

Focused Ultrasound

State of U.S. Research
Development and Adoption



FOCUSED
ULTRASOUND
FOUNDATION

Spring 2014

About the Focused Ultrasound Foundation

The Focused Ultrasound Foundation is a medical technology research, education and advocacy organization dedicated to improving the lives of millions of people with serious medical disorders by accelerating the development and adoption of focused ultrasound. The Foundation is unique in that it supports a platform technology that utilizes multiple mechanisms of action to treat a wide variety of diseases.

Positioned at the nexus of the large, diverse group of stakeholders comprising the ultrasound community, the Foundation functions as an independent, trusted and unbiased third party, aligning organizations into a cohesive ecosystem with a single goal: to make focused ultrasound technology available to patients in the shortest time possible. The Foundation works to establish a patient centric culture, instill a sense of urgency in all stakeholders, and alleviate barriers to progress.

The Foundation catalyzes collaboration and partnerships, organizes and funds research, spearheads advocacy and patient support initiatives, and organizes meetings, symposia and workshops to create and disseminate knowledge and increase awareness of focused ultrasound. Early-stage research funded by the Foundation “de-risks” subsequent investment, thus encouraging other funding sources such as disease-specific foundations, the NIH, and the biomedical industry to become more involved.

The Foundation is on the leading edge of the venture philanthropy and social entrepreneurship movements and is a model of how private philanthropy can work in concert with academia, industry and government to bridge the gap between research and commercialization of a high-impact medical technology.

Established in 2006 as a tax exempt organization, the Foundation is based in Charlottesville Virginia and has global activities.

About Focused Ultrasound

Focused ultrasound is a revolutionary, noninvasive therapeutic technology with the potential to transform the treatment of many serious medical disorders including tumors of the brain, breast, prostate, liver and other organs, Parkinson’s disease, epilepsy, and stroke. With ongoing research, focused

ultrasound could address unmet clinical needs and provide treatments which are superior to best current therapy, thereby improving the quality of life and longevity for millions of patients around the world.

This breakthrough technology uses ultrasonic energy guided by magnetic resonance or ultrasound imaging to treat tissue deep in the body without incisions or radiation. Multiple intersecting beams of ultrasound are directed and concentrated with on a target as small as a grain of rice, much like a magnifying glass can focus multiple beams of light on a single point.

A variety of profound biological effects result at the focal point where the beams converge; where individual beams pass unfocused through adjacent tissue on the way to their target, they exert no effect or damage. Integrated magnetic resonance and ultrasound imaging identifies and targets the tissue to be treated, guides and controls the treatment interactively, in real time, and provides immediate confirmation of the effectiveness of the therapy. Because focused ultrasound offers many mechanisms of action, treatment of a wide variety of conditions is possible.

Focused ultrasound has the potential to be the ultimate in noninvasive surgery, an alternative or complement for radiation therapy, the means to dissolve blood clots and restore circulation through blocked vessels, and a way to deliver drugs in extremely high concentration to a precise point in the body, thus avoiding systemic toxicity.

Focused ultrasound is performed in an outpatient setting without general anesthesia. There are no incisions or scars, minimal pain and discomfort, and more rapid recovery. The technology has the potential to result in fewer complications such as infection or blood clots, avoid the toxic side effects of drugs and radiation therapy, and deliver treatment that is safer and more effective, costs less, and produces an immediate and verifiable effect.

Focused ultrasound is approved in the US and EU and a number of other countries for treatment of uterine fibroids and approved in the EU and other countries for treatment of bone metastases and prostate cancer. In addition, extensive research is being conducted around the world on a number of clinical applications.

Charts by subjects

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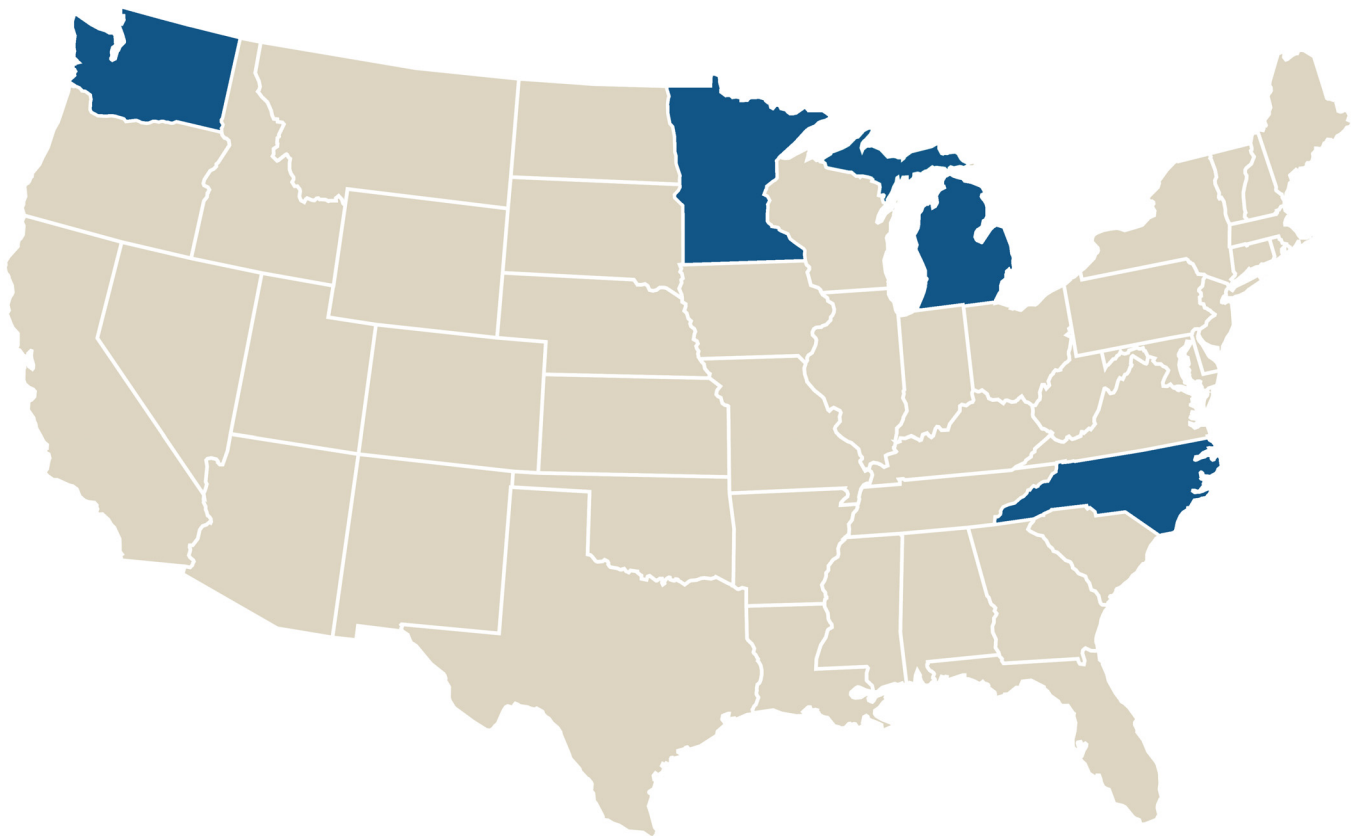
The information in this report was provided by manufacturers and the focused ultrasound research community to the Focused Ultrasound Foundation. The FUS Foundation aims to provide the most accurate information, if you have more current or updated information please send it to: progress@fusfoundation.org.

US Based Manufacturers

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Ultrasound Guidance

- Histosonics, Inc.**, Ann Arbor MI
- International Cardio Corporation, LLC**, Minnetonka MN
- Kona Medical**, Bellevue WA
- Mirabilis Medical**, Bothell WA
- SonaCare Medical, LLC**, Charlotte NC

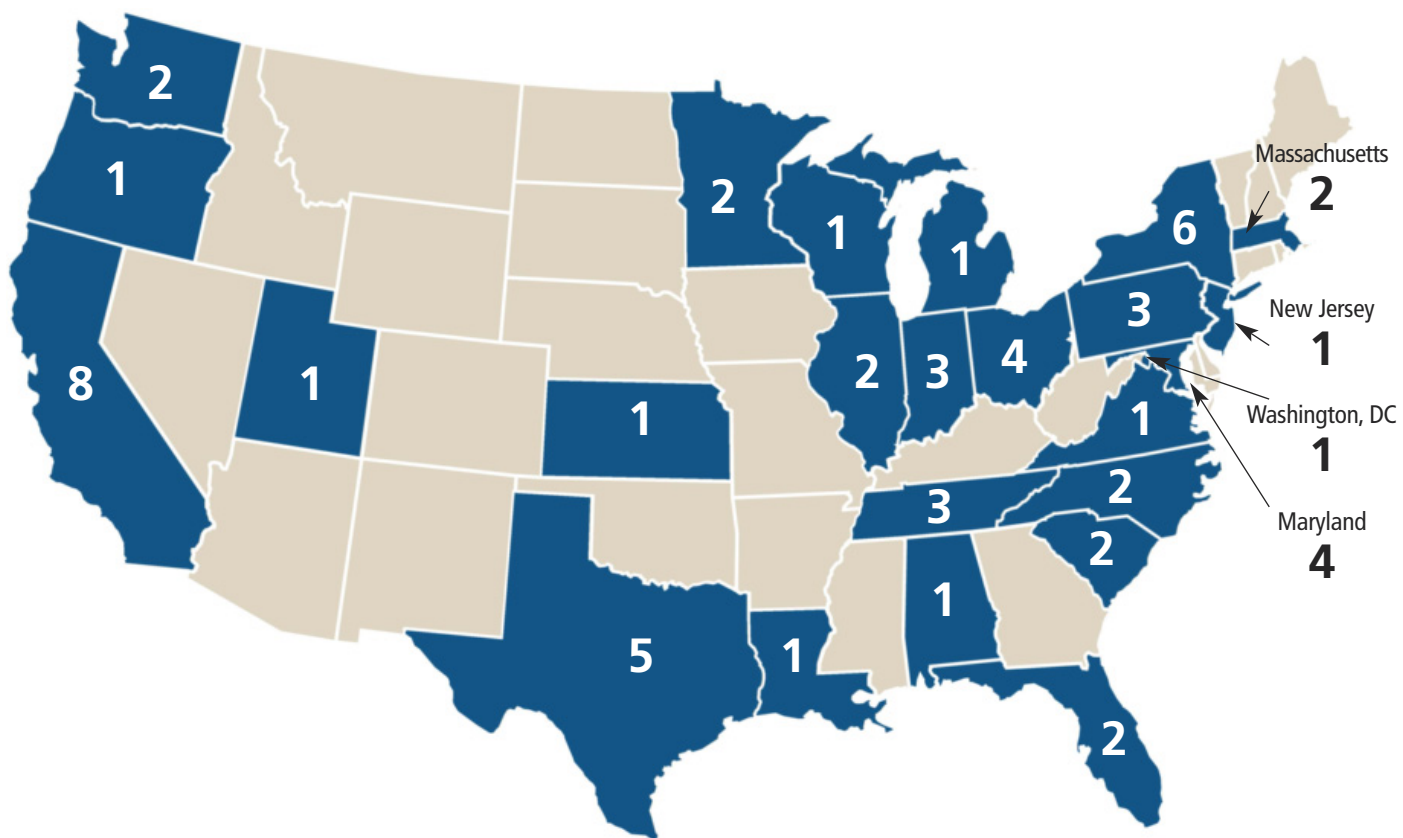


See page 20 for regulatory approval information

US Research Sites

61
Sites

25
States



US Research Sites

61

- Technical Research Site
- Pre-Clinical Research Site
- Clinical Research Site

- ■ ■ **Alabama**
Urology Centers of Alabama, Homewood
- ■ ■ **California**
 - ■ ■ City of Hope, Duarte
 - ■ ■ Stanford University Medical Center
 - ■ ■ UCLA/Brainsonix, Los Angeles
 - ■ ■ UCLA Ronald Reagan Medical Center, Los Angeles
 - ■ ■ University of California Davis
 - ■ ■ University of California at San Diego
 - ■ ■ University of California San Diego (UCSD) Thornton Hospital, La Jolla
 - ■ ■ University of California San Francisco (UCSF), San Francisco
- ■ ■ **Washington, DC**
 - ■ ■ Children's National Hospital
- ■ ■ **Florida**
 - ■ ■ Specialists in Urology, PA, Naples
 - ■ ■ University MRI & Diagnostic Imaging Centers - South, Boca Raton
- ■ ■ **Illinois**
 - ■ ■ University of Chicago
 - ■ ■ University of Illinois at Urbana-Champaign (UIUC), Urbana
- ■ ■ **Indiana**
 - ■ ■ Indiana University Health, University Hospital, Indianapolis
 - ■ ■ Indiana University School of Medicine, Indianapolis
- ■ ■ **Kansas**
 - ■ ■ University of Kansas - KU Bioengineering Research Center Mechanical Engineering, Lawrence
- ■ ■ **Louisiana**
 - ■ ■ Tulane University, New Orleans
- ■ ■ **Massachusetts**
 - ■ ■ Boston University
 - ■ ■ Brigham and Women's Hospital (BWH), Boston
- ■ ■ **Maryland**
 - ■ ■ Johns Hopkins University School of Medicine, Baltimore
 - ■ ■ National Institutes of Health (NIH), Bethesda
 - ■ ■ University of Maryland School of Medicine, Baltimore
 - ■ ■ Walter Reed National Military Medical Center, Bethesda
- ■ ■ **Michigan**
 - ■ ■ University of Michigan (UMich), Ann Arbor
 - ■ ■ William Beaumont Health Systems, Royal Oak
- ■ ■ **Minnesota**
 - ■ ■ Mayo Clinic - Minnesota, Rochester
 - ■ ■ University of Minnesota, Minneapolis
- ■ ■ **North Carolina**
 - ■ ■ Duke University, Durham
 - ■ ■ Wake Forest University Baptist Medical Center, Winston-Salem

Continued on next page.

US Research Sites

61

- Technical Research Site
- Pre-Clinical Research Site
- Clinical Research Site

Continued from previous page.

New Jersey

- ■ ■ Artann Laboratories, Lambertville

New York

- ■ Columbia University, New York
- ■ Memorial Sloan-Kettering Cancer Center, New York
- ■ Montefiore Medical Center, Bronx
- ■ New York University (NYU) Langone Medical Center and School of Medicine, New York
- ■ NYP - Weill Cornell Medical Center, New York
- ■ Winthrop University Hospital, Mineola

Ohio

- ■ Cleveland Clinic, Cleveland
- ■ ProMedica Toledo Hospital, Toledo
- ■ University Hospitals of Cleveland Case Medical Center, Cleveland
- ■ University of Cincinnati, Cincinnati

Oregon

- Oregon Health and Science University, Portland

Pennsylvania

- ■ Drexel University, Philadelphia
- ■ Fox Chase Cancer Center, Philadelphia
- Urologic Consultants of Southeastern Pennsylvania, Bala Cynwyd

South Carolina

- ■ Grand Strand Urology, Myrtle Beach
- ■ Medical University of South Carolina (MUSC), Charleston

Tennessee

- ■ ■ Southeast Urology Network, Memphis
- ■ ■ Urology Associates, Nashville
- ■ ■ Vanderbilt University, Nashville

Texas

- ■ ■ CHI St. Luke's Health, Houston
- ■ ■ The Methodist Hospital, Houston
- ■ ■ University of Texas MD Anderson Cancer Center, Houston
- ■ Urology of San Antonio, San Antonio
- UT Southwestern, Dallas

Utah

- ■ University of Utah, Salt Lake City

Virginia

- ■ ■ University of Virginia (UVA) Health System, Charlottesville

Washington

- ■ ■ Swedish Neurosciences Institute, Seattle
- ■ University of Washington, Seattle

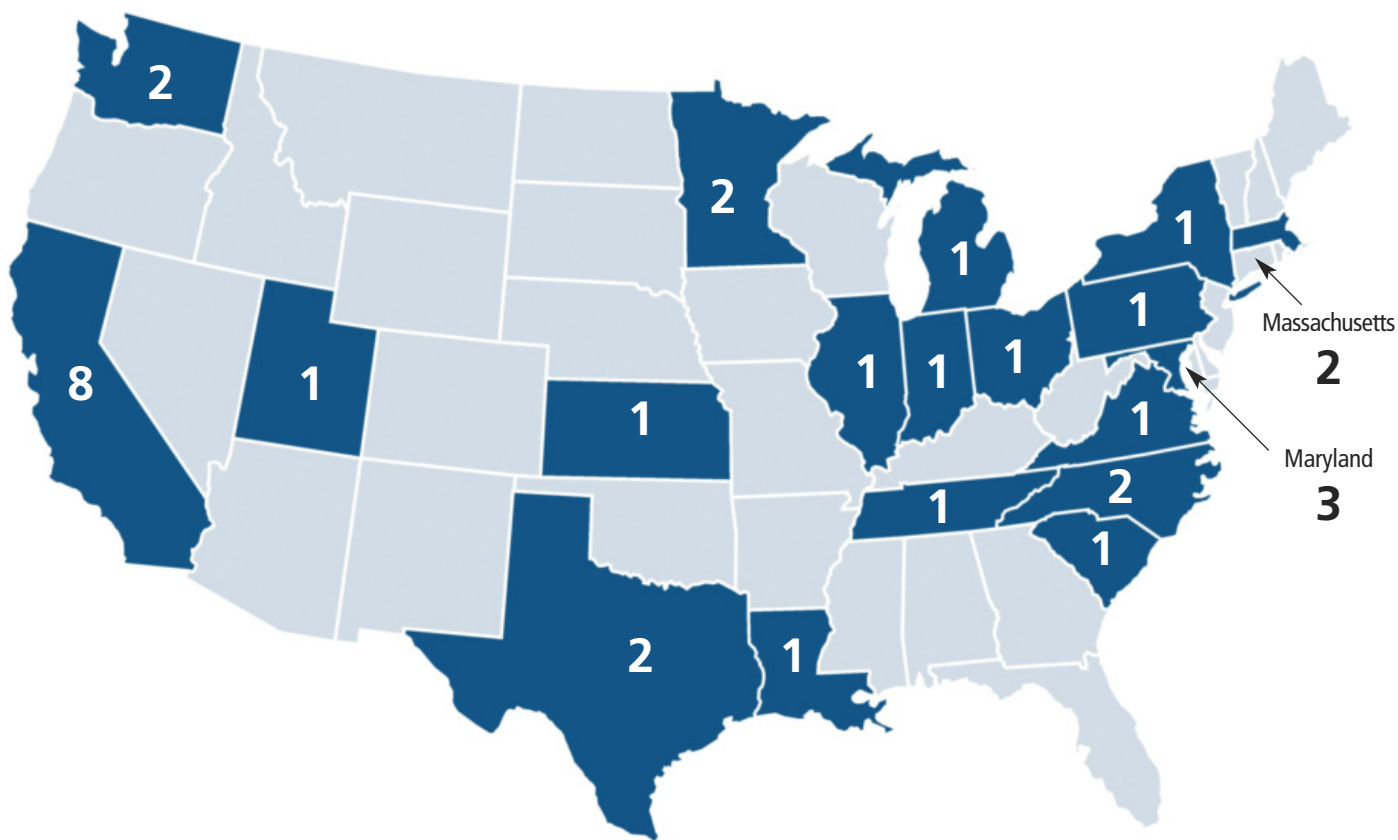
Wisconsin

- ■ University of Wisconsin Carbone Cancer Center, Madison

Technical US Research Sites

33
Sites

19
States



Technical US Research Sites

33
Sites

- MR imaging for FUS guidance
- Focused Ultrasound Physics
- Focused Ultrasound Transducer technology
- Ultrasound imaging for FUS guidance
-
- Amplification of cancer biomarker
- Clot lysis
- Drug Delivery
- Drug activity enhancement
- Immunomodulation
- Neuromodulation
- Radio sensitization
- Sonodynamic therapy
- Tissue destruction (Histotripsy)
- Tissue destruction (Thermal Ablation)
- Vasodilatation

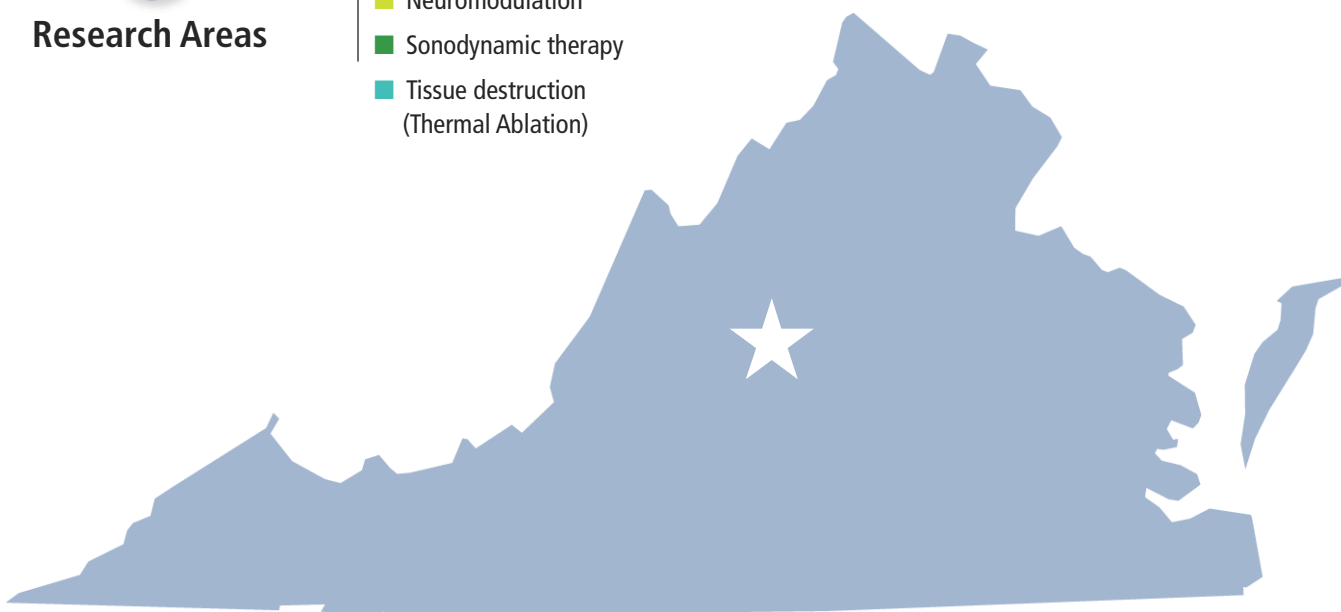
- California**
 - ■ ■ ■ City of Hope
 - ■ ■ ■ Stanford University Medical Center
 - ■ ■ ■ UCLA/Brainsonix
 - ■ ■ ■ UCLA Ronald Reagan Medical Center
 - ■ ■ ■ University of California, Davis
 - ■ ■ ■ University of California at San Diego
 - ■ ■ ■ University of California San Diego (UCSD) Thornton Hospital
 - ■ ■ ■ University of California San Francisco (UCSF)
- Illinois**
 - ■ ■ ■ University of Chicago
- Indiana**
 - ■ ■ ■ Indiana University School of Medicine
- Kansas**
 - ■ ■ ■ University of Kansas - KU Bioengineering Research Center Mechanical Engineering
- Louisiana**
 - ■ ■ ■ Tulane University
- Massachusetts**
 - ■ ■ ■ Boston University
 - ■ ■ ■ Brigham and Women's Hospital (BWH)
- Maryland**
 - ■ ■ ■ Johns Hopkins University School of Medicine
 - ■ ■ ■ National Institutes of Health (NIH)
 - ■ ■ ■ University of Maryland School of Medicine
- Michigan**
 - ■ ■ ■ University of Michigan (UMich)
- Minnesota**
 - ■ ■ ■ Mayo Clinic - Minnesota
 - ■ ■ ■ University of Minnesota
- New York**
 - ■ ■ ■ Columbia University
- North Carolina**
 - ■ ■ ■ Duke University
 - ■ ■ ■ Wake Forest University Baptist Medical Center
- Ohio**
 - ■ ■ ■ University of Cincinnati
- Pennsylvania**
 - ■ ■ ■ Drexel University
- South Carolina**
 - ■ ■ ■ Medical University of South Carolina (MUSC)
- Tennessee**
 - ■ ■ ■ Vanderbilt University
- Texas**
 - ■ ■ ■ CHI St. Luke's Health
 - ■ ■ ■ University of Texas MD Anderson Cancer Center
- Utah**
 - ■ ■ ■ University of Utah
- Virginia**
 - ■ ■ ■ University of Virginia (UVA) Health System
- Washington**
 - ■ ■ ■ Swedish Neurosciences Institute
 - ■ ■ ■ University of Washington

Technical Research Site, Virginia

6

Research Areas

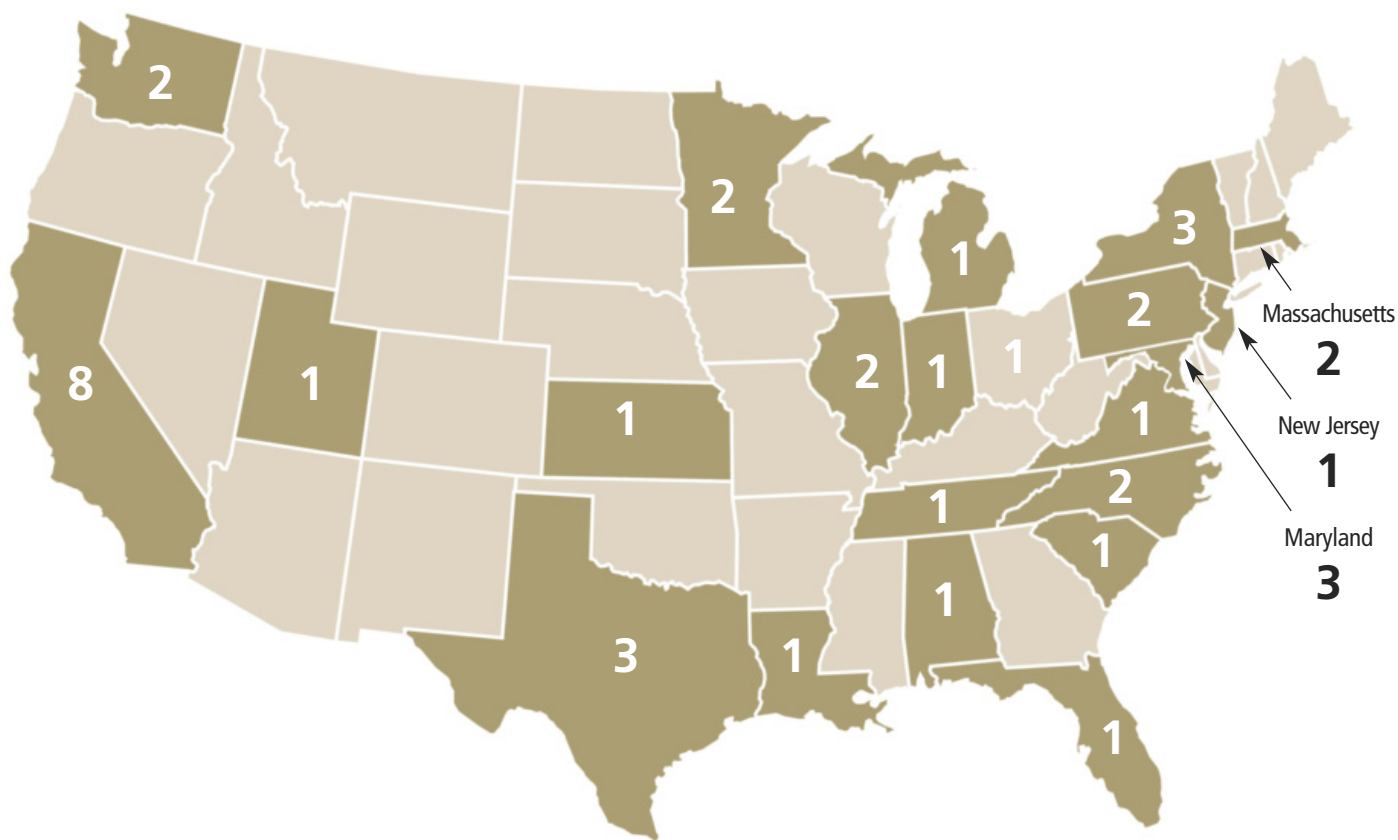
- MR imaging for FUS guidance
- Clot lysis
- Drug Delivery
- Neuromodulation
- Sonodynamic therapy
- Tissue destruction (Thermal Ablation)



Pre-clinical US Research Sites

40
Sites

21
States



Pre-clinical US Research Sites

40
Sites

- Alzheimer's Disease
- Atherosclerosis
- Atrial fibrillation
- Back and neck pain
- Benign Prostatic Hypertrophy
- Bladder tumors
- Bone Metastases
- Brain Tumors
- Breast Cancer
- Breast Fibroadenoma
- Cancer pain
- Colon
- Epilepsy
- Essential Tremor
- Glaucoma
- Hydrocephalus
- Hypertension
- Kidney Tumors
- Liver Tumor
- Neuropathic pain
- Obsessive-compulsive Disorder
- Osteoarthritis
- Osteoid Osteoma
- Pancreatic Tumor
- Parkinson's Disease
- Prostate Cancer
- Prostate Tumors
- Septal perforation
- Soft Tissue Tumors
- Stroke
- Thyroid & Parathyroid tumors
- Trigeminal neuralgia
- Uterine Fibroids
- Uterine Adenomyosis

- Alabama**
 - Urology Centers of Alabama
- California**
 - City of Hope
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- New York**
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 - Memorial Sloan-Kettering Cancer Center
 - NYP - Weill Cornell Medical Center
- New Jersey**
 - Artann Laboratories
- North Carolina**
 - Duke University
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- Pennsylvania**
 - Drexel University
 - Fox Chase Cancer Center
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- Virginia**
 - University of Virginia (UVA) Health System
- Washington**
 - Swedish Neurosciences Institute
 - University of Washington

Pre-clinical Research Site, Virginia

5
Indications

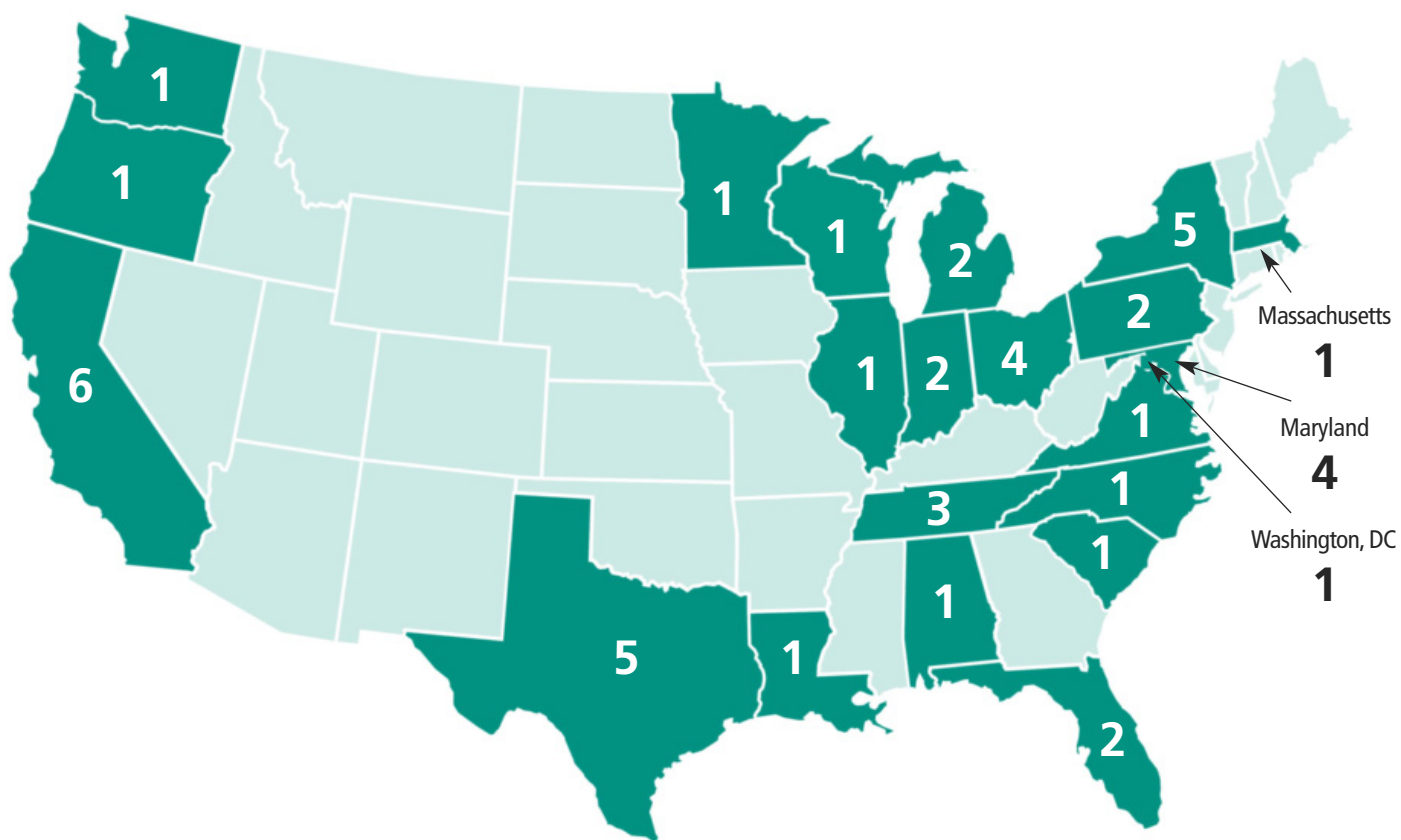
- Brain tumors
- Epilepsy
- Essential tremor
- Osteoarthritis
- Parkinson's disease



Clinical US Research Sites

47
Sites

22
States



Clinical US Research Sites

47 Sites

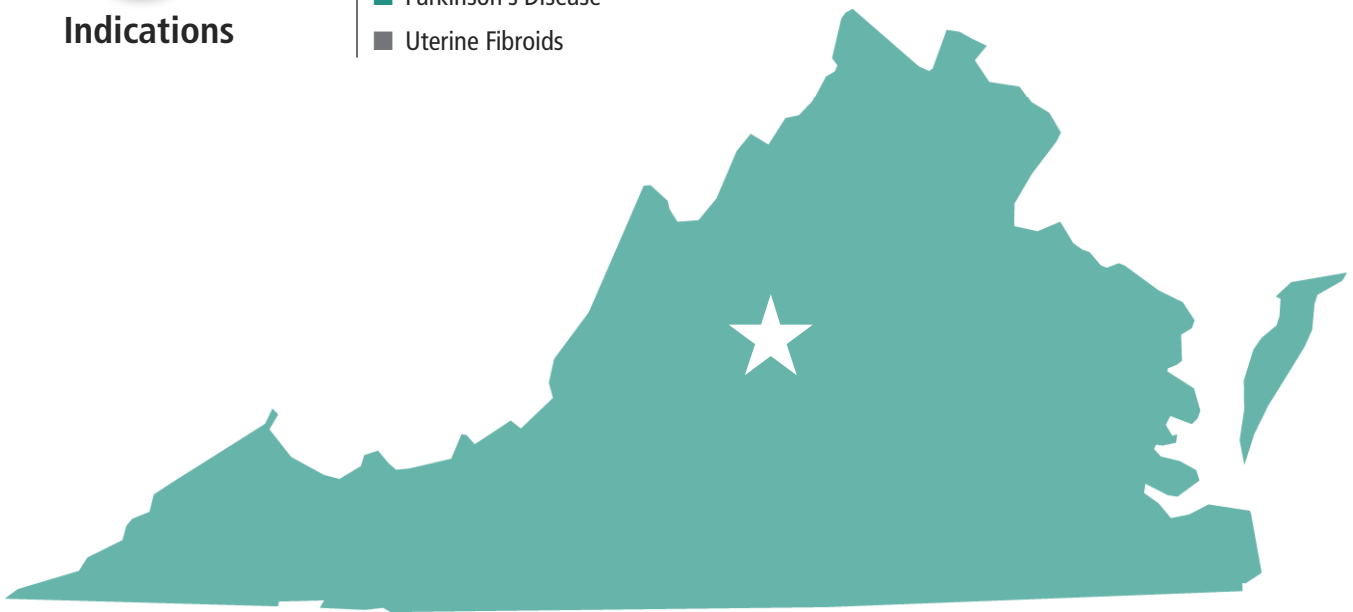
- Alzheimer’s Disease
- Atherosclerosis
- Atrial fibrillation
- Back and neck pain
- Benign Prostatic Hypertrophy
- Bladder tumors
- Bone Metastases
- Brain Tumors
- Breast Cancer
- Breast Fibroadenoma
- Cancer pain
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- Hydrocephalus
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- Kidney Tumors
- Liver Tumor
- Neuropathic pain
- Obsessive-compulsive Disorder
- Osteoarthritis
- Osteoid Osteoma
- Pancreatic Tumor
- Parkinson’s Disease
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- Prostate Tumors
- Septal perforation
- Soft Tissue Tumors
- Stroke
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 - University of California San Francisco (UCSF)
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 - University of Chicago
- Indiana**
 - Indiana University Health, University Hospital
 - Metropolitan Urology
- Louisiana**
 - Tulane University
- Massachusetts**
 - Brigham and Women’s Hospital (BWH)
- Maryland**
 - Johns Hopkins University School of Medicine
 - National Institutes of Health (NIH)
 - University of Maryland School of Medicine
 - Walter Reed National Military Medical Center
- Michigan**
 - University of Michigan (UMich)
 - William Beaumont Health Systems
- Minnesota**
 - Mayo Clinic - Minnesota
- New York**
 - Memorial Sloan-Kettering Cancer Center
 - Montefiore Medical Center
 - New York University (NYU) Medical Center and School of Medicine
 - NYP - Weill Cornell Medical Center
 - Winthrop University Hospital
- North Carolina**
 - Duke University
- Ohio**
 - Cleveland Clinic
 - ProMedica Toledo Hospital
 - University Hospitals of Cleveland Case Medical Center
 - University of Cincinnati
- Oregon**
 - Oregon Health and Science University
- Pennsylvania**
 - Fox Chase Cancer Center
 - Urologic Consultants of Southeastern Pennsylvania
- South Carolina**
 - Grand Strand Urology
- Tennessee**
 - Southeast Urology Network
 - Urology Associates
 - Vanderbilt University
- Texas**
 - CHI St. Luke’s Health
 - The Methodist Hospital
 - University of Texas MD Anderson Cancer Center
 - Urology of San Antonio
 - UT Southwestern
- Virginia**
 - University of Virginia (UVA) Health System
- Washington**
 - Swedish Neurosciences Institute
- Wisconsin**
 - University of Wisconsin Carbone Cancer Center

Clinical Research Site, Virginia

5
Indications

- Bone Mestases
- Brain Tumors
- Essential Tremor
- Parkinson's Disease
- Uterine Fibroids



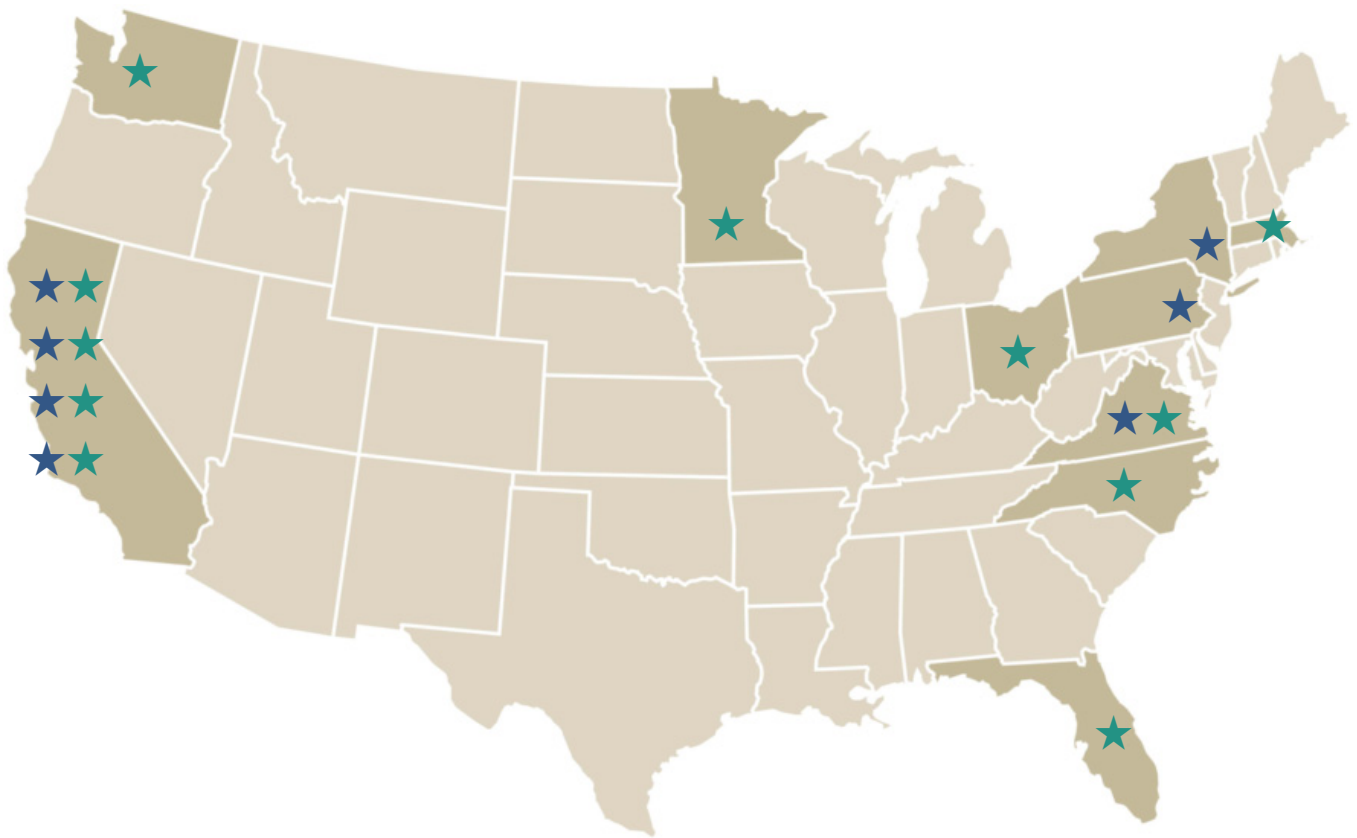
US Commercial Treatment Sites

7

Bone Metastases

11

Uterine Fibroids



US Commercial Treatment Sites

7

Bone Metastases

City of Hope, Duarte
 Fox Chase Cancer Center, Philadelphia
 Memorial Sloan-Kettering Cancer Center, New York
 Stanford University Medical Center, Stanford
 UCLA Ronald Reagan Medical Center, Los Angeles
 University of California San Francisco (UCSF), San Francisco
University of Virginia (UVA) Health System, Charlottesville

11

Uterine Fibroid

Brigham and Women’s Hospital (BWH), Boston
 Duke Health Center at Southpoint, Durham
 Focused Ultrasound Northwest, Seattle
 Mayo Clinic - Minnesota, Rochester
 Riverside Methodist Hospital, Columbus
 Stanford University Medical Center. Stanford
 UCLA Ronald Reagan Medical Center. Los Angeles
 University of California San Diego (UCSD) Thornton Hospital, La Jolla
 University of California San Francisco (UCSF), San Francisco
 University MRI & Diagnostic Imaging Centers - South, Boca Raton
University of Virginia (UVA) Health System, Charlottesville

Commercial Treatment Site, Virginia

1
Sites

- Bone Metastases
- Uterine Fibroids



Regulatory Approvals

	US FDA Approval	International Regulatory Approval
US Based Manufacturers		
Histosonics	—	—
International Cardio Corporation, LLC	—	—
Kona Medical	—	—
Mirabilis Medical, Inc.	—	—
Sonacare Medical, LLC	—	Prostate Cancer

Internationally Based Manufacturers		
Alpinion Medical Systems	—	—
Chongqing HAIFU Medical Technology	— — — — — —	Breast Cancer Soft Tissue Tumors Kidney Tumors Liver Tumors Uterine Fibroids Osteoid Osteoma
EDAP TMS S.A.	—	Prostate Cancer
InSightec Ltd.	— Bone Metastases — — Uterine Fibroids — —	Back & Neck Pain Bone Metastases Breast Cancer Essential Tremor Uterine Fibroids Uterine Adenomyosis Osteoid Osteoma
Philips Healthcare	— —	Bone Metastases Uterine Fibroids
Slender Medical	—	—
Supersonic Imagine	—	—
Theraclion	— —	Thyroid & Parathyroid tumors Breast Fibroadenoma

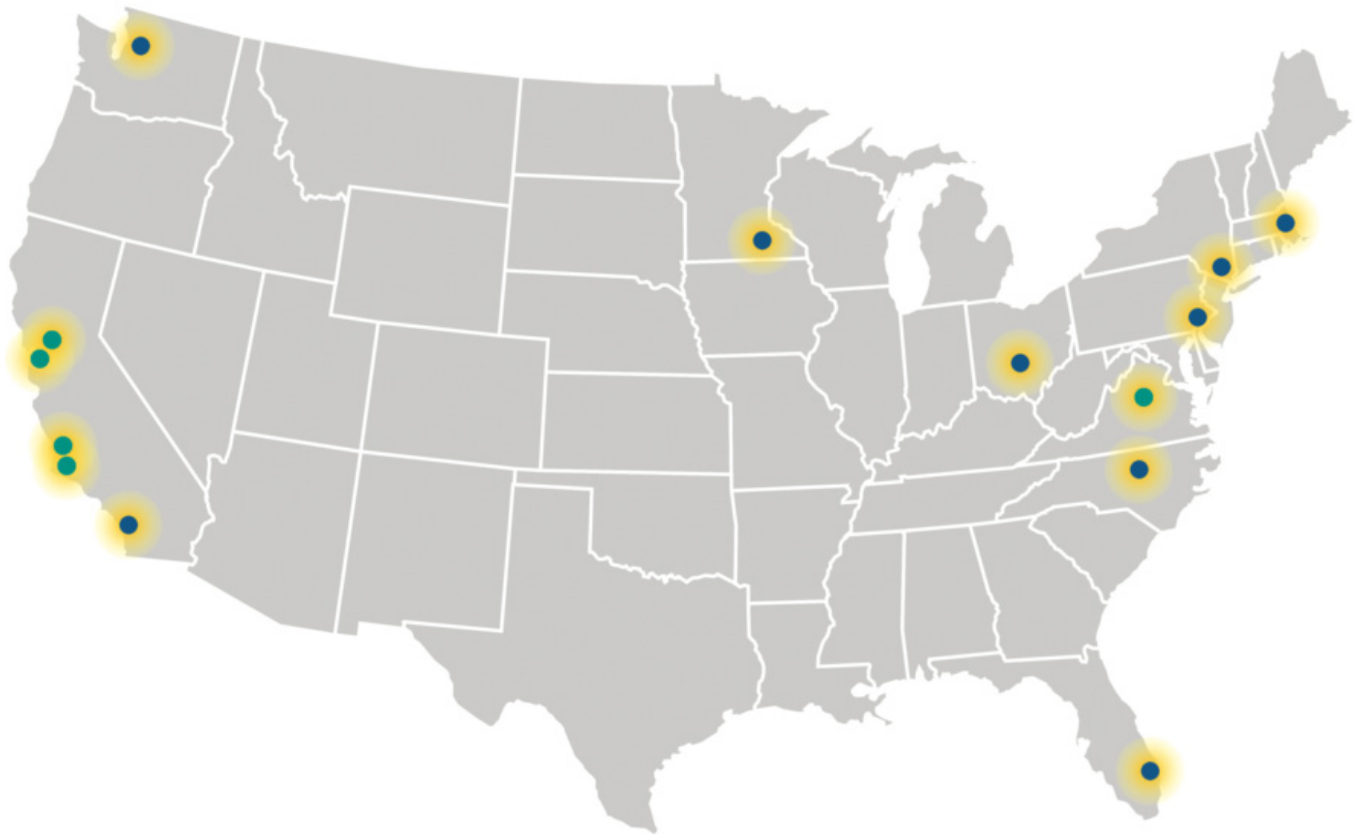
US Treatment Sites

18
Sites

2
Treatment Types

Number of indications treated at site

- 1
- 2



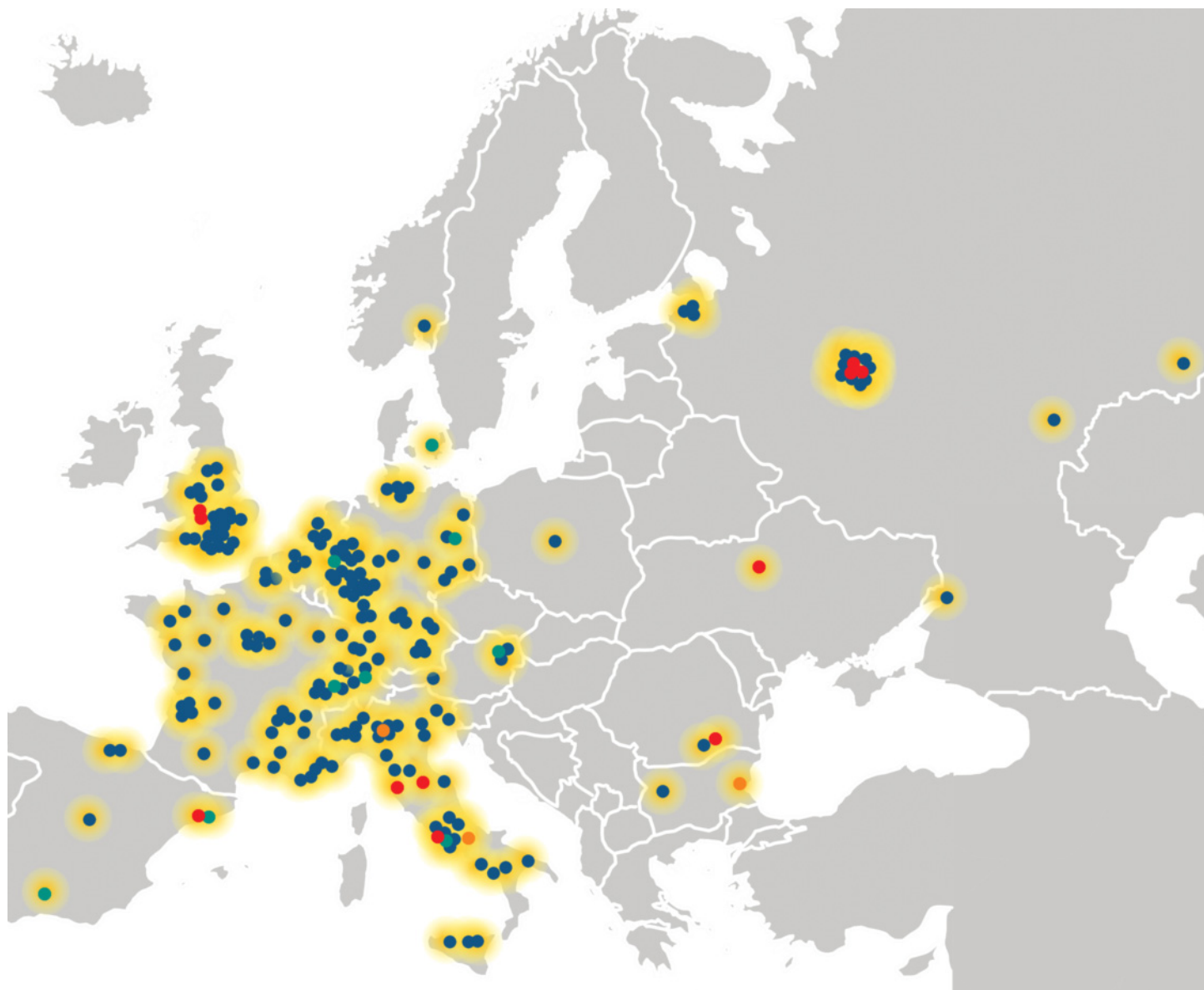
European Treatment Sites

211
Sites

9
Treatment Types

Number of indications treated at site

- 1 ● 4
- 2 ● 5
- 3 ● 6





FOCUSED ULTRASOUND FOUNDATION

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www.fusfoundation.org

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434.326.9829 OFFICE

progress@fusfoundation.org EMAIL

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