

### State of the Field Team

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# **Focused Ultrasound Foundation**

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# **Dear Colleagues and Stakeholders,**

It is my great pleasure to welcome you to the *State of the Field 2025*, a powerful new chapter in the story of focused ultrasound. What began as a modest effort to track developments in this emerging field has grown into a vital resource for researchers, clinicians, industry leaders, policymakers, and patient advocates around the world.

As Editor-in-Chief of both the written and digital editions, I'm excited to share how this year's report continues to evolve—not only in content, but also in how we deliver it. More than a collection of charts and statistics, this report offers a comprehensive and dynamic narrative of where the field stands today and where it's headed tomorrow.

To better serve our growing, global audience, we've introduced a two-part format for 2025. This written summary captures a moment in time, providing historical context and long-term trend analysis. The all-new interactive digital platform offers a richer, more flexible experience. The data is updated regularly and designed to let you explore by area of interest, whether that is clinical indications, research and treatment sites, regulatory authorizations, insurance coverage, or commercial manufacturers.

Focused ultrasound is advancing at a remarkable pace, and staying aligned with its momentum is essential. This report is designed to inform, inspire, and equip you with insights into research progress, clinical use, market dynamics, and adoption trends. It also aims to foster transparency, promote collaboration, and encourage meaningful connections across sectors.

Within these pages, you'll find a curated overview of clinical indications, patient treatment volumes, research activity worldwide, regulatory and reimbursement milestones, and key developments from industry leaders. These insights would not be possible without the generous contributions of our partners, especially the commercial manufacturers who shared their individual data to help us paint a full picture of industry-wide trends. I extend my heartfelt thanks to each of them for their collaboration and trust.

I encourage you to explore both versions of the report, share them widely, and return often, especially to the digital platform, which will be updated with new data throughout the year. If you have questions, feedback, or would like to request permission for reproduction, please don't hesitate to reach out to me at <code>info@fusfoundation.org</code>.

The start of 2025 represents a major leap forward in the focused ultrasound ecosystem. I'm thrilled to help bring this story to life with deeper access, smarter tools, and more powerful data than ever before.

Until next year,

Emily White, MD *Editor-in-Chief* 



# Thank you

We extend our deepest gratitude to the hundreds of scientists, clinicians, and industry partners around the world who generously contribute their data to this report. Your self-reported insights form the backbone of this publication, and it simply would not be possible without your commitment and collaboration.

We are equally grateful to our Board of Directors, Council members, and dedicated donors. Your continued support powers the Foundation's mission and makes the development of this report—and so much more—possible.

A heartfelt thank you goes to the incredible State of the Field team: Sara, Mary Rose, and Mike. Your talent, passion, and relentless dedication breathe life into this report each year.

- Mary Rose, your mastery in maintaining order across hundreds of spreadsheets and your meticulous meeting notes have saved us time and again.
- Mike, your ability to process and harmonize millions of data points—regardless of how complex or abstract the request—is nothing short of extraordinary.
- Sara, your visionary eye and creative storytelling turn raw data into powerful visuals that illuminate the journey and impact of focused ultrasound technology.

Each week, you show up with enthusiasm, creativity, and a can-do spirit that transforms ideas into action. You are the heart of this project, and your contributions elevate this report beyond information—it becomes a story of progress, possibility, and purpose.

Thank you all.

# **Digital State of the Field 2025**

www.fusfoundation.org/the-technology/interactive-state-of-the-field

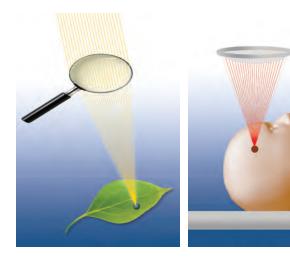
# Introduction

# Focused Ultrasound in Brief

Focused ultrasound is an early-stage, noninvasive therapeutic technology that can potentially improve the lives of millions of patients with various severe medical disorders. It offers a disruptive, game-changing alternative or complement to surgery, radiation therapy, drug delivery, and cancer immunotherapy.

This revolutionary technology can potentially increase the quality and longevity of life and decrease the cost of care by transforming the treatment of a broad range of indications. Focused ultrasound treats tissue with multiple intersecting beams of high-frequency sound, which can be focused accurately on targets deep in the body without damaging surrounding structures, much as beams of light can be focused on a point with a magnifying glass. At the focal point where the beams converge, the ultrasound energy can act in multiple ways to induce biological effects, enabling the treatment of various medical disorders.

Varying ultrasound power, utilizing continuous versus pulsing modes, and changing the total treatment time can all create different ultrasound applications. These applications can be categorized based on the type of energy they deliver thermal or mechanical—and whether treatment effects are permanent or transient. When focused ultrasound produces a high-power, continuous pressure wave, thermal energy accumulates rapidly at the focal point. This technique, termed thermal ablation, is used most frequently in the clinic and produces permanent effects. However, additional ultrasound treatment regimens are under investigation in preclinical and clinical trials. One of the most promising ultrasound applications currently in clinical trials is a low-power, pulsed treatment that produces mild mechanical forces capable of enhancing drug delivery to the brain by temporarily opening the blood-brain barrier. This effect is transient; treated tissue reverts to normal within a few hours.



Additionally, low-intensity focused ultrasound can deliver deep-brain reversible neuromodulation with acoustic sonications at millimeter precision. Researchers are using it to treat movement disorders like epilepsy and tremor, and psychiatric disorders like depression and addiction.

The effects induced by focused ultrasound can vary greatly depending on the application and the targeted tissue type. These biological effects are sometimes uniquely paired to a set of ultrasound parameters, as with blood-brain barrier disruption or neuromodulation. Still, others may be induced by multiple ultrasound applications. One active area of research is immunomodulation, which alters the immune response in treated tissue. The altered immune response depends on the nature of the focused ultrasound treatment parameters, although most treatments induce a response.

# Introduction

# Focused Ultrasound Today

The year 2024 marked a period of exceptional momentum for the field of focused ultrasound, fueled by the relentless efforts of researchers, clinicians, and industry innovators around the globe. Nearly 151,000 patients were treated using approximately 1,700 focused ultrasound devices worldwide, bringing the total number of treatments to over one million to date—a major milestone for the field.

The pace of technological advancement continues to accelerate. As of this year, 178 clinical indications are in various stages of development, and that number is growing rapidly. Focused ultrasound devices with regulatory authorization are now approved to treat 38 different diseases, expanding the reach of this transformative therapy.

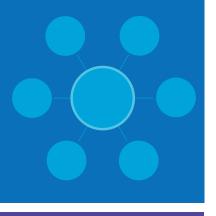
In 2024 alone, seven new indications were identified, and eight more advanced to first-in-human clinical trials. Most notably, four focused ultrasound companies achieved their first regulatory authorizations, joining 18 other commercial-stage manufacturers contributing to the global impact of this technology.

While focused ultrasound is not a solution for every patient or every condition, the field continues to push forward, driven by a shared mission to define where this noninvasive modality delivers the greatest therapeutic and cost-effective value. The progress is real, the potential is vast, and the work ahead is both critical and inspiring.

# **Development Pipeline**







# Overview

This chapter offers a high-level overview of the focused ultrasound indication pipeline, along with an in-depth exploration of each indication's mechanisms of action and stage of development. The State of Research and Regulatory Authorizations—commonly referred to as the "rainbow chart"—highlights the most advanced stage of research, regulatory authorization, or reimbursement for each indication, regardless of geographic location. Additional details on regional status can be found later in the report.

In 2024, three new indications entered the preclinical stage: cardiomyopathy, nicotine addiction, and pulmonary hypertension. Three others progressed to first-in-human clinical trials, marking an important milestone for insomnia, chronic pain, and postpartum symptoms. In addition, nonalcoholic steatohepatitis (NASH), obesity, cerebral palsy, and rhinitis also advanced to first-in-human trials, reflecting the field's continued expansion into a diverse range of therapeutic areas.

To view this chapter in an interactive format, please visit: www.fusfoundation.org/the-technology/indication-development-pipeline

# I. Indication Development Pipeline

- I. 2 Overview
- I. 3 Indication Development Pipeline

# State of Research and Regulatory Authorizations

- I. 4 By Body System
- I. 8 By Area of Interest

# Indication Development Pipeline

# 178 indications

4

# Companies with first authorizations

Arrayus Technologies INC

Burlington, Ontario, Canada

FUSMobile INC

Alpharetta, Georgia, USA

SonoMotion INC

South San Francisco, California, USA

TOOsonix AS

Hørsholm, Denmark

7

### **New indications**

Cardiovascular

Cardiomyopathy

Neurological

Addiction, nicotine
Insomnia
Pain, chronic

Ophthalmological

Vision impairment

Pulmonary

Pulmonary hypertension

Women's health

Postpartum symptoms

Development stagePreclinicalClinical trials

8

# Indications advanced to first-in-human clinical trials

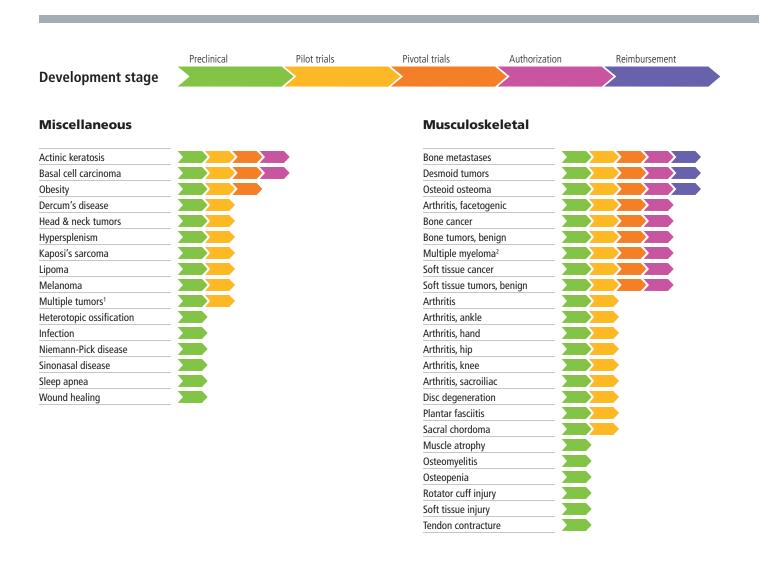
Gastrointestinal	Nonalcoholic steatohepatitis (NASH)
Miscellaneous	Obesity
Neurological	Addiction, nicotine Cerebral palsy Insomnia Pain, chronic
Pulmonary	Rhinitis
Women's health	Postpartum symptoms

# State of Research and Regulatory Authorizations by Body System



<sup>†</sup> New in 2024

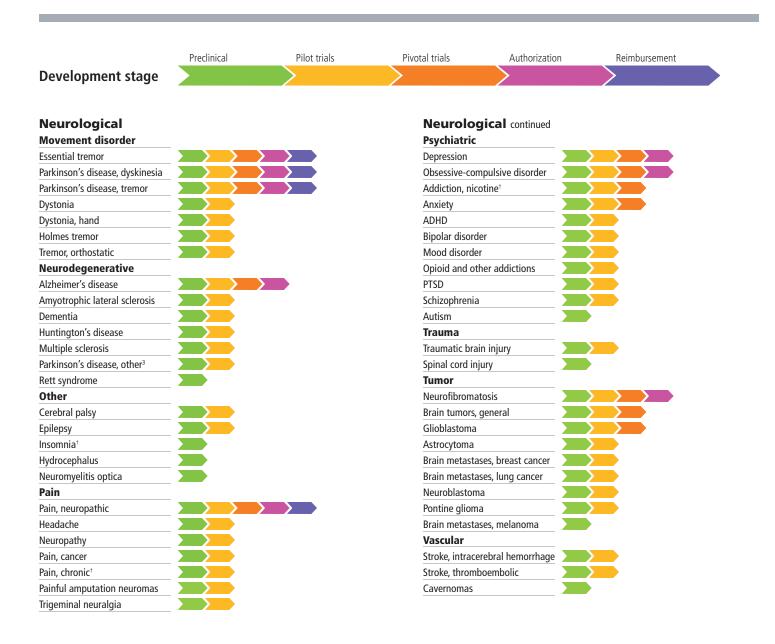
# State of Research and Regulatory Authorizations by Body System continued



<sup>1</sup> Protocols inclusive of more than one indication

<sup>2</sup> Multiple myeloma approval is based on bone metastases.

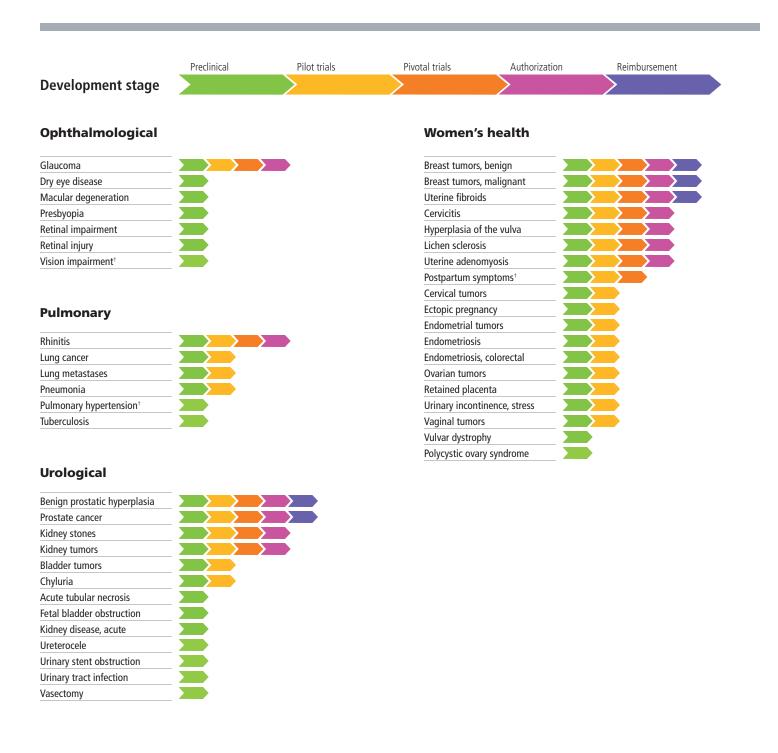
# State of Research and Regulatory Authorizations by Body System continued



<sup>3</sup> Treatment of the underlying cause of the disease

<sup>†</sup> New in 2024

# State of Research and Regulatory Authorizations by Body System continued



<sup>†</sup> New in 2024

# Areas of Interest

# A note on multiple listings

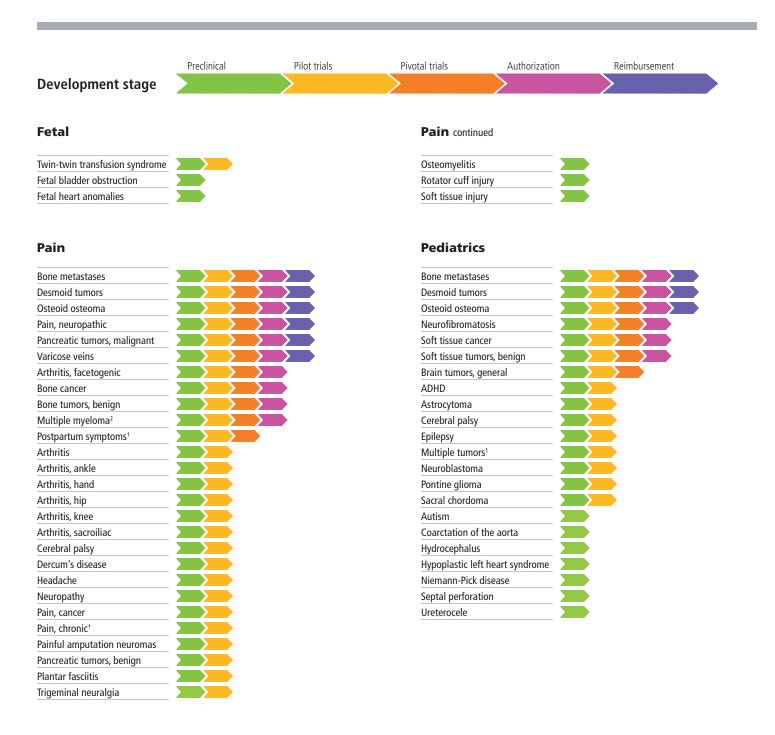
In the chart commonly referred to as the "rainbow chart" (see pages I.4–I.7), indications are organized by body systems—groups of tissues that work together to perform specific functions. Each indication is listed only once under the body system to which it belongs. For example, bone metastases appears solely in the Musculoskeletal category and is not duplicated elsewhere.

To provide an alternative perspective, a second chart (pages I.9–I.10) organizes indications into four overarching Areas of Interest: Fetal, Oncology, Pain, and Pediatrics. Indications

relevant to these focus areas may appear in multiple categories within this chart. For instance, bone metastases appears under Oncology, Pain, and Pediatrics.

Viewing the data through this lens helps to reveal emerging patterns and cross-cutting trends that may not be as apparent when organized strictly by body system.

# State of Research and Regulatory Authorizations by Area of Interest

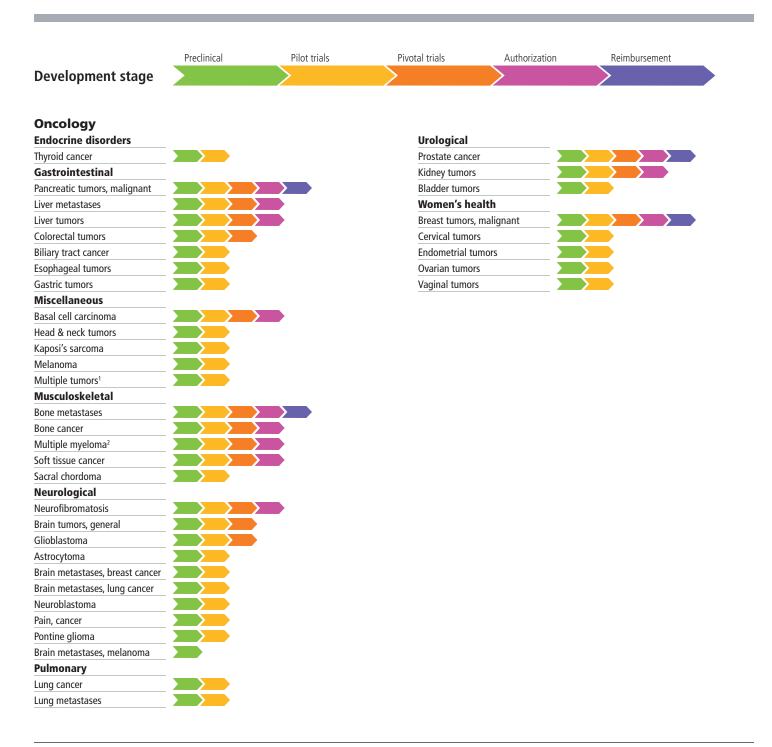


<sup>1</sup> Protocols inclusive of more than one indication

<sup>2</sup> Multiple myeloma approval is based on bone metastases.

<sup>†</sup> New in 2024

# State of Research and Regulatory Authorizations by Area of Interest continued



<sup>1</sup> Protocols inclusive of more than one indication

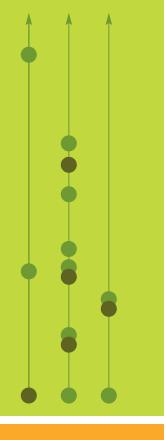
<sup>2</sup> Multiple myeloma approval is based on bone metastases.

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# Mechanisms of Action







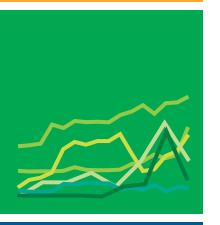
# Mechanisms of Action Ultrasound Applications and Biological Effects

Focused ultrasound is a medical technology that provides a uniquely flexible treatment platform, making it applicable to a wide range of diseases and conditions. It can produce treatments across the spectrum of thermal to mechanical effects, and these various treatments elicit a multitude of responses in biological tissues. In this report, a mechanism of action is defined by an ultrasound application applied to the body that produces a biological effect.

Varying ultrasound power, utilizing continuous versus pulsing modes, and changing the total treatment time create all different ultrasound applications. These applications can be categorized based on the type of energy they deliver, thermal or mechanical, and whether treatment effects are permanent or transient. When focused ultrasound produces a high-power, continuous pressure wave, thermal energy accumulates rapidly at the focal point. This technique, termed thermal ablation, is used most frequently in the clinic and produces permanent effects. Still, additional ultrasound treatment regimens are under investigation in preclinical experiments and clinical trials. One of the most promising ultrasound applications assessed in clinical trials is a low-power, pulsed treatment that produces mild mechanical forces capable of enhancing drug delivery to the brain. This effect is transient; treated tissue reverts to normal within a few hours.

The effects induced by focused ultrasound can vary greatly depending on the ultrasound application and the type of tissue targeted. These biological effects are sometimes uniquely paired to ultrasound parameters, as with blood-brain barrier (BBB) disruption. Still, others may be induced by multiple ultrasound applications.

To view this chapter in an interactive format, please visit: www.fusfoundation.org/the-technology/sotf-mechanisms-of-action

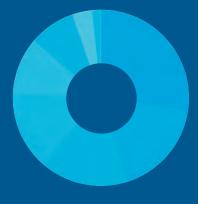


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- II. 2 Mechanisms of Action Ultrasound Applications and Biological Effects
- II. 3 Clinical Trials for Indications with New MOAs

### Research

- II. 4 Ultrasound Applications and Biological Effects
- II. 5 Ultrasound Applications and Biological Effects Graphic
- II. 6 Research Sites by Region



# Clinical Trials for Indications with New MOAs



# 2024

No. of Trials	MOA	Indication	Clinical Trial ID
1	Nonthermal		
	Alteration of tissue mechanics	Postpartum symptoms	ChiCTR210004958
8	Nonthermal		
	Neuromodulation	Addiction, nicotine	NCT06405074
		Insomnia	KCT0007512
		Obesity	NCT06249711
		Pain, chronic	NCT05674903, NCT06249724,
			NCT05901610, NCT06297200,
			NCT06628180

The nine clinical trials listed above were all initiated in 2024 and represent first-in-human studies exploring new mechanisms of action for treating various diseases. Prior to October 2023, thermal ablation—the destruction of tissue—was the only mechanism of action with regulatory authorization anywhere in the world.

That landscape is now shifting rapidly. In 2024, the majority of new studies involving both novel indications and mechanisms of action focused on neuromodulation. Notably, five separate trials investigating neuromodulation for chronic pain launched this year alone—an exciting and significant step forward in the evolution of focused ultrasound therapy.

# Ultrasound Applications and Biological Effects\* *Table*

#### **HISTOTRIPSY**

# 9

### biological effects

Alteration of tissue mechanics
Amplification of cancer
biomarkers
Chemosensitization
Clot lysis
Immune cell trafficking
Immunomodulation
Liquid biopsy
Radiosensitization
Tissue destruction

#### **HYPERTHERMIA**

# **13**

### biological effects

Amplification of cancer biomarkers Chemosensitization Drug delivery Drug delivery, immunotherapeutic Drug delivery, vehicle Immune cell delivery Immune cell trafficking Immunomodulation Increased vascular permeability Liquid biopsy Radiosensitization Tissue destruction Vasodilation

#### NONTHERMAL

# 29

### biological effects

Alteration of tissue mechanics Amplification of cancer biomarkers Angiogenesis BNB opening<sup>1</sup> BNB opening<sup>1</sup>, drug delivery Cardiac pacing Chemosensitization Clot lysis Drug delivery Drug delivery, immunotherapeutic Drug delivery, vehicle Gene delivery Immune cell delivery Immune cell trafficking Immunomodulation Increased vascular permeability Kidney stone fragmentation Kidney stone propulsion

Liquid biopsy
Neuromodulation
Radiosensitization
Sonodynamic therapy
Sonoporation
Stem cell delivery
Stem cell trafficking
Tissue destruction
Vascular occlusion
Vasoconstriction
Vasodilation

# NONTHERMAL, BBB OPENING

# 8

# biological effects

BBB opening
Drug delivery
Drug delivery,
immunotherapeutic
Drug delivery, vehicle
Gene delivery
Glymphatic stimulation
Immune cell delivery
Stem cell delivery

#### THERMAL ABLATION

10

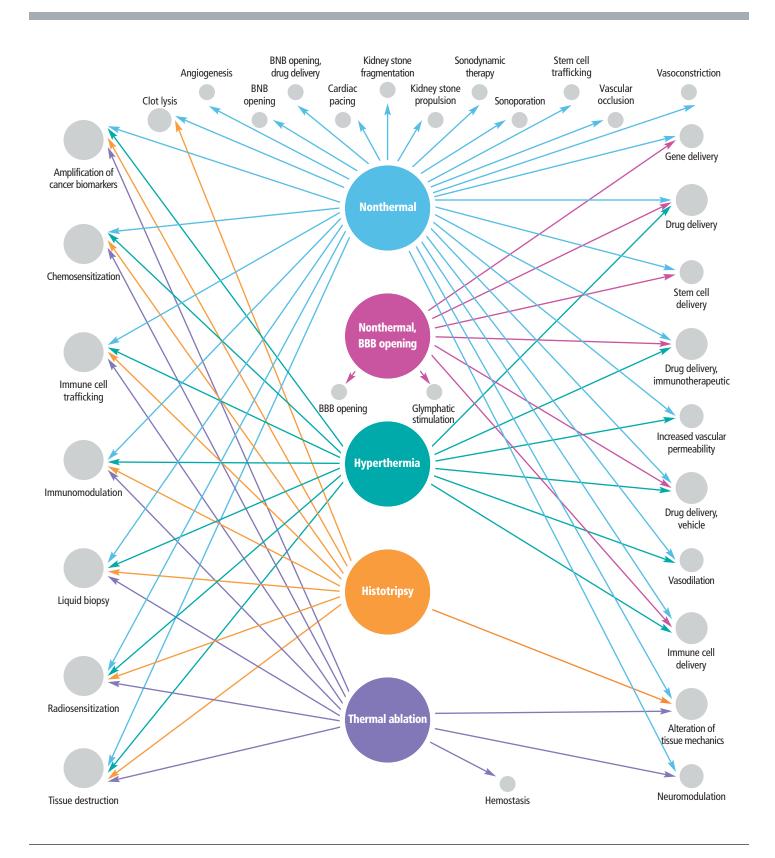
# biological effects

Alteration of tissue mechanics
Amplification of cancer
biomarkers
Chemosensitization
Hemostasis
Immune cell trafficking
Immunomodulation
Liquid biopsy
Neuromodulation
Radiosensitization
Tissue destruction

<sup>\*</sup> This table lists all mechanisms of action utilized across all treatments and research types. Not all of these are being investigated specifically in mechanisms of action research projects and may not appear in other tables in this section. All other tables reflect self-reported data by research and treatment sites.

<sup>1</sup> BNB opening stands for blood-nerve barrier opening.

# Ultrasound Applications and Biological Effects *Graphic*



# Mechanisms of Action Research Sites by Region\*



		Regions				
	■ N. America	■ Europe	Asia	Oceania	■ Mid East	
Histotripsy   32 sites						
Alteration of tissue mechanics	1	_	_	1	_	2
Amplification of cancer biomarkers	3	_	_	_	_	3
Chemosensitization	2	_	_	_	_	2
Immune cell trafficking	2	_	_	_	_	2
Immunomodulation	6	3	_	_	_	9
Liquid biopsy	3	_	_	_	_	3
Radiosensitization	_	1	_	_	_	1
Tissue destruction	20	7	2	1	_	30
Hyperthermia   37 sites						
Chemosensitization	1	_	_	_	_	1
Drug delivery	11	8	2	1	1	23
Drug delivery, immunotherapeutic	2	2	_	_	_	4
Drug delivery, vehicle	1	2	_	_	_	3
Immune cell trafficking	1	_	_	_	_	1
Immunomodulation	2	1	_	_	_	3
Increased vascular permeability	1	_	_	_	_	1
Radiosensitization	3	3	1	_	_	7
Tissue destruction	6	2	3	_	1	12
Nonthermal I 135 sites						
Alteration of tissue mechanics	1	_	1	_	_	2
Amplification of cancer biomarkers	6	_	1	_	_	7
Angiogenesis	3	1	2	_	_	6
BNB opening, drug delivery	1	_	_	_	_	1
Cardiac pacing	_	_	_	_	1	1
Chemosensitization	5	2	_	_	_	7
Clot lysis	12	2	2	_	_	16
Drug delivery	13	7	2	1	1	24
Drug delivery, immunotherapeutic	8	2	_	1	_	11

For more information about specific mechanisms of action research sites, please visit: www.fusfoundation.org/the-technology/research-sites. Use the "search by biological effects research" dropdown menu.

<sup>\*</sup> Research sites may be working in more than one mechanism of action area of research.

# Mechanisms of Action Research Sites by Region\* continued



			Regions			Total
	■ N. America	Europe	■ Asia	Oceania	■ Mid East	
Nonthermal continued						
Drug delivery, vehicle	27	9	18	_	2	56
Gene delivery	6	_	_	_	_	6
Immune cell delivery	2	_	_	_	_	2
Immune cell trafficking	4	_	_	_	_	4
Immunomodulation	14	4	3	_	_	21
Increased vascular permeability	1	_	_	_	_	1
Kidney stone fragmentation	2	_	_	_	_	2
Liquid biopsy	6	2	1	_	_	9
Neuromodulation	27	12	13	1	3	56
Radiosensitization	4	_	_	_	_	4
Sonodynamic therapy	6	6	7	1	_	20
Sonoporation	9	2	2	_	_	13
Stem cell delivery	6	_	_	_	1	7
Stem cell trafficking	3	_	_	_	_	3
Tissue destruction	20	12	11	1	_	44
Vascular occlusion	7	2	3	_	_	12
Nonthermal, BBB opening I 79 sites						
Blood-brain barrier opening	19	14	5	_	_	38
Drug delivery	25	16	19	1	1	62
Drug delivery, immunotherapeutic	3	1	1	_	_	5
Drug delivery, vehicle	2	_	_	1	-	3
Gene delivery	3	1	1	_	_	5
Immune cell delivery	2	_	_	_	-	2
Stem cell delivery	_	_	1	_	_	1
Thermal ablation I 66 sites						
Amplification of cancer biomarkers	2	1	_	_	_	3
Chemosensitization	2	1	_	_	_	3
Hemostasis	1	_	_	_	_	1

For more information about specific mechanisms of action research sites, please visit: www.fusfoundation.org/the-technology/research-sites. Use the "search by biological effects research" dropdown menu.

<sup>\*</sup> Research sites may be working in more than one mechanism of action area of research.

# Mechanisms of Action Research Sites by Region\* continued



	Regions					Total
	■ N. America	■ Europe	Asia	Oceania	■ Mid East	
Thermal ablation continued						
Immune cell trafficking	3	1	_	_	_	4
Immunomodulation	7	3	2	_	-	12
Neuromodulation	3	_	1	_	_	4
Radiosensitization	1	_	_	_	-	1
Tissue destruction	29	18	11	1	3	62

For more information about specific mechanisms of action research sites, please visit: www.fusfoundation.org/the-technology/research-sites. Use the "search by biological effects research" dropdown menu.

 $<sup>\</sup>ensuremath{^{\star}}$  Research sites may be working in more than one mechanism of action area of research.

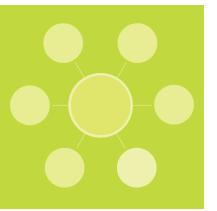
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# Research and Treatment Sites





# State of Research



As in previous reports, this section highlights research activity across commercial, clinical, preclinical, mechanisms of action, and technical research domains.

In 2024, the field experienced substantial growth with 125 new commercial treatment sites established worldwide. The largest share of new clinical activity is in the United States and China.

Meanwhile, the number of preclinical, mechanism of action, and technical research sites remained remarkably consistent with last year, reflecting ongoing stability in foundational and exploratory research efforts.

# **III.** Research and Treatment Sites

- III. 2 State of Research
- III. 3 Research and Commercial Treatment Sites by Region

#### **Commercial Treatment**

- III. 4 Sites by Region
- III. 4 Top Countries for Commercial Treatment
- III. 4 Top Countries with Commercial Treatment Growth
- III. 5 Sites by Country
- III. 6 Sites by Indication and Body System

#### **Clinical Research**

- III. 8 Sites by Region
- III. 8 Top Countries for Clinical Research
- III. 8 Top Countries with Clinical Research Growth
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# **Preclinical Research**

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- III.12 Top Countries for Preclinical Research
- III.12 Top Countries with Preclinical Research Growth
- III.13 Sites by Country
- III.14 Sites by Indication and Body System

#### **Mechanisms of Action Research**

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- III.16 Top Countries for MOA Research
- III.16 Top Countries with MOA Research Growth
- III.17 Sites by Country
- III.18 Sites by Ultrasound Application and Country
- III.20 Sites by Ultrasound Application and Region
- III.21 Research Sites by Ultrasound Application

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- III.22 Top Countries for Technical Research
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- III.23 Sites By Country
- III.24 Research Types by Region
- III.25 Research Types



# Research and Commercial Treatment Sites by Region

Number of sites

2024

	Total	North America	Europe	Asia	South America	Oceania	Mid East / Africa
Commercial treatment	1,328	304	337	645	11	4	20 / 7
Clinical research	318	100	104	101	2	5	4/2
Preclinical research	159	70	45	37	_	3	4 / –
MOA research	177	75	43	50	_	3	6 / —
Technical research	154	62	51	38	-	2	1/-



# Commercial Treatment Sites



# 1,328 Sites worldwide

North America	Europe	Asia	South America	Oceania	Middle East	Africa
<b>304</b>	<b>337</b>	645	11	4	20	7

Annual growth by region from 2019–2024

**23**%

7%

**26**%

2%

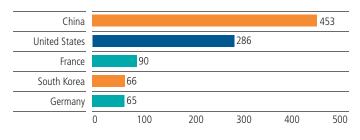
7%

11%

**24**%

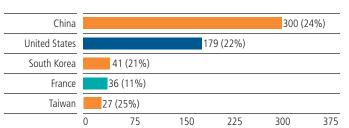
# **Top Countries for Treatment**

Number of sites



# **Top Countries with Commercial Treatment Growth**

Sites added, cumulative 2019 to 2024



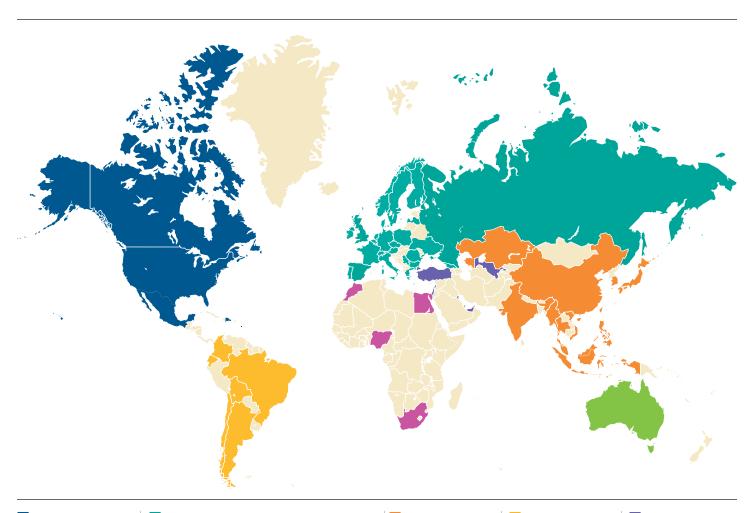
# **Commercial additional content**

For more information about specific clinical research sites and indications, please visit:

www.fusfoundation.org/the-technology/sotf-research-treatment-sites

# Commercial Treatment Sites





# North America

- 8 Canada
- 1 Dominica
- Dominican Republic
- 8 Mexico
- 286 United States
  - 121 Central
  - 94 Eastern
  - 52 Pacific
  - 19 Mountain

# Europe

- 2 Belgium
- Bulgaria
- Czech Republic
- 2 Denmark

- 26 Italy
- Lativa 1

- 7 Austria

- Finland
- 90 France
- 1 Georgia
- 65 Germany
- 4 Greece
- Ireland
- Monaco
- 4 The Netherlands

# 3 Norway

- 23 Poland
- 2 Portugal
- 2 Romania
- 36 Russian Federation
- 2 Serbia
- 22 Spain
- 1 Sweden
- 12 Switzerland
- 2 Ukraine
- 25 United Kingdom

# Asia

- 453 China
  - 7 India
- 1 Indonesia
- 56 Japan
- 1 Kazakhstan
- 4 Malaysia
- 1 Myanmar
- Philippines
- 5 Singapore
- 66 South Korea
- 40 Taiwan
- Vietnam
- 8 Thailand

# South America

- 2 Argentina
- 1 Bolivia
- 3 Brazil
- 2 Chile
- 1 Colombia
- 2 Ecuador

# Oceania

4 Australia

# Middle East

- 3 Israel
- 1 Kuwait
- 2 Lebanon
- 1 Qatar
- 7 Turkey
- United Arab **Emirates**
- 1 Uzbekistan

# Africa

- 3 Egypt
- 1 Morocco
- 2 Nigeria
- South Africa

# Commercial Treatment Sites by Indication and Body System

55 indications are being treated at commerical sites worldwide.



16

Cardiovascular sites
2 indications

89

Musculoskeletal sites
9 indications

563
Women's health sites
13 indications

**19** 

Endocrine disorders sites
1 indication

**183** 

Neurological sites 18 indications **171** 

**Gastrointestinal sites** 6 indications

**15** 

Ophthalmological sites
1 indication

4

Miscellaneous sites 2 indications

**604** 

**Urological sites**3 indications

For more information about specific treatment sites and indications, please visit: https://www.fusfoundation.org/the-technology/treatment-sites/.

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#### Clinical Research Sites

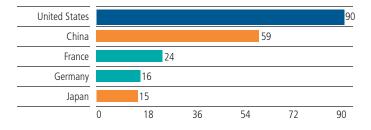


# 318 Sites worldwide\*

North America	Europe	Asia	South America	Oceania	Middle East	Africa
100	104	101	2	5	4	2
		Annual gro	owth by region from 2	019–2024		
<b>20</b> %	<b>4</b> %	11%	_	6%	_	_

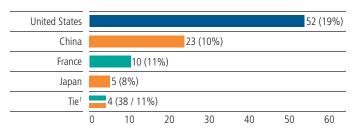
#### **Top Countries for Clinical Research**

Number of sites



#### Top Countries with Clinical Research Growth

Sites added, cumulative 2019 to 2024



#### Clinical research additional content

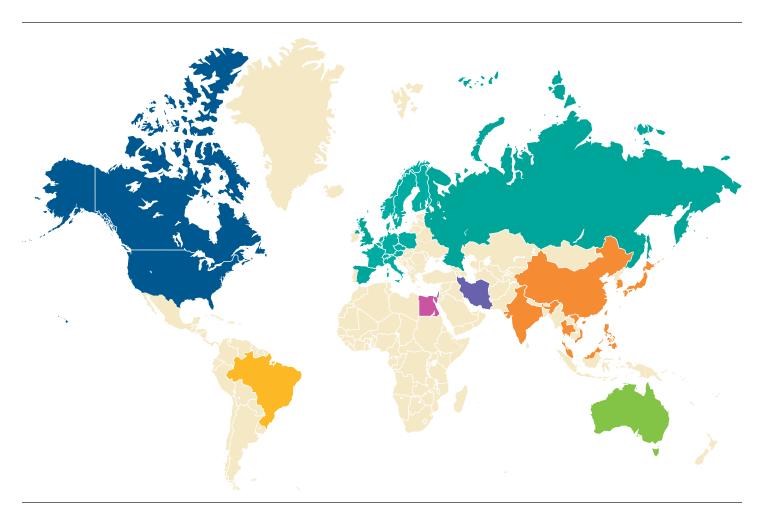
For more information about specific clinical research sites and indications, please visit: www.fusfoundation.org/the-technology/sotf-research-treatment-sites

<sup>\*</sup> Clinical research sites treat patients as part of a clinical study.

<sup>1</sup> Two-way tie: Belgium and Taiwan

# Clinical Research Sites by Country





#### ■ North America

- 10 Canada
- 90 United States

#### Europe

- 1 Austria
- 5 Belgium
- 2 Czech Republic
- 2 Denmark
- 2 Finland
- 24 France
- 16 Germany
- 9 Italy
- 5 The Netherlands
- 4 Norway
- 2 Poland
- 4 Russian Federation
- 9 Spain
- 1 Sweden
- 5 Switzerland
- 13 United Kingdom

#### Asia

- 59 China
- 2 India
- 15 Japan
- 1 Malaysia
- 1 Philippines
- 11 South Korea
- 10 Taiwan
- 1 Thailand
- 1 Vietnam

#### South America

2 Brazil

#### Oceania

5 Australia

#### ■ Middle East

- 1 Iran
- 3 Israel

#### Africa

2 Egypt

# Clinical Research Sites by Indication and Body System

91 indications are being researched at clinical sites worldwide.



16

Cardiovascular sites
5 indications

**52** 

Musculoskeletal sites
12 indications

96

Urological sites
7 indications

4

Endocrine disorders sites
1 indication

134

Neurological sites
37 indications

**78** 

Women's health sites 9 indications **55** 

**Gastrointestinal sites** 8 indications

3

Ophthalmological sites
1 indication

16

Miscellaneous sites
10 indications

1

**Pulmonary sites**1 indication

For more information about specific clinical research sites and indications, please visit: www.fusfoundation.org/the-technology/research-sites. Use the "search by disease research" and/or "search by research stage" dropdown menu.

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#### Preclinical Research Sites\*

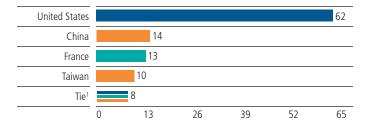


# 159 Sites worldwide



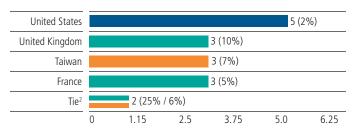
### **Top Countries for Preclinical Research**

Number of sites



#### **Top Countries with Preclinical Research Growth**

Sites added, cumulative 2019 to 2024



#### Preclinical research additional content

For more information about specific clinical research sites and indications, please visit:

www.fusfoundation.org/the-technology/sotf-research-treatment-sites

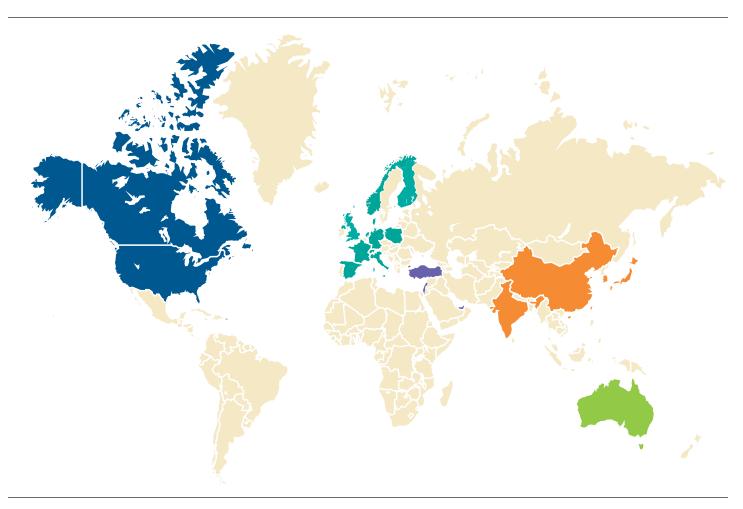
<sup>\*</sup> Preclinical research sites conduct nonhuman FUS research to collect data in support of the safety or feasibility of clinical applications.

<sup>1</sup> Three-way tie: Canada, United Kingdom, and South Korea

<sup>2</sup> Two-way tie: Italy and South Korea

# Preclinical Research Sites by Country





#### ■ North America

- 8 Canada
- 62 United States

### Europe

- 1 Cyprus
- 1 Denmark
- 1 Finland
- 13 France
- 6 Germany
- 3 Italy
- 2 The Netherlands
- 2 Norway
- 1 Poland
- 4 Spain
- 3 Switzerland
- 8 United Kingdom

#### Asia

- 13 China
- 1 India
- 3 Japan
- 1 Singapore
- 8 South Korea
- 10 Taiwan

#### Oceania

3 Australia

#### ■ Middle East

- 2 Israel
- 1 Turkey
- 1 United Arab Emirates

# Preclinical Research Sites by Indication and Body System

104 indications are being researched at preclinical sites worldwide.



26

Cardiovascular sites 15 indications

34

Musculoskeletal sites 14 indications

> 30 Urological sites

> > 8 indications

4

**Endocrine disorders sites** 3 indications

**87** 

Neurological sites 31 indications

39

Women's health sites 8 indications 44

**Gastrointestinal sites** 8 indications

8

Ophthalmological sites
5 indications

24

Miscellaneous sites
10 indications

4

**Pulmonary sites** 2 indications

For more information about specific preclinical research sites and indications, please visit: www.fusfoundation.org/the-technology/research-sites. Use the "search by disease research" and/or "search by research stage" dropdown menu.



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#### Mechanisms of Action Research Sites\*

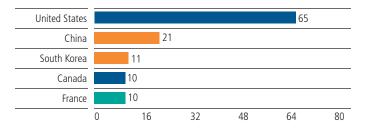


# Sites worldwide



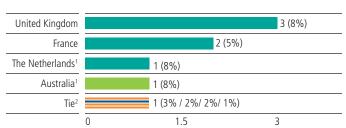
### **Top Countries for MOA Research**

Number of sites



#### Top Countries with MOA Research Growth

Sites added, cumulative 2019 to 2024



#### MOA research additional content

For more information about specific clinical research sites and indications, please visit: www.fusfoundation.org/the-technology/sotf-mechanisms-of-action

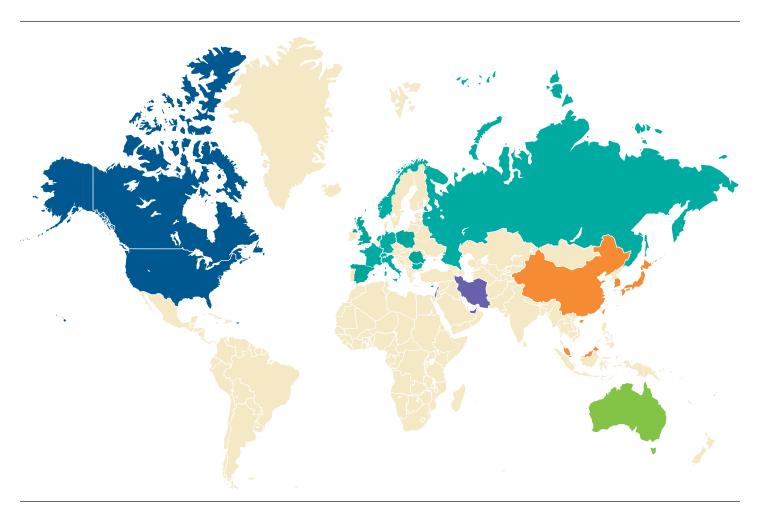
<sup>\*</sup> Mechanisms of action research sites conduct basic science research to understand how focused ultrasound affects the body.

<sup>1</sup> Two-way tie: The Netherlands and Australia

<sup>2</sup> Four-way tie: Taiwan, Canada, South Korea, and China

# Mechanisms of Action Research Sites by Country





#### ■ North America

- 10 Canada
- 65 United States

#### Europe

- 1 Bulgaria
- 1 Cyprus
- 10 France
- 5 Germany
- 5 Italy 3 The Ne
- 3 The Netherlands
- 2 Norway
- 1 Poland
- 1 Russian Federation
- 2 Spain
- 3 Switzerland
- 9 United Kingdom

#### Asia

- 21 China
- 9 Japan
- 1 Malaysia
- 1 Singapore
- 11 South Korea
- 7 Taiwan

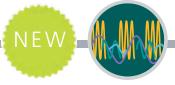
#### Oceania

3 Australia

#### ■ Middle East

- 2 Iran
- 3 Israel
- 1 United Arab Emirates

Mechanisms of Action Research Sites by Ultrasound Application and Country\*



		Ultrasound Applications							
	Histotripsy	Hyperthermia	Nonthernal	Nothermnal, BBB Opening	Thermal Ablation				
North America	3					165			
Canada	1	4	7	3	7	22			
United States	20	15	55	28	25	143			
Europe	4				5 &	91			
Bulgaria	_	-	<u> </u>		1	1			
Cyprus	_	_	1	1	-	2			
France	2	3	7	6	5	23			
Germany	2	1	5	2	3	13			
Italy	1	1	4	2	3	11			
The Netherlands	2	1	1	2	1	7			
Norway	_	_	2	1	_	3			
Poland	_	_	_	1	1	2			
Russian Federation	_	_	_	_	1	1			
Spain	_	_	2	2	1	5			
Switzerland	_	_	1	2	-	3			
United Kingdom	1	4	7	5	3	20			

<sup>\*</sup> Mechanisms of action research sites may be working in more than one mechanism of action research area.

Mechanisms of Action Research Sites by Ultrasound Application and Country\* continued



		Totals				
	Histotripsy	Hyperthermia	Nonthernal	Nothermnal, BBB Opening	Thermal Ablation	
Asia	3/4					76
China	1	3	13	7	6	30
Japan	_	_	8	5	1	14
Malaysia	_	-	1		5 5 -	1
Singapore	_	_	1		V 42 -	1
South Korea	1	1	8	5	3	18
Taiwan	_	2	5	4	1	12
Oceania	÷/-				1-04	7
Australia	1	1	2	2	1	7
Middle East						10
Iran	_	_	1	-	1	2
Israel	_	1	3	1	2	7
United Arab Emirates	_	_	1	_	_	1

<sup>\*</sup> Mechanisms of action research sites may be working in more than one mechanism of action research area.

Mechanisms of Action Research Sites by Ultrasound Application and Region\*

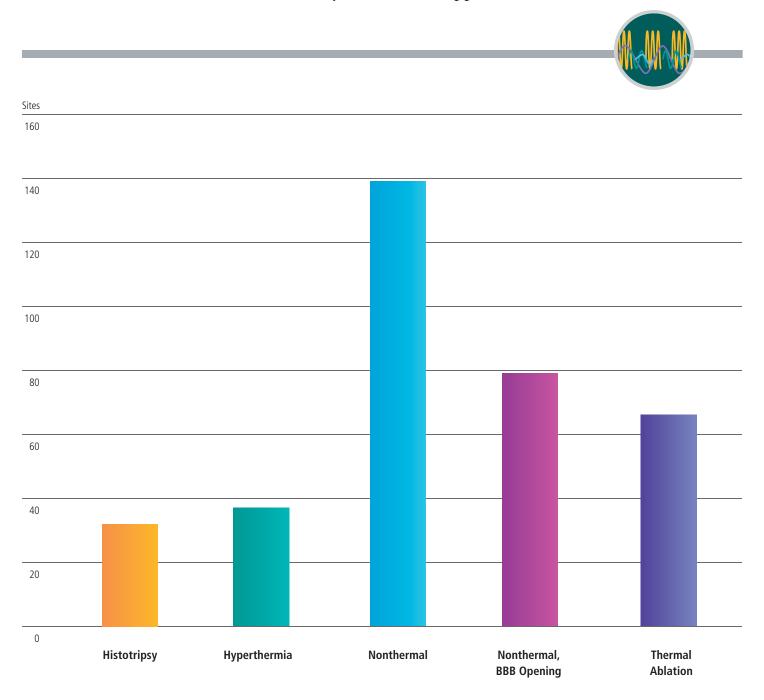


# **Ultrasound Applications**

	Histotripsy	Hyperthermia	Nonthernal	Nothermnal, BBB Opening	Thermal Ablation	Unique Sites
North America	21	19	62	31	32	75
Europe	8	10	30	24	19	43
Asia	2	6	36	21	11	50
Oceania	1	1	2	2	1	3
Middle East	-	1	5	1	3	6

<sup>\*</sup> Mechanisms of action research sites may be working in more than one mechanism of action research area.

# Mechanisms of Action Research Sites by Ultrasound Application\*



<sup>\*</sup> Mechanisms of action research sites may be working in more than one mechanism of action research area.

# Technical Research Sites by Region

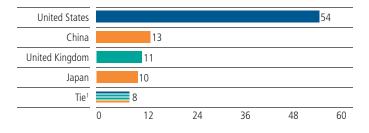


# 154 Sites worldwide



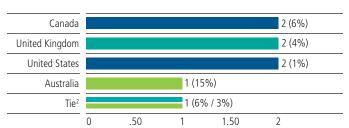
### **Top Countries for Technical Research**

Number of sites



#### **Top Countries with Technical Research**

Sites added, cumulative 2019 to 2024

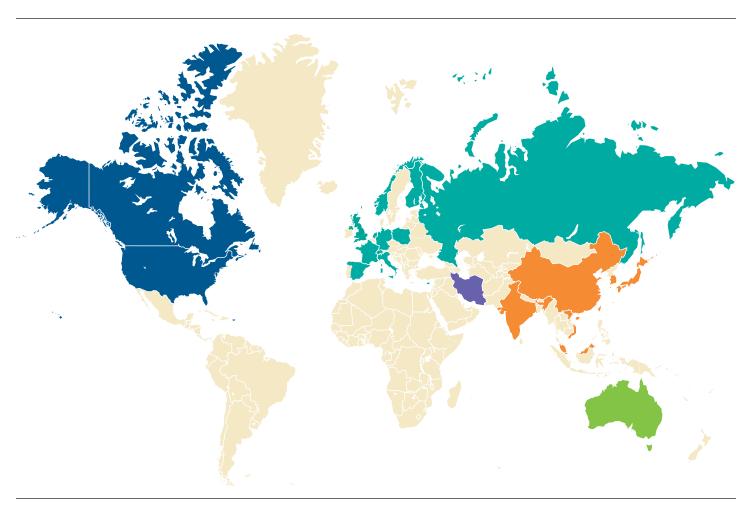


<sup>1</sup> Four way tie: Canada, France, Germany, and South Korea

<sup>2</sup> Two way tie: The Netherlands and South Korea

# Technical Research Sites by Region





#### ■ North America

- 8 Canada
- 54 United States

#### Europe

- 1 Cyprus
- 2 Finland
- 8 France
- 8 Germany
- 7 Italy
- 4 The Netherlands
- 1 Norway
- 2 Poland
- 1 Russian Federation
- 2 Spain
- 4 Switzerland
- 11 United Kingdom

#### Asia

- 13 China
- 1 India
- 10 Japan
- 1 Singapore
- 8 South Korea
- 4 Taiwan
- 1 Vietnam

#### Oceania

2 Australia

#### ■ Middle East

1 Iran

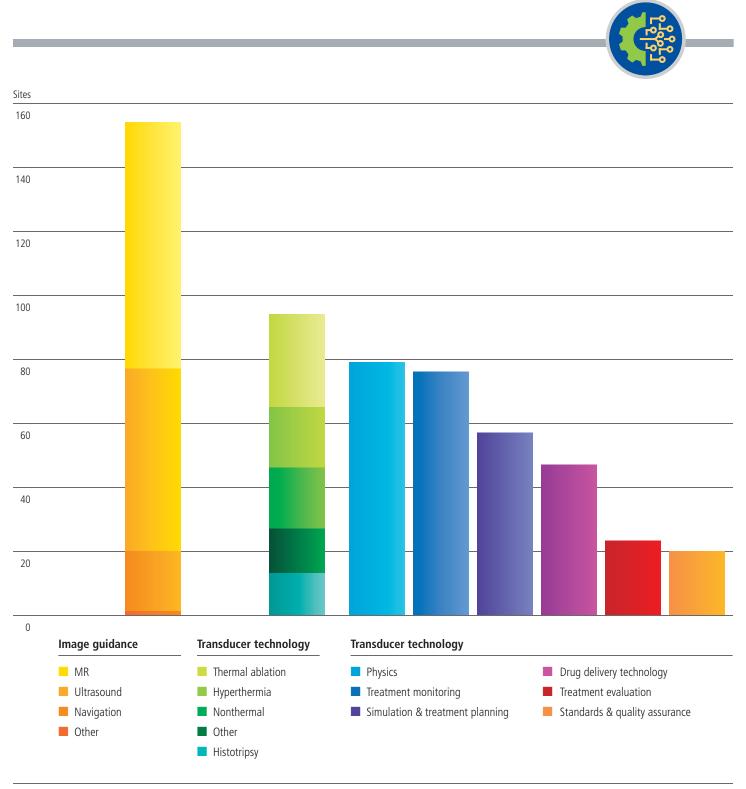
#### Technical Research Sites\*



		8	Sites	(Tel		Totals
	North America	Europe	Asia	Oceania	Middle East	
Image guidance		1				154
MR	28	30	19	• <u> </u>	-	
Navigation	6	8	2	_	100	
Other	1	1	2	<del>-</del>	, 4° -	
Ultrasound	30	18	9	- \ -	· A	
Transducer technology			(4)		The state of the s	94
Histotripsy	8	3	2	_		
Hyperthermia	9	8	2	_	_	
Nonthermal	11	4	4	_	<u>-</u>	y
Other	9	4	_	1	_	-
Thermal ablation	11	12	6	_	_	
Physics	39	26	14	_	_	79
Treatment monitoring	31	28	15	1	1	76
Simulation & treatment planning	27	23	7	_	_	57
Drug delivery technology	25	16	4	2	_	47
Treatment evaluation	12	9	2	_	_	23
Standards & quality assurance	9	8	3	_	_	20

 $<sup>^{\</sup>star}$   $\,$  Technical research sites may be working in more than one technical research area.

# Technical Research Types\*



 $<sup>^{\</sup>star}$   $\,$  Technical research sites may be working in more than one technical research area.

# Research Landscape



#### Overview

#### **About this Chapter**

In the 2025 report, we've combined several related topics into a single chapter, as much of the detailed information has transitioned to the interactive online version of the *State of the Field*. Here, you'll find a summary of key updates on Centers of Excellence, awareness efforts (including publications and meeting abstracts), and veterinary medicine. For more in-depth data and expanded content, we encourage you to explore the interactive platform.



# IV. Research Landscape

IV. 2 Overview

#### **Centers of Excellence**

- IV. 3 Highlights
- IV. 3 Locations
- IV. 6 Year Established
- IV. 7 Number of Indications Being Treated or Studied

#### **FUS Abstracts**

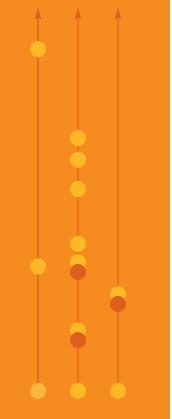
- IV. 8 Scientific Visibility and Engagement
- IV. 9 Presented at FUS Meetings
- IV.10 Presented at Other Symposia

#### **Publications**

- IV.13 Scientific Publications and Open Access
- IV.13 FUS Publications
- IV.13 FUS Publications and Citations
- IV.14 2024 Top Source Titles

#### **Veterinary Medicine**

- IV. 15 FUS Veterinary Applications
- IV. 15 Value Chain
- IV. 16 State of Research by Indication and MOA
- IV. 18 Veterinary Program Sites



Highlights



# New Centers of Excellence

2024

341

COE publications
2024

COE increase in publications
In 2024 over 2023

TOK

FUS publications

Cumulative

300K

FUS citations

Cumulative

#### Centers of Excellence Locations



Established in 2009, the Centers of Excellence (COE) program brings together leading experts and cutting-edge technical resources at luminary sites around the world. These centers are formed through strategic partnerships among academia, industry, and the Focused Ultrasound Foundation to showcase the potential of focused ultrasound technology and to serve as collaborative hubs for research, clinical advancement, and innovation.

COEs are powerhouses of focused ultrasound research. In 2023 alone, they were responsible for 212 peer-reviewed publications, reflecting their impact and productivity. These sites not only drive the scientific progress of the field, but also train the next generation of focused ultrasound researchers and clinicians, while generating the intellectual property that will help fuel future commercialization.

This report highlights 15 designated Centers of Excellence, all recognized by the Focused Ultrasound Foundation and listed on our website.

In 2024, we proudly welcomed four new Centers of Excellence to the program: Virginia Tech, Seoul National University Hospital, Columbia University, and Chongqing Haifu Hospital.

Together, these centers represent the global leadership and collaborative energy propelling focused ultrasound forward.

To view more details about COEs in an interactive format, please visit:

www.fusfoundation.org/the-technology/sotf-centers-of-excellence

#### Centers of Excellence Locations continued



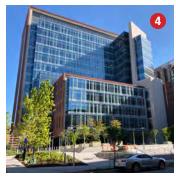
University of Virginia Health System Charlottesville, VA



The Institute of Cancer Research and The Royal Marsden, London, England



Brigham and Women's Hospital Boston, MA



University of Maryland School of Medicine Baltimore, MD



Sunnybrook Health Sciences Centre Toronto, Canada



Stanford University School of Medicine Stanford, CA



Lyon, France



Physics for Medicine Paris Paris, France



Children's National Hospital Washington, DC



University Medical Center Utrecht Utrecht, The Netherlands



University of Oxford Oxford, England



Virginia Tech Blacksburg, VA



Seoul National University Hospital Seoul, South Korea



Columbia University New York, NY



Chongqing Haifu Hospital Chongqing, China

# Year Center of Excellence Established

Established	Name	Location	2024 Publications
2024	Chongqing Haifu Hospital	Chongqing, China	90
2024	Columbia University	New York, NY	24
2024	Seoul National University Hospital	Seoul, South Korea	5
2024	Virginia Tech	Blacksburg, VA	22
2023	University of Oxford	Oxford, England	14
2021	University Medical Center Utrecht	Utrecht, The Netherlands	7
2020	Children's National Hospital	Washington, DC	3
2019	Physics for Medicine Paris	Paris, France	7
2017	Inserm - LabTAU	Lyon, France	25
2016	Stanford University School of Medicine	Stanford, CA	29
2016	Sunnybrook Health Sciences Centre	Toronto, Canada	45
2016	University of Maryland School of Medicine	Baltimore, MD	10
2015	Brigham and Women's Hospital	Boston, MA	30
2013	The Institute of Cancer Research and The Royal Marsden	London, England	4
2009	University of Virginia Health System	Charlottesville, VA	26

# Number of Indications Being Treated or Studied

Center of Excellence	<b>Commercial</b> Treatment	Clinical Research Studies	<b>Preclinical</b> Research Studies	<b>MOA</b> Studies	<b>Technical</b> Studies	<b>Veterinary</b> Research
Chongqing Haifu Hospital	14	6	6	_	_	_
Columbia University	_	7	7	7	4	_
Seoul National University Hospital	4	2	5	9	3	_
Virginia Tech	_	5	18	13	8	6
University of Oxford	1	11	16	_	_	_
University Medical Center Utrecht	4	8	3	12	7	_
Children's National Hospital	2	11	2	6	10	_
Physics for Medicine Paris	_	_	3	4	9	_
Inserm - LabTAU	2	5	17	11	7	_
Stanford University School of Medicine	10	5	10	17	8	4
Sunnybrook Health Sciences Centre	2	17	17	14	12	_
University of Maryland School of Medicine	2	6	14	12	7	_
Brigham and Women's Hospital	5	4	10	12	6	_
The Institute of Cancer Research and The Royal Marsden	_	4	4	11	8	1
University of Virginia Health System	4	11	49	35	5	_

#### Scientific visibility and engagement

In 2024, focused ultrasound continued to gain momentum across the global scientific and medical communities. One thousand seventy-six abstracts related to focused ultrasound were presented at professional meetings worldwide.

Of those, 571 abstracts were shared at nine symposia dedicated exclusively to focused ultrasound, highlighting the depth and specialization developing within the field. Additionally, 505 focused ultrasound presentations were delivered at 52 other conferences and symposia, where the technology was featured as part of broader scientific programs. This marks a significant rise from just 170 abstracts in 2020, reflecting a threefold increase in five years.

We continue to see steady growth in symposia participation and scholarly publication, with a notable surge in engagement from physician specialty societies. This trend suggests broader exposure and growing interest among practicing clinicians, a critical step toward integrating focused ultrasound into mainstream clinical practice.

# Presented at FUS Meetings

Meetings	2020	2021	2022	2023	2024
Totals	268	310	<b>555</b>	407	<b>571</b>
Asian Pacific Society for Transcranial Focused Ultrasound Surgery <sup>1</sup>	_	_	-	_	90
Dutch Symposium on Therapeutic Ultrasound to the Brain <sup>2</sup>	-	_	_	_	16
Focused Ultrasound Foundation Symposium, FUSF	257	_	202	_	_3
In Vivo Ultrasound Imaging Gordon Research Conference					18
International Symposium on Therapeutic Ultrasound, ISTU	*	241	281	261	301
iTRUSST Focused Ultrasound Neuromodulation	-	60	35	75	77
Japanese Society for Therapeutic Ultrasound	*	_	_	16	_ 3
Korean Society for Therapeutic Ultrasound	6	_	29	48	63
Taiwan Association of Interventional and Therapeutic Ultrasound	5	9	8	7	6

<sup>1</sup> First inaugural meeting

<sup>2</sup> Non-recurring meeting

<sup>3</sup> Not held in 2024

 $<sup>^{\</sup>star}$  Cancelled due to COVID-19 pandemic.

# Presented at Other Symposia

Symposium	2020	2021	2022	2023	2024
Totals	170	180	354	487	<b>505</b>
Acoustical Society of America	13	30	76	90	58
Alzheimer's Association International Conference <sup>1</sup>	- 15	_	70	_	2
American Association for Cancer Research	7	5	7	5	5
American Association of Neurological Surgeons	-	_	9	4	6
American Association of Physicists in Medicine	6	4	3	7	3
American Epilepsy Society	_	_	7	2	4
American Institute of Ultrasound in Medicine	_	5	12	22	14
American Psychiatric Association <sup>1</sup>	_	_	-	_	1
American Society of Clinical Oncology	4	1	_	2	3
American Society of Functional Neuroradiology <sup>1</sup>		_	_	_	5
American Society of Gene & Cell Therapy	_ :	_	_	8	11
American Society of Neuroradiology <sup>2</sup>	_ :	_	_	4	11
American Society for Radiation Oncology	2	2	3	2	2
American Society for Stereotactic and Functional Neurosurgery	*	_	9	_	18
American Urological Association	*	5	13	15	17
Biomedical Engineering Society	9	7	1	40	**
Brainbox Initiative Conference <sup>1</sup>	_	_	· _	_	16
British Medical Ultrasound Society <sup>3</sup>	_ :	_	_	6	5
Cardiovascular and Interventional Radiology Society of Europe	10	8	6	13	17
Congress of Neurological Surgeons <sup>3</sup>	_	_	7	9	8
European Association of Neuro Oncology <sup>3</sup>	_	_	3	6	3

<sup>1</sup> New meeting being followed as of 2024 for focused ultrasound content

<sup>2</sup> New meeting being followed as of 2023 for focused ultrasound content

 $<sup>\,\,</sup>$  New meeting being followed as of 2022 for focused ultrasound content  $\,$ 

<sup>\*</sup> Cancelled due to COVID-19 pandemic.

<sup>\*\*</sup> Information is not yet available.

# Presented at Other Symposia continued

Symposium	2020	2021	2022	2023	2024
				0 0 0 0	o o o o o o o o o o o o o o o o o o o
	:		•	•	
European Association of Urology	5	6	6	5	9
European Conference on Interventional Oncology	-	7	2	2	4
European Congress of Radiology	15	2	3	8	7
European Molecular Imaging Meeting <sup>1</sup>	-	-	_	- -	11
European Society of Hyperthermic Oncology <sup>3</sup>	-	-	9	15	1
European Symposium on Ultrasound Contrast Imaging <sup>1</sup>	-	-	_	_	14
Congress of European Federation of Societies for			0 0 0	9 0 0 0	•
Ultrasound in Medicine and Biology <sup>2</sup>	-	_	<u> </u>	4	4
IEEE Engineering in Medicine & Biology Society	2	2	1	7	6
IEEE International Ultrasonics Symposium	57	72	45	85	34
IEEE South Asian Ultrasonics Symposium <sup>1</sup>	-	-	_	_	16
IEEE UFFC Latin America Ultrasonics Symposium <sup>1</sup>	-	_	<u> </u>		10
International Bubble Conference <sup>3</sup>	-	-	2	5	2
International Society for Magnetic Resonance in Medicine	33	12	32	19	30
International Sterotactic Radiosurgery Society <sup>4</sup>	-	_	6	· ·	3
International Symposium on Pediatric Neuro-Oncology <sup>1</sup>	-	_	<u> </u>	_	3
North American Neuromodulation Society <sup>1</sup>	-	_	<u> </u>		5
NYC Neuromodulation Conference <sup>1</sup>	-	_	<u> </u>	_	15
Pancreatic Cancer UK Discovery and Translational Research Forum <sup>1</sup>	-	-	_	<u> </u>	4
Radiological Society of North America	7	4	26	8	24
Society for Image-Guided Neurointerventions <sup>1</sup>	_	_	_	_	5

<sup>1</sup> New meeting being followed as of 2024 for focused ultrasound content

<sup>2</sup> New meeting being followed as of 2023 for focused ultrasound content

 $<sup>\,\,</sup>$  New meeting being followed as of 2022 for focused ultrasound content  $\,$ 

<sup>4</sup> Held biennially

<sup>\*</sup> Cancelled due to COVID-19 pandemic.

<sup>\*\*</sup> Information is not yet available.

# Presented at Other Symposia continued

Symposium	2020	2021	2022	2023	2024
Society for Neuroscience <sup>2</sup>	-	_	_	41	26
Society for Surgical Oncology <sup>1</sup>	- :	_	_	_	1
Society for Thermal Medicine	*	5	10	3	12
Society of Interventional Radiology	*	3	21	20	12
Society of Interventional Oncology <sup>2</sup>	- :	_	_	3	3
Society of Neuro-Oncology, SNO	-	-	10	14	10
SNO Biennial Pediatric Neuro-Oncology Research Conference	- :	_	_	4	_ 4
UK Symposium on Neuromodulation and Neurotechnology <sup>1</sup>	- :	_	_	_	4
Veterinary Cancer Society Annual Conference <sup>2</sup>	- :	_	_	3	0
World Society for Stereotactic and Functional Neurosurgery <sup>3</sup>	-	_	25	6	21

<sup>1</sup> New meeting being followed as of 2024 for focused ultrasound content

<sup>2</sup> New meeting being followed as of 2023 for focused ultrasound content

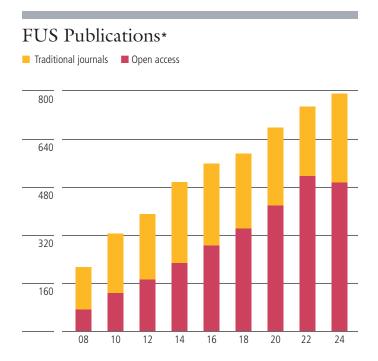
 $<sup>\,\,</sup>$  3  $\,$  New meeting being followed as of 2022 for focused ultrasound content

<sup>4</sup> Not held in 2024

<sup>\*</sup> Cancelled due to COVID-19 pandemic.

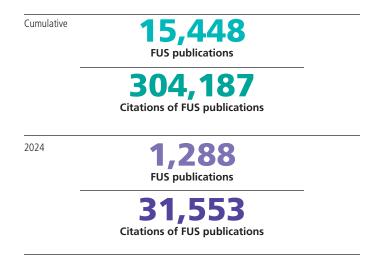
<sup>\*\*</sup> Information is not yet available.

#### **Publications**



<sup>\*</sup> Source: Web of Science Core Collection as of January 22, 2024

#### FUS Publications and Citations\*



<sup>\*</sup> Source: Web of Science Core Collection as of January 22, 2024

#### Scientific publications and open access

In 2024, the upward trend in focused ultrasound publications has continued, building on the steady growth seen in recent years. Alongside this increase, the adoption of Transparency and Openness Promotion (TOP) practices in scientific publishing is gaining momentum, enhancing access for clinicians and researchers entering the field.

Importantly, more journals are embracing open-access publishing, which allows for full-text availability of scientific articles, not just abstracts. As a result, a simple online search

now provides immediate access to comprehensive research, removing the barriers once imposed by paywalls and subscription-only platforms. This shift is playing a key role in accelerating knowledge-sharing and expanding the reach of focused ultrasound science globally.

# Publications—2024 Top Source Titles



# Publications—2024 Top Source Titles

Records	Scientific publication titles	
35	International Journal of Hyperthermia	
26	Ultrasound in Medicine and Biology	
18	Scientific Reports	
15	IEEE Transactions on Ultrasonics, Ferroelectrics, and Frequency Control	]
15	Ultrasonics	tie >
15	Ultrasonics Sonochemistry	J
14	Nature Communications	
13	Brain Stimulation	]
13	Frontiers in Neurology	tie >
13	Physics in Medicine and Biology	J

<sup>\*</sup> Source: Web of Science Core Collection as of January 22, 2024

# Veterinary Medicine

#### **FUS veterinary applications**

Veterinary medicine presents a valuable opportunity to expand both research and commercialization of focused ultrasound (FUS). With fewer regulatory hurdles than human medicine, this space allows for accelerated innovation while also providing critical data from naturally occurring disease models to inform and support human clinical trials.

One key advantage of focused ultrasound in veterinary care is its noninvasive approach, which can shorten hospital stays and reduce overall treatment costs, an important factor for pet owners who typically pay out of pocket. Its ability to target tissue precisely and enhance the effectiveness of certain therapies makes it especially attractive in this setting.

Currently, the most promising veterinary applications are in oncology, particularly for conditions where surgery may negatively impact quality of life. Clinical trials in animals have shown focused ultrasound to be both well-tolerated and effective in treating soft tissue sarcomas, oral tumors, and osteosarcomas. Ongoing research is now exploring its

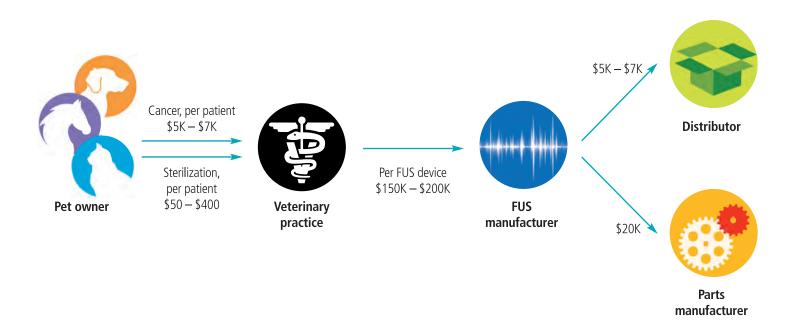
use in treating more aggressive cancers, including mammary, bladder, brain, and liver cancers.

Excitingly, focused ultrasound is also gaining traction outside oncology. New veterinary applications include feline diabetes and urinary tract stones, expanding the therapeutic potential of FUS even further.

In recent years, the field has progressed beyond traditional thermal ablation. Emerging modalities such as histotripsy, sonodynamic therapy, neuromodulation, and drug and gene delivery are actively being explored. These techniques may offer unique advantages by minimizing the risk of damage to nearby structures, a particularly important consideration for veterinary patients due to their smaller size and the common presence of lesions on sensitive areas like the limbs.

Focused ultrasound is helping reshape the future of veterinary medicine, offering innovative, less invasive solutions that benefit both animals and the advancement of human healthcare.

#### Value Chain



# State of Veterinary Research by Indication and MOA

	Development stage	MOAs
Oncological		
Bladder cancer	2020	■ Thermal ablation - tissue destruction
Brain tumors	2021	Histotripsy - tissue destruction
Chronic wound	2018	Nonthermal - drug delivery
Glaucoma	2018	■ Thermal ablation - tissue destruction
Hepatocellular carcinoma	2016	Nonthermal - drug delivery
	2019	Nonthermal - sonodynamic therapy
	2021	Histotripsy - tissue destruction
Lipoma	2022	Histotripsy - tissue destruction
Lung cancer	2018	■ Thermal ablation - tissue destruction
Oral tumors*	2019	■ Thermal ablation - immunomodulation
	2024	Histotripsy - immunomodulation
	2020	Nonthermal - sonodynamic therapy
Osteosarcoma	2023	■ Thermal ablation - immunomodulation
	2020	Histotripsy - immunomodulation
	2019	Nonthermal - sonodynamic therapy
Prostate tumors	2019	Nonthermal - sonodynamic therapy
Sarcoids	2024	Histotripsy - tissue destruction
Sarcomas	2021	Histotripsy - immunomodulation
Soft tissue tumors**	2018	■ Thermal ablation - immunomodulation
	2021	Nonthermal - sonodynamic therapy
	2020	Histotripsy - immunomodulation
	2018	Nonthermal - drug delivery
Mammary tumors	2023	■ Thermal ablation - tissue destruction
Lymphoma	2023	■ Thermal ablation - tissue destruction

<sup>\*</sup> Oral tumors includes oral melanoma, plasmacytoma (of the gums/lips), ameloblastomas, salivary gland tumors, and squamous cell carcinoma (of the gums/lips).

<sup>\*\*</sup> Soft tissue tumors include soft tissue sarcoma and mast cell tumors.

#### State of Veterinary Research by Indication and MOA continued

	Development stage Proposed Clinical trial Clinical practice	MOAs
Miscellaneous		
Diabetes	2023	Nonthermal - neuromodulation
Epilepsy	2020	■ Thermal ablation - tissue destruction
Kidney stones	2022	Nonthermal - kidney stone fragmentation
Spay/neuter	2018	■ Thermal ablation - tissue destruction
Pain		
Elbow/hip dysplasia	2018	Nonthermal - neuromodulation
Osteoarthritis	2018	Nonthermal - neuromodulation
Soft tissue injuries	2018	Nonthermal - neuromodulation

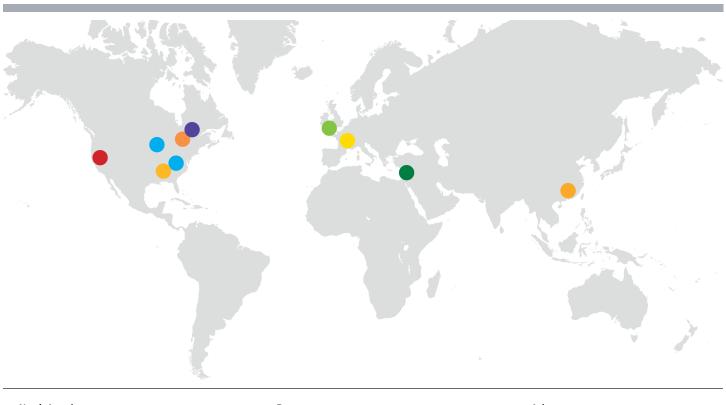
#### **Veterinary advances**

As the veterinary focused ultrasound field continues to advance, researchers and clinicians are exploring more technically demanding indications, including glioblastoma and bladder cancer. In a notable development for 2024, horses are now being treated for sarcoid, expanding the species and conditions being addressed with focused ultrasound.

The technology is also gaining ground in emergency medicine, with applications such as feline urolith treatment,

and in endocrinology, where it is being used to manage diabetes. In addition to traditional thermal ablation, the veterinary field is now actively utilizing a broader range of focused ultrasound modalities, including histotripsy, sonodynamic therapy, neuromodulation, and drug and gene delivery. These advanced approaches may offer significant advantages—particularly in minimizing collateral damage to surrounding tissues—making them especially valuable for veterinary patients with unique anatomical and clinical considerations.

# Veterinary Program Sites



#### North America

- Auburn University College of Veterinary Medicine<sup>1</sup>
- Ontario Veterinary College
- Stanford University
   In collaboration with University of California, Davis, School of Veterinary Medicine
- Veterinary Specialty Clinic for Anesthesia and Neurology (VSCAN)<sup>1</sup>
- Virginia-Maryland College of Veterinary Medicine In collaboration with University of Minnesota<sup>2</sup>

#### Europe

- Cyprus University of Technology
- Institute of Cancer Research
- LabTAU

#### Asia

China Agriculture University Animal Hospital<sup>1</sup>

<sup>1</sup> New in 2024

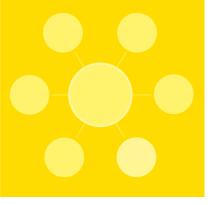
<sup>2</sup> New collaboration in 2024

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# Patient Access







#### Overview



2024 marked a major achievement for the focused ultrasound community, crossing the milestone of one million patient treatments worldwide. This moment reflects years of innovation, dedication, and global collaboration across research, clinical care, and industry.

Notably, brain treatments continue to rise steadily, with more than 7,000 performed in 2024 alone, bringing the cumulative total to just under 25,000. This growth underscores the increasing recognition of focused ultrasound's potential in treating neurological disorders.

To view patient treatment data in an interactive format, please visit: www.fusfoundation.org/the-technology/sotf-patient-access



#### V. Patient Access

V. 2 Overview

#### **Commercial Treatments Sites**

- V. 3 Patient Treatments
- V. 4 By Region and Country
- V. 5 Treatment Sites
  - V. 5 Number of Sites
  - V. 5 Top Countries for Treatment
  - V. 5 Top Countries for Commercial Treatment Growth
- V. 6 By Country
- V. 8 By Indication
  - V. 8 Cumulative
  - V. 9 2024
  - V. 9 Annual

V. 10 Oncology Treatments by Indication

V. 10 Cumulative

V. 11 2024

V. 11 Annual

V.12 Brain Treatments by Indication

V.12 Cumulative

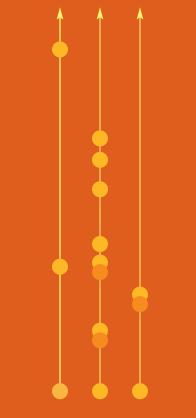
V.13 2024

V.13 Annual

V.14 Other Treatments by Indication

V.14 Cumulative

V.14 2024



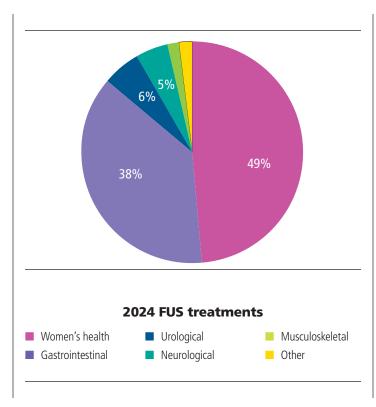
#### **Patient Treatments**

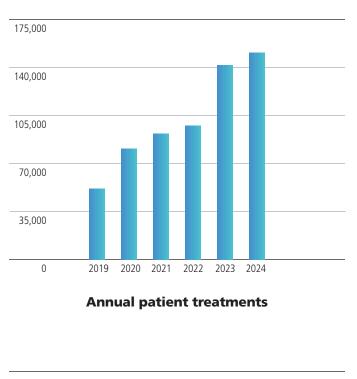


# **150,942**

#### **FUS treatments in 2024**

1,015,298 cumulative treatments





# Commercial treatments center on cancer and women's health

Treatments for women's health comprise nearly half of the treatments to date. The next largest sector is gastrointestinal indications with 38%. Urological and neurological are the next highest categories with approximately 5% each.

# Commercial Treatments Sites by Region and Country



# 2024



North America	Europe	Asia	South America	Oceania	Middle East	Africa
Canada Dominica Dominican Republic Mexico United States	Austria Belgium Bulgaria Czech Republic Denmark Finland France Georgia Germany Greece Ireland Italy Latvia Monaco The Netherlands Norway Poland Portugal Romania Russian Federation Serbia Spain Sweden Switzerland Ukraine United Kingdom	China India Indonesia Japan Kazakhstan Malaysia Myanmar Philippines Singapore South Korea Taiwan Thailand Vietnam	Argentina Bolivia Brazil Chile Colombia Ecuador	Australia	Israel Kuwait Lebanon Qatar Turkey United Arab Emirates Uzbekistan	Egypt Morocco Nigeria South Africa

# Commercial Treatments Sites by Region

•

Number of Sites

2024

1,328

**Commercial Treatment Sites** 

304 North America

337
Europe

645 Asia

T T South America

4 Oceania

**20**Middle East

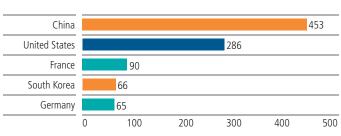
**7** Africa

# Top Countries

2024

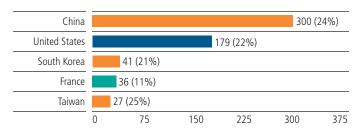
#### **Top Countries for Treatment**

Number of sites



#### **Top Countries with Commercial Treatment Growth**

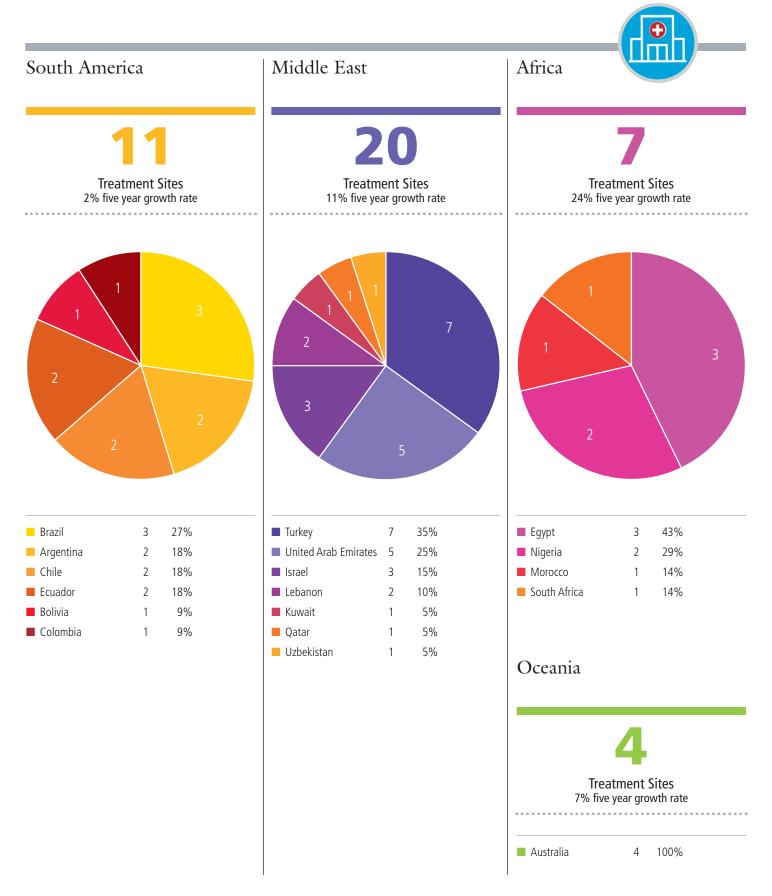
Sites added, cumulative 2019 to 2024



## Commercial Treatments Sites by Country

#### North America Europe Asia **Treatment Sites Treatment Sites Treatment Sites** 23% five year growth rate 7% five year growth rate 26% five year growth rate 90 22 121 23 25 65 26 94 China ■ US, Central 121 40% France 90 27% 453 70% Eastern 94 31% 19% South Korea Germany 65 66 10% 52 Pacific 17% Russian Federation 36 11% Japan 56 9% Mountain 19 6% Taiwan 8 Italy 26 8% 40 6% Canada 3% 25 7% ■ Thailand 8 8 United Kingdom 1% Mexico 3% 2 Poland 23 7% India 7 1% Other\* 1% Other\* Spain 22 7% 15 2% \* Dominica and Dominican Republic 12 Switzerland 4% \* Indonesia, Kazakhstan, Malaysia, Myanmar, Austria 7 2% Philippines, Singapore, and Vietnam Greece 1% ■ The Netherlands 1% 3 1% Norway Other\* 14 4% \* Belgium, Bulgaria, Czech Republic, Denmark, Finland, Georgia, Ireland, Latvia, Monaco, Portugal, Romania, Serbia, Sweden, and Ukraine

# Commercial Treatments Sites by Country continued



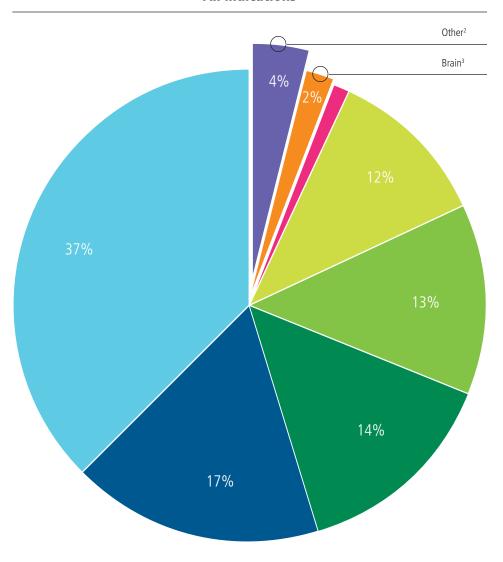
## Commercial Treatments Sites by Indication—Cumulative



#### **All indications**

#### 1,015,298 total treatments<sup>1</sup>

Uterine fibroids	378,927	37%
Liver tumors	175,673	17%
Uterine adenomyosis	139,119	14%
Pancreatic tumors	130,772	13%
Prostate diseases	110,609	12%
Other <sup>2</sup>	42,947	4%
Brain³	24,808	2%
Ectopic pregnancy	12,443	1%



<sup>1</sup> The number of patient treatments reported is lower than the actual number of procedures because of incomplete reporting from manufacturers and treatment sites. Companies reporting patient treatment values were: Alpinion Medical Systems, CarThera, Chongqing Haifu Medical Technology, EDAP TMS, EyeSonix, Hangzhou Fusong Technology, HistoSonics, Image Guided Therapy; IMGT co, Insightec, NaviFUS; Neurosona, Profound Medical; Shanghai A&S, Shende Medical, Shenzhen PRO-HITU Medical, Sonablate, Sonire Therapeutics, Spire Therapeutic, Theraclion, TOOsonix, Ultrathera, VeinSound sas, and Zhonghui Medical.

<sup>2</sup> For an expanded list of these indications, please refer to Cumulative Other Treatments by Indication, on p. V.14.

<sup>3</sup> For an expanded list of these indications, please refer to Cumulative Brain Treatments by Indication, on p. V.12.

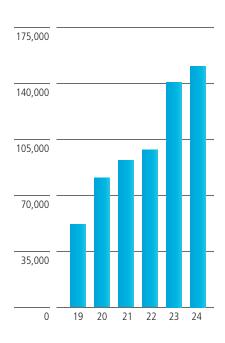
#### Commercial Treatments Sites by Indication—2024

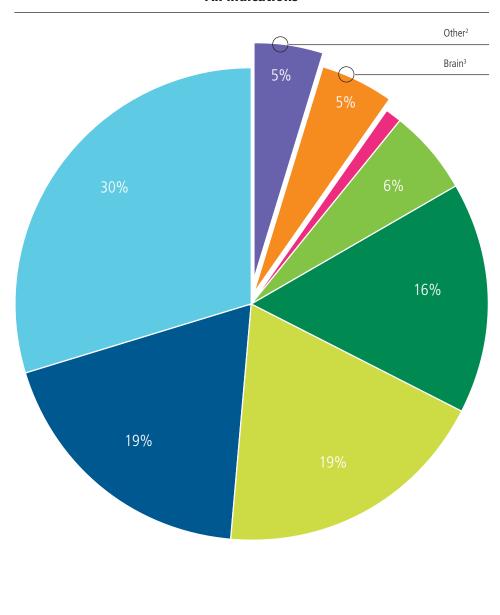


#### **All indications**

#### 150,942 total treatments<sup>1</sup> Uterine fibroids 45,743 30% Liver tumors 28,635 19% Pancreatic tumors 28,129 19% Uterine adenomyosis 24,438 16% Prostate diseases 8,390 6% Other<sup>2</sup> 7,301 5% ■ Brain³ 7,161 5% Ectopic pregnancy 1,415 1%

#### **Annual Patient Treatments**





<sup>1</sup> The number of patient treatments reported is lower than the actual number of procedures because of incomplete reporting from manufacturers and treatment sites. Companies reporting patient treatment values were: Alpinion Medical Systems, CarThera, Chongqing Haifu Medical Technology, EDAP TMS, EyeSonix, Hangzhou Fusong Technology, HistoSonics, Image Guided Therapy; IMGT co, Insightec, NaviFUS; Neurosona, Profound Medical; Shanghai A&S, Shende Medical, Shenzhen PRO-HITU Medical, Sonablate, Sonire Therapeutics, Spire Therapeutic, Theraclion, TOOsonix, Ultrathera, VeinSound SAS, and Zhonghui Medical.

<sup>2</sup> For an expanded list of these indications, please refer to 2024 Other Treatments by Indication, on p. V.14.

<sup>3</sup> For an expanded list of these indications, please refer to 2024 Brain Treatments by Indication, on p. V.13.

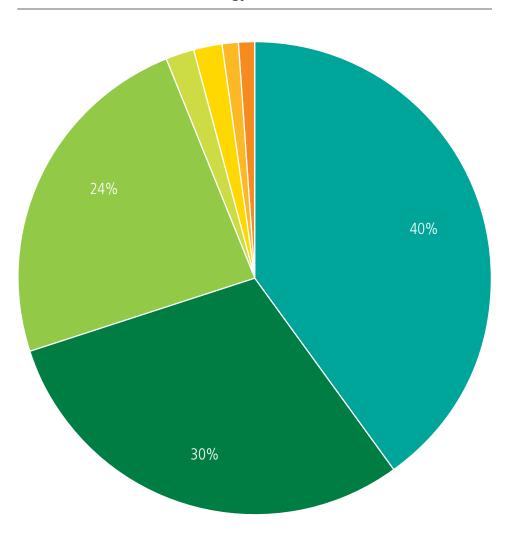
# Oncology Treatments by Indication—Cumulative



#### **Oncology indications**

#### 434,617 total treatments

Liver tumors	175,673	40%
Pancreatic tumors	130,772	30%
Prostate cancer	103,746	24%
Tumors, unspecified	8,118	2%
Soft tissue cancer	8,034	2%
Bone metastases	5,133	1%
Other <sup>1</sup>	2,193	1%
<ul> <li>Brain tumors<sup>2</sup></li> </ul>	948	<1%



<sup>1</sup> Includes, in descending order of patient treatments: Endometrial tumors; Breast tumors, malignant; Basal cell carcinoma; Bone cancer; Neurofibromatosis; Kidney tumors; Gastric tumors; Abdominal paraganglioma; Hemangioma; Abdominal tumor; Granular cell tumor of the gluteals; Kaposi's sarcoma; Cervical tumors; Sacral chordoma; Schwannoma; Spleen tumor

<sup>2</sup> Includes, in descending order of patient treatments: Glioblastoma; Brain tumors, general; Pontine glioma; Brain metastases, lung cancer; Astrocytoma; Ganglioglioma

# Oncology Treatments by Indication—2024

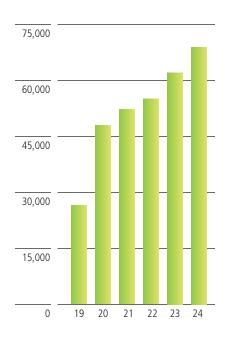


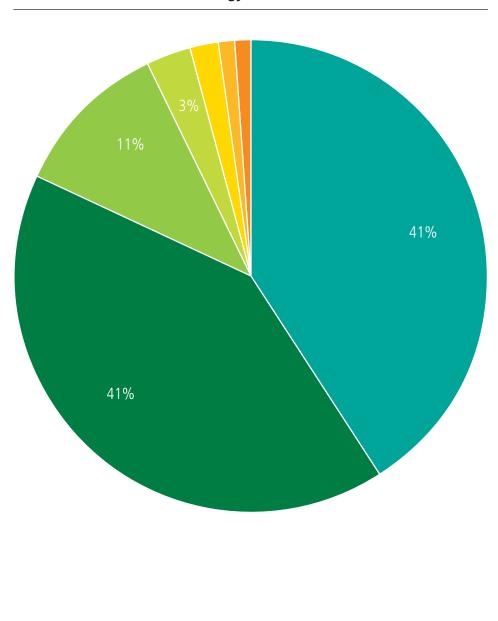
#### **Oncology indications**

#### 69,118 total treatments<sup>1</sup>

- 15	20.625	410/
Liver tumors	28,635	41%
Pancreatic tumors	28,129	41%
Prostate cancer	7,805	11%
Tumors, unspecified	1,784	3%
Soft tissue cancer	1,517	2%
Bone metastases	557	1%
Other <sup>1</sup>	399	1%
<ul> <li>Brain tumors<sup>3</sup></li> </ul>	292	<1%

# Annual Oncology Treatments





<sup>1</sup> Includes, in descending order of patient treatments: Endometrial tumors; Bone cancer; Basal cell carcinoma; Breast tumors, malignant; Gastric tumors; Neurofibromatosis

<sup>2</sup> Includes, in descending order of patient treatments: Glioblastoma; Pontine glioma; Brain metastases, lung cancer; Brain tumors, general

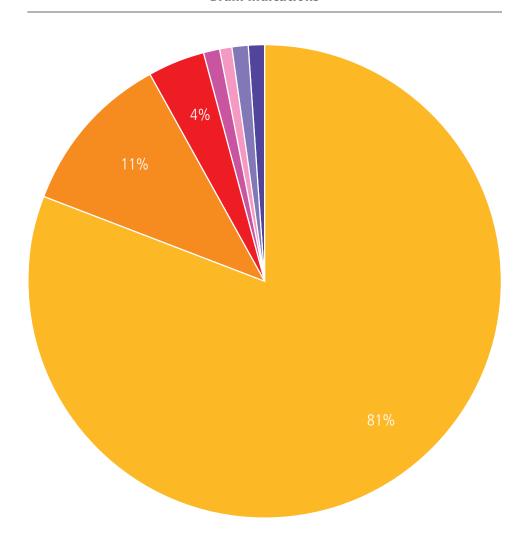
# Brain Treatments by Indication—Cumulative



#### **Brain indications**

#### 24,808 total brain treatments

Essential tremor	20,210	81%
Parkinson's disease	2,796	11%
■ Brain tumors¹	948	4%
Neuropathic pain	275	1%
Alzheimer's disease	195	1%
Psychiatric <sup>2</sup>	191	1%
Other movement disorders <sup>3</sup>	150	1%
— Other brain <sup>4</sup>	43	<1%



<sup>1</sup> Includes, in descending order of patient treatments: Glioblastoma; Brain tumors, general; Pontine glioma; Brain metastases, lung cancer; Astrocytoma; Ganglioglioma

<sup>2</sup> Includes, in descending order of patient treatments: Depression; Obsessive-compulsive disorder; Opioid and other addictions; Anxiety

<sup>3</sup> Includes, in descending order of patient treatments: Dystonia; Epilepsy; Dystonia, hand

<sup>4</sup> Includes, in descending order of patient treatments: Traumatic brain injury; Stroke, thromboembolic; Blood-brain barrier opening; Stroke, intracerebral hemorrhage

# Brain Treatments by Indication—2024

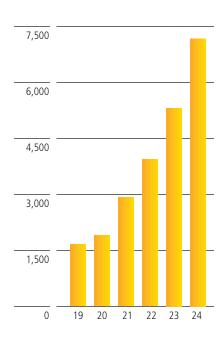


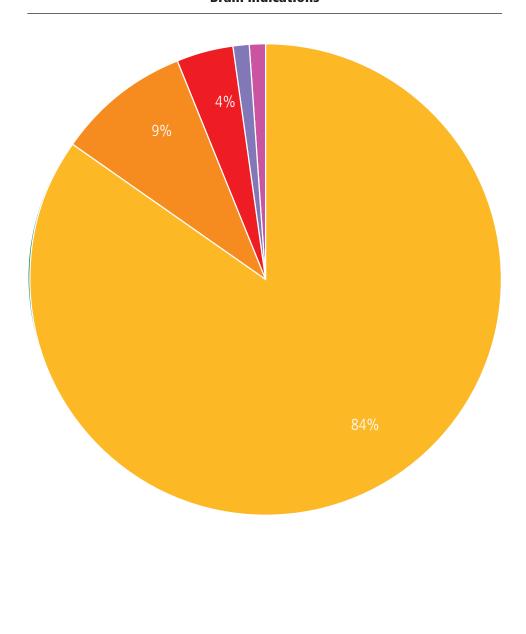
#### **Brain indications**

#### 7,161 total brain treatments

Essential Tremor	6,001	84%
Parkinson's disease	666	9%
■ Brain tumors¹	107	4%
Psychiatric <sup>2</sup>	97	1%
Neuropathic pain	40	1%
<ul> <li>Other movement disorders<sup>3</sup></li> </ul>	29	<1%
— Alzheimer's disease	22	<1%
— Other brain⁴	14	<1%

# Annual Oncology Treatments





<sup>1</sup> Includes, in descending order of patient treatments: Glioblastoma; Pontine glioma; Brain metastases, lung cancer; Brain tumors, general

<sup>2</sup> Includes, in descending order of patient treatments: Depression; Obsessive-compulsive disorder

<sup>3</sup> Includes, in descending order of patient treatments: Dystonia; Epilepsy

<sup>4</sup> Includes, in descending order of patient treatments: Stroke, thromboembolic; Stroke, intracerebral hemorrhage

#### Other Treatments by Indication



#### Cumulative<sup>1</sup>

Tumors, unspecified	8,118	
Soft tissue cancer	8,048	
Glaucoma	6,202	
Bone metastases	5,133	
Breast tumors, benign	3,215	
Thyroid nodules	2,620	
Varicose veins	2,291	
Retained placenta	2,281	
Breast tumors, malignant	1,028	
Endometriosis	624	
Arthritis, facetogenic	566	
Endometrial tumors	503	
Soft tissue tumor, benign	437	
Osteoid osteoma	366	
Bone cancer	281	
Desmoid tumors	219	
Basal cell carcinoma	135	
Arthritis, sacroiliac	106	

#### 42,938 total treatments

#### $2024^{2}$

Tumors, unspecified	1,784	
Soft tissue cancer	1,541	
Breast tumors, benign	1,405	
Varicose veins	768	
Bone metastases	557	
Endometriosis	275	
Retained placenta	246	
Thyroid nodules	235	
Endometrial tumors	108	
Basal cell carcinoma	100	

7,301 total treatments

<sup>1</sup> Indications not shown, in descending order of patient treatments: hypersplenism; gastric tumors; arthritis, sacroiliac; hypertension; heart valve calcifications; hyperparathyroidism; actinic keratosis; arthritis; basal cell carcinoma; neurofibromatosis; dermatology research; tattoo removal; bone tumors, benign; kidney tumors; hepatic cysticercosis; peripheral artery disease; seborrheic keratosis; head & neck tumors; vascular malformations and angiomas; painful amputation neuromas; abdominal paraganglioma; hemangioma; cervicitis; verucca vulgaris; abdominal tumor; amyotrophic lateral sclerosis; arteriovenous malformations; granular cell tumor of the gluteals; kaposi's sarcoma; cervical tumors; sacral chordoma; schwannoma; and spleen tumor

<sup>2</sup> Indications not shown, in descending order of patient treatments: soft tissue tumor, benign; arthritis, sacroiliac; bone cancer; breast tumors, malignant; osteoid osteoma; desmoid tumors; basal cell carcinoma; hypersplenism; hepatic cysticercosis; gastric tumors; glaucoma; neurofibromatosis; cervicitis; peripheral artery disease; and actinic keratosis

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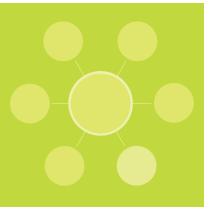
# FUS Industry





#### Overview

From publicly available sources and industry reporting, we estimate that the field employs approximately 4,500 individuals worldwide. Approximately 65% of this workforce is employed by a FUS device manufacturer. One-third are based in the United States. This year's median company size is 21 employees; nearly half of the companies have 25 or fewer employees. Over 1,600 focused ultrasound devices are used worldwide for commercial treatment.



## **VI. FUS Industry**

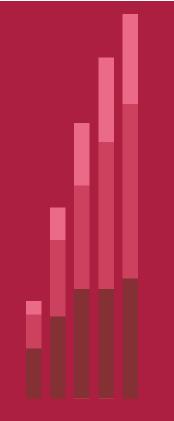
VI. 2 Overview

# **Company Types, Employees, and Locations**

- VI. 3 Geographic Distribution
- VI. 4 Companies
- VI. 5 Employees
- VI. 6 Employee Distribution
- VI. 7 Employee Locations

#### **FUS Devices**

- VI. 8 Number in Use
- VI. 9 By Region
- VI.10 Distributors by Region
- VI.12 With Treatment and Planning Guidance by Region



Geographic Distribution of Companies

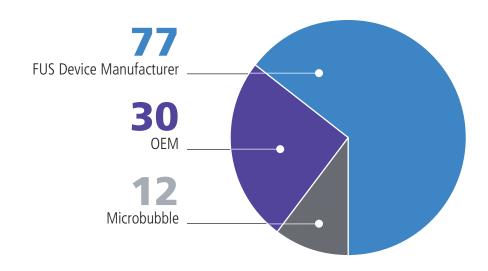
2024

	North America	Europe	Asia	Oceania	Middle East
120 FUS companies	<b>56</b>	26	32	1	5
FUS device manufacturers	34	16	22	1	4
22 Companies with authorizations	7	5	9	_	1

119
FUS companies\*



# **Company distribution by type**

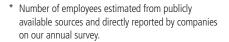


<sup>\*</sup> This analysis includes all FUS industry companies where employee information was available, including FUS device manufacturers, OEM, and microbubble companies.

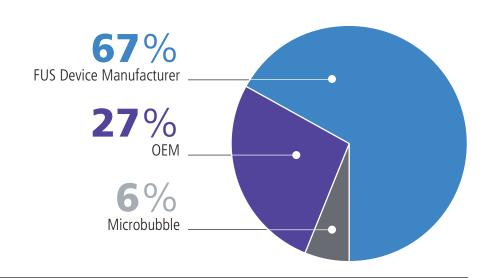
# **Employees**







# **Employee distribution**



In 2024, the focused ultrasound industry added approximately 1,000 new employees, reflecting steady growth and increasing commercial activity across the field. Two-thirds of the current workforce is employed by focused ultrasound device manufacturers, which, despite often being early-stage companies with small teams, outnumber OEMs and microbubble-focused organizations.

The United States remains the leading hub for focused ultrasound employment, followed by South Korea. Canada, Taiwan, and China—together, these countries account for just over 80% of the global workforce. The remaining professionals are widely distributed across other regions, underscoring the increasingly global nature of the focused ultrasound ecosystem.

## Employee Distribution\*

21 employees

is the median company size

46%

of companies have

25 or fewer employees

10%

of the total workforce is employed by the

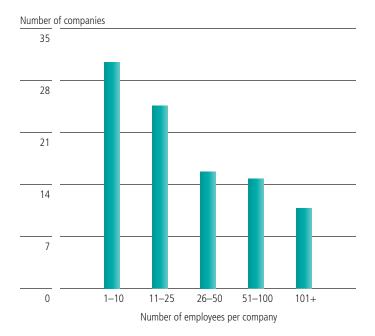
50 smallest companies

**50**%

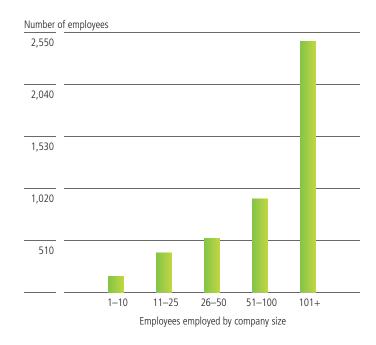
of the total workforce is employed by the

8 largest companies

# Number of Companies



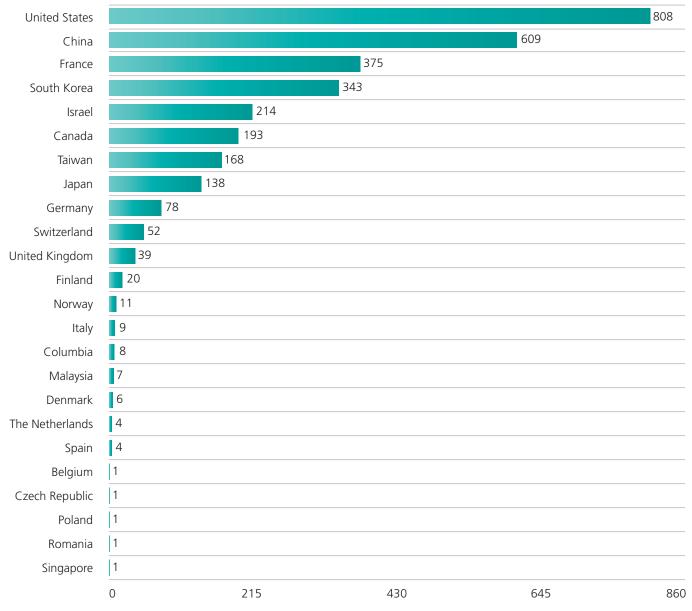
# Number of Employees



<sup>\*</sup> This analysis includes device manufacturers, OEM, and microbubble companies.

# FUS Employee Locations





<sup>\*</sup> Number of employees directly reported by companies on our annual survey



Number and Growth

2024

1 642

**FUS devices** 

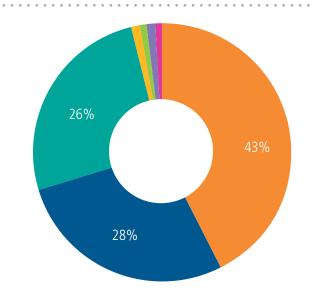
4.3%

**Growth** 

2024 over 2023

# Worldwide Distribution

2024



■ North America	28%
Europe	26%
Asia	43%
South America	1%
Oceania	1%
■ Middle East	1%
Africa	<1%

# FUS Device Use by Region



#### North America

**470** 

**Devices** 



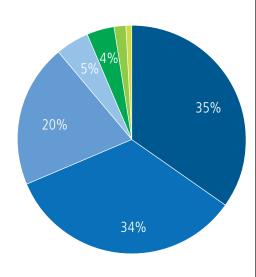
**428** 

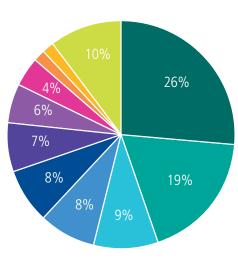
Devices

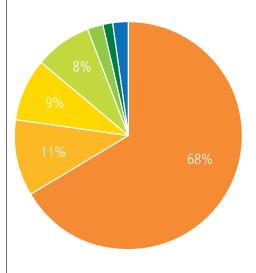
#### Asia

**731** 

Devices









<sup>\*</sup> Dominica and Dominican Republic

■ France	113
Germany	79
United Kingdom	39
Russian Federation	35
■ Italy	33
■ Spain	30
Poland	24
Switzerland	17
■ The Netherlands	8

AustriaOther\*

7

43

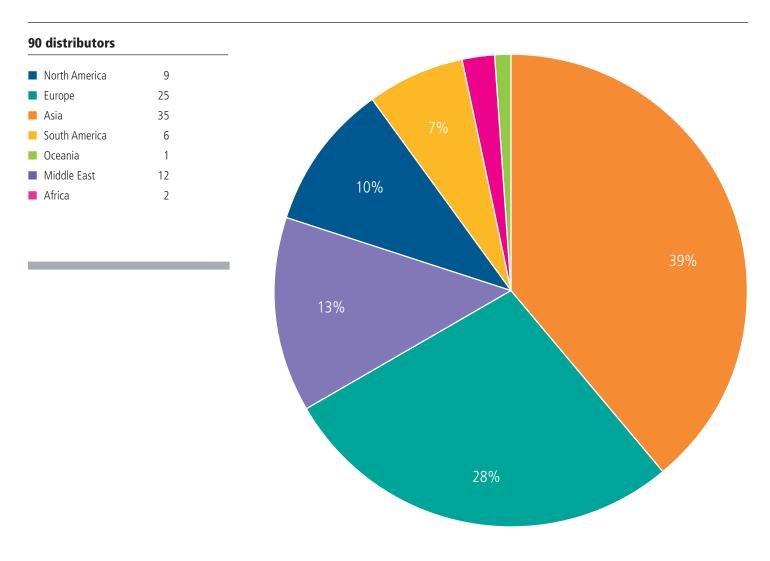
China	487
South Korea	79
Japan	64
■ Taiwan	60
■ India	16
■ Thailand	9
Other*	16

<sup>\*</sup> Indonesia, Kazakhstan, Malaysia, Myanmar, Philippines, Singapore, and Vietnam

<sup>\*</sup> Belgium, Bulgaria, Czech Republic, Denmark, Finland, Georgia, Greece, Ireland, Latvia, Monaco, Norway, Portugal, Romania, Serbia, Sweden, and Ukraine

# Distributors by Region





#### Commercial device availability and global distribution

As of 2024, twenty-two focused ultrasound device manufacturers have commercial products with regulatory authorization available on the market. Asia and Europe lead in the number of device distributors, which aligns with their high volume of authorizations and more mature commercialization environments. These regions drive global access and adoption through well-established regulatory pathways and expanding clinical infrastructure.

# FUS Devices with Treatment and Planning Guidance



Manufacturer	Device	Treatment guidance	Planning guidance
North America			
Research & Development			
Acoustic MedSystems	ACOUSTx	Ultrasound -	<u> </u>
		CT-fluoroscopy, MRI,	
		and 3D targeting	
Acoustiic	AgilitUS	MR guidance	MR guidance
	WaveMatrix	Unguided	Not used
Alpheus Medical	CV01	_	_
Attune Neurosciences	ATTN201	Image fusion	MR guidance
Avvio Medical <sup>1</sup>	Acoustic Enhancer	_	_
BrainSonix	BXPulsar 1001 LIFUP	MR guidance	MR guidance
	BXPulsar 1002 LIFUP	MR guidance	MR guidance
Cordance Medical	NeuroAccess	_	MR/CT Guidance
Delsona Therapeutics	Ultranav (prototype)	Image fusion	Neuronavigation
Exo Imaging	Performance Ultrasound Platform	_	_
EyeSonix	iSonix	Unguided	Visual guidance
FUS Instruments	DS-50	_	_
	LP-100	MR guidance	_
	RK-100	_	_
	RK-20	Other guidance	_
	RK-300	MR guidance	_
	RK-50	Other guidance	_
International Cardio	HIFU Synthesizer	US guidance	US guidance
Longevity Biomedical	Aureva Pulse	US guidance	Not used
	Reflow RVO	US guidance	Not used

<sup>1</sup> Manufacturer was formerly known as Applaud Medical

# FUS Devices with Treatment and Planning Guidance continued



Manufacturer	Device	Treatment guidance	Planning guidance
North America			
Research & Development			
MR Instruments	DuoFLEX ACCESS Coil	MR guidance	MR guidance
	MR-guided TRUST		
	(Transcranial Ultrasound Stimulation)	MR guidance	MR guidance
NeurGear	ZenBud	_	_
NovusTX Devices	NovuStim	Other guidance	MR/CT guidance
Openwater	Open-LIFU 2.0	_	_
SonoMotion	Break Wave	_	_
Sonosa Medical	Sonosa Therapeutic	US guidance	Not used
Spire Therapeutic	Diadem	MR guidance	MR guidance

# FUS Devices with Treatment and Planning Guidance continued



Manufacturer	Device	Treatment guidance	Planning guidance
North America			
Commercial			
Acoustic MedSystems	<b>→</b> TheraVision	_	_
Arrayus	<b>→</b> Symphony	US & MR guidance	MR guidance
FUSMobile	♣ Neurolyser	Other guidance	Not used
HistoSonics	+ Edison	US guidance	US guidance
Profound Medical	<b>→</b> Sonalleve	MR guidance	MR guidance
	<b>→</b> TULSA-PRO	MR guidance	MR guidance
Sonablate Corp.	<b>→</b> Sonablate	US guidance	MR/US fusion
	<b>→</b> Sonatherm	US guidance	US guidance
SonoMotion	<b>→</b> Stone Clear	US guidance	_

<sup>♣</sup> Device with authorization

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# FUS Devices with Treatment and Planning Guidance continued

Manufacturer	Device	Treatment guidance	Planning guidance
Europe			
Research & Development			
CarThera	SonoCloud 1	Unguided	Not used
	SonoCloud 9	Unguided	Not used
Cardiawave	Valvosoft	US guidance	US guidance
EDAP TMS	EDAP (prototype)	US guidance	US guidance
	Mfocus	US guidance	US guidance
Image Guided Therapy	ЗВор	Stereotactic frame	_
	LabFUS	MR guidance	MR guidance
	Neuromod System	Neuronavigation	Neuronavigation
	Rodent FUS System	MR guidance	MR guidance
	TargetedFUS	MR guidance	MR guidance
	UFOGUIDE	MR guidance	MR guidance
Medsonic	Bone phantoms - Medsonic	MR guidance	_
	MR-Compatible Transducers	MR guidance	_
	Robotic Systems	MR guidance	_
	Shinsei motor electronic system	MR guidance	_
	Skull phantoms - Medsonic	MR guidance	_
OxSonics	SonoTran System	US guidance	US guidance
TOOsonix	System ONE-R	Image fusion	Visual guidance
TRANS-FUSIMO	TransFUSIMO Treatment System	MR guidance	MR guidance
VeinSound, sas	PHEA1	US guidance	US guidance
	Veinsound v2.0	US guidance	US guidance



Manufacturer	Device	Treatment guidance	Planning guidance
Europe			
Commercial			
EDAP TMS	+ Ablatherm	Image fusion	US guidance
	+ Focal One	Image fusion	MR guidance,
			US guidance, biopsies
EyeTechCare	+ EyeOP1	Unguided	_
Storz Medical	◆ NEUROLITH	Neuronavigation	MR guidance
TOOsonix	◆ System ONE-M	Image fusion	Visual guidance
Theraclion	+ Echopulse	US guidance	US guidance
	<b>→</b> SONOVEIN	US guidance	Not used

<sup>♣</sup> Device with authorization

Manufacturer	Device	Treatment guidance	Planning guidance
Asia			
Research & Development			
Alpinion Medical Systems	VIFU2000	US guidance	US guidance
Chongqing Haifu Medical Technology	CKC100	Unguided	Not used
	CKC200	Unguided	Not used
	CZF300	Unguided	Not used
	CZF500	Unguided	Other
	CZG100	Unguided	Not used
	CZG100A	Unguided	Not used
	CZG200	Unguided	Not used
	CZG300	Unguided	Not used
	CZG400	Unguided	Not used
	JCU-S1A	US guidance	US guidance
	JCU-S3A	US guidance	US guidance
	LCA200	Unguided	Not used
	LCA300	Unguided	Not used
Hangzhou Fusong Technology	TF200 HIFU Thyroid Device	US guidance	US guidance
IMGT co	IMD10	US guidance	US guidance
Korust	Le Mette	Unguided	Not used
	RHINOS	Other guidance	Other
	UTIMS	Unguided	Not used
Mianyang Sonic Electronic	CZ901	US guidance	_
NaviFUS	NaviFUS System (Model 001)	Neuronavigation	MR/CT guidance
	NaviFUS System (Model 101)	Other guidance	MR/CT guidance
	NaviFUS System (Model 101-K)	Other guidance	MR/CT guidance
Neurosona	NS-US100	Other guidance	MR/CT guidance
	NS-US200	Other guidance	MR/CT guidance

Manufacturer	Device	Treatment guidance	Planning guidance
Asia			
Research & Development			
Shende Medical	Aceso-NIA	MR guidance	MR/CT guidance
	Aceso-PIA	MR guidance	MR guidanc3
Shenzhen Huikang Medical Apparatus	HIFU 2001	US guidance	_
Shenzhen PRO-HITU Medical	PRO 6G	Unguided	Not used
	PRO 6S	US guidance	US guidance
	PRO3008	US guidance	US guidance
	PRO300S	US guidance	US guidance
	UT-1000	Unguided	Not used
	UT-2000	Unguided	Not used
	UT-3000	Unguided	Not used
	UT-4000	Unguided	Not used
Sonire Therapeutics	Suizenji	US guidance	CT guidance
Sound Wave	LIPUS-Brain	_	MR guidance
Zhonghui Medical <sup>1</sup>	Histotripsy	US guidance	US guidance
	SUV-I	US guidance	US guidance
	SUV-II	US guidance	US guidance

<sup>1</sup> Commonly known as Sinoways



Manufacturer	Device	Treatment guidance	Planning guidance
Asia			
Commercial			
Alpinion Medical Systems	+ Alpius 900	US guidance	US guidance
Changjiangyuan Technology Development	♣ NUTAS - Non-invasive Ultrasound Tumor Ablation System	US guidance	US guidance
	◆ SUPER Knife-Focused Beam Therapy System	US & MR guidance	_
Chongqing Haifu Medical Technology	<b>◆</b> CZB	Other guidance	Other
	<b>◆</b> CZF	Unguided	Not used
	<b>◆</b> JC	US guidance	US guidance
	<b>+</b> JC200	US guidance	US guidance
	<b>+</b> JC200A	US guidance	US guidance
	<b>→</b> JC200B	US guidance	US guidance
	<b>→</b> JC200C	US guidance	US guidance
	<b>→</b> JC200D	US guidance	US guidance
	<b>→</b> JC200D0	US guidance	US guidance
	<b>→</b> JC200D1	US guidance	US guidance
	<b>→</b> JC200D2	US guidance	US guidance
	<b>+</b> JC200D3	US guidance	US guidance
	<b>→</b> JC210	US guidance	US guidance
	<b>→</b> JC220	US guidance	US guidance
	<b>+</b> JC300	US guidance	US guidance
	+ JC300P	US guidance	US guidance
	<b>+</b> JC300S	US guidance	US guidance
	<b>+</b> JCQ-B100	US guidance	US guidance
	<b>+</b> JCQ-B130	US guidance	US guidance
	<b>+</b> JCQ-B150	US guidance	US guidance
EpiSonica	◆ ArcBLATE (ARC-100M)	MR guidance	MR guidance

<sup>+</sup> Device with authorization



Manufacturer	Device	Treatment guidance	Planning guidance
Asia			
Commercial			
Shanghai A&S	+ HIFUNIT9000	US guidance	MR guidance
Shende Medical	◆ Aceso-UIA	MR guidance	MR guidance
Shenzhen PRO-HITU Medical	◆ PRO 5G	Other guidance	Visual guidance
	→ PRO2008	US guidance	US guidance
	<b>→</b> PRO300	US guidance	US guidance
Wuxi Haiying Electronic Medical	<b>+</b> HY2900	US guidance	_
Zhonghui Medical <sup>1</sup>	<b>+</b> HIFU-2001	US guidance	US guidance
	<b>◆</b> SUA-I	US guidance	US guidance

<sup>♣</sup> Device with authorization

<sup>1</sup> Commonly known as Sinoways

Manufacturer	<u>Device</u>	Treatment guidance	Planning guidance
Middle East			
Research & Development			
NINA Medical	LOTUS-1	US guidance	US guidance
Vensica Therapeutics <sup>1</sup>	The Vibe	_	_
	Vensica (prototype)	US guidance	_

Manufacturer	Device	Treatment guidance	Planning guidance
Middle East			
Commercial			
Insightec	<b>◆</b> Exablate Body	MR guidance	MR guidance
	+ Exablate Neuro	MR guidance	MR/CT guidance
	<b>◆</b> Exablate Prostate	MR guidance	MR guidance

<sup>♣</sup> Device with authorization

<sup>1</sup> Manufacturer was formerly known as Vensica Medical

Manufacturer	Device	Treatment guidance	Planning guidance
Oceania			
Research & Development			
Ultrathera	UltraTheraPilot	Image-guided navigation	MR guidance

# Regulatory Authorizations





#### Overview

# Regulatory authorization The first step toward clinical use

Before a medical procedure can be introduced into clinical practice, the underlying technology—such as a focused ultrasound device—must first receive regulatory authorization from the appropriate governing body. This decision is based on robust clinical data that demonstrates the safety and effectiveness of the technology.

Importantly, regulatory authorization is typically disease-specific, meaning a device must go through the approval process separately for each condition or indication it intends to treat. Once authorized, physicians may begin treating patients commercially, often starting on a cashpay basis while insurers evaluate whether to provide reimbursement. To make these treatments broadly accessible, especially to larger patient populations, widespread reimbursement is essential. In 2024, Monaco, Georgia, and Dominica joined the growing list of countries that have granted regulatory authorization for focused ultrasound devices, further expanding global access to this innovative technology.

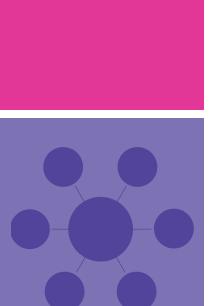
To view this chapter in an interactive format, please visit: www.fusfoundation.org/the-technology/sotf-regulatory-authorizations



VII. 2 Overview

#### **Authorizations**

- VII. 3 Global Highlights
- VII. 4 By Indication and Region Graphic
- VII. 5 Global Landscape of Approved Indications and Manufacturers
- VII.10 By Region and Manufacturer
- VII.14 By Indication and Region

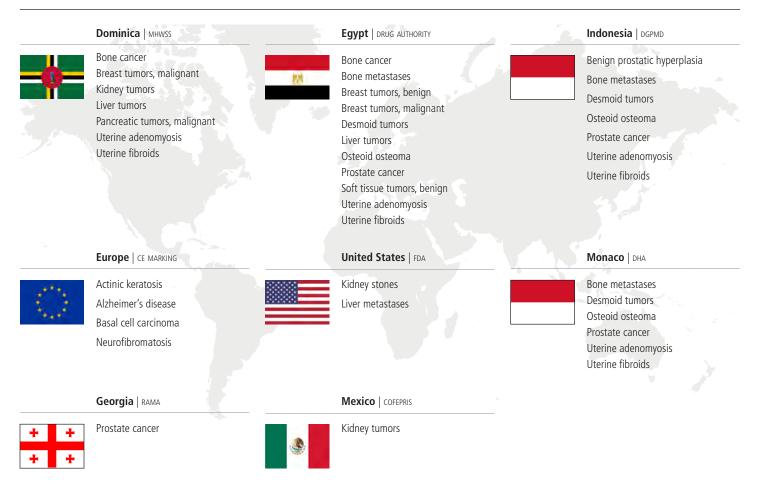


# Global Highlights

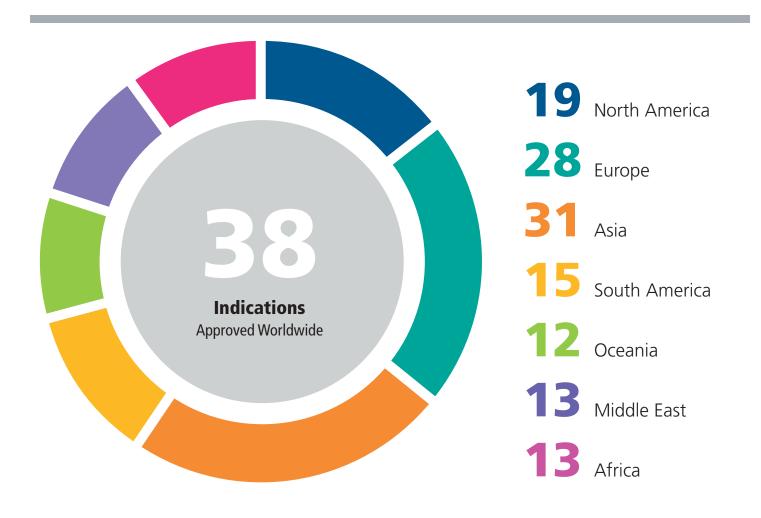
# 2024

# 39

# New global regulatory authorizations



FUS Regulatory Authorizations by Indication and Region *Graphic* 



# Global Landscape of Authorized Indications and Manufacturers

Indication regional authorizations	Indications	Manufacturers
	Cardiovascular	
• •	Varicose veins	Theraclion
	Endocrine disorders	
• •	Thyroid nodules	Theraclion
	Gastrointestinal	
	Liver metastases	HistoSonics
	Liver tumors	Chongqing Haifu Medical Technology
		HistoSonics
•		Shanghai A&S
•		Zhonghui Medical
• • • • •	Pancreatic tumors, malignant	Chongqing Haifu Medical Technology
	Miscellaneous	
•	Actinic keratosis	TOOsonix
	Basal cell carcinoma	TOOsonix
	Soft tissue ablation, excluding prostate	Acoustic MedSystems
• •		Sonablate
	Musculoskeletal	
• •	Arthritis, facetogenic	FUSMobile
		Insightec
	Bone cancer	Chongqing Haifu Medical Technology
• • • •		Insightec
•		Zhonghui Medical
• • •	Bone metastases	Insightec
• • • •		Profound Medical
•		Shanghai A&S
•		Shende Medical
Approval regions	North America	South America • Africa
-	•	Oceania
	<ul><li>Asia</li></ul>	Middle East

# Global Landscape of Authorized Indications and Manufacturers continued

Indication regional authorizations	Indications	Manufacturers
	Musculoskeletal continued	
• • •	Bone tumors, benign	Insightec
• • •	Desmoid tumors	Profound Medical
• • •	Multiple myeloma	Insightec
• • • •	Osteoid osteoma	Profound Medical
	Soft tissue cancer	EpiSonica
		Shanghai A&S
•		Zhonghui Medical
•	Soft tissue tumors, benign	Chongqing Haifu Medical Technology
	Neurological	
•	Alzheimer's disease	Storz Medical
•	Depression	Insightec
	Essential tremor	Insightec
	Neurofibromatosis	TOOsonix
	Obsessive-compulsive disorder	Insightec
	Pain, neuropathic	Insightec
• • •	Parkinson's disease, dyskinesia	Insightec
• • • • •	Parkinson's disease, tremor	Insightec
	Ophthalmological	
• •	Glaucoma	EyeTechCare
	Pulmonary	
•	Rhinitis	Chongqing Haifu Medical Technology

Approval regions	<ul><li>North America</li></ul>	<ul><li>South America</li></ul>	<ul><li>Africa</li></ul>
	<ul><li>Europe</li></ul>	<ul><li>Oceania</li></ul>	
	<ul><li>Asia</li></ul>	<ul><li>Middle East</li></ul>	

# Global Landscape of Authorized Indications and Manufacturers continued

Indication regional authorizations	Indications	Manufacturers
	Urological	
	Benign prostatic hyperplasia	EDAP TMS
		Insightec
• • •		Profound Medical
		Sonablate
	Kidney stones	SonoMotion
	Kidney tumors	Chongqing Haifu Medical Technology
• • • •	Prostate cancer	EDAP TMS
		Insightec
• • •		Profound Medical
		Sonablate
	Women's health	
•	Breast tumors, benign	Chongqing Haifu Medical Technology
• •		Theraclion
	Breast tumors, malignant	Chongqing Haifu Medical Technology
•		Shanghai A&S
•		Zhonghui Medical
	Cervicitis	Chongqing Haifu Medical Technology
•	Hyperplasia of the vulva	Shenzhen PRO-HITU Medical
	Lichen sclerosis	Shenzhen PRO-HITU Medical
•	Uterine adenomyosis	Alpinion Medical Systems
		Chongqing Haifu Medical Technology
• • • •		Insightec
• • • •		Profound Medical
•		Shenzhen PRO-HITU Medical
Annual varies	North Amorine	Courth America
Approval regions		South America • Africa Oceania
		Middle East

# Global Landscape of Authorized Indications and Manufacturers continued

Indication regional authorizations	Indications	Manufacturers
	Women's health continued	
•	Uterine fibroids	Alpinion Medical Systems
		Arrayus
		Chongqing Haifu Medical Technology
		Insightec
		Profound Medical
• •		Shanghai A&S
• •		Shenzhen PRO-HITU Medical
		Wuxi Haiying Electronic Medical
•		Zhonghui Medical

**Approval regions** 

North America

Europe

Asia

South America

Oceania

Middle East

Africa



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# Regulatory Authorizations by Region and Manufacturer

Indications	North America	Europe	Asia	South America	Oceania	Mid East/Africa
marcations	- North America				— Occuma	- Wild Ed3t/Airied
Cardiovascular						
Varicose veins		<b>A</b>	<b>A</b>			
Endocrine						
Thyroid nodules		<b>A</b>	<b>A</b>			
Gastrointestina	al					
Liver metastases	•					
Liver tumors	•	•	• • •	•		•
Pancreatic tumors, malignant	•	•	•	•		•
Miscellaneous						
Actinic keratosis		<b>A</b>				
Basal cell carcinoma		<b>A</b>				
Soft tissue ablation, excluding prostate	••	•				

#### **Manufacturers** North America Middle East **Europe** Asia Acoustic MedSystems, US ▲ EDAP TMS, France Alpinion Medical Systems, South Korea Insightec, Israel Arrayus, Canada ▲ EyeTechCare, France Chongqing Haifu Medical Technology, China FUSMobile, US ▲ Storz Medical, Switzerland EpiSonica, Taiwan HistoSonics, US ▲ TOOsonix, Denmark Shanghai A&S, China Profound Medical, Canada Shende Medical, China ▲ Theraclion, *France* Sonablate, US Shenzhen PRO-HITU Medical, China SonoMotion, US Wuxi Haiying Electronic Medical, China Zhonghui Medical, China

# Regulatory Authorizations by Region and Manufacturer continued

Indications	North America	Europe	Asia —	South America	Oceania	Mid East/Africa
Musculoskeleta	al					
Arthritis, facetogenic	_	•	<b>•</b>		<b>*</b>	
Bone cancer	•	• •	• • •	•	•	• •
Bone metastases	•		■ • •		•	•
Bone tumors, benign		<b>•</b>	<b>♦</b>		<b>•</b>	
Desmoid tumors						
Multiple myeloma		<b>•</b>	<b>♦</b>		<b>•</b>	
Osteoid osteoma						
Soft tissue cancer			• • •			
Soft tissue tumors, benign	1		•			•
Neurological						
Alzheimer's disease		<b>A</b>				
Depression			•			
Essential tremor	•	<b>♦</b>	<b>•</b>	•	<b>•</b>	•
Neurofibromatosis		<b>A</b>				
OCD			<b>•</b>			

#### **Manufacturers**

#### North America

- Acoustic MedSystems, US
- Arrayus, Canada
- FUSMobile, US
- HistoSonics, US
- Profound Medical, Canada
- Sonablate, US
- SonoMotion, US

#### Europe

- ▲ EDAP TMS, France
- EyeTechCare, France
- ▲ Storz Medical, Switzerland
- ▲ TOOsonix, Denmark
- ▲ Theraclion, *France*

#### Asia

- Alpinion Medical Systems, South Korea
- Chongqing Haifu Medical Technology, China
- EpiSonica, Taiwan
- Shanghai A&S, China
- Shende Medical, China
- Shenzhen PRO-HITU Medical, China
- Wuxi Haiying Electronic Medical, *China*
- Zhonghui Medical, China

#### Middle East

♦ Insightec, Israel

# Regulatory Authorizations by Region and Manufacturer continued

Indications	North America	Europe	Asia	South America	Oceania	Mid East/Africa
<b>Neurological</b> co	ntinued					
Pain, neuropathic	•	•	•	•	•	•
Parkinson's dyskinesia	•	•	•	·	·	·
Parkinson's tremor	•	•	•	•	•	•
Ophthalmologi	ical	•	•	•	<u> </u>	•
Glaucoma	lear	<u> </u>	_			
			_			
Pulmonary						1
Rhinitis			•			
Urological						
BPH						
Kidney stones		•	•	•		•
Prostate cancer					•	
Women's healt	h					
Breast tumors, benign		<b>A</b>	<b>A</b> •			•
Breast tumors, malignant	•	•	• • •	•		•
Cervicitis			•			

#### **Manufacturers**

#### North America

- Acoustic MedSystems, US
- Arrayus, Canada
- FUSMobile, US
- HistoSonics, US
- Profound Medical, Canada
- Sonablate, US
- SonoMotion, US

#### Europe

- ▲ EDAP TMS, France
- ▲ EyeTechCare, France
- ▲ Storz Medical, Switzerland
- ▲ TOOsonix, Denmark
- ▲ Theraclion, *France*

#### Asia

- Alpinion Medical Systems, South Korea
- Chongqing Haifu Medical Technology, China
- EpiSonica, Taiwan
- Shanghai A&S, China
- Shende Medical, China
- Shenzhen PRO-HITU Medical, China
- Wuxi Haiying Electronic Medical, China
- Zhonghui Medical, China

#### Middle East

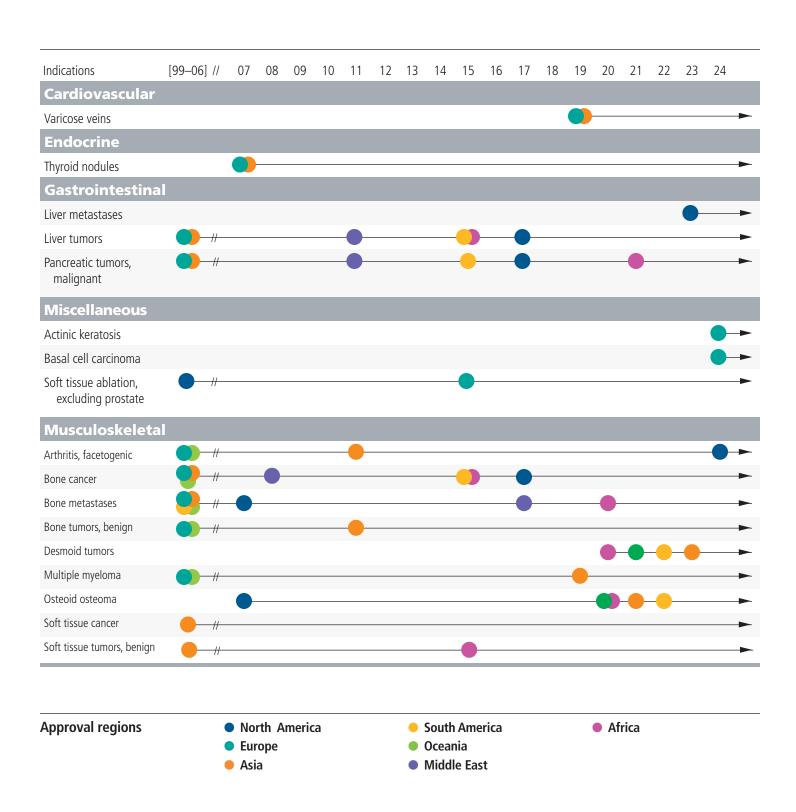
♦ Insightec, *Israel* 

# Regulatory Authorizations by Region and Manufacturer continued

Indications	North America	Europe	Asia	South America	Oceania	Mid East/Africa
Women's healt	<b>h</b> continued					
Hyperplasia of the vulva			•			
Lichen sclerosis			•			
Uterine adenomyosis	•	■•+		•	<b>*</b>	
Uterine fibroids				•	<b>*</b>	■••

#### **Manufacturers** North America Middle East **Europe** Asia Acoustic MedSystems, US ▲ EDAP TMS, France Alpinion Medical Systems, South Korea Insightec, Israel Arrayus, Canada Chongqing Haifu Medical Technology, China ▲ EyeTechCare, France FUSMobile, US ▲ Storz Medical, Switzerland EpiSonica, Taiwan HistoSonics, US ▲ TOOsonix, Denmark Shanghai A&S, China Profound Medical, Canada ▲ Theraclion, *France* Shende Medical, China Sonablate, US Shenzhen PRO-HITU Medical, China SonoMotion, US Wuxi Haiying Electronic Medical, China Zhonghui Medical, China

### Regulatory Authorizations by Indication and Region



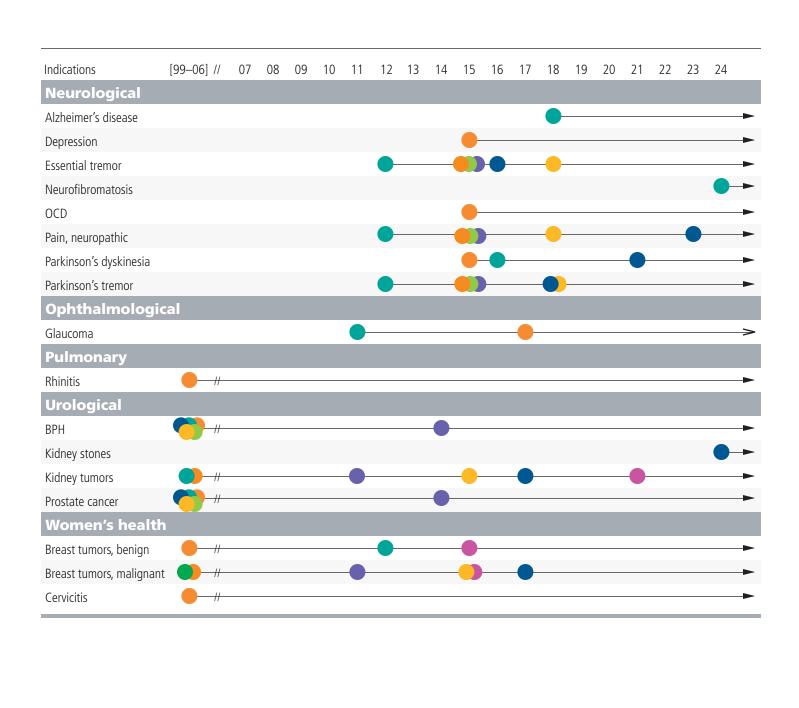
# Regulatory Authorizations by Indication and Region continued

North America

**Europe** 

Asia

**Approval regions** 



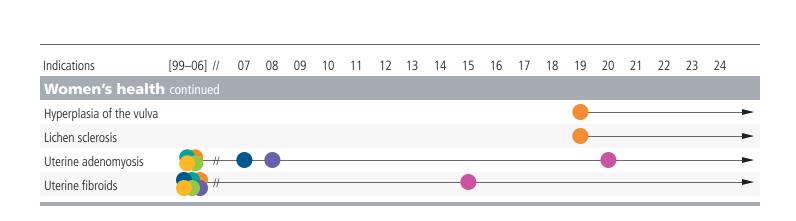
Africa

South America

Middle East

Oceania

# Regulatory Authorizations by Indication and Region continued







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# Clinical Device Manufacturers





#### Overview

# Industry Outlook The Shift Toward Global Commercialization

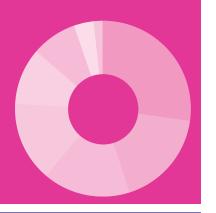
In the wake of exponential advancements, the focused ultrasound industry has moved beyond its inflection point. The question is no longer "if" focused ultrasound will play a critical role in modern medicine, but "when" it will become a mainstream standard of care.

We are now seeing clear signs of a transition from a research-driven environment to a commercially focused industry. This shift is especially evident in 2024, as the field celebrates a significant milestone: over one million patient treatments worldwide. As more companies expand into patient-facing markets, with growing emphasis on marketing and sales, the commercialization of focused ultrasound is accelerating.

To keep pace with this evolution, we are committed to tracking the key data points and metrics that define this global transformation. Doing so allows us to accurately assess progress, identify trends, and share meaningful insights with all stakeholders.

A heartfelt thank you goes to our industry partners, who consistently share valuable company data year after year. Your collaboration enables us to present a comprehensive, aggregated view of the field and to better understand the path forward for focused ultrasound.

View more details from this chapter in an interactive format, please visit: www.fusfoundation.org/the-technology/sotf-commercial-fus-manufacturers

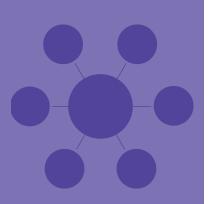


#### VIII. Clinical Device Manufacturers

VIII. 2 Overview

#### **Authorizations**

- VIII. 3 Global Summary
- VIII. 4 Indications Authorized by Manufacturer
- VIII. 6 Manufacturers with Regulatory Authorizations
- VIII. 7 For Companies by Region and Indication



# Summary of Global Authorizations

2024

46
Regulatory agencies

4446
Authorizations worldwide

# Number of Indication Authorizations by Manufacturer

	North America	Europe	Asia	South America	Oceania	Mid East / Africa
Manufacturer	Troitin, illionida	24.575	7 1510		3 234	
Acoustic MedSystems	1	-	_	_	-	_
Alpinion Medical Systems	-	_	2	_	-	-
Arrayus	1	_	_	_	-	_
Changjiangyuan Technology Development	-	1	_	_	-	-
Chongqing Haifu Medical Technology	7	7	11	7	_	7/9
EDAP TMS	2	1	1	1	-	<b>-/1</b>
EpiSonica	_	_	1	_	_	_
EyeTechCare	_	1	1	_	_	_
FUSMobile	1	1	_	_	_	_
HistoSonics	2	_	_	_	_	_
Insightec	8	12	14	3	11	8 / –
Profound Medical	6	7	7	5	-	3/5

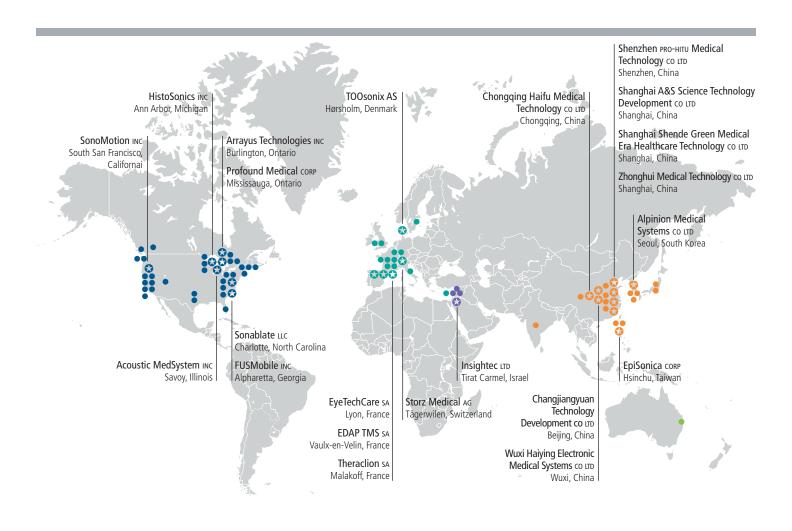
# Number of Indication Authorizations by Manufacturer continued

	North America	Europe	Asia	South America	Oceania	Mid East / Africa
Manufacturer continued						
Shanghai A&S	_	1	5	_	_	_
Shende Medical	_	1	_	_	-	_
Shenzhen PRO-HITU Medical	_	1	4	_	_	_
Sonablate	3	3	2	2	2	2 / –
SonoMotion	1	_	_	_	_	_
Storz Medical	_	1	_	_	-	_
Theraclion	_	3	3	_	_	_
TOOsonix	_	3	_	_	-	_
Wuxi Haiying Electronic Medical	_	-	1	_	-	_
Zhonghui Medical	-	-	5	-	-	-



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# Manufacturers with Regulatory Authorizations\*





Clinical device manufacturers that have a device or devices with regulatory approvals by regional location.

Company listings of devices, approved indications, and regulatory agencies granting approvals are found on the subsequent pages.



Location of clinical device manufacturers without approved devices by region

Approvals may have changed or been updated since publication. For the most up-to-date information please visit: fusfoundation.org/the-foundation/programs/regulatory-approvals-search.

### Regulatory Authorizations for Companies by Region and Indication

#### North America

#### Acoustic MedSystems

Soft tissue ablation, excluding prostate

#### Arrayus

Uterine fibroids

#### Chongqing Haifu Medical Technology

Bone cancer
Breast tumors,
malignant
Kidney tumors
Liver tumors
Pancreatic tumors,
malignant
Uterine adenomyosis
Uterine fibroids

#### **EDAP TMS**

Benign prostatic hyperplasia Prostate cancer

#### FUSMobile

Arthritis, facetogenic

#### HistoSonics

Liver metastases Liver tumors

#### Insightec

Benign prostatic hyperplasia Bone metastases Essential tremor Pain, neuropathic Parkinson's disease, dyskinesia Parkinson's disease, tremor Prostate cancer Uterine fibroids

#### **Profound Medical**

Benign prostatic hyperplasia Bone metastases Osteoid osteoma Prostate cancer Uterine adenomyosis Uterine fibroids

#### Sonablate

Benign prostatic hyperplasia Prostate cancer Soft tissue ablation, excluding prostate

#### SonoMotion

Kidney stones

## Europe

#### Changjiangyuan Technology Development

Tumor ablation

Bone cancer

#### Chongqing Haifu Medical Technology

Breast tumors, malignant Kidney tumors Liver tumors Pancreatic tumors, malignant Uterine adenomyosis Uterine fibroids

#### EDAP TMS

Prostate cancer

#### EyeTechCare Glaucoma

Glaucoma

# FUSMobile

Arthritis, facetogenic

#### Insightec

Arthritis, facetogenic
Bone cancer
Bone metastases
Bone tumors, benign
Essential tremor
Multiple myeloma
Pain, neuropathic
Parkinson's disease,
dyskinesia
Parkinson's disease,
tremor
Prostate cancer
Uterine adenomyosis
Uterine fibroids

#### **Profound Medical**

Benign prostatic hyperplasia Bone metastases Desmoid tumors Osteoid osteoma Prostate cancer Uterine adenomyosis Uterine fibroids

#### Shanghai A&S Uterine fibroids

Shende Medical Bone metastases

#### Shenzhen PRO-HITU Medical Uterine fibroids

#### Sonablate

Benign prostatic hyperplasia Prostate cancer Soft tissue ablation, excluding prostate

#### Storz Medical

Alzheimer's disease

#### Theraclion

Breast tumors, benign Thyroid nodules Varicose veins

#### **TOOsonix**

Actinic keratosis Basal cell carcinoma Neurofibromatosis

#### Asia

#### Alpinion Medical Systems

Uterine adenomyosis Uterine fibroids

#### Chongqing Haifu Medical Technology

Bone cancer

Breast tumors, benign
Breast tumors,
malignant
Cervicitis
Kidney tumors
Liver tumors
Pancreatic tumors,
malignant
Rhinitis

Soft tissue tumors, benign Uterine adenomyosis Uterine fibroids

#### **EDAP TMS**

Prostate cancer

# **EpiSonica**Soft tissue cancer

EveTechCare

Arthritis, facetogenic

#### Glaucoma Insightec

Bone cancer
Bone metastases
Bone tumors, benign
Depression
Essential tremor
Multiple myeloma
Obsessive-compulsive
disorder
Pain, neuropathic
Parkinson's disease,
dyskinesia
Parkinson's disease,
tremor
Prostate cancer

Uterine adenomyosis Uterine fibroids

#### **Profound Medical**

Benign prostatic hyperplasia Bone metastases Desmoid tumors Osteoid osteoma Prostate cancer Uterine adenomyosis Uterine fibroids

#### Shanghai A&S

Bone metastases
Breast tumors,
malignant
Liver tumors
Soft tissue cancer
Uterine fibroids

#### Shenzhen PRO-HITU Medical

Hyperplasia of the vulva Lichen sclerosis Uterine adenomyosis Uterine fibroids

#### Sonablate

Benign prostatic hyperplasia Prostate cancer

#### **Theraclion**

Breast tumors, benign Thyroid nodules Varicose veins

#### Wuxi Haiying Electronic Medical

Uterine fibroids

#### Zhonghui Medical<sup>1</sup>

Bone cancer Breast tumors, malignant Liver tumors Soft tissue cancer Uterine fibroids

<sup>1</sup> Commonly known as Sinoways.

#### Regulatory Authorizations for Companies by Region and Indication continued

#### South America

#### Chongqing Haifu Medical Technology

Bone cancer Breast tumors, malignant Kidney tumors

Liver tumors
Pancreatic tumors,

malignant Uterine adenomyosis Uterine fibroids

#### EDAP TMS

Prostate cancer

#### Insightec

Essential tremor Pain, neuropathic Parkinson's disease, tremor

#### **Profound Medical**

Bone metastases Desmoid tumors Osteoid osteoma Uterine adenomyosis Uterine fibroids

#### Sonablate

Benign prostatic hyperplasia Prostate cancer

#### Oceania

#### Insightec

Arthritis, facetogenic Bone cancer Bone metastases Bone tumors, benign Essential tremor Multiple myeloma Pain, neuropathic Parkinson's disease, tremor Prostate cancer

Uterine adenomyosis

# Uterine fibroids **Sonablate**

Benign prostatic hyperplasia Prostate cancer

#### **■ Middle East**

Bone cancer

#### Chongqing Haifu Medical Technology

Breast tumors, malignant Kidney tumors Liver tumors Pancreatic tumors, malignant Uterine adenomyosis

#### Insightec

Uterine fibroids

Bone cancer
Bone metastases
Essential tremor
Pain, neuropathic
Parkinson's disease,
tremor
Prostate cancer
Uterine adenomyosis
Uterine fibroids

#### **Profound Medical**

Benign prostatic hyperplasia Prostate cancer Uterine fibroids

#### Sonablate

Benign prostatic hyperplasia Prostate cancer

#### Africa

#### Chongqing Haifu Medical Technology

Bone cancer
Breast tumors, benign
Breast tumors,
malignant
Kidney tumors
Liver tumors
Pancreatic tumors,
malignant
Soft tissue tumors,
benign
Uterine adenomyosis
Uterine fibroids

#### **EDAP TMS**

Prostate cancer

#### **Profound Medical**

Bone metastases Desmoid tumors Osteoid osteoma Uterine adenomyosis Uterine fibroids



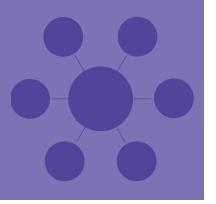
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# Financial Landscape



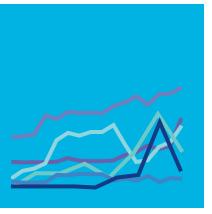


## Overview



For the lay reader of this report, it is vital to understand the MedTech investment environment in 2024 to understand how the focused ultrasound space was affected.

In summary, 2024 was a standout year for MedTech financing. While overall deal counts stayed flat, investment dollars increased significantly, especially in later-stage opportunities. Early-stage innovation regained traction, exit values hit historic highs, and IPOs made a modest comeback. However, exit timelines remain extended, underscoring continued emphasis on clinical and commercial validation before companies reach maturity.



# IX. Financial Landscape

IX. 2 Overview

#### **FUS Investments**

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- IX. 4 2024 Industry Investments
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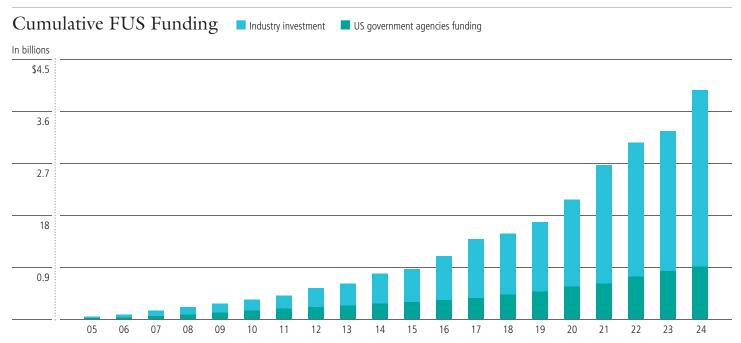
## **US Government Funding of FUS**

- IX.14 Research—Top Funders
- IX.15 Total Funding by Agency
- IX.17 Funding Over Time

## **FUS Investments**

The focused ultrasound ecosystem mirrored the standout year in the overall MedTech market in 2024 and experienced a significant increase in overall funding, with \$419MM reported, a 3x increase compared to 2023.

Four companies received half of the money raised in 2024, while the other fifteen companies shared the remainder.



The values in this graph may not reflect the annual values shown in the previous State of Field reports because of new information on investments.

# 2024 FUS Industry Investments\*

Pre-seed	Seed	Series A	Series B	Series C	Series D	Series F	■ Grant	Debt	Post-IPO Equity
----------	------	----------	----------	----------	----------	----------	---------	------	-----------------

Manufacturer	Funding type	Investors	Funding date	Money raised, millions \$US
Insightec LTD				
	■ Series F	Ally Bridge Group Baillie Gifford & Co. Catalio Capital Management Fayez Sarofim & Co. Fidelity Management & Research Co. Gilmartin Capital LLC Nexus Neurotech Ventures Perceptive Advisors York Capital Management LLC	6.18.2024	\$150.0M
HistoSonics INC				
	■ Series D	Alpha Wave Amzak Health HealthQuest Capital Johnson & Johnson Lumira Ventures State of Wisconsin Investment Board Venture Investors LLC Yonjin Venture	8.15.2024	\$102.0M
Openwater				
	■ Series B	BOLD Capital Partners Dyson, Esther Gabriel, Peter Khosla Ventures Plum Alley Ventures	8.22.2024	\$ 54.0M
Profound Medical corp				
	Post-IPO Equity Post-IPO Equity Grant	INOVAIT	12.10.2024 1.16.2024 6.14.2024	\$ 40.2M \$ 2.9M \$ 0.1M
Exo Imaging INC				
	■ Debt		8.2.2024	\$ 20.7M

 $<sup>\</sup>ensuremath{^{\star}}$  Source: Crunchbase, Pitchbook, and company press releases

# 2024 FUS Industry Investments\* continued

■ Pre-seed ■ Seed ■ Series A ■ Series B ■ Series C ■ Series D ■ Series F ■ Grant ■ Debt ■ Post-IPO Equity

Manufacturer	Funding type	Investors	Funding date	Money raised, millions \$US
<b>EXACT Therapeutics</b> AS				
	Post-IPO Equity	GE Healthcare	12.2.2024	\$ 13.0M
Vensica Therapeutics				
	Series C	Israel Biotech Fund Laborie Medical Technologies corp Merz Pharmaceuticals LLC	10.29.2024	\$ 11.0M
SecondWave Systems INC				
	■ Grant ■ Grant	National Institutes of Health US Department of Defense, Defense Advanced Research Projects Agency	3.27.2024 5.9.2024	\$ 3.0M \$ 3.0M
NaviFUS corp				
	Post-IPO Equity		3.15.2024	\$ 5.0M
RebrAln				
	■ Seed	Karista sas Nouvelle-Aquitaine Co-Investissement (NACO)	1.1.2024	\$ 3.6M
Cardiawave SA				
	Series A		6.26.2024	\$ 3.0M
Sonus Microsystems				
	■ Pre-Seed	LDV Capital	2.26.2024	\$ 2.1M
SonoVascular INC				
	■ Seed		10.29.2024	\$ 1.8M
Sonogen Medical INC				
	■ Seed ■ Seed ■ Grant	Old Line Capital Partners TEDCO National Science Foundation	10.1.2024 1.15.2024 6.1.2024	\$ 0.6M \$ 0.5M \$ 0.3M
Therasonic SAS				
	Series A	Institut Gustave Roussy M2Care	5.17.2024	\$ 1.1M

 $<sup>\</sup>ensuremath{^{\star}}$  Source: Crunchbase, Pitchbook, and company press releases

# 2024 FUS Industry Investments\* continued

■ Pre-seed ■ Seed ■ Series A ■ Series B ■ Series C ■ Series D ■ Series F ■ Grant ■ Debt ■ Post-IPO Equit	Pre-seed	Seed	Series A	Series B	Series C	Series D	Series F	■ Grant	Debt	Post-IPO Equity
--	----------	------	----------	----------	----------	----------	----------	---------	------	-----------------

Manufacturer	Funding type	Investors	Funding date	Money raised, millions \$US
Cordance Medical INC				
	■ Grant	National Cancer Institute	9.19.2024	\$ 0.4M
Surf Therapeutics				
	■ Seed		5.19.2024	\$ 0.3M
INIA Biosciences INC				
	<b>■</b> Grant	National Science Foundation	4.1.2024	\$ 0.3M
Sound Blade Medical				
	<b>■</b> Grant	INOVAIT	9.24.2024	\$ 0.1M

\$419.0M USD Total

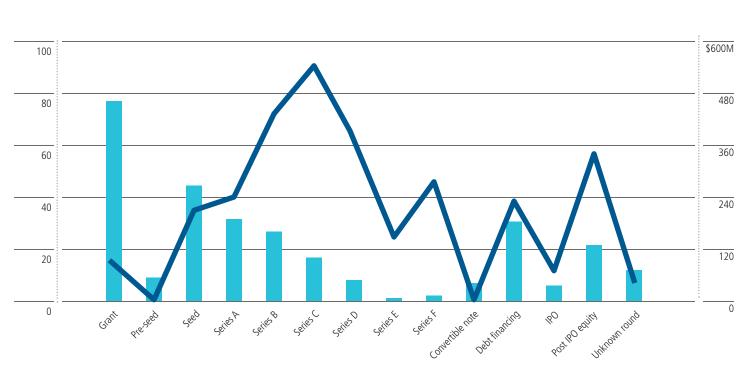
Nineteen focused ultrasound companies raised money in 2024. The majority were small rounds for early-stage companies. Four later-stage companies raised larger rounds comprising approximately 50% of the total amount invested in 2024.

 $<sup>\</sup>ensuremath{^{\star}}$  Source: Crunchbase, Pitchbook, and company press releases

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# FUS Industry Investments by Stage

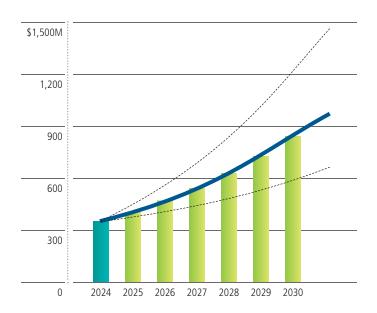
■ Number of investments ■ Value of investments in millions of dollars



Source: Crunchbase, Pitchbook, and industry press releases

# **FUS Market Projection**

Revenue in millions of dollars



Market value and growth rate estimates were compiled from the following websites:

https://dataintelo.com/report/high-intensity-focused-ultrasound-hifu-treatment-market

https://www.24marketreports.com/life-sciences/global-highintensity-focused-ultrasound-equipment-2024-217

https://www.360marketupdates.com/global-high-intensity-focused-ultrasound-hifu-market-26505073

https://www.businessgrowthreports.com/global-high-intensity-focused-ultrasound-system-market-26681901

https://www.factmr.com/report/mri-guided-focused-ultrasound-device-market https://www.kingpinmarketresearch.com/global-high-intensity-focused-ultrasound-hifu-market-26505073

https://www.kingpinmarketresearch.com/global-high-intensity-focused-ultrasound-hifu-market-27857333

https://www.linkedin.com/pulse/europe-high-intensity-focused-ultra-sound-system-tvfuf/

https://www.marketreportsworld.com/global-high-intensity-focused-ultrasound-system-market-26318534

https://www.marketresearchguru.com/global-high-intensity-focused-ultrasound-hifu-market-26356897

https://www.marketresearchintellect.com/product/global-high-intensity-focused-ultrasound-hifu-treatment-market-size-and-forecast/

https://www.reliableresearchreports.com/magnetic-resonance-image-

https://www.researchreportsworld.com/2024-2031-report-on-global-high-intensity-focused-ultrasound-hifu-market-26913575

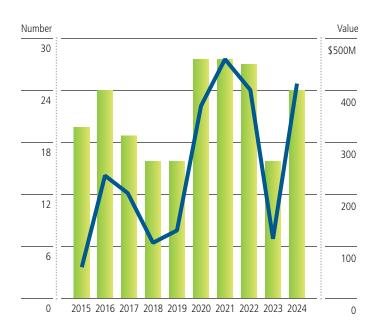
guided-focused-ultrasound-system-market-r1649709

https://www.researchreportsworld.com/global-high-intensity-focused-ultrasound-system-market-26333434

https://www.verifiedmarketreports.com/product/high-intensity-focused-ultrasound-hifu-therapy-market-size-and-forecast/

## FUS Industry Investments Over Time

■ Number of investments ■ Value of investments in millions of dollars



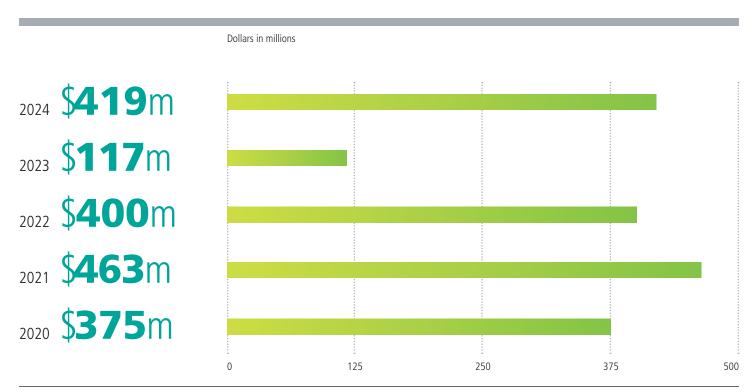
Source: Crunchbase, Pitchbook, and industry press releases

#### **Annual investments trends**

Focused ultrasound investments rebounded nicely in 2024 compared to the previous year. This follows the trend of an uptick in healthcare investments in general as venture capital rebounded after a deflated 2023.

# FUS Industry Investments\*

Annual



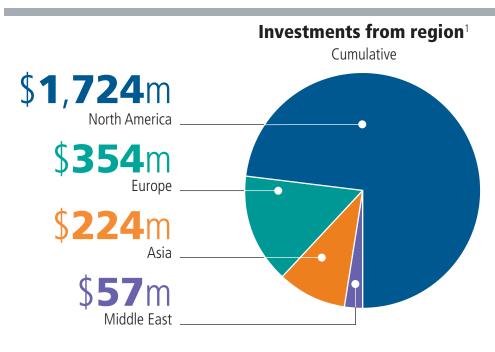
<sup>\*</sup> Sources Crunchbase, Pitchbook, and industry press releases

The values in this graph may not reflect the annual values shown in the previous State of Field reports because of new information on investments.

#### 1.8B invested in the last 5 years

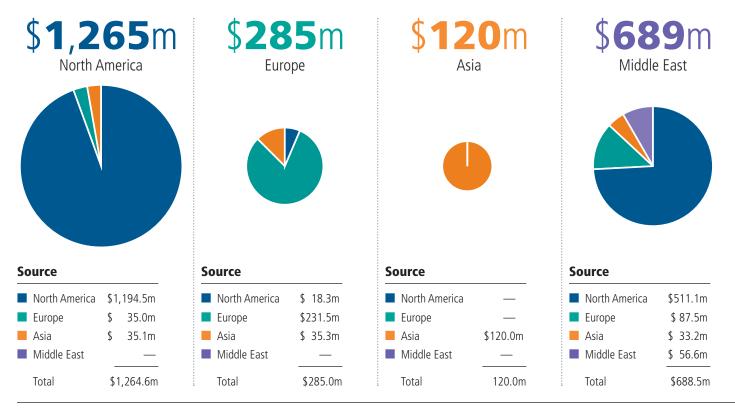
Over the past six years, investments in focused ultrasound have shown steady and significant growth, with cumulative funding now surpassing \$3 billion. Of that, \$1.8 billion was invested in just the last five years, underscoring the accelerating momentum within the field. As the ecosystem expands and companies advance toward later stages of development, we anticipate larger investment rounds and a more robust pipeline of mature, investable opportunities. The graph above highlights these trends, reflecting the rising confidence in focused ultrasound and its growing commercial potential.

## Flow of Investments\*



# **Disbursement to FUS Companies**

Cumulative

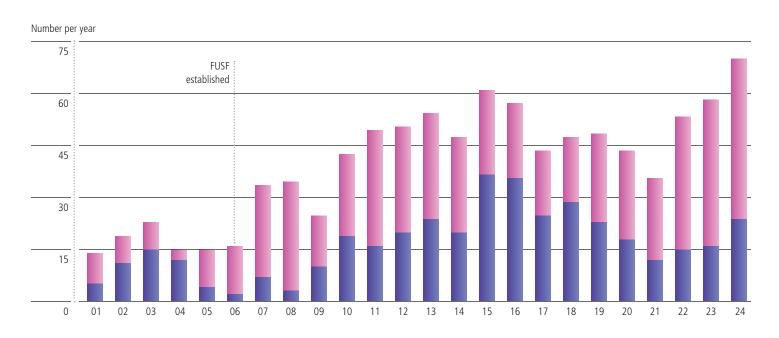


<sup>\*</sup> Sources Crunchbase and industry press releases

<sup>1</sup> Inclusion in this analysis requires that the investor is known. Since this information is not available for all investments, the total above is underrepresented. The total investment in the industry is \$3,091M.

## Focused Ultrasound Industry Patents





Sources https://ppubs.uspto.gov/pubwebapp/ https://patentscope.wipo.int/search/en/structuredSearch.jsf

Terms searched: "focused ultrasound", HIFU, histotripsy, LIFU, LIPUS, MRgFUS, "ultrasound ablation"

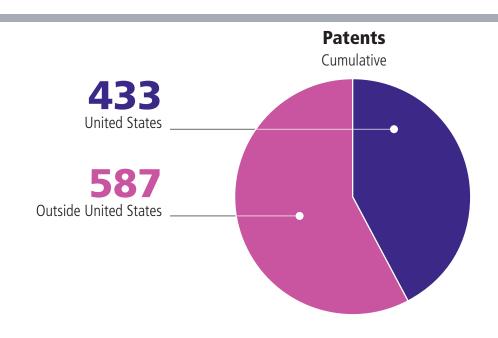
Patent activity continues to be a strong indicator of innovation in focused ultrasound. While most patents issued through the World Intellectual Property Organization (WIPO) were nationalized across all participating countries, it's important to note that China—home to 12 of the 69 focused ultrasound device manufacturers—is not a WIPO member, and therefore not represented in this dataset.

Looking more closely at the numbers, not shown graphically, the U.S. Patent and Trademark Office (USPTO) issued most of its focused ultrasound patents to U.S.-based inventors and assignees. Similarly, 58% of WIPO filings came from applicants based in the U.S.—a trend likely driven

by the country's prolific academic patenting infrastructure, which outpaces many other nations.

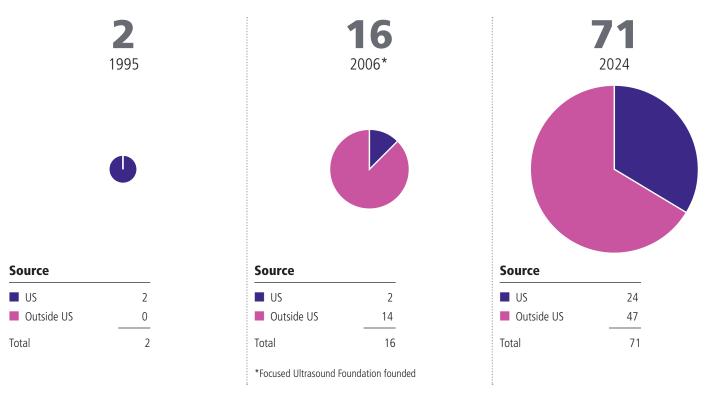
The accompanying graph illustrates a strong four-year upward trend in patent filings both within and outside the U.S., reflecting the global acceleration of innovation in this rapidly advancing field.

# Focused Ultrasound Industry Patents continued



# **Snapshot of Growth in Patents**

Number per year

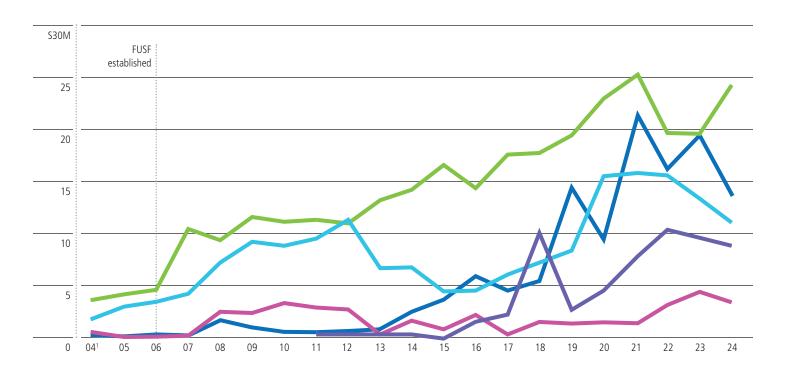


Sources: https://ppubs.uspto.gov/pubwebapp/ and https://patentscope.wipo.int/search/en/structuredSearch.jsf Search terns: "focused ultrasound", HIFU, histotripsy , LIFU, LIPU, LIPUS, MRgFUS, "ultrasound ablation"

## Research—United States Top Federal Government Funders

■ NCI ■ NIBIB ■ NINDS ■ NHLBI ■ NIMH

Dollars in millions



1 The first record of funding for focused ultrasound research by the US Federal Government was in 2004.

Sources https://projectreporter.nih.gov/reporter.cfm https://www.usaspending.gov/search

Terms searched: "focused ultrasound", HIFU, histotripsy, LIFU, LIPU, MRgFUS, "ultrasound ablation"

# United States federal government focused ultrasound grants

Federal funding for focused ultrasound in the U.S. was a mixed picture in 2024. While the overall budget for the National Institutes of Health (NIH) has remained largely flat over the past 15 years, the portion directed toward focused ultrasound research continues to grow—a promising sign that the technology is being recognized for its potential to transform patient care.

The National Cancer Institute (NCI) remains the leading federal funder of focused ultrasound research. Notably, NCI support for focused ultrasound increased significantly in 2024, even in the face of a \$15 million decrease in its overall budget compared to 2023. This trend is consistent with how federal agencies prioritize funding, channeling resources toward innovations with the greatest potential for clinical impact.

# Total FUS Funding by United States Government Agencies

2024 FUS funding	Total FUS funding <sup>1</sup> 2004 <sup>2</sup> –2024	Granting agency
\$24,311,003	\$307,617,938	■ NCI   National Cancer Institute
\$12,179,480	\$178,318,432	■ NIBIB   National Institute of Biomedical Imaging and Bioengineering
\$8,587,259	\$135,598,185	■ NINDS   National Institute of Neurological Disorders and Stroke
\$3,440,565	\$54,804,938	■ NHLBI   National Heart, Lung, and Blood Institute
\$8,492,949	\$43,759,863	■ NIMH   National Institute of Mental Health
_	\$32,924,533	NCRR <sup>3</sup>   National Center for Research Resources
\$1	\$25,023,588	OD   Office of the Director, NIH
\$1,488,267	\$17,265,064	NSF   National Science Foundation
\$1,853,682	\$16,913,189	NEI   National Eye Institute
\$2,813,329	\$17,809,359	NIA   National Institute on Aging
\$1,715,540	\$16,617,159	NIDDK   National Institute of Diabetes and Digestive and Kidney Diseases
\$96,874	\$12,322,149	NICHD   Eunice Kennedy Shriver National Institute of Child Health and Human Development
\$5,219,851	\$16,429,481	NIDA   National Institute on Drug Abuse
_	\$9,520,073	CDMRP   Congressionally Directed Medical Research Programs
\$2,393,925	\$9,886,466	NIGMS   National Institute of General Medical Sciences
\$638,514	\$4,290,857	NIDCR   National Institute of Dental and Craniofacial Research
\$4,210,105	\$4,210,105	DOD   US Department of Defense
\$678,195	\$3,653,225	NIAMS   National Institute of Arthritis and Musculoskeletal and Skin Diseases
_	\$2,974,108	FIC   John E. Fogarty International Center
_	\$2,772,219	CNRM   Center For Neuroscience and Regenerative Medicine
\$1,320,377	\$3,318,779	NIAAA   National Institute on Alcohol Abuse and Alcoholism
_	\$1,516,636	NINR   National Institute of Nursing Research

Source

 $https://projectreporter.nih.gov/reporter.cfm\ and\ https://www.usaspending.gov/search$ 

Terms searched: "focused ultrasound", HIFU, histotripsy, LIFU, LIPU, MRgFUS, and "ultrasound ablation"

<sup>1 2023</sup> funding for focused ultrasound was \$95,486,757.

<sup>2</sup> The first record of funding for focused ultrasound research by the US Federal Government was in 2004.

<sup>3</sup> Agency dissolved in 2012.

# Total FUS Funding by United States Government Agencies continued

2024 FUS funding	Total FUS funding <sup>1</sup> 2004 <sup>2</sup> –2024	Granting agency
_	\$909,727	NIDCD   National Institute on Deafness and Other Communication Disorders
_	\$779,990	NCMHD   National Institute on Minority Health and Health Disparities
_	\$236,003	CLC   Clinical Center
\$236,968	\$465,863	NCCIH   National Center for Complementary and Integrative Health
_	\$223,196	NHGRI   National Human Genome Research Institute
_	\$74,250	NCATS   National Center for Advancing Translational Sciences
\$79,676,884	\$920,235,375	TOTAL

Sources

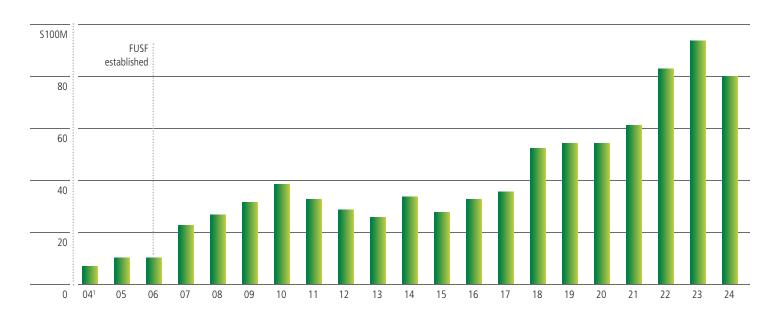
Terms searched: "focused ultrasound", HIFU, histotripsy, LIFU, LIPU, MRgFUS, and "ultrasound ablation"  $\,$ 

<sup>1 2023</sup> funding for focused ultrasound was \$95,486,757.

<sup>2</sup> The first record of funding for focused ultrasound research by the US Federal Government was in 2004.

 $https://projectreporter.nih.gov/reporter.cfm\ and\ https://www.usaspending.gov/search$ 

# FUS Funding by United States Government Agencies



1 The first record of funding for focused ultrasound research by the US Federal Government was in 2004.

Sources https://projectreporter.nih.gov/reporter.cfm https://www.usaspending.gov/search

Terms searched: "focused ultrasound", HIFU, histotripsy, LIFU, LIPU, MRgFUS, "ultrasound ablation"

\$881 M

Total US investment in FUS research

## **Clinical trials and MOA research fuel funding**

As shown in the graph above, NIH funding for focused ultrasound has steadily increased over the past decade, with particularly high levels over the last three years. This growth reflects a surge in research reaching the clinical trial stage and a growing interest in diverse mechanisms of action beyond thermal ablation.

The slight decrease in funding seen in 2024 may be attributed to the natural pause between funding cycles, as agencies await results from previously supported studies before committing new resources. This is common in translational research, especially as clinical trials typically progress more slowly than preclinical, bench-based studies.

# Reimbursement





#### Overview

In today's healthcare landscape, insurance reimbursement is essential for patient access and the adoption of innovative technologies like focused ultrasound. Since very few patients are able—or willing—to pay out-of-pocket for treatment, coverage by government or private insurers plays a pivotal role in bringing new procedures into routine clinical practice.

However, reimbursement is far from a simple transaction. It's not just about submitting a bill and receiving payment. Instead, it involves a complex system of policies, coding structures, and payer-specific processes. As many patients and physicians know firsthand, navigating this system can be challenging.

Because insurers in many countries require preauthorization, and coverage often varies by region, we strongly encourage patients to verify coverage with their insurer before undergoing treatment. Despite these complexities, there is good news: focused ultrasound is now reimbursed for several conditions in many parts of the world.

In the United States, reimbursement is available—at varying levels—for focused ultrasound treatments for bone metastases, essential tremor, Parkinson's disease, uterine fibroids, and prostate cancer. The reimbursement landscape in Europe is more fragmented.

While the path to reimbursement can be complex, the growing number of approved and covered focused ultrasound treatments worldwide reflects a positive trajectory that continues to open doors for more patients to benefit from this innovative technology.

To view this chapter in an interactive format, please visit: www.fusfoundation.org/the-technology/sotf-insurance-coverage

## X. Reimbursement

- X. 2 Overview
- X. 3 Global and US Reimbursement Levels

## **Global Insurance Coverage**

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- X. 5 By Region
- X. 8 By Country

#### **US Insurance Coverage**

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- X.10 States Providing Coverage
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Global and US Reimbursement Levels

2024

## Reimbursement

18

**Countries offer some level of reimbursement** 

Indications worldwide have regulatory authorizations

42%

have reimbursement

have reimbursement in at least one country

Indications have US FDA authorizations

**50**%

have reimbursement

6 indications are insured in some states

### About Reimbursement

In healthcare, reimbursement refers to payment for services provided after a medical encounter, including office visits, diagnostic tests, imaging, and procedures. Unlike most industries, healthcare providers are typically paid only after the service has been delivered, which adds complexity to the system.

After a physician or healthcare provider performs a procedure in a hospital or clinic, a claim is submitted to a payer, which may be a private insurance company, a self-funded health plan, or a government agency. The payer may reimburse the provider, healthcare facility, or patient for all or part of the treatment cost based on rules and coverage policies.

However, the process is far from straightforward. Payers do not automatically reimburse every procedure. Many treatments require prior authorization, meaning the provider must obtain approval before delivering the service to ensure the possibility of payment.

Before agreeing to cover a new treatment or procedure, payers typically require robust evidence that it is safe, at least as effective as the standard of care, and cost-effective, either immediately or over time. Payers also carefully analyze clinical outcomes and provider costs data to inform their coverage decisions.

In this environment, securing reimbursement is critical to making innovative treatments—like focused ultrasound—widely accessible to patients.

## Indications reimbursed

Number by region

- 6 North America
- 15 Europe
  - 6 Asia
  - 7 Oceania
  - 5 Middle East

# Insurance Coverage by Region\*

-					
Indications	North America	Europe	Asia	Oceania	Middle East
ВРН		France Germany	Singapore	Australia	Saudi Arabia
Bone metastases	United States <sup>1</sup>	Germany Italy <sup>2</sup>	Malaysia South Korea	*** Australia	Israel Saudi Arabia
Breast tumors, benign		Germany <sup>3</sup>			
Breast tumors, malignant		Germany <sup>3</sup>			
Desmoid tumors		Germany <sup>3</sup>			
Essential tremor	Canada <sup>4</sup> United States <sup>1</sup>	Denmark Germany Italy² The Netherlands Switzerland United Kingdom	Japan	Australia	Israel
Glioblastoma		France <sup>5</sup>			
Osteoid osteoma		Germany Italy <sup>2</sup>			
Pain, neuropathic		Germany Italy <sup>2</sup> Switzerland			israel
Pancreatic tumors		Germany <sup>3</sup>			
Parkinson's dyskinesia	United States <sup>1</sup>				

<sup>\*</sup> All coverage decisions are conditional. The most current policy documents from the individual insurers should be referenced for a complete description.

<sup>1</sup> A detailed analysis of government and private coverage status in individual US states is available on pages X.10–X.17 of this section.

<sup>2</sup> In Italy: Essential tremor and TDPD are covered in Abruzzo, Lombardia, and Sicily. Neuropathic pain is covered in Milan. Bone metastases and osteoid osteoma are covered in Abruzzo, Emilia Romagna, Lazio, and Lombardia. Uterine Fibroids are covered by all regions that provide "essential levels of assistance": Abruzzo, Basilicata, Emilia Romagna, Lazio, Lombardy, Marche, Tuscany, and Umbria.

<sup>3</sup> In Germany: Codes that are not specific to FUS procedures, but can be used to bill for them.

<sup>4</sup> In Canada, essential tremor and uterine fibroids are covered only in the province of Ontario.

<sup>5</sup> In France: Reimbursement of SonoCloud-9 clinical trials. Expires 12/19/2029.

# Insurance Coverage by Region\* continued

Indications	North America	Europe	Asia	Oceania	Middle East
Parkinson's tremor	United States <sup>1</sup>	Germany  Italy <sup>2</sup> Switzerland	Japan		Israel
Prostate cancer	United States <sup>1</sup>	France Germany Switzerland United Kingdom	Japan Singapore South Korea	Australia Australia	Saudi Arabia
Thyroid nodule		Germany <sup>3</sup>			
Uterine fibroids	Canada <sup>4</sup> United States <sup>1</sup>	Germany Italy <sup>2</sup>	China  Malaysia  South Korea  Vietnam	Australia Australia	Israel Saudi Arabia
Varicose veins		Germany <sup>3</sup>			

<sup>\*</sup> All coverage decisions are conditional. The most current policy documents from the individual insurers should be referenced for a complete description.

<sup>1</sup> A detailed analysis of government and private coverage status in individual US states is available on pages X.10–X.17 of this section.

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<sup>4</sup> In Canada, essential tremor and uterine fibroids are covered only in the province of Ontario.

<sup>5</sup> In France: Reimbursement of SonoCloud-9 clinical trials. Expires 12/19/2029.

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# Insurance Coverage by Country\*

	BPH	Bone metastases	Breast tumors, benign	Breast tumors, malignant	Desmoid tumors	Essential tremor	Glioblastoma	Osteoid osteoma	Pain, neuropathic	Pancrea tumors
th America										
Canada <sup>4</sup>										
United States <sup>1</sup>										
ope										
Denmark										
France							<b>5</b>			
Germany			<b>3</b>	3	■3					3
Italy <sup>2</sup>										
The Netherlands										
Switzerland										
United Kingdom										
China										
Japan										
Malaysia										
Singapore										
South Korea										
Vietnam										

<sup>\*</sup> All coverage decisions are conditional. The most current policy documents from the individual insurers should be referenced for a complete description.

<sup>1</sup> A detailed analysis of government and private coverage status in individual US states is available on pages X.10–X.17 of this section.

<sup>2</sup> In Italy: Essential tremor and TDPD are covered in Abruzzo, Lombardia, and Sicily. Neuropathic pain is covered in Milan. Bone metastases and osteoid osteoma are covered in Abruzzo, Emilia Romagna, Lazio, and Lombardia. Uterine Fibroids are covered by all regions that provide "essential levels of assistance": Abruzzo, Basilicata, Emilia Romagna, Lazio, Lombardy, Marche, Tuscany, and Umbria.

<sup>3</sup> In Germany: Codes that are not specific to FUS procedures, but can be used to bill for them.

<sup>4</sup> In Canada, essential tremor and uterine fibroids are covered only in the province of Ontario.

<sup>5</sup> In France: Reimbursement of SonoCloud-9 clinical trials. Expires 12/19/2029.

# Insurance Coverage by Country\* continued

	Parkinson's dyskinesia	Parkinson's tremor	Prostate cancer	Thyroid nodules	Uterine fibroids	Varicose veins		
th America								
Canada <sup>4</sup>								
United States <sup>1</sup>								
ope								
Denmark								
France								
Germany		=		3		3		
Italy <sup>3</sup>		-						
The Netherlands								
Switzerland								
United Kingdom								
1								
China								
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Malaysia								
Singapore								
South Korea								
Vietnam								
ania								
Australia								
dle East								
Israel		-			-			
Saudi Arabia								

- \* All coverage decisions are conditional. The most current policy documents from the individual insurers should be referenced for a complete description.
- 1 A detailed analysis of government and private coverage status in individual US states is available on pages X.10–X.14 of this section.
- 2 In Italy: Essential tremor and TDPD are covered in Abruzzo, Lombardia, and Sicily. Neuropathic pain is covered in Milan. Bone metastases and osteoid osteoma are covered in Abruzzo, Emilia Romagna, Lazio, and Lombardia. Uterine Fibroids are covered by all regions that provide "essential levels of assistance": Abruzzo, Basilicata, Emilia Romagna, Lazio, Lombardy, Marche, Tuscany, and Umbria.
- 3 In Germany: Codes that are not specific to FUS procedures, but can be used to bill for them.
- 4 In Canada, essential tremor and uterine fibroids are covered only in the province of Ontario.
- 5 In France: Reimbursement of SonoCloud-9 clinical trials. Expires 12/19/2029.

# Insurance Coverage in the United States

# Positive trends in US reimbursement



Over the past five years, U.S. reimbursement for focused ultrasound treatments has steadily increased. While progress has been modest for conditions like prostate cancer and tremor-dominant Parkinson's disease, the most significant gains have been seen in essential tremor.

In 2019, only about 25% of the insured population had coverage for essential tremor treatments. Today, that number has grown to more than 70%, helping to drive a sharp rise in procedure volume from just over 1,000 treatments in 2019 to more than 6,000 in 2024.

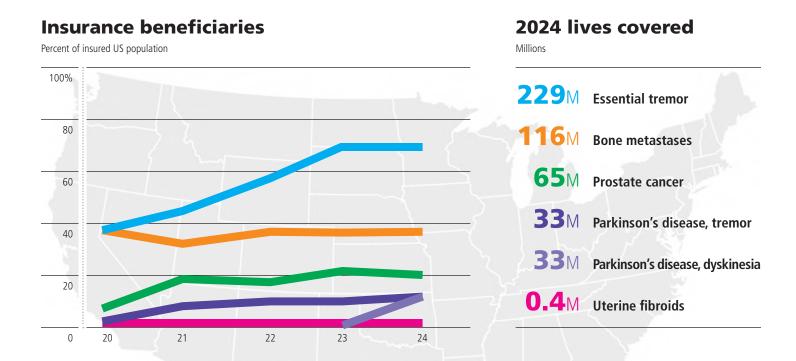
As both awareness and insurance coverage continue to expand, we anticipate ongoing growth in the number of patients benefiting from focused ultrasound therapies.

## **States providing coverage**

Number of states + Washington, DC

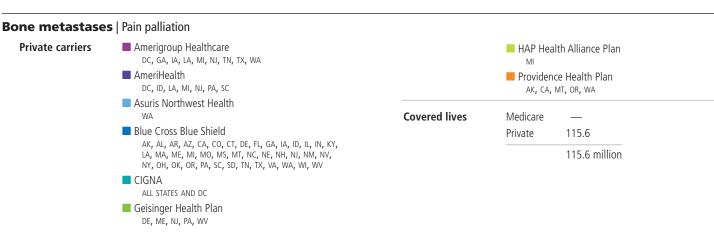
<b>E</b> 4		
<b>3</b> I	Bone	metastases

7 Uterine fibroids



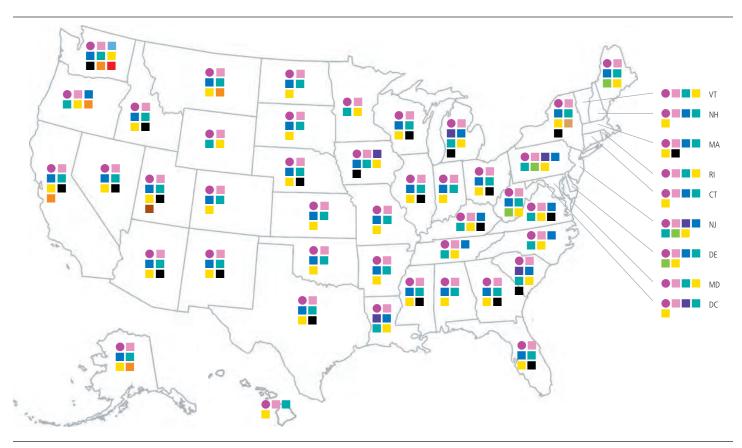
# $Bone\ metastases\ |\ {\tt Pain\ palliation}$





<sup>\*</sup> All coverage decisions are conditional. The most current policy documents from the individual insurers should be referenced for a complete description.

## Essential tremor



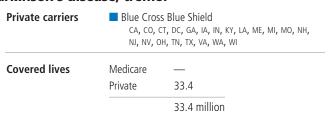


<sup>\*</sup> All coverage decisions are conditional. The most current policy documents from the individual insurers should be referenced for a complete description.

# Parkinson's disease, dyskinesia



#### Parkinson's disease, tremor



<sup>\*</sup> All coverage decisions are conditional. The most current policy documents from the individual insurers should be referenced for a complete description.

# Parkinson's disease, tremor



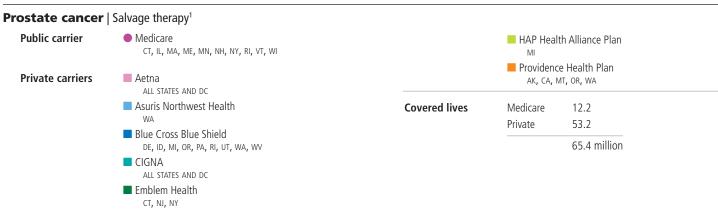
## Parkinson's disease, tremor



<sup>\*</sup> All coverage decisions are conditional. The most current policy documents from the individual insurers should be referenced for a complete description.

# Prostate cancer | Salvage therapy<sup>1</sup>





<sup>\*</sup> All coverage decisions are conditional. The most current policy documents from the individual insurers should be referenced for a complete description.

<sup>1</sup> Local treatment for recurrent prostate cancer following radiation therapy

# Uterine fibroids



#### **Uterine fibroids**



<sup>\*</sup> All coverage decisions are conditional. The most current policy documents from the individual insurers should be referenced for a complete description.

# Focused Ultrasound Foundation





#### Foundation Overview

The Foundation is a unique medical research, education, and advocacy organization created as the catalyst to accelerate the development and adoption of focused ultrasound and thereby reduce death, disability, and suffering for countless patients. To achieve its goals, the Foundation utilizes an approach that is entrepreneurial, high-impact, high-performance, market-driven, and results-oriented.

By identifying opportunities and overcoming barriers, the Foundation is shortening the time from laboratory research to widespread treatment.

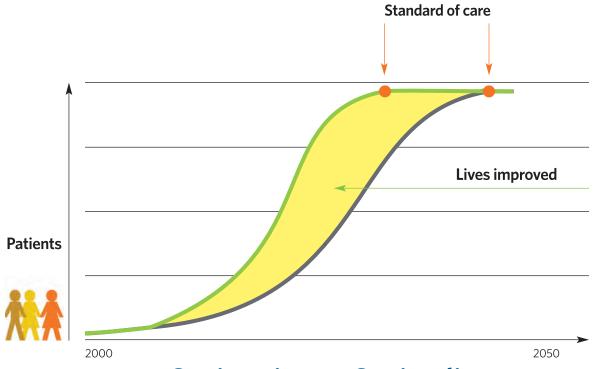
#### Major initiatives include

- Influencing the direction of the field, setting research priorities, and creating an urgent, patient-centric culture
- Providing resources, both human and financial capital
- Fostering collaboration and stimulating innovation
- Creating, aggregating, and sharing knowledge
- Cultivating the next generation of clinicians and scholars
- Increasing awareness

The Foundation has a robust research program that organizes, conducts, and supports clinical trials and preclinical laboratory studies emphasizing brain disorders, oncology, and immunotherapy. It is the world's largest nongovernmental source of focused ultrasound research funding.

Our mission is to accelerate the development and adoption of focused ultrasound as a mainstream standard of care. Through hard work, calculated risk-taking, and innovation, we are committed to ensuring that focused ultrasound is widely available in the shortest time possible.

## fusfoundation.org



Saving time = Saving lives

# FUS Partners' Role in the Industry

To help accelerate the transition of the field from a primarily science-based research environment to a commercialization and patient treatment space focused on marketing and sales, the Foundation created FUS Partners in April of 2018. The FUS Partners program serves as a galvanizing force in facilitating the rapid success of the commercial stakeholder segment of the focused ultrasound ecosystem and thus helps speed the time from laboratory research to widespread adoption and utilization of the technology.

By its reputation as a trusted, independent, unbiased third party with an extensive network, FUS Partners is uniquely positioned to advance the field significantly and effectively by identifying commercial opportunities, connecting stakeholders, and enhancing the flow of information between strategic and financial investors and focused ultrasound companies.

#### Goals

- Produce a quantum change in the adoption rate of focused ultrasound as a mainstream standard of care
- Grow and rationalize the device manufacturers' segment of the focused ultrasound community by taking a holistic approach to the support of key stakeholders within the ecosystem

#### **Activities**

#### **Regulatory & Reimbursement**

- Engage with FDA, CMS, and commercial payers to inform them of the state of the field and obtain guidance for regulatory approvals and reimbursement
- Connect manufacturers with regulatory and reimbursement consultants
- Host educational webinars and workshops for manufacturers on best practices and strategies for coverage, reimbursement, coding and billing, etc.

### **Financial & Human Capital**

- Connect institutional, strategic, and individual investors with manufacturers in need of financing, facilitate due diligence, and prepare investor relations materials
- Support focused ultrasound companies in attracting and hiring talent

#### **Strategic Partnerships & Technology Transfer**

- Connect manufacturers with academic research laboratories, strategic sponsors, and other manufacturers of focused ultrasound and related equipment and components
- Facilitate the growth, consolidation, and leapfrog phases of the industry

#### **Advocacy**

- Inform regulatory agencies, payers, and MedTech advocacy organizations about focused ultrasound
- Connect and engage focused ultrasound manufacturers with advocacy organizations

#### **Intellectual Property**

- Track the field of focused ultrasound IP and US Patents issued
- Educate academic researchers and focused ultrasound companies about why, what, and how to patent
- Connect researchers and focused ultrasound companies with intellectual property consultants

The Focused Ultrasound Foundation wishes to thank its exceptional Board of Directors and Council for their steadfast dedication to helping make focused ultrasound a clinical reality and improving the lives of millions of patients.

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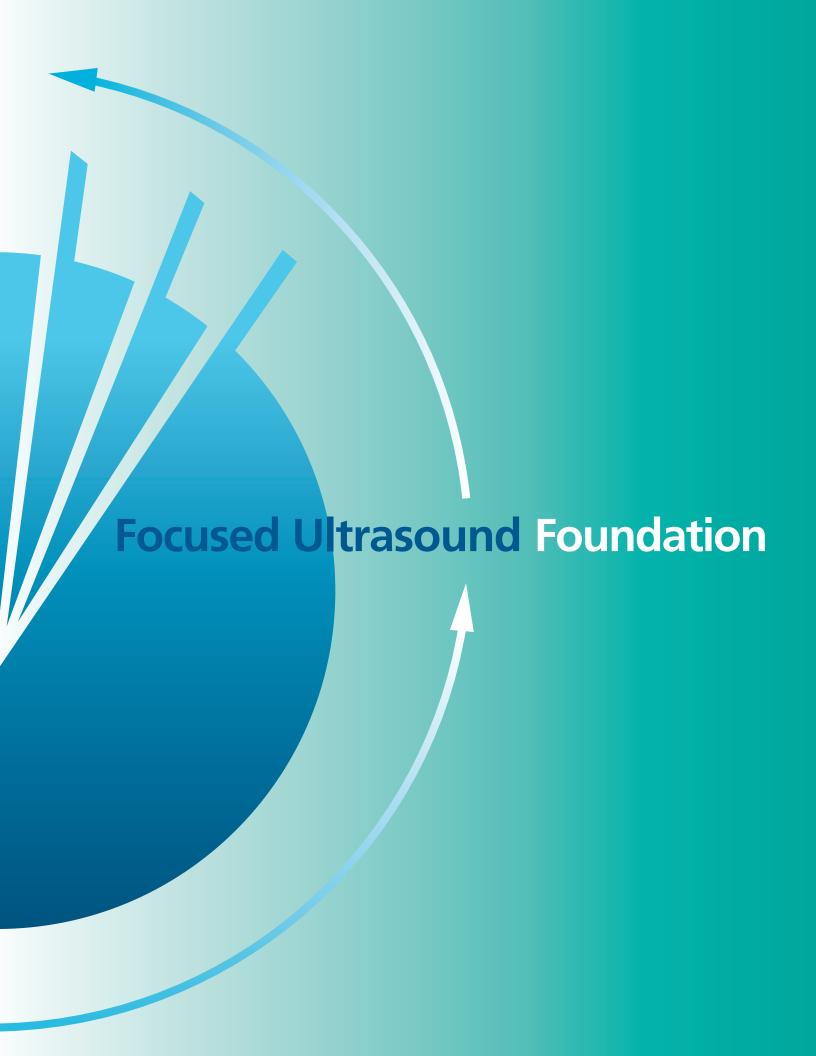
**The Focused Ultrasound Foundation** encourages widespread distribution of the *2025 State of the Field Report* in part or its entirety. Inquiries for reproduction can be directed to Emily White at ewhite@fusfoundation.org.

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The Focused Ultrasound Foundation strives to provide the most accurate information possible and therefore works proactively with the manufacturers and research sites to collect the most current data available in advance of the release of this publication. This report is based on data through December 31, 2024. The Focused Ultrasound Foundation assumes no responsibility for any errors or omissions, as every precaution has been taken to verify the accuracy of the information contained herein. No liability is assumed for damages that may result from the use of information contained within. If you note something out of date or inaccurate, please submit the new information/updates to: info@fusfoundation.org.







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