fogarty innovation

at El Camino Health

2025 Annual Report

In Memoriam
February 25, 1934 - December 28, 2025

A Message from Andrew Cleeland

This year's Annual Report is a tribute to our founder—and my friend—Dr. Tom Fogarty. Tom's inventions changed medicine, and the challenges he faced bringing them to patients compelled him to reshape the field of medtech innovation. He encouraged physicians to innovate, reached across the medtech landscape to improve understanding among essential stakeholders, and founded Fogarty Innovation to mentor and support aspiring innovators to make the journey a little easier and a lot less lonely. Years of clinical practice gave Tom deep empathy for the patient experience, and his insistence on keeping patients at the center of innovation continues to shape our work today.

From early on, Tom had confidence in his ideas, and he pursued them with unmatched grit and determination. But he didn't do it alone. As his son Tommy Fogarty recalled, "One of his biggest strengths was that he surrounded himself with people who could help him achieve his goals."

That same belief in the power of collaboration shaped Fogarty Innovation's most important milestones in 2025:

Strengthening our bond with El Camino Health – Fogarty Innovation was founded on the El Camino Health campus 18 years ago. From the beginning, it has been a meaningful partnership, enabling Fogarty startups to benefit from early clinician input, while providing El Camino Health with access to emerging technologies and clinical research opportunities that reinforce its role as an innovation leader. Together, we've helped launch numerous groundbreaking companies and technologies. Building on this track record, we integrated "at El Camino Health" into our logo—a visible reminder of a partnership that's not only enduring, but deepening.

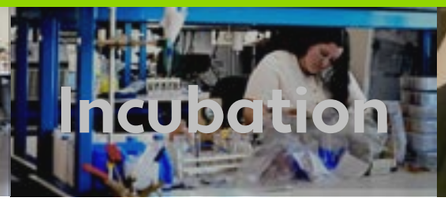
Launching the Thomas J. Fogarty Innovation Prize – in October, we brought together leaders from across the global medtech community to celebrate the inaugural Thomas J. Fogarty Innovation Prize—an evening that highlighted the power of collaboration and shared purpose in advancing healthcare innovation. The Fogarty Prize, which includes an unrestricted $100,000 cash award, honors an innovator or team who has successfully developed and commercialized a life-changing medical technology. It was conceived by Mike and Linda Mussallem to honor Tom Fogarty's extraordinary impact and was made possible through their foundational gift.

Building the Future with the Cardiovascular Research Foundation (**CRF**) – Following years of close collaboration and shared vision, we announced our merger with CRF. This partnership unites two organizations committed to purpose-driven innovation and significantly expands our reach and impact. Fogarty Innovation will continue to operate across the full spectrum of medical technology innovation, addressing challenges that extend well beyond cardiovascular medicine. However, with direct access to CRF's broader clinical, research, education, and policy platforms, we can move beyond institutional coordination to address one of the central challenges in healthcare innovation: the fragmentation of the medtech ecosystem.

Technology is advancing rapidly, but the systems needed to bring innovation to patients have not kept pace. While many stakeholders play essential roles in bringing new technologies to patients, they operate independently and have different, sometimes even competing priorities and incentives. As a result, promising innovations often stall for reasons that have little to do with the underlying technology. These challenges are becoming even more urgent as advances in artificial intelligence, data analytics, and real-world evidence expand what is scientifically and clinically possible in medicine.

Building on Fogarty Innovation's experience in early-stage company building and CRF's global leadership in clinical research and physician engagement, we are developing a new platform to align stakeholders earlier, generate meaningful clinical evidence, and help new technologies reach patients more efficiently and equitably. This work, along with an expansion of our global programs and partnerships, will be our central focus in 2026. We look forward to working with you as we build this next chapter together.

Andrew Cleeland
CEO, Fogarty Innovation



Advancing Human Health

Fogarty Innovation is an action-oriented nonprofit organization that advances human health by training the next generation of innovators and accelerating medtech innovation from concept to clinical impact. We pursue this mission through three integrated capabilities: education, incubation, and alliances.

Our tailored education initiatives provide the practical skills, perspective, and networks needed to succeed in the complex world of medical technology. Through our incubation programs, we help entrepreneurs and early-stage companies evaluate ideas, hone business strategies, and build successful companies that deliver valuable new solutions to patients. And our alliances program brings together stakeholders across the ecosystem to improve understanding, strengthen collaboration, and move new technologies into clinical use more efficiently while expanding equitable access to their benefits.

Our status as a nonprofit organization is central to our ability to accomplish these goals; enabling us to convene these communities, share knowledge openly, and keep the focus on improving patient outcomes.

Following are some of our key accomplishments across these areas in 2025.

Education

Dr. Fogarty founded Fogarty Innovation with the goal of supporting medtech entrepreneurs and helping them overcome some of the field's most daunting challenges.

Today, one of the essential ways we realize that goal is through education.

Led by Chief Commercial Strategy Officer Marga Ortigas-Wedekind, Fogarty Education produces a twice-monthly cadence of practical educational programs designed to meet the needs of innovators and early-stage companies. All of these events are free and open to the public.

In shaping the curriculum, Ortigas-Wedekind draws on three primary inputs: the topics Fogarty staff wish they had understood earlier in their own careers, subjects requested by program attendees, and timely perspectives that help innovators keep up with the rapidly changing landscape. "Things are evolving so quickly—it's important to help young companies understand the future they're launching their products into," she said.

> **"It's important to help young companies understand the future they're launching their products into."**

In 2025, Fogarty Education organized 21 Lunch & Learns—90-minute lunchtime sessions—on topics such as AI in medicine, building confidence, corporate culture, design control, partnership strategy, risk management, valuation, and policy updates. Other lunch programs featured accomplished individuals whose experiences offer valuable lessons. Guests in these sessions included physician innovator and corporate leader Todd Brinton, MD; pioneering entrepreneur, investor, and company builder Bill Starling; and public health leader Nancy Messonnier, MD.

Also in 2025, we organized two half-day workshops—multi-panel programs that explore more complex topics in greater depth—focused on fundraising and leadership.

In addition to our public-facing offerings, Fogarty convenes roundtables for our companies-in-residence focused on clinical/regulatory/quality and intellectual property. These closed sessions facilitate sharing of expertise and provide a safe opportunity to address specific company concerns.

Lefteroff Internship

Now in its 12th year, the Lefteroff Internship Program provides an immersive summer experience in medical technology, combining hands-on learning, professional development, and engagement with industry and hospital leaders. From nearly 150 applicants, 22 students were selected, representing 18 colleges and universities in the U.S. and abroad.

Most interns work directly with Fogarty's startups, where they contribute to projects and help advance company goals. Along the way, they collaborate with Fogarty staff, ask questions, and explore a range of potential career paths.

The experience leaves a lasting impact—sparking new friendships, ideas, and ambitions. Connor Lo, a rising senior in mechanical engineering, saw the importance of soft skills through his work with Novocuff, a maternal health company working to improve outcomes for

mothers at risk of early labor. "It was motivating to know how meaningful our project was," he said. "I learned that technical expertise isn't enough—soft skills are just as important, especially in small teams."

> **"I learned that technical expertise isn't enough—soft skills are just as important."**

To date, the Lefteroff Internship has served 157 students.

Diversity by Doing HealthTech (DxD)

Diversity by Doing HealthTech (DxD) is an industry-driven collaborative dedicated to expanding opportunities in the medtech innovation ecosystem to achieve better health outcomes for all. Led by executive director Ingrid Ellerbe and senior program manager Claudine Joseph, DxD was founded and is supported as a partnership between Stanford Biodesign and Fogarty Innovation.

In 2025, DxD celebrated its sixth year and expanded its reach further upstream in the talent pipeline through a pilot program for high school students: Health Innovation for Underrepresented Minorities. This interdisciplinary summer camp introduced students to biomedical innovation by challenging them to develop solutions to health inequities.

DxD's most immersive offering is Pathways in Health Technology, an eight-weekend program that equips community college students from traditionally

underrepresented backgrounds with the skills, mindset, network, and support needed to thrive in medtech careers. The 2025 cohort included 27 students from Bay Area community colleges, with majors ranging from mechanical engineering and biochemistry to nursing and the humanities. Two-thirds of participants were women, and more than half were first-generation college students.

"We're extremely proud of the growth we see in our Pathways students," said Joseph. "Three years in, we're seeing our alumni land internships, complete four-year degrees and step into healthtech careers, and continue to expand their networks and expertise."

> **"We're extremely proud of the growth we see in our Pathways students."**

Core aspects of Pathways include working with mentors from medtech companies Cala Health, Element Science, Intuitive Surgical, Pulmonx, and Shockwave Medical on real projects, physician shadowing, speed mentoring, and workshops that build self-confidence, communication, and collaboration skills. New program elements in 2025 included a day at the University of California, San Francisco (UCSF), where students explored specialty care, global health, and the role of economics in health innovation.

Expanding What I Believed was Possible: The Impact of Pathways

Measured one student at a time, the impact of the Pathways program has been extraordinary.

For student Mariana Rodriguez, Pathways inspired a new career goal. "One of the most pivotal experiences was shadowing Dr. Zachary Edmonds at El Camino Health. In just one day, we witnessed procedures like lumbar punctures and bone marrow biopsies. Dr. Edmonds greeted us with warmth and generosity, showing us what it means to lead with both skill and heart. For years, I had dreamed of becoming a nurse. This experience gave rise to a new dream: becoming a doctor."

> **"This experience gave rise to a new dream: becoming a doctor."**

Other DxD programs include a Health Exploration Workshop for college students interning in the medtech ecosystem, quarterly speed mentoring events for early- and mid-career industry professionals, and a leadership seminar for founders, managers, and executives.

To date, DxD has served:

312	468	335	150
STUDENTS	MENTEES	MENTORS	PARTICIPATING COMPANIES

Incubation

Dr. Fogarty devoted the second half of his career to supporting the next generation of medtech innovators. Recognizing that the innovation journey is "damn hard," he established Fogarty Innovation to mentor first-time founders, provide access to clinicians and healthcare leaders, and create a collaborative community where innovators could support and learn from one another.

Those objectives continue to define our incubation programs today. Operating out of a 30,000-square-foot "living laboratory" on the campus of El Camino Health, Fogarty's veteran senior team provides "full-contact coaching," working side-by-side with startup leaders on a daily basis to help with everything from product development through financing, clinical pathways, reimbursement, and commercialization.

As Chief Innovation Officer Mike Regan described, "Our entrepreneurs are trying to change the world, and that's a tall order. Each brings extraordinary talent and a record of accomplishment, but there are countless challenges involved in turning an idea into a successful company. Our goal is to help them throughout that journey by providing the support they need to navigate the obstacles along the way."

> **"Our entrepreneurs are trying to change the world, and that's a tall order."**

Fogarty's incubation programs also provide founders with access to an extended network of more than 300 subject-matter experts, along with a culture rooted in openness, generosity, and mutual support. Companies in our programs are selected to be complementary rather than competitive, allowing teams to share advice, learn from one another, and build lasting relationships.

All participants become part of our "Fogarty Family," with ongoing access to coaching and opportunities to engage in educational programming long after their time in the building ends.

In 2025, 32 companies participated across our incubation programs, each designed to meet the specific needs of entrepreneurs and startups at different stages of the innovation journey. As their technologies and business strategies evolve, many companies progress from one program to the next, ensuring they receive the optimal level of coaching and support.

So You Have an Idea: The Invention Acceleration Program (IAP)

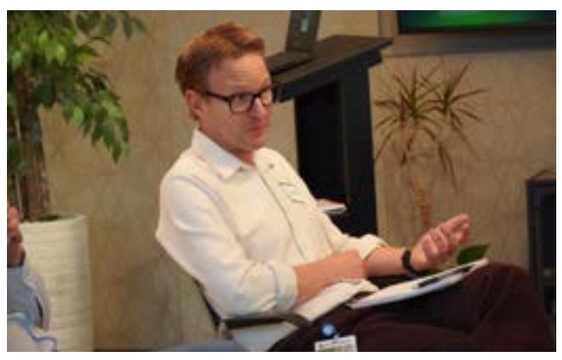
Our earliest-stage program, the IAP is structured as partnership, most often with a hospital or university system, and designed to accelerate the journey from idea to company formation. Led by Director John Morriss, it is a six-month, highly interactive program for clinicians and researchers who have an idea for a solution to an important problem in patient care but are uncertain how, and whether, to take it forward.

Over the course of the program, we help these aspiring innovators define the value proposition for relevant stakeholders, advance the solution, understand the pathway and obstacles to commercialization, and gauge capital requirements and funding sources.

In partnership with Stanford Mussallem Center for Biodesign, six projects rotated through the IAP in 2025:

- **easyBAT**- basophil activation test for allergies
- **KoolGuard** – prevention of oral mucositis
- **Micro OCT** – high resolution imaging of the cochlea
- **Clearoson** – ultrasonic clearance of brain waste
- **Semtana** – automated neurological assessment
- **SnipTag** – skin tag removal system

Each project team made significant progress during their time with us.



"We look back at everything we did and it feels like four years compressed into six months," reported Elisabet Rosàs Canyelles, PhD, one of the principal entrepreneurs of KoolGuard. "The weekly meetings pushed us to meet our goals and prove that we could drive the project much further than we imagined," she said.

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Company Accelerator Program (CAP)

The CAP supports startups in later stages, such as Series A or B funding, as they aim to accelerate growth. It provides targeted guidance to help companies navigate specific challenges, for example developing a commercialization strategy or addressing reimbursement hurdles. Because CAP companies can be hybrid, the program allows us to coach companies around the globe.

In 2025, we hosted 11 companies in this program, two in partnership with the University of Minnesota:

- **Adialante** – a compact, low-cost, focused MRI scanner (University of Minnesota)
- **Amara Health** – a digitally delivered, app-based treatment for overactive bladder
- **Aurora Medical Technologies** – a novel suturing platform for flexible endoscopic procedures
- **Auricle** – a minimally-invasive cochlear neurostimulation device to restore hearing in adults with severe high-frequency hearing loss (progressed from IAP to CAP)
- **Corveus Medical** – a catheter-based procedure to reduce the clinical burden of congestive heart failure
- **LearUP** – an AI-powered, fully-integrated, cloud-based platform to improve clinical trial management
- **Proxima Rx** – a catheter-based procedure for benign prostatic hyperplasia
- **SecondWave** – a noninvasive, wearable ultrasound stimulation platform to treat inflammation (University of Minnesota)
- **Selera Medical** – a minimally invasive device to improve outcomes for symptomatic chronic heart failure (progressed from IAP to CAP)
- **Synkopi Medical** – a bi-atrial pressure monitoring device to improve medical management of heart failure
- **Tidal Medical Technologies** – a smart device to improve adherence to respiratory therapy in post-surgical patients

Companies-in-Residence (CIR)

The CIR program is our most comprehensive incubation program, providing an onsite, multi-year home for early-stage medtech companies, most of which are led by first-time CEOs. It is also our longest-standing program, having been established when Dr. Fogarty founded the organization in 2007.

Designed for companies that have some seed or grant funding and a working prototype, the CIR program provides "full-contact coaching" across disciplines to support continued growth and progress.

Following are 2025 progress updates from our CIRs.

- **Boomerang Medical** is advancing a breakthrough bioelectric neuromodulation technology for Inflammatory Bowel Disease (IBD). The company is currently in an FDA-approved pivotal study at leading IBD centers across the U.S. and was recognized with the "Emerging Leader in IBD" award from the Crohn's and Colitis Foundation.
- **Eclipse Regenesis**, which is developing the first device-based restorative therapy for short bowel syndrome, has successfully treated 12 pediatric and adult patients at four different centers across the country. Early study results are encouraging and all patients continue to do well.
- **Enspectra Health** is leading digital dermatology with the VIO™ System, which delivers actionable cellular information noninvasively in real time. In 2025, data from the clinical trial supporting FDA clearance was published in *JAMA Dermatology*, demonstrating strong alignment between Enspectra's noninvasive imaging and traditional histopathology. The team is currently exploring applications in dermatology in response to industry interest in skin longevity and regeneration.

- **G-Tech** has developed GutTracker®, a wearable diagnostic patch for chronic gastrointestinal disorders that measures motility of the entire GI tract noninvasively over multiple days. The company published and presented new data showing potential actionability of the test results and commercially launched GutTracker to an ambulatory GI disorder market of more than 45 million office visits per year.
- **iDentical**, which is revolutionizing dentistry with the first drill-free, 3D-printed dental implants, made progress on multiple fronts. Notable achievements include securing a strong VC lead investor for its $10M Series A round, completing three-year follow-ups for its first-in-human clinical study with 100% success (n=10) and continued enrollment in its pivotal clinical study.
- **Immergo Labs**, which is developing a virtual reality platform for physical therapists that aims to empower movement and enhance accessibility in physical rehabilitation, is live with a paid alpha launch serving 11 clients across four providers while conducting a VA usability study to inform enterprise deployment. The company has been approved to sell its technology through a major VA purchasing program and is now working to secure its first contract.

- **Materna Medical** is a novel OBGYN platform company defining a $25B market in the most common pelvic conditions for women. Its first commercial product, Milli, treats vaginismus and associated painful intercourse and is in use by over 5,000 patients. For its second product, Ellora™, the company has enrolled over 700 patients in two pivotal studies aiming to show reduced pelvic floor injuries during childbirth. Materna is in an interactive De Novo review with FDA and successfully received a new procedure code from CMS for reimbursement of Ellora™ when it launches.

- **Novocuff, Inc.** is developing a device intended to improve outcomes for pregnancies affected by preterm premature rupture of membranes (PPROM) or cervical shortening. The device is designed to reinforce the cervix and improve amniotic fluid retention. The company received IDE approval from the FDA for their randomized controlled pivotal study, RETAIN, for patients with PPROM.
- **Ryme Medical** applies Targeted Lung Denervation to alleviate the symptoms of chronic obstructive pulmonary disease through an innovative catheter technology. Ryme completed enrollment of its pilot study with clinically meaningful reduction in symptoms and improvement in quality of life for treated patients and has received approval from the FDA to initiate its pivotal clinical study.

New Coaching Staff

We were pleased to welcome two new additions to our bench of exceptional coaches and domain experts.

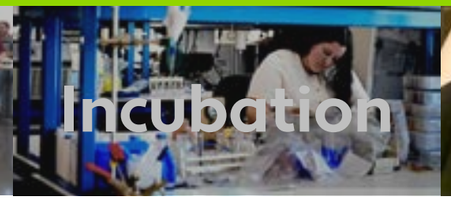
Dominique Filloux brings more than three decades of medtech experience to his role as Chief Development Officer. In this capacity, he works with Fogarty's resident companies as an advisor and coach with an emphasis on R&D and operations, including quality assurance, quality management systems, regulatory, and clinical affairs.

Matt Hillebrenner joined Fogarty after 22 years at the FDA, where he was most recently Deputy Director, Office of Product Evaluation and Quality in the Center for Devices and Radiological Health. As Director of Government Affairs, Matt helps medtech startups and entrepreneurs better navigate the regulatory environment and engage more effectively with government agencies.

Alumni Updates

Our alumni companies are forever part of the Fogarty family. They reach out periodically for advice, join our educational events, and participate in our student development programs. We are proud to celebrate their many accomplishments, including those highlighted below.

- **Flosonics Medical** secured a $20M Series C funding in 2024 to advance FloPatch™, the world's first wireless, wearable Doppler ultrasound for hemodynamic assessments. Since its debut at El Camino Health, 10+ health systems have adopted the technology to enable dynamic assessments for sepsis care.
- **HeartFlow** uses AI-driven analysis of coronary CT angiography scans to create a detailed 3D model of the heart and assess blood flow to noninvasively evaluate coronary artery disease and guide clinical decision-making. In 2025, the company completed an IPO raising approximately $364 million and received FDA clearance for its next-generation HeartFlow Plaque Analysis platform.
- **Intervene** received FDA 510(k) clearance in October 2025 after pivoting from deep venous reflux and BlueLeaf valve formation to chronic deep vein obstruction via the Recana. The company initiated clinical cases in the US and Europe with safe and successful results and plans to expand limited commercial and post-market clinical research in 2026.
- **Melio** has created a faster, culture-free way to diagnose bloodborne infections by integrating a proprietary assay with advanced microfluidics and machine-learning techniques. In 2025, the company welcomed a new chief product officer and is preparing for early-access programs and commercialization.
- **Raydiant Oximetry** has developed a non-invasive fetal pulse oximeter to more accurately identify fetal distress during labor. In 2025, the company closed a $7.5 million Series A3 and announced a strategic partnership with GE HealthCare Technologies Inc.
- **UltraSight** expands access to cardiac ultrasound through real-time AI guidance that enables non-experts to acquire diagnostic-quality images. In 2025, the company deepened its Mayo Clinic collaboration, was favorably evaluated in independent Stanford research, presented six abstracts at ACC, and signed partnerships with medical device manufacturers.



Alliances

As an inventor, Dr. Fogarty experienced firsthand how many different stakeholders influence whether new medical technologies ultimately reach the bedside. His frustration with roadblocks and misunderstandings led him to reach across the table and work with government agencies and others to help them understand the startup experience and their shared goal of making care better for patients and easier for physicians. The value of those endeavors inspired the creation of Fogarty Innovation's alliances program.

Today, under the leadership of Chief Alliance Officer Allie Gregorian, the program serves as a bridge across these communities—helping clinicians, entrepreneurs, industry leaders, policymakers, and health systems better understand one another's perspectives and work together to help promising technologies reach patients more effectively and equitably.

Reflecting the integration of Fogarty's capabilities, the Alliances program increasingly serves as a platform for educational programming that helps physician innovators learn the process of translating ideas into viable products and companies. In 2025, Fogarty delivered bespoke programming to leading clinical and research communities, giving clinicians practical exposure to the financial, regulatory, and business considerations that shape successful innovation.

The growing focus on healthcare innovation and entrepreneurship is also reflected in visits from academic partners, such as the University of Minnesota and Indiana University, that have launched programs in this area. Fogarty regularly hosts these groups to share its approach and inspire potential innovators through conversations with founders, demonstrations of technologies in development, and discussions about the challenges and rewards of bringing new solutions into patient care.

Fogarty also works closely with organizations that shape the broader medtech landscape. In 2025, these collaborations included DeviceTalks West, the Medical Device Manufacturers Association and MedtechWOMEN, among others. Together, these partnerships broaden exposure to our industry, inform and educate our constituents, and help innovators stay abreast of the changing political landscape.

In 2025, Fogarty expanded its local and international outreach while deepening relationships with existing partners. Highlights from these collaborations include:

Cardiovascular Research Foundation® (CRF®) & TCT MedTech Innovation Forum

2025 was the fourth year that Fogarty Innovation has partnered with CRF to organize the MedTech Innovation Forum, a full day event on the first day of TCT, CRF's annual scientific symposium. The MedTech Innovation Forum brings clinicians, entrepreneurs, regulators, and investors together to learn, collaborate, and act on bold ideas that can transform patient care.

The 2025 Forum drew an audience of over 3,500 to Moscone Center in San Francisco. Sessions explored approaches to the process of innovation and examined the ways in which AI is reshaping medicine, from enhanced diagnostics to closing gaps in access.

As always, every seat in the house was filled for the Shark Tank Innovation Competition, as crowds gathered to learn about technological developments with the potential to dramatically change patient care. We wrapped the day with a look at challenges and opportunities ahead in the cheekily-titled closing session, "Are We Making MedTech Great Again?"

Describing the Forum, Juan F. Granada, MD, President and CEO of CRF, observed, "This event serves as the bridge between clinical need and disruptive innovation, helping accelerate the development of treatments that will shape the future of cardiovascular medicine."

Added Cleeland, "This gathering isn't just a conference—it's a launchpad."

> **"This gathering isn't just a conference—it's a launchpad."**

The long-standing collaboration of the two organizations culminated in the announcement of Fogarty Innovation's strategic merger with CRF on the TCT main stage the next day. The merger creates a unified platform to accelerate the development and adoption of transformative healthcare technologies.

El Camino Health

For 18 years, Fogarty Innovation has worked closely with El Camino Health to improve patient care through innovation. This valuable collaboration enables Fogarty startups to work directly with clinicians to refine products, validate clinical and economic value, and better understand real-world care delivery. In turn, El Camino Health gains early access to novel technologies, educational programming, and clinical research initiatives that reinforce its standing as one of the nation's most innovative community hospitals.

Together, the organizations have launched numerous impactful companies and technologies, including most recently, the Flosonics FloPatch, a wireless Doppler ultrasound that monitors blood flow in real time. El Camino Health subsequently became the first health system in the world to adopt this advanced technology for sepsis management.

American Heart Association (AHA)

In 2025, Fogarty Innovation launched a new alliance with the American Heart Association beginning with a series of practical educational sessions for AHA Ventures and Studio Red researchers, clinicians, and emerging entrepreneurs. The sessions focused on key aspects of intellectual property, market access, commercialization strategy, and the pathways required to translate promising cardiovascular innovations into viable healthcare solutions.

Building on this early engagement, Fogarty and AHA are collaborating on the development of an Innovation Day at the AHA Scientific Sessions in 2026.

American Urological Association (AUA)

Deepening a partnership formed last year, Fogarty Innovation teamed up with AUA again in 2025 to produce the Innovation Nexus conference. This one-day event convenes startups, entrepreneurs, venture capitalists, investors, and urologists to advance innovation in urology. Fogarty senior staff led practical sessions including, "The Good, the Bad and the Ugly: How to Approach Investors," and "From Idea to Impact: Navigating the Path from Concept to Commercialization," among others.

Boys and Girls Clubs of the Peninsula (BGCP)

Our long history of partnering with BGCP includes student participation in the Lefteroff Internship, as well as hands-on career exploration events. This year, we hosted a high school career day that included a tour of our facilities with former BGCP member and now Fogarty Education and Communication Associate, Lizbeth Villalobos, and an up-close look at how several of our startups are solving problems in healthcare with innovative devices. The students also toured clinical departments at El Camino Health and participated in discussions with Fogarty staffers whose expertise ranged from engineering to finance, regulatory, and marketing.

Dartmouth 3D Scholars

Dartmouth Health, in partnership with the Geisel School of Medicine at Dartmouth, has launched the 3D Scholars Program, a one-year certificate course designed to equip practicing clinicians with the skills and knowledge to excel in medical device development and leadership. The program builds on the success of the Dartmouth Device Development (3D) Symposium, established more than 20 years ago to convene stakeholders within the device development ecosystem.

Fogarty Innovation, which has been a regular participant in the Symposium, is partnering in the 3D Scholars program as an extramural advisor and the host of a multi-day retreat focused on innovation in Silicon Valley.

Mayo Clinic

As part of our expanding partnership with Mayo Clinic, this year we hosted an Innovation Workshop for the clinical staff at the Mayo Clinic Rochester Cardiology & Radiology Innovation Summit. Focusing on how to translate an idea into a product and business opportunity, Fogarty senior staff led a half-day program that covered defining a value proposition, product development, IP, navigating the regulatory and reimbursement pathways, fundraising and more.

Additionally, for the third consecutive year, Fogarty Innovation contributed to the development of the agenda and participated in panel discussions at the Beahrs Surgical Innovation Summit, a convening that accelerates surgical innovation by bringing together leaders from across the clinical, industry, academic, and investment communities to address unmet needs in surgical care.

Stanford Mussallem Center for Biodesign

Our enduring collaboration with the Stanford Mussallem Center for Biodesign reflects our shared commitment to educating the next generation of medtech innovators and advancing translational research. Throughout the year, we worked together on inventor selection and mentorship within the IAP. In addition, Fogarty leaders provided lectures and coaching to Biodesign fellows and students on practical topics including regulatory strategy and commercialization. We also sponsored the annual Lefteroff Memorial Innovator's Workbench, and partnered with Stanford Biodesign, MedTech Innovator, Research Corporation Technologies, Inc., and Wilson Sonsini to co-host the 2025 Innovator's Reception at the J.P. Morgan Healthcare Conference

UCSF-Stanford Pediatric Device Consortium

Fogarty Innovation continues to support the UCSF–

Stanford Pediatric Device Consortium (PDC), an initiative dedicated to advancing technologies that address unmet needs in pediatric care. As part of this alliance, Fogarty provides structured evaluation and coaching to help promising pediatric device startups to strengthen their development and move closer to clinical impact.

After participating as one of the judges at the 2025 UCSF-Stanford Pediatric Device Consortium Pitch Competition, Cleeland and the Fogarty team selected four companies to take through our Fogarty Physical, a cross-functional assessment that helps identify obstacles and optimize progress. We also selected one company, AVaTAR Medtech, to join our CAP program.

Later in the year, Cleeland participated as a judge in the 6th Annual Harrison Innovation Symposium at UCSF, which brings together professionals, researchers, and students who share a passion for improving children's health through creativity, technology, and collaboration.

Global Alliances

A*STAR (Agency for Science, Technology, and Research) Singapore

Our multi-year collaboration with A*STAR continued to evolve and strengthen in 2025. We started the year by hosting the Singapore Biodesign Fellows for the U.S. immersion phase of their training. During their stay, the fellows advanced their projects and participated in discussions and workshops that address all aspects of bringing a new technology to the U.S. market.

In March, Fogarty staffers traveled to Singapore to attend the fellows' graduation ceremony and celebrate the 15th anniversary of the Singapore Biodesign program.

In August, we signed a formal partnership with MedTech Catapult, a national initiative designed to fund and accelerate later-stage health technology companies. The program provides participants with practical frameworks for evaluating emerging medical technologies and identifies those best-positioned for development, while connecting entrepreneurs with capital, mentorship, and partners across manufacturing, design, and regulatory pathways. Fogarty senior staff subsequently delivered a five-day symposium for the program.

Japan METI

For the third consecutive year, we were delighted to host a delegation of researchers, entrepreneurs, fellows, first-time CEOs and officials from the Japan Agency for Medical Research and Development (AMED), Ministry of Economy, Trade and Industry (METI), and Japan Biodesign to discuss the early stage medtech ecosystem and successful translation. The visit included founder pitches with real-time feedback and practical guidance to entrepreneurs seeking to navigate the U.S. market.

Later in the year, executives from Tokyo Biodesign visited Fogarty Innovation to discuss formalizing a program of mentorship and support for select Japanese medtech startups in 2026.

The Inaugural Thomas J. Fogarty Innovation Prize and Gala

In October, Fogarty Innovation celebrated a defining milestone in its mission to advance human health with the inaugural Thomas J. Fogarty Innovation Prize and Gala. The Fogarty Prize celebrates the power of technology innovation to transform healthcare and improve the lives of patients everywhere.

Reflecting Dr. Fogarty's conviction, "An idea by itself has no importance whatsoever. It's the implementation of that idea and its acceptance by others that brings true benefit to our patients," the Prize honors an individual or team who has translated a breakthrough concept into a therapy that is helping patients around the world.

The Prize was presented during a sold-out, black-tie gala in San Francisco attended by more than 350 leaders from the medtech, healthcare, venture capital, academic, and public sectors.

At the heart of the evening was the announcement of the winner(s): Allan Zingeler, Raju Viswanathan, PhD, and Michael Mahoney for their work on the FARAPULSE™ PFA Platform, a pulsed-field ablation (PFA) technology that has reshaped the treatment of atrial fibrillation, the most common sustained cardiac arrhythmia affecting millions of patients worldwide.

FARAPULSE embodies the Prize's core criteria—clinical impact, commercial adoption, and substantial patient benefit. Leveraging precisely-timed electrical pulses to selectively eliminate problematic heart tissue while preserving critical structures, FARAPULSE has been adopted at unprecedented speed in clinical practice, offering a safer and more efficient alternative to traditional thermal ablation therapies.

Cleeland emphasized that the Prize was conceived not simply to recognize bold ideas, but to honor individuals who have overcome the many challenges involved in bringing new technologies into clinical practice. "The Fogarty Prize recognizes remarkable innovators whose breakthroughs ripple across lives, families, and entire communities," he said.

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The other two 2025 finalists are pioneers in their respective fields: Dr. John Adler, recognized for advances in frameless stereotactic radiosurgery (CyberKnife and ZAP Surgical Systems); and Dr. Michael Harrison, a trailblazer in the development of fetal surgery. Their journeys were showcased during the gala.

The Prize, which includes an unrestricted $100,000 award and a custom-cast bronze medallion, was made possible by the Linda and Mike Mussallem Foundation. Their support helped establish the award as a permanent fixture in the medtech innovation community calendar.

Sustaining the legacy
Strengthening the future

Dr. Fogarty understood that meaningful innovation is never the work of one person alone. Progress happens when curious minds, determined innovators, and generous partners come together around a shared purpose: to improve the lives of patients.

Fogarty Innovation was created to carry forward that spirit.

The accomplishments highlighted throughout this report reflect what is possible when that community comes together. Through our education, incubation, and alliance programs, we help innovators develop ideas, build companies, and navigate the complex path from concept to clinical impact.

But just as Tom surrounded himself with people who helped turn bold ideas into reality, our mission also depends on the community that stands behind it.

As a nonprofit organization, Fogarty Innovation relies on philanthropic partners who believe, just as Tom did, that bold ideas deserve mentorship, collaboration, and the resources required to become real solutions for patients.

Your support is one of the most meaningful ways to honor Dr. Fogarty's legacy. By joining this community of supporters, you help ensure that his spirit of curiosity, collaboration, and determination continues to shape the future of medicine.

Together, we can continue to surround the next generation of innovators with the people, guidance, and support they need to achieve their goals—and ultimately improve the lives of patients around the world.

We invite you to join us in carrying this legacy forward.

To learn more, visit www.fogartyinnovation.org/donate or contact Allie Gregorian: allie@fogartyinnovation.org

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