrasound. During 2010, its website drew a total of 31,827 unique visitors, 36 percent more than the previous year. Fans following Fibroid Relief on Facebook grew to 3,530, a dramatic annual increase of 111 percent.

In August, 2010, the Fibroid Relief website launched a new patient support feature: a Comprehensive Patient Reimbursement Toolkit. Developed to help uterine fibroid patients access focused ultrasound as their treatment of choice, the kit contains template letters and tips for navigating the process for insurance coverage. By year-end, the download tally for this kit reached 737.

During 2010, Fibroid Relief hosted five patient education events. Two took place in Los Angeles, two were held in conjunction with St. Mary's Hospital in London and one was organized in partnership with Porter Adventists Hospital in Denver.

















Reimbursement meeting



Calling for reimbursement Jeri P., FUS patient Los Angeles, USA

A professional audio engineer, Jeri P., was ready to have an MR-quided focused ultrasound procedure for uterine fibroids, when she learned that her insurance company would not cover its cost. Subsequently treated in a focused ultrasound clinical trial, she says, "It still doesn't make sense that my insurance company would rather reimburse me for a hysterectomy than for focused ultrasound. Hysterectomy is major surgery and has risks associated with anesthesia and infection and has a long recovery time. To me, reimbursing for an FDA-approved, outpatient, noninvasive focused ultrasound procedure should be a no brainer."

Regulatory Affairs. A key aim of the Foundation's newly launched Regulatory Affairs Program is to support researchers in developing preclinical and clinical study protocols required by the FDA approval process. Toward that end, the program has engaged consultants to map out a regulatory pathway that identifies key steps in the approval process.

Expected to start in the near future, other program initiatives will provide guidance and support related to the FDA approval process for investigator-initiated IDE's and for applications for compassionate use treatments.

Reimbursement. In fall 2010, the Foundation launched a major initiative to expand private payer reimbursement for MR-guided focused ultrasound procedures in the US. Near-term, this initiative will concentrate on increasing patient access to and reimbursement for uterine fibroid treatments.

To initiate this project, the Foundation has formed a Reimbursement Working Group and created a new position, Director of Patient Access. Working group members include Foundation board and team members as well as representatives from the field's leading corporate partners, InSightec, Philips Healthcare and General Electric.

Assisted by a reimbursement consultancy group, the working group is now performing a situation analysis. Project parameters include: 1) payer and coding market assessment and strategy; 2) review and analysis of published literature; and 3) development of a value dossier on the treatment environment and the health economic benefits of MR-guided focused ultrasound. When recommendations are received in early 2011, the Foundation plans to initiate outreach activities to payers, professional societies, patient advocates and other influencers.

communications





The Foundation's website (top image) and e-newsletter were upgraded significantly in 2010.

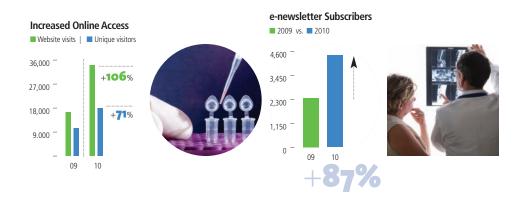
To provide timely and comprehensive information to stakeholders and interest groups around the world, the Foundation engages in a robust online communications program that includes our comprehensive website, monthly newsletter, blogs and social media sites.

Website. By far, the most widely-accessed gateway to the Foundation is our <u>website</u>, which is now recognized as the most comprehensive, trusted and up-to-date source of focused ultrasound information. In 2010, www.fusfoundation.org was the top site returned in Google searches for focused ultrasound information. It drew more than 34,000 visits, averaging 2,850 per month.

In recognition of our website's importance in serving and supporting the stakeholders we serve, the Foundation continues to invest in improving its appearance and functionality. During 2010, we added more than 200 articles and 70 videos to our content.

Social media. In late 2010, the Foundation expanded our cyberspace presence to Facebook, Twitter and YouTube. We ended the year with 224 followers on Facebook and Twitter, and these sites generated more than 500 YouTube views and visits to our website.

Newsletter. Our <u>e-newsletter</u> underwent major upgrades in 2010. In addition to incorporating video interviews and other visual content, we increased its frequency to monthly. Public response has been highly favorable as indicated by the 87% increase in our subscriber base from 2,358 in 2009 to 4,400 in 2010.



organization



Newest Foundation board member Andrew von Eschenbach, M.D.

Dr. von Eschenbach is a thought leader and healthcare visionary of international stature. He has the distinction of being the only person to have served both as Commissioner of the US Food and Drug Administration and as Director of the National Cancer Institute at the National Institutes of Health. In 2006, *Time* magazine named him one of the "100 most influential people to shape the world." He was selected in both 2007 and 2008 as one of the *Modern Healthcare/Modern Physician's* "50 Most Powerful Physician Executives in Healthcare." Dr. von Eschenbach currently serves as President of Samaritan Health Initiatives.

Board of Directors. The Foundation welcomed two new board members in 2010: internationally-recognized healthcare leader Lodewijk J.R. de Vink and former FDA commissioner Andrew von Eschenbach, M.D. Both have brought immense experience, keen insights and a unique perspective to advising and guiding the Foundation.

Foundation Team. The Foundation expanded its <u>team</u> during 2010. Tina Krall and Tracey Daniels are now leading our Fibroid Relief initiative as Executive Director and Patient Support Outreach Associate, respectively. Our fundraising team now consists of Director of Development Kimberly Skelly and Development Assistant Megan McKinley. Ellen McKenna is Director of Communications, and Sara Horton is Controller. Strengthened by these new additions, our team remains dynamic, dedicated and highly entrepreneurial.

Foundation Council

The Foundation Council is a special advocacy group that builds goodwill and increases awareness of our work and mission.

Co-chairs

Dorothy N. Batten Charles H. Seilheimer, Jr.

Members

John B. Adams, Jr.
Jane P. Batten
Edgar M. Bronfman, Sr.
Thomas N. and Nancy J. Chewning
Ceceila S. Howell
Paula F. Newcomb
Mary Lou Seilheimer
Alice H. Siegel
Ambassador Nicholas F. Taubman

financial overview

2010 **Program Spending**

\$ Millions

0.9	Centers of Excellence
0.9	Brain Program

0.5 External Research Awards

0.5 Symposium

0.4 Patient Support

0.2 Drug Delivery

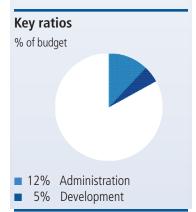
0.2 Development

0.2 Collaborative Research Network

0.2 Newsletter and website

0.1 Fellowship Program

4.1 Total



Since our inception in 2006, the Foundation has received more than \$28 million in contributions and commitments. We are grateful to the individuals, foundations and corporations that have made our work possible.

As conscientious stewards of these contributions, we adhere to a system of strong financial, cash management and project management disciplines. Our team performs due diligence and careful oversight of all our projects and programs. Primarily, our funding is invested in research that advances the field of MR-guided focused ultrasound.

The achievements of the Foundation's first four years have paved the way for a highly successful future. Private support remains essential for our continued success and for the attainment of our 2011–2013 fundraising goal of \$45 million. We intend to efficiently invest these funds in new research and initiatives that promise to move the dial of progress ever further and faster.

"I am inspired by the Foundation's unique pursuit of new approaches to treating cancer and other terrible diseases.

What could be more important than investing in a solution that could potentially save millions of lives all over the world?"

Felicia Warburg Rogan, FUS Foundation donor



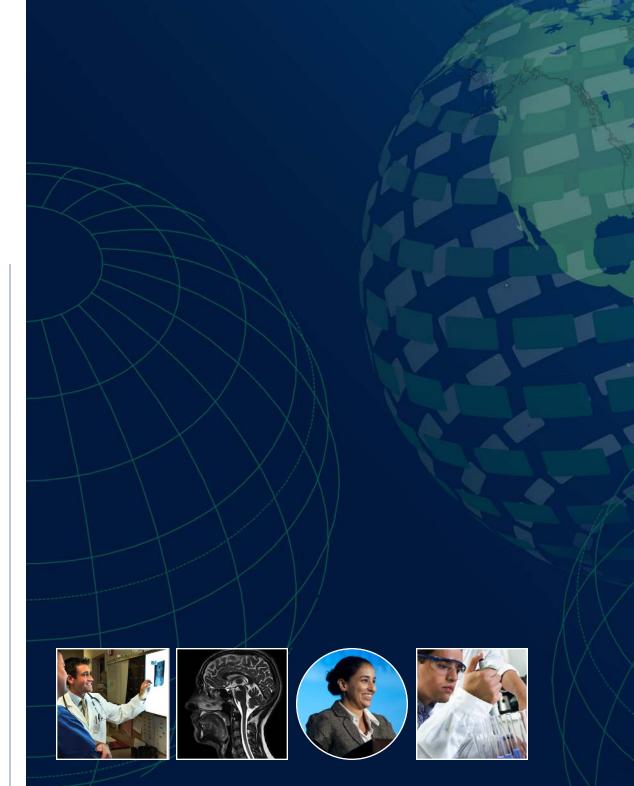








giving hope | alleviating pain | saving lives





www.fusfoundation.org

Charlottesville VA . 434.220.4993 T