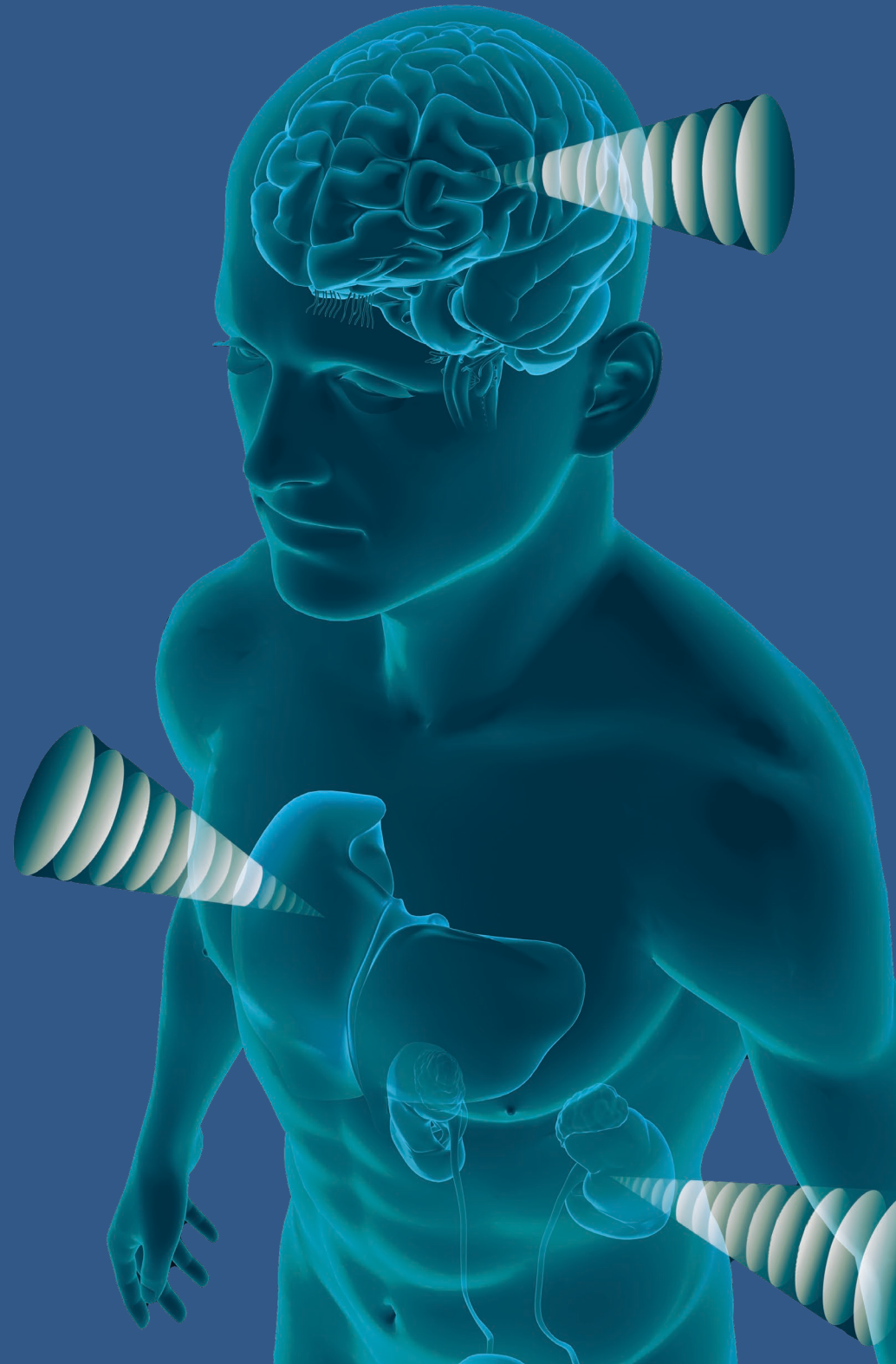




UK FOCUSED ULTRASOUND  
FOUNDATION

# The Power of Sound in Medicine Case for Support



## INTRODUCTION

The UK Focused Ultrasound Foundation was created in 2021 and founded as a direct result of the successful 15-year history of the Focused Ultrasound Foundation in the United States, headquartered in Virginia.

### Our Vision

Our vision is that focused ultrasound will be used to improve the quality of life and longevity of millions of patients with serious medical conditions in the shortest time possible.

### Our Mission

The Foundation's mission is to accelerate the development of new applications of focused ultrasound and its widespread adoption as a standard of care across the UK.

### Our Values

#### Patient Centric

We are uncompromisingly, passionately, and obsessively committed to decreasing death, disability and suffering for patients with serious medical disorders.

#### Catalytic

We are a nimble, potent organisation, harnessing a contagious enthusiasm to instill similar energy in others to precipitate change.

#### Entrepreneurial

We believe that we can create a reality from an imagined future through human action in an environment where our accomplishments will exceed the resources available.

#### Pioneering

We relentlessly pursue excellence in all of our activities through hard work, risk-taking, and innovation.



# What is Focused Ultrasound?

Focused ultrasound is a non-invasive therapeutic technology that is transforming the treatment of many medical disorders by using ultrasonic energy to target tissue deep in the body without incisions or radiation.

Focused ultrasound is the marriage of two **innovative** technologies:

## Imaging Technology

Used to identify and target the tissue to be treated, guide and control the treatment in real time, and confirm the effectiveness of the treatment. For example, ultrasound, MRI, X-ray and neuronavigation.



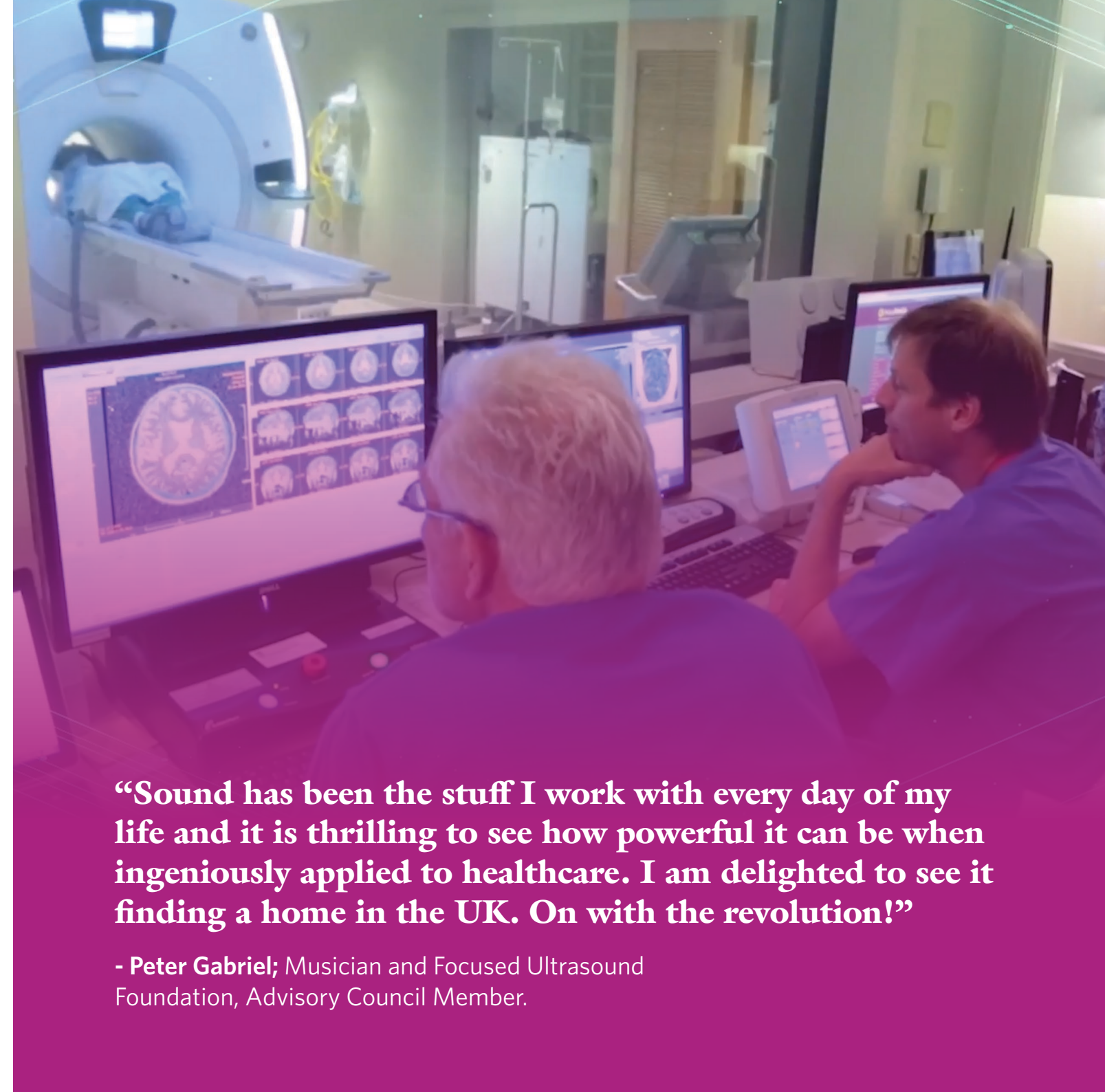
## Focused Ultrasound

Provides the energy to treat tissue deep in the body precisely and non-invasively.

**“Focused ultrasound today has been called medicine’s best kept secret. It’s where magnetic resonance (MR) imaging was in its evolution 30 years ago – at that time, nobody had ever heard of MR scanning; but today, virtually everybody we know has had an MR scan, or MRI, and it has revolutionized diagnosis.**

**Focused ultrasound is where MR scanning was 30 plus years ago, but it’s a therapeutic rather than diagnostic technology and it’s transforming medicine.”**

- **Neal Kassell, MD**; Founder of the Focused Ultrasound Foundation, Trustee of the UK Focused Ultrasound Foundation.



**“Sound has been the stuff I work with every day of my life and it is thrilling to see how powerful it can be when ingeniously applied to healthcare. I am delighted to see it finding a home in the UK. On with the revolution!”**

- **Peter Gabriel**; Musician and Focused Ultrasound Foundation, Advisory Council Member.

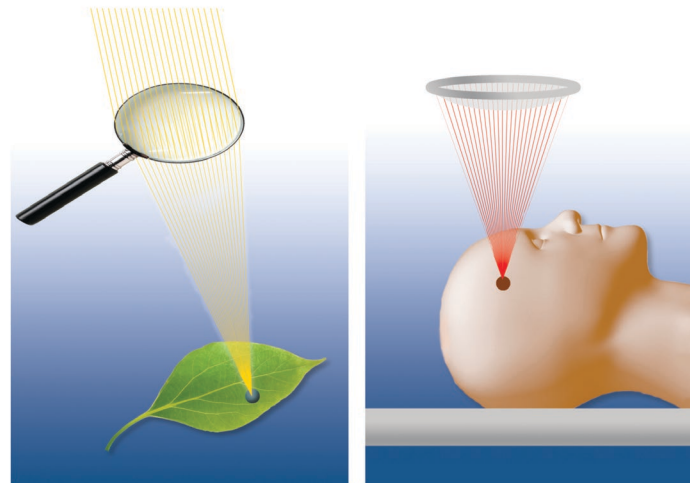
## THE TECHNOLOGY

### How Does it Work?

If you imagine a magnifying glass to focus beams of sunlight on a single point to burn a hole in a leaf, focused ultrasound uses an acoustic lens to concentrate multiple intersecting beams of ultrasound on a target deep in the body with extreme precision and accuracy.

Where each of the individual beams passes through the tissue, there is no effect. But, at the focal point, the convergence of the multiple beams of focused ultrasound energy results in many important biological effects, creating the possibility of treating a variety of medical disorders.

Focused ultrasound treatments can be performed on an outpatient basis, require no incisions, and can result in minimal discomfort and few complications, allowing for rapid recovery.



**“In focused ultrasound, I have found no other cause that could potentially save so many lives.”**

- John Grisham, #1 New York Times Bestselling Author and US Focused Ultrasound Foundation Board Member

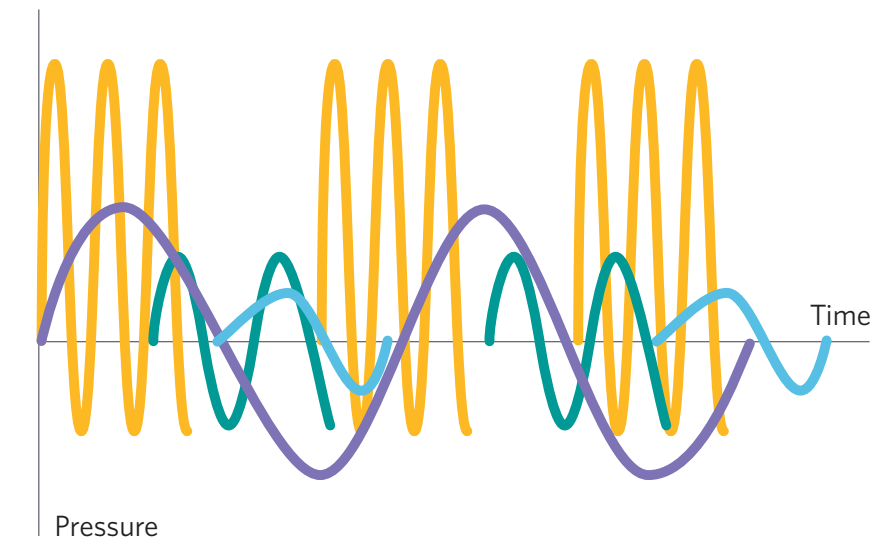
### Types of Application

Varying ultrasound power – for example, utilising continuous versus pulsing modes, and changing the total treatment time – can create different ultrasound applications. These applications are categorized based on the type of energy they deliver – thermal or mechanical – and whether the effects of treatment 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 currently used most frequently in the clinic, and produces permanent effects.

### Sound Waves Differ Depending On Their Application

- Histotripsy
- Hyperthermia
- Nonthermal
- Thermal ablation



### Types of Treatable Indications

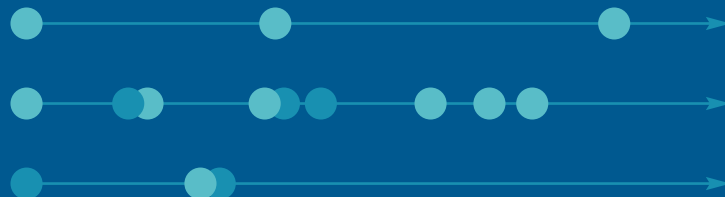
There are approximately 170 treatable types of disease that focused ultrasound can and will support through continued investment in research and clinical trials.

These include but are not limited to:

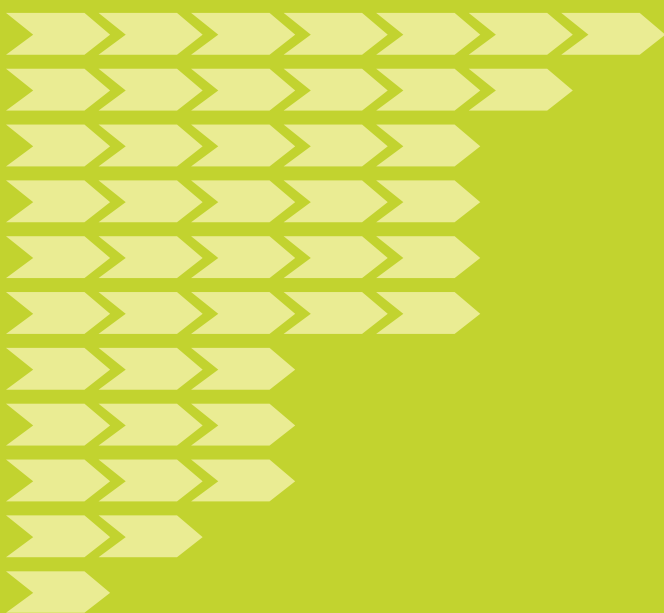
Brain Cancers  
Pancreatic Cancer  
Bone Metastases  
Prostate Cancer  
Kidney Tumors  
Liver Cancer  
Breast Tumors  
Arthritis  
Glaucoma  
Thyroid Nodules  
Thyroid Cancer  
Depression & OCD  
Essential Tremor  
Parkinson's Disease  
Alzheimer's Disease  
Uterine Fibroids  
Endometriosis  
Twin-Twin Transfusion Syndrome

GLOBAL  
IMPACT  
TO DATE

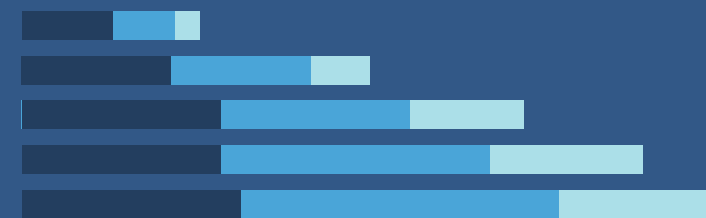
170  
Treatable  
Indications



\$393M  
FUS Company  
Investment  
in 2021



52,034  
Oncology Treatments  
in 2021



338  
Research Sites



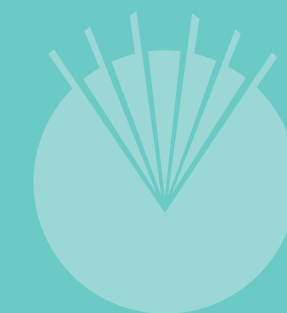
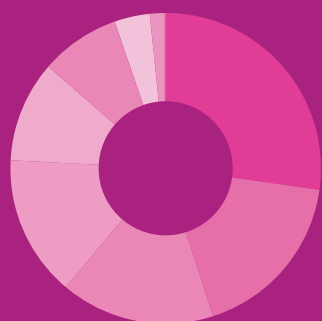
62  
Unique  
Mechanisms of  
Action



92,365  
Patient Treatments  
in 2021



32  
Regulatory  
Approved  
Indications



58  
Manufacturers

805  
Treatment Sites

# Our Footprint in the UK

## Research Sites

- Dundee**  
Dundee University
- Edinburgh**  
University of Edinburgh
- Leeds**  
Leeds University
- Oxford**  
Oxford University
- London**  
Imperial College  
King's College  
University College  
St. Mary's Hospital  
Charing Cross Hospital  
University College London Hospitals
- Southampton**  
Southampton University Hospitals
- Plymouth**  
University of Plymouth

## Centres of Excellence

- Sutton**  
Institute of Cancer Research and  
The Royal Marsden Hospital

## FUS Industry

- Oxford**  
OxSonics Ltd.  
OrthoSon Ltd.
- Dorchester**  
Precision Acoustics Ltd.

## Clinical Sites

- Dundee**  
Ninewells Hospital and Medical School
- Leeds and Newcastle**  
Leeds Teaching Hospitals and  
The Newcastle Upon Tyne Hospitals
- Birmingham**  
Birmingham Heartlands Hospital  
Priory Hospital
- Oxford**  
Churchill Hospital
- London**  
Bupa Cromwell Hospital  
King Edward VII's Hospital  
St. Mary's Hospital  
Charing Cross Hospital  
University College London Hospitals
- Guildford**  
Whiteley Clinic
- Basingstoke**  
Basingstoke and North Hampshire Hospitals  
BMI The Hampshire Clinic
- Southampton**  
Southampton University Hospitals
- Dorchester**  
Winterbourne Hospital





# UK TRANSLATION

## Pillars of Focus

The Foundation is a unique medical research, education, and advocacy organisation created as the catalyst to accelerate the development and adoption of focused ultrasound and thereby reduce death, disability, and suffering for countless patients.



## Focus on Action



## Current Availability and Access

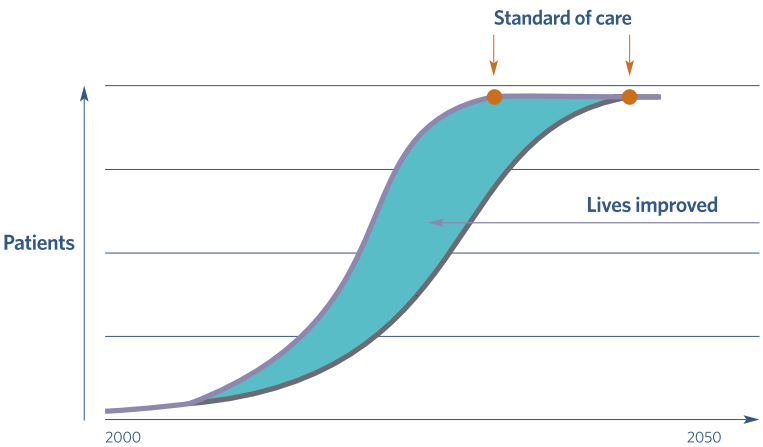
In the UK, the National Institute for Health and Care Excellence (NICE) provides Health Technology Assessments for new clinical procedures, which are used as guidance for reimbursement by the National Health Service (NHS). However, a positive NICE guidance does not automatically result in NHS coverage. Since April 2021, focused ultrasound treatment for both prostate cancer and essential tremor has NHS coverage and NICE approval.

Indication/Treatment guidance	NICE use	NHS coverage
Essential tremor	●	●
Parkinson’s tremor	●	●
Prostate cancer	●	●
Uterine fibroids—US guided	●	●
Uterine fibroids—MRI guided	●	●
Breast fibroadenoma	●	●
Thyroid nodules	●	●

● Approved ● NICE use - research only NHS coverage - discussion only, no decision yet ● Not approved

To date, FUS treatments for other medical disorders, such as pancreatic cancer, brain tumours, Parkinson’s disease, rectal and pelvic cancers and varicose veins are limited to either private healthcare expenses or grant-funded research in the UK.

## Saving time = Saving lives





## CASE STUDY

### Focus on Prostate Cancer Paul Sayer's Story

It was an agonising decision – and one faced by thousands of British men each year. Paul Sayer had been given the devastating news that he had prostate cancer. It was aggressive – and his surgeon said the best chance was a major operation.

They could get him into theatre within ten days. And yet, possibly more frightening than the cancer itself was the possibility that the procedure would render him incontinent and impotent – for the foreseeable future at least.

The alternative, he was told, was radiotherapy. But there were similar risks and less chance of a cure.

Paul mentioned to his GP that he had read about another option: high-intensity focused ultrasound (HIFU). The scalpel free treatment involves energy beams that blast tumour cells with pinpoint accuracy. Afterwards, few patients suffer the incontinence or sexual problems that often go hand-in-hand with a more major operation.

**‘The way I understood it, HIFU attacks the tumour directly without damaging anything else. And because of this, there was less chance of damaging the nerves round the prostate that control continence and erections, which appealed to me.’**

Paul decided to contact and meet the HIFU surgeon he'd read about. Professor Hashim Ahmed, a consultant surgeon at Imperial College Healthcare NHS Trust, told him he was ‘a perfect candidate’ for HIFU. Armed with this information, he asked his GP to refer him for treatment.

‘My GP hadn't heard of HIFU for prostate cancer, but agreed.’

The procedure was carried out in July 2018. Paul says:

**‘I was out of hospital that night. I had a catheter for a week and after that, I just got on with my life. I didn't suffer any complications. And, although I'm having regular tests to monitor things, the cancer is gone.’**

Surgery often leaves men with long-term erectile dysfunction, and four in ten will still need an incontinence pad after a year. Whereas HIFU could save patients from such complications.

## Thousands of men in the UK are not so lucky.



# Transforming Medicine through the Power of Sound

Focused ultrasound can be performed nearly everywhere in the body. One place of particular interest and where it can create significant medical advantage is in the brain.

Additional ultrasound treatment regimens are currently under investigation in preclinical experiments 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, and treated tissue reverts to normal function within a few hours.

The novel procedure gets drugs into the brain by overcoming a major hurdle: the blood-brain barrier, a thin protective layer of specialized cells lining the very small blood vessels guarding the human body's most privileged organ. It keeps out the bad stuff, such as pathogens, but it also prevents potentially useful things from

getting in. As a result, virtually all medications for conditions such as brain cancer and neurodegenerative diseases are effectively unable to reach the site where they are needed most.

**Focused ultrasound is “science-fiction medicine that is rapidly becoming non-fiction,” says Brad Wood, Director of the National Institutes of Health Center for Interventional Oncology.**

Numerous teams around the world have now shown that opening the blood-brain barrier with ultrasound is safe and feasible, so the next hurdle is proving the medical benefits.

Preclinical research for treating Alzheimer's Disease with focused ultrasound also has shown encouraging results. For starters, simply opening the blood-brain barrier appears to have positive cognitive effects such as improving memory function.

Consider the effects of Alzheimer's: The disease and its related forms of dementia affect 57 million people worldwide, a number expected to triple by 2050. Hundreds of drugs for Alzheimer's have failed in clinical trials at a cost of billions of dollars. Some researchers speculate that's because they don't get to the brain in adequate concentrations. Providing high doses by conventional means would require potentially toxic doses. An obvious benefit of focused ultrasound is that because the dose is targeted to the brain, lower quantities would be effective.

**“Many experts believe this therapeutic technology will one day revolutionize brain medicine for a range of impossible or hard-to-cure conditions, from brain cancer to Alzheimer's, Parkinson's, and ALS.” National Geographic Article; Can Ultrasounds Deliver Drugs to our Brains? May 2022**

**“For many experts and patients, approved focused ultrasound treatments can't come soon enough.”**

- Victoria Jaggard, National Geographic

# Our Governance

The UK Focused Ultrasound Foundation wishes to thank its exceptional Trustees and Advisory 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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**“After working in the field for over 20 years, my hope is that my peers and I are creating a legacy that will make focused ultrasound a common practice for treatment and improved standard of patient care across the UK.”**

**- Professor Gail ter Haar, The Institute of Cancer Research**

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To learn more about the UK Focused  
Ultrasound Foundation please contact:

**Lacie Riseborough**

Director of Strategy & Impact

[lriseborough@ukfusf.org](mailto:lriseborough@ukfusf.org)

+44 7907 467 881



**[www.ukfusf.org](http://www.ukfusf.org) | 10 Queen Street Place, London, EC4R 1BE**

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Registered Charity Number: 1193966