

Overview

The Foundation's mission is to improve the lives of millions of people worldwide afflicted with a wide variety of serious medical disorders in the shortest time possible – "saving time, saving lives."

From a handful of initial potential indications and no approved therapies, there are now over 180 indications in many body systems, 30+ mechanisms of action, and a growing number of therapies with regulatory approval and reimbursement.

Focused ultrasound is an early-stage, noninvasive alternative or complement to surgery and radiation therapy, a new way to deliver drugs and other therapeutic agents more safely and effectively and enhance cancer immunotherapy. It increases the quality and longevity of life while improving access to care and reducing its cost.

Given the field's exponential advancement, the focused ultrasound (FUS) industry is at an inflection point, reflecting a shift in mindset from "if" focused ultrasound will have a critical place in the therapeutic armamentarium to "when" it will be widely available as a mainstream standard of care. The field is transitioning from a focus on research (science) to commercialization (industry) and patient treatment – the core mission of the Foundation.

To accelerate this transition, the FUS Partners program acts as a galvanizing force to facilitate the commercial success of 80+ industry players globally, which will ultimately shorten the timeline from laboratory research to widespread clinical use.

The Foundation works to serve as a trusted, independent, unbiased third party with an extensive network, making FUS Partners uniquely positioned to significantly advance the field by identifying commercial opportunities, connecting key stakeholders, and enhancing the flow of information between strategic or financial investors and FUS companies.

FUS Partners essentially provides investment banking and management consulting services to industry partners without any fees. It does so because a healthy, thriving FUS industry directly supports the core mission of the Focused Ultrasound Foundation.

Goals

The primary goals of the FUS Partners program are:

- To help the FUS industry ecosystem become more competitive by assisting industry players with business and financing challenges, surfacing best practices, encouraging alliances, and sharing resources
- To produce a step change in the adoption rate of FUS therapeutics as a mainstream standard of care

Activities

FUS Partners provides integral support to the FUS commercial sector by sharing the Foundation's domain expertise and institutional knowledge through a variety of activities:

Regulatory & Reimbursement

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

Financial and Human Capital

- Connect institutional, strategic, and individual investors with manufacturers in need of financing
- Facilitate due diligence and preparing investor relations materials
- Support FUS companies in attracting and hiring talent

Strategic Partnerships & Technology Transfer

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

Advocacy

- Inform regulatory agencies, payers and MedTech advocacy organizations about FUS clinical trials and potential to decrease cost of care while improving quality
- Connect and engage FUS manufacturers with advocacy organizations

Intellectual Property

- Educate academic researchers and FUS companies on why, what, and how to patent
- Connect researchers and FUS companies with intellectual property consultants

FUS Partners does not make investments or provide investment advice and does not receive any compensation for its activities.

FUS Partners encourages donations to the Foundation from involved parties as a way to advance the field and de-risk investments and/or partnerships.

Donations are completely voluntary, and any party may participate in FUS Partners activities regardless of giving status.

Organization

Kevin Passarello, JD, is an advisor to FUS Partners and oversees the program. He is a shareholder of Buchanan Ingersoll & Rooney in Washington, DC, where he focuses on corporate finance and emerging technology companies. He leads the Firm's university technology transfer initiatives and co-chairs its Advanced Technologies Group. Mr. Passarello was the Director of Translational Programs and Development at the Bio-complexity Institute and Initiative at the University of Virginia. A serial entrepreneur, he co-founded venture-backed technology companies in the areas of enterprise software, mobile hardware, and AI in health care, serving in roles including CEO, COO, and general counsel. He also co-founded a private equity management and advisory firm. Kevin has been an entrepreneur-in-residence at the University of Virginia, Virginia Tech, and Virginia Commonwealth University and was an Innovation Fellow in Biocomplexity at Virginia Tech. He holds a JD from Georgetown University Law Center.

Cindy Clark, JD, joined the Foundation in 2023 and serves as Commercial Initiatives and Strategy Director. A serial entrepreneur, she brings over 25 years of successful commercialization experience in the life science industry. Ms. Clark has held executive leadership roles at two public biotech companies, as well as early-stage companies developing drugs, devices, diagnostics, and combination products. She also served as president of the non-profit Center of Innovation for Medical Technology in North Carolina. Throughout her career, she has contributed to the launch of numerous healthcare products and collaboration deals, including several successful exits. Cindy holds a JD from the Washington College of Law.

Philip Keevil, MBA, joined the Foundation in 2018 as an advisor and currently serves as Chair of the UK Foundation. He brings over 40 years of experience in private equity and investment banking. His career includes Chair of the Risk Advisory Group and senior corporate finance roles in London and New York with Citi, S.G. Warburg and Lazard Frères, following his career start at Morgan Stanley. He also served as Chair of the Risk Advisory Group. Mr. Keevil is a member of the Advisory Council of the London Symphony Orchestra, a trustee of its American Foundation, and a Freeman of the City of London. He was also director of BritishAmerican Business, founding member of the Business Advisory Forum at Oxford's Saïd Business School, a governor of the City of London School for Girls, and trustee of St. Bernard's School in New York and St. Andrew's School in Delaware. He holds an MBA with High Distinction from Harvard and BA and MA degrees with honors from Oxford.

Mark Carol, MD, joined the Foundation in August 2020 as senior consultant, contributing to reimbursement and regulatory activities. He previously served as CEO of SonaCare Medical (SCM) for six years. Under his leadership, SCM secured FDA clearance for its focused ultrasound prostate cancer device, obtained C- and CPT codes for the technology, and achieved regulatory authorization in China, along with broader global expansion. Before joining SCM, Dr. Carol spent 20 years in the radiation oncology field and was instrumental in several seminal developments in the field, including intensity-modulated radiation therapy, image-guided radiation therapy, and inverse treatment planning. He also contributed to innovations in frameless and image-guided stereotactic surgery. He holds an MD from the University of Rochester School of Medicine.

Advisory Council

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and CEO of Quest Diagnostics

Focused Ultrasound Foundation

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