



Institutional Profile

Founded in 1921 by four renowned physicians, Cleveland Clinic is a nonprofit, multispecialty academic medical center established to provide outstanding patient care based upon the principles of cooperation, compassion, and innovation. Cleveland Clinic is recognized as one of the nation's top four hospitals by *U.S. News & World Report* and is celebrating its 16th consecutive year as America's top heart center.

Medical research and innovation is ingrained in the culture of Cleveland Clinic. Over the years, its physicians have contributed substantially to the advancement of patient care, from the very beginning with Clinic co-founder George Crile's novel carotid clamp and forceps clamp, through coronary angiography breakthroughs, the first heart bypass surgery and pioneering heart transplant work, to the recent first-ever near-total face transplant in the U.S.

The Cleveland Clinic's Lerner Research Institute is home to laboratory-based, translational and clinical biomedical research and includes 650,000 square feet of research facilities and more than 1,200 scientists and support personnel who generated in excess of 1,360 health care-related studies and journal publications in 2010.

Cleveland Clinic sponsors one of the nation's largest physician-graduate training programs. In May 2002, Cleveland Clinic created a medical school dedicated to developing physician-scientists. Cleveland Clinic Lerner College of Medicine of Case Western Reserve University combines education and research in an innovative five-year program that mentors medical students to become the next generation of physician investigators.

Technology Commercialization Office (TCO) Profile

Innovations, the Clinic's corporate venturing arm, was established in 2000 to promote innovation for improved treatment of the sick through the deployment of Cleveland Clinic technology. Innovations' mission includes bringing world-class innovations to market by commercializing new technologies developed at Cleveland Clinic and translating emerging therapies, devices, and diagnostics into beneficial medical products through licenses, equity partnerships, and start-up companies. In 2010 it was ranked as one of the top 30 health care corporate venturing units in the world by *Global Corporate Venturing* magazine.

Innovations operates as a departmental unit within the Cleveland Clinic executive administrative structure and reports to the Chief of Staff in the Office of Professional Staff Affairs. The 2010 budget of \$8.5 million covers legal fees, staff salaries and benefits, strategic translational research investments and other operational needs.

Sixteen Innovations employees are dedicated to the management of more than 200 disclosures annually; executing 30-35 licenses and dozens of other transactions annually; and creating, capitalizing and governing three to five new companies each year. The most active departments measured by disclosures are Heart and Vascular Institute, Neurological Institute, Anesthesia, and Orthopedics. The disclosure profile breakdown is: 60% device, 14% software, 11% diagnostic, 8% research tools, and 7% therapeutic.

The Medical Innovation Playbook - The Top Health Care Centers In America

In a little more than a decade, Innovations has executed six licenses that have generated in excess of \$1 million in revenue, had one start-up company achieve IPO, and supported the acquisition of two Clinic spin-off companies.

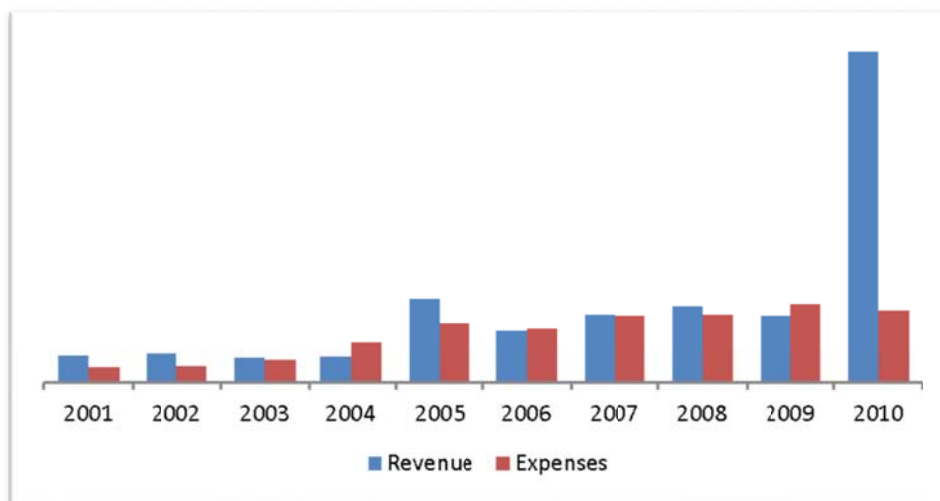


Figure 1: Innovations Revenue and Expenses: 2001-2010

Fit Within the Organization

Innovations' main function is to facilitate innovation within Cleveland Clinic, track, evaluate, protect, and commercialize inventions made by Clinic physicians and researchers, including the creation of new companies for the right opportunities. Though not primarily responsible for Materials Transfer Agreements and Sponsored Research Agreements, Innovations assists with negotiating such documents, particularly when associated with a technology under Innovations' management. In addition, Innovations personnel lead applications for state-supported translational research funding and manage research operations resulting from such funds. Further, Innovations leads efforts to in-license diagnostic tests for utilization in the Clinic's Pathology and Lab Medicine Institute and the Clinic's Reference Laboratory.

Cleveland Clinic Law Department is integral to all transactional elements of the Clinic's Commercialization Process and, in cooperation with Innovations, is responsible for creation of all license, option, research, and inter-institutional agreements, as well as articles of incorporation, stock subscription, and all other corporate documents related to start-up formation. Agreements are negotiated by Innovations staff, then approved by counsel, and ultimately submitted to the Chief of Staff for signature.

In conjunction with the Law Department, Innovations plays a leading role in identifying and managing conflict of interest (COI) issues relating to the commercial exploitation of Clinic innovations. Innovations' Executive Director is an active member of the COI committee, and assists in the creation of Conflict Management Plans to protect individual and institutional interests.

TCO Structure/Function

Innovations consists of four functional teams that work closely with one another: Commercialization/Licensing, New Ventures and Alliances, Operations, and Technology Development.

When new disclosures are received, they are vetted for start up potential and then routed to Commercialization or New Ventures, as appropriate. For certain technologies, the pathway is not immediately obvious; in those cases parallel paths of evaluation and development are pursued until a preferred commercialization route becomes evident.

The Licensing team is comprised of eleven professionals dedicated to evaluation, marketing, protection and licensing, and management of intellectual property (IP). The Licensing team is also responsible for Government reporting and license compliance functions.

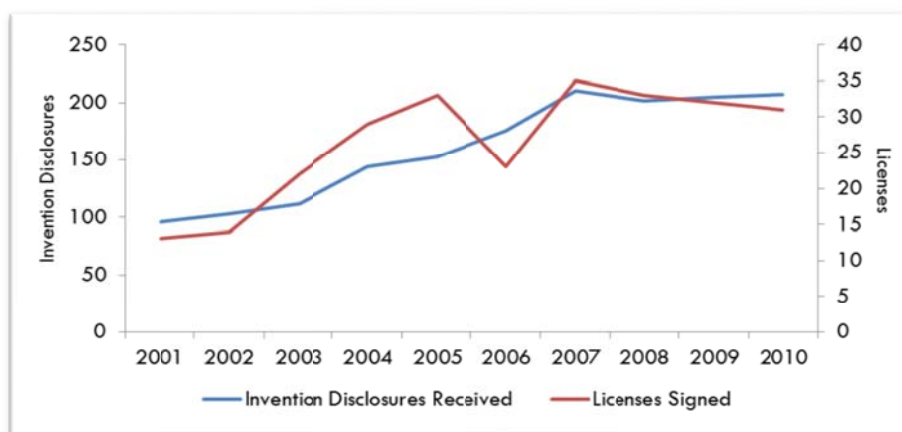


Figure 2: Inventions and Licenses

The Product Development Fund (PDF), an internal translational fund included within the Innovations office budget, is used to accelerate commercialization through such means as:

- Prototype development
- Proof of principle experimentation
- Data generation
- Third-party validation or assessment.

The PDF investment is used to validate technology, decrease investment risk, and strengthen and clarify patent protection. There are 20–25 competitive awards per year, averaging \$30,000 per award with a 6 to 12 month performance period. The Clinic’s dedicated internal prototyping group, Medical Device Solutions, plays a major role in R&D enabled by the PDF.

The Clinic’s Commercialization Council provides final approval of PDF awards. The Commercialization Council is comprised of two dozen prominent Clinic physicians and researchers, and meets monthly to evaluate PDF applications and advise on internal strategy regarding institutional policies and programs related to innovation.

The New Ventures team is comprised of four professionals and is dedicated to creation, capitalization and governance of start-up companies from Cleveland Clinic technology. When a platform technology merits a start-up company, New Ventures will identify the largest market opportunities and most active investment sectors, to position the start-up appropriately.

The Medical Innovation Playbook - The Top Health Care Centers In America

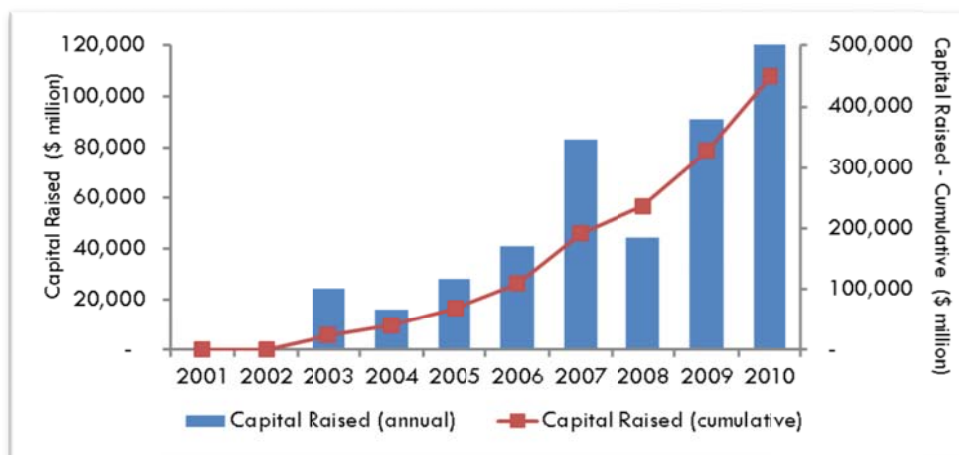


Figure 3: Capital Raised

Innovations' Advisory Board (IAB) assists the New Ventures team in this process. The IAB, made up of sixteen prominent venture investors and industry executives, and its committees meet up to a dozen times a year and advise on deal strategy, company creation, investments, market conditions, investor recruitment, and portfolio management.

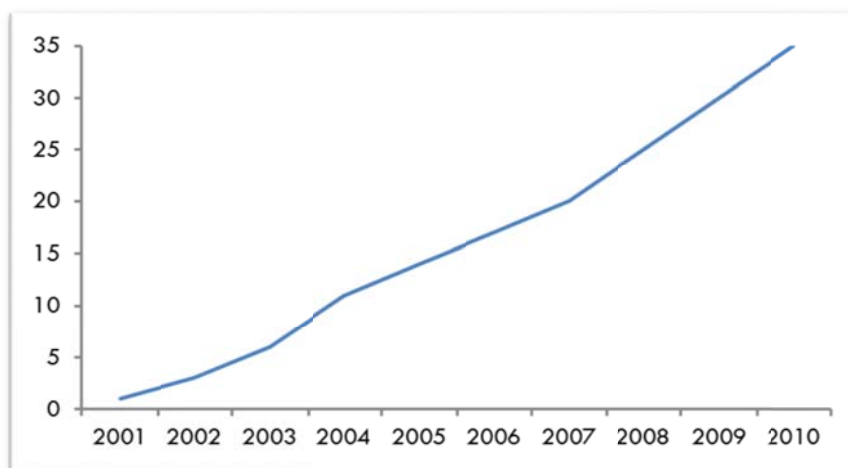


Figure 4: Spin-offs Created (cumulative)

The IAB vets business plans for Clinic start-ups and provides guidance on Clinic investments into such companies. Investments in Clinic start-ups are made from the \$10 million Ohio BioValidation Fund (OBVF), which is managed by Innovations, and are approximately \$250,000-\$500,000 per eligible spin-off. The OBVF is an evergreen fund capitalized by the Clinic and by Ohio's Third Frontier Program – a technology-based economic development initiative that supports existing industries and fosters the formation and attraction of new companies in Ohio's emerging industry sectors. To date, Cleveland Clinic has received \$5.8 million from the state of Ohio in support of its OBVF.

Also involved in start-up creation are Executives in Residence (EIR). These current or former CEOs and/or venture capitalists identify innovative and potentially equitable technologies and provide leadership and direction to nascent start-ups. There are currently three EIRs working with Innovations.

The Medical Innovation Playbook - The Top Health Care Centers In America

Under the leadership of Innovations, the Clinic has been awarded more than \$145 million in technology development funding from the Ohio Department of Development within the last decade; including \$60 million for the Global Cardiovascular Innovation Center (GCIC) consortia. The GCIC staff comprises the bulk of the Technology Development team and the consortia provides funding for commercialization by attracting established companies to Ohio, accelerates their product development efforts, and supports start-up company incubation within the 50,000 square foot incubator facility.

TCO Initiatives/Programs

Innovations engages in a variety of special internal and external initiatives that enhance commercialization at Cleveland Clinic. The annual Medical Innovation Summit brings regional, national, and international attention to Innovations. The Summit attracts upwards of 1,000 attendees and draws top CEOs, venture investors, medical leaders, and journalists who meet for three days to learn about, discuss, and see the latest technologies and trends that will shape the future of medicine.

Innovations has a formal departmental outreach program with Cleveland Clinic physicians, making 3-4 dozen presentations annually during which the Innovations mission and commercialization process are described to potential inventors. Under the IP Policy, any invention made at any time by Clinic personnel is the property of Cleveland Clinic.

Innovations also holds Inventor Forums to expose Clinic staff to other inventors who have successfully traversed the commercialization pathway, as well as successful investors in innovations and technology start-ups. Cleveland Clinic inventors are recognized through the Clinic's annual Inventors Award Dinner and the annual \$50,000 Sones Innovations Award, which goes to the top innovator of the year.

As an alternative to the typical approach to evaluating new ideas submitted by inventors, Innovations holds Structured Invention sessions, where prominent physicians in a particular department or discipline are brought together to brainstorm potential solutions to the most pressing patient care needs in their medical area. A facilitator leads these sessions, with other participants, such as patent counsel, engineers, or other subject matter experts, augmenting the group. Structured Invention is an iterative process – concepts arising from a session are evaluated for patentability and feasibility, and results are discussed with the group at subsequent sessions during which the concept is modified or replaced with new ideas.

Innovations is also heavily invested in generating new sources of capital to spur innovation. Staff lead pursuit of grant awards from the state of Ohio's \$2 billion Third Frontier economic development initiative, as well as management of such grants once awarded.

A groundbreaking partnership was established in 2011 when Cleveland Clinic and MedStar Health agreed to create an innovation alliance to benefit patients through collaborative innovation projects, research, clinical investigation, and commercialization application. MedStar Health is a \$4 billion not-for-profit, regional health care system based in Columbia, Maryland. It is the largest health care provider in the Maryland and Washington, D.C. regions and its nine hospitals, the MedStar Health Research Institute, and 20 other health-related companies are recognized regionally and nationally for excellence in medical care.

The innovation alliance will be a joint effort of Innovations and the MedStar Institute for Innovation (MI2), with collaboration on multiple fronts, beginning with MedStar utilizing Innovations' comprehensive technology development and commercialization services infrastructure. The integration of capabilities between the two organizations will focus on development and rapid deployment of new technologies.

Website Address: www.clevelandclinic.org/innovations