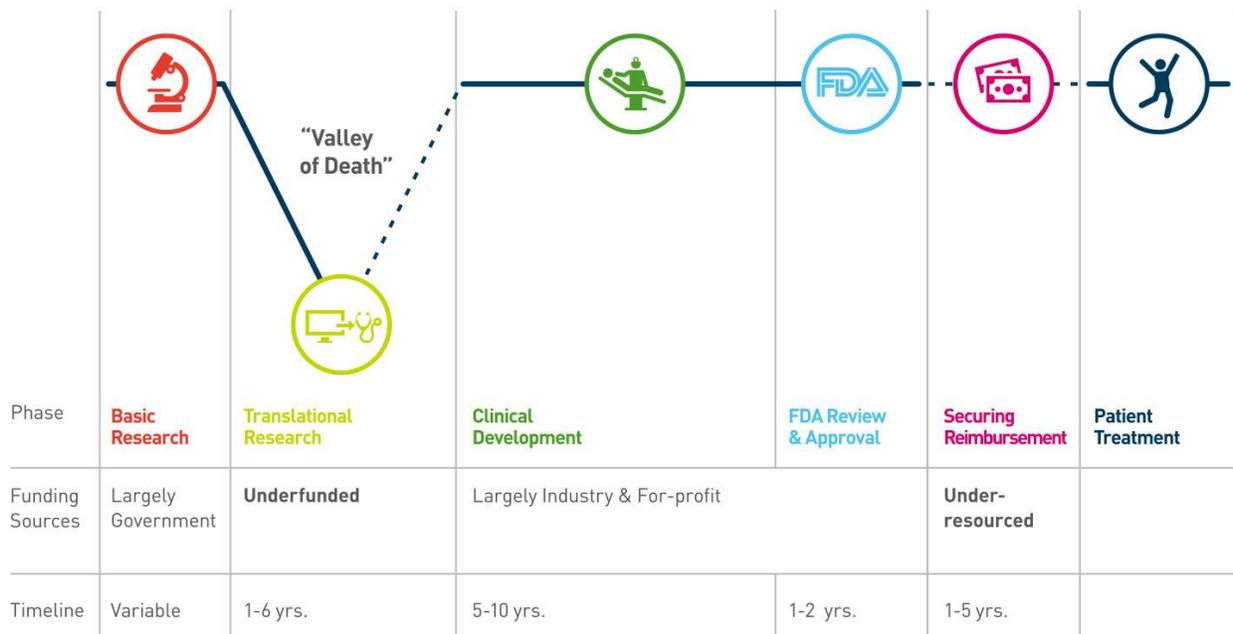


The Role of Philanthropy in Medical Device Development

The Federal Government, through the National Institutes of Health (NIH), often shoulders major funding for initial research in the life sciences. Once the potential of new medical technologies are validated, corporations and venture capitalists are financially motivated to support clinical trials and other critical steps toward commercialization. The transition between such basic research and medical application includes the vital period of translational research.

It is here, in the translational phase, that researchers take risks that require resources (time, funding) to develop basic scientific concepts into revolutionary new clinical approaches for the prevention, diagnosis and treatment of disease. The phase of translational research is traditionally underfunded, and has been referred to as “The Valley of Death.”

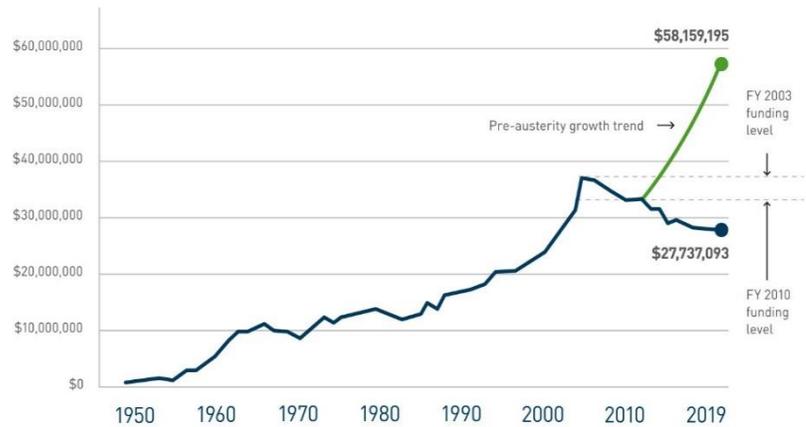


“The Valley of Death” for research and development is widening

In the past decade, federal budget cuts, constrained corporate resources, and an increasingly complex legal and regulatory system have created a risk-averse environment. Since 2004 the budget for the National Institutes for Health (NIH) has decreased by more than 20 percent and the average size of NIH awards has diminished. Meanwhile, FDA review and approval time are increasing.

The medical device industry faces additional hurdles. A 2.3% excise tax on medical device manufacturers went into effect January 1, 2013. Companies are uncertain of future sales, reimbursement levels and intellectual property rights. They are not financially motivated to invest early on if a potential product is unlikely to create higher industry profit than currently available devices. New regulations additionally limit industry's ability to conduct university-based research creating time-consuming barriers.

In this slow turn-around, high-risk climate, venture capitalists are not motivated to commit their funds. Between 2007 and 2013, medical device investments fell by 40 percent. Initial research phase funding has fallen even more dramatically.



NIH Funding in thousands. . NIH funding for medical research and development is on the decline.

Promising treatments and cures are in danger of being abandoned

Today's philanthropists are realizing that to cross the "valley" we need an iconoclastic model. As Bill Gates recently put it:

When you come to the end of the innovations that business and government are willing to invest in, you still find a huge unexplored space of innovation where the returns can be fantastic. This space is a fertile area for what I've called "catalytic philanthropy"...There are innovations out there that could generate earth-shaking returns. But if you're in the private sector, you can't even look at these investments because the returns won't come to the innovator; they'll go to poor people or society generally. The magic of philanthropy is that it throws off that constraint.

"Catalytic philanthropy" can bridge the valley

When engaged in catalytic philanthropy, a cross-sector community, joined by a foundation, uses capitalistic approaches to innovate in systematic ways. Foundations harness the collective power of the public, private and academic trifecta, fostering collaborations and serving as incubators. Because they are independent and neutral third parties, foundations can aggregate and share information, and produce credible outcomes. Foundations can move rapidly and have the flexibility to fund high-risk pilot studies outside the industry roadmap. They can inspire follow-on funding from government, incentivize companies to engage sooner, and engage experts with extensive experience in the regulatory process to ensure a smooth and well-defined strategy toward FDA approval.

Individual donors can turbocharge medical research and development

Compassionate donors have long been involved in propelling medical research. In the early 20th century, it was the unerring vision of John D. Rockefeller that brought the field of molecular biology into being. His foundation's unprecedented investments in other areas, like infectious diseases and psychiatry, shed light on humanity's understanding of physical and mental wellbeing.

Modern pioneers in medical philanthropy include Paul Allen, Michael Milken, Ewing Marion Kauffman and Michael J. Fox. These individuals and their foundations often use the catalytic model to select and fund research projects that will bring new drugs dedicated to specific diseases to market. Of the 60 organizations participating in FasterCures' The Research Acceleration and Innovation Network, 78% report that they partner with biotechnology and pharmaceutical companies.



Partnerships Make Progress. 78% of organizations participating in FasterCures' report that they partner with biotechnology and pharmaceutical companies.

By seeding early wins, these foundations de-risk research and spur further development by industry, improving the chances that new and affordable drugs will be made available to patients.

Medical device research and development is fraught with the same challenges that face drug development: cost, time and regulatory hurdles. Foundations are uniquely positioned to support the early stages of medical device research and the uptake of improved clinical practices using innovative technologies.

Once devices are FDA-approved there are often additional hurdles before insurance companies will cover new treatments. While the "Valley of Death" is underfunded, the process of reimbursement for medical device development is under-resourced – companies are not always prepared to create the additional data insurance companies require. This means that promising technologies that have made it across the Valley of Death to achieve FDA approval might not be adopted into mainstream medicine. Foundations can provide philanthropic support for additional trials and data collection to ensure that FDA-approved treatment options are covered by insurance companies and become broadly available to patients. Foundations can also ensure that the medical community is informed about available treatment options, facilitate training, set standards for patient care, and cultivate the next generation of scientists and clinicians.

Individual gifts have an outsized impact

Private funding for bio-medical research and device development might seem counterintuitive, but medicine is different from other industries—it directly effects quality of life and survival. The public supports the creative process of the medical industry through tax dollars used by the NIH. Outright giving by individual donors is only a small share of overall spending on medical research and development in the United States. However, individual gifts are growing, and the flexibility of these funds has an outsized impact on medical discovery.

Private donors are free from the restraints of shareholders, voters and peer-review protocols. Individual gifts can be

used by foundations to front resources for high-risk, early stage proof of concept and pilot studies. Donors can advance the cause and move the needle where the political will and corporate motivation are lacking. Donors can accelerate development and adoption of medical devices and allow more patients to be treated more effectively at a lower cost, improving lives and feeding the medical economy which will generate taxes to support additional causes.

The Focused Ultrasound Foundation is a model for catalytic philanthropy: collaboration is key

The Focused Ultrasound Foundation exemplifies the success that can be achieved through cross-sector collaboration. Founded in 2006, the Foundation is dedicated to accelerating the development and adoption of focused ultrasound, an early-stage, noninvasive therapeutic technology with the potential to revolutionize medicine.

Much like a magnifying glass focusing multiple beams of light on a single point, focused ultrasound concentrates intersecting beams of ultrasound energy with extreme precision on a target as small as a grain of rice deep in the body. As individual beams pass through healthy tissue, there is no effect. But at the focal point, where the beams combine, the resulting ultrasound energy does its healing work. The possibilities of focused ultrasound include treatment of a range of cancers, neurological diseases, pain management, and even psychiatric disorders.

Since its inception, the Focused Ultrasound Foundation has made targeted investments in research, education and advocacy. The Foundation's role is essential to maintaining momentum in the field. Towards this end, it is:

- Supporting critical research by filling gaps in public and private funding through the engagement of compassionate donors.
- Helping to identify needs and drive improvements to the technology.
- Educating clinicians about benefits to their practice and patients.
- Increasing the pace of the regulatory process.
- Paving the pathway for widespread reimbursement.

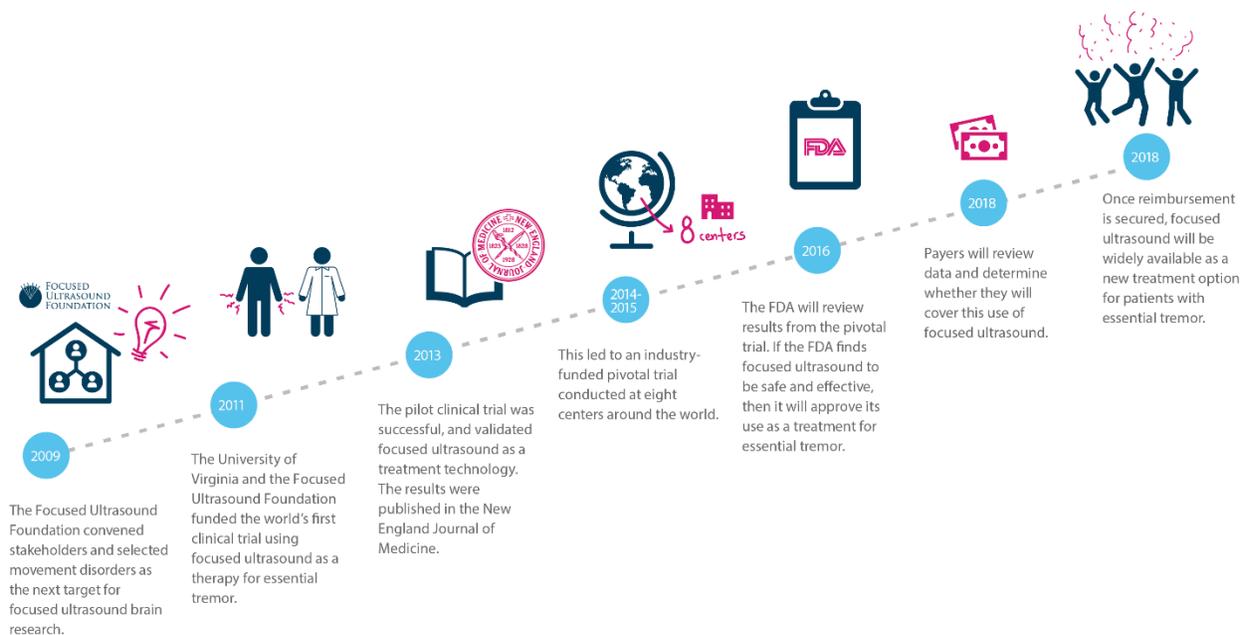
As stated by Dr. Neal Kassell, Founder, "The fuel for innovation is collaboration, and we are pursuing a variety of initiatives to break down silos of secrecy and enable individuals and organizations to work together."

The Foundation's model of using philanthropic capital to seed the highest risk, early stage research and encourage follow-on funding from other sources has been incredibly successful. To date, the Foundation has helped to fund 76 research projects, spending \$4.8 million on completed projects which has led to \$22.5 million in follow-on funding from the NIH, the



Follow-on Funding. The Focused Ultrasound Foundation's investment of \$4.8 million in completed projects has resulted in \$22.5 million in follow-on funding from government, industry, and other philanthropies.

Michael J. Fox Foundation for Parkinson's Research, the Epilepsy Foundation of America and the Binational Industrial Research and Development (BIRD) Foundation.



Focused Ultrasound Foundation Accelerates Essential Tremor Pathway. Serving Patients in Need, Faster.

The Focused Ultrasound Foundation has already significantly accelerated the potential of focused ultrasound as a treatment option. The Foundation took a leading role in convening stakeholders from academia, industry and government who identified movement disorders as an unmet medical need which should be prioritized for focused ultrasound research. The Foundation then partnered with neurosurgeons at the University of Virginia to design and fund a pilot study using focused ultrasound to treat essential tremor (ET). The pilot was successful and provided preliminary evidence that focused ultrasound could safely and effectively treat a targeted area deep within the brain. This research paved the way for a pivotal study currently in progress, which could be the final step towards FDA approval of focused ultrasound as a completely non-invasive medical treatment option for essential tremor. It also had a broader impact on the field, increasing awareness of focused ultrasound as a groundbreaking technology, and validating its use for medical applications throughout the body.

The philanthropic positioning of the Focused Ultrasound Foundation allows the Foundation to convene stakeholders, bridge sector divides and serve as a force multiplier for intellectual capital while remaining independent. Today, focused ultrasound is being studied to treat nearly 60 diseases at more than 160 research sites around the globe. Progress on this scale simply would not be possible without the shared vision and combined determination of many – generous donors, dedicated researchers, industry experts, and medical professionals.

May 13, 2015