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# The Global Cardiovascular Innovation Center: A Successful Catalyst and Magnet for New Business in Ohio

by Mark Low, Managing Director, GCIC

At the 10th anniversary of the Center, companies supported have secured over \$1Billion in new funding, over 1000 jobs have been created, and 25 new products are either in the market or in clinical trials serving patients worldwide. This is our story.



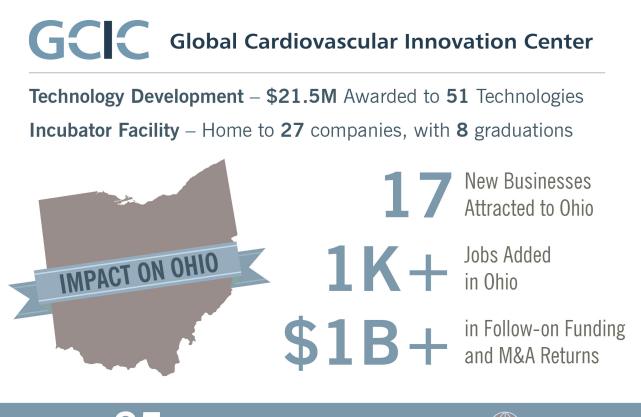
### Abstract

The Global Cardiovascular Innovation Center (GCIC) is a multi-institutional product development and commercialization consortium made possible through a \$60 million grant from the State of Ohio's Third Frontier Program. Founded in 2007, the consortium is led by the Cleveland Clinic and is comprised of Case Western Reserve University, The Ohio State University, The University of Cincinnati, The University of Toledo and University Hospitals of Cleveland along with economic development partners BioOhio, BioEnterprise, and Team Northeast Ohio. GCIC is focused on developing, incubating, and commercializing innovative cardiovascular technology for the benefit of patients worldwide and to facilitate economic development in the State of Ohio. www.gcic.org

Estimated at more than \$475 Billion, cardiovascular medicine is the largest healthcare market opportunity in the U.S. The cardiovascular disease burden poses clear medical, scientific, and commercial challenges.

Leveraging the worldwide healthcare reputation of our lead institution, Cleveland Clinic, and its number one ranking in cardiac care, along with the statewide strengths of our partner clinical institutions, GCIC is building cross-institution partnerships and industry relationships to facilitate the development and adoption of new cardiovascular technologies geared towards improving patient care. Cardiovascular research and development – along with millions of patients – will benefit from the progress made through companies affiliated with GCIC.

This whitepaper highlights our accomplishments, dissects our approach, and identifies the factors that have led to our success.



### The Charge

Simply put, GCIC was established to advance cardiovascular innovation and to contribute to Ohio economic development. In 2007 the State of Ohio made an unprecedented commitment of \$60 Million to establish the Center through its Ohio Third Frontier program, laying out a challenging set of specific objectives by which to measure success.

### Our Approach

GCIC organized around five core programs to pursue these objectives.

**Commercialization Funding Program:** A technology development program to provide funding to early stage companies developing cardiovascular healthcare solutions.

**Company Attraction Program:** A program offering incentives to companies to establish new businesses in Ohio to grow the cardiovascular cluster.

**Product Development Acceleration:** Providing product management and business planning support by industry-experienced technical staff.

**New Company Incubation:** Operating and managing a newly constructed incubator facility for start-up companies.

**Preclinical Investigation Capabilities:** Operating a state-of-the-art preclinical facility for sponsored research, product validation, and procedure training.

Through diligent focus on selecting and supporting technologies in these programs, GCIC has far exceeded each and every goal originally established.

### The Results

Since beginning of operations in early 2007, GCIC has achieved significant success in promoting and supporting technology based economic development throughout the state of Ohio.

In Commercialization Support and Progress:

- Product development funding awards totaling \$21.5 Million.
- Supporting 51 different technologies in companies and research institutions throughout the state.
- Resulting in 11 products having reached the market to serve patients, 14 having advanced to human clinical trials, and 12 others continuing to progress through earlier stages of product development.

In Company Attraction:

- 17 new businesses attracted to and operating in Ohio.
- Bringing new key design, manufacturing, and business resources to the state.

In Product Development and Testing:

- Providing product management and business development support by industry-experienced staff.
- Operating preclinical investigation facilities to evaluate and demonstrate product developments.

In New Company Incubation:

• Constructed and operating a 50,000 square foot incubator facility, now home to 17 full-time and 10 part-time tenant companies, with 8 other companies having graduated to expand and grow their businesses.

Resulting in Added Jobs and Further Investment:

- Greater than <u>1,000 new jobs to-date</u> in companies funded, attracted or incubated by GCIC.
- Greater than <u>\$1 Billion in follow-on funding</u> and M&A transactions secured a 19:1 return on total State dollars expended to-date.

These commercialization and economic development results are forecast to continue to grow significantly as the companies which were supported continue to mature.

### **Success Stories**

Of the 51 different technologies supported by GCIC, there is a significant success rate in advancing projects through product development and into the market. More than 70% of the funded projects are continuing to advance through progressive stages of development with eleven projects having reached the ultimate commercialization goal of being introduced into the market and used to diagnose and treat patients. Notable examples of companies and technologies supported by GCIC include:

Juventas Therapeutics is a clinical stage biotechnology company developing novel non-viral gene therapies that activate natural processes to repair the body. The primary focus is the treatment of non-healing wounds in patients with advanced peripheral artery disease (PAD). The lead product candidate, JVS-100, is a non-viral gene therapy that expresses Stromal cell-Derived Factor-1, or SDF-1, a naturally occurring signaling protein that has been shown to recruit the body's own stem cells to promote tissue repair in a broad range of disease states. Juventas was founded in 2007 with an exclusive license from the Cleveland Clinic. Juventas has raised more than \$49 million from investors including Triathlon Medical Ventures, Venture Investors, Fletcher Spaght Ventures, New Science Ventures, Early Stage Partners, Reservoir Venture Partners, The Cleveland Clinic, GCIC, Takeda Ventures, Green Cross Holdings Corporation and POSCO Capital.

**Cleveland HeartLab (CHL)**, established in 2009, commercializes unique diagnostic and prognostic technologies enabling nearer term detection of potentially serious clinical events. CHL received early funding from GCIC to conduct product development and has gone on to raise over \$56 million in follow-on funding from investors, including premier venture capital firms, such as Health Care Ventures and Excel Medical, both of Boston. CHL now employs over 200 people. **CardioInsight Technologies** is a company formed in 2006 to develop technology to provide non-invasive simultaneous, 3-D, multi-chamber mapping and localization of cardiac arrhythmia mechanisms. The technology originated from research at Case Western Reserve University and University Hospitals Case Medical Center in Cleveland. GCIC provided three funding awards to the company to support development of the technology which has been used on more than 1,600 patients in Europe and the United States, and it also has been featured in more than 120 peer reviewed journals and presentations. Medtronic acquired CardioInsight in 2015 and continues to operate the company as an Ohio-based business.

**Enable Injections** is a Cincinnati-based company founded in 2010 that is developing novel devices for administration of therapeutic drugs. In October 2016 the company closed a \$30M Series A equity financing, and now employs over 50 people. GCIC provided early project development funding to the company in 2012 and participated in the Series A funding round.

**VentureMed Group** of Toledo is developing novel interventional devices to treat peripheral vascular disease. Its first product, the Flex Scoring Catheter, funded in large part by an investment by GCIC, has received both European and U.S. regulatory approvals and is being marketed in both regions. A second product also designed for peripheral vascular intervention is in development with further support from GCIC.

Minimally Invasive Devices is a Columbus-based company founded in 2006 that develops and is commercializing products to facilitate continuous clear vision during laparoscope-guided surgery, thereby saving time, reducing costs, and improving outcomes of such procedures. GCIC provided early stage development funding to the company which has secured more than \$35M in equity financing and is now marketing the product in the U.S. and internationally. Success of the program has also resulted in new opportunity for program expansion and growth:

NIH Center for Accelerated Innovations (NCAI). Based in large part on the successful relationships established by GCIC and demonstrated commercialization outcomes of the program, Cleveland Clinic successfully competed for an NIH award to establish an NIH Center for Accelerated Innovations (NCAI). The NCAI-Cleveland Clinic, <u>www.ncai-cc.ccf.org</u>, includes partnering institutions Case Western Reserve University, The Ohio State University, Cincinnati Children's Hospital Medical Center, the University of Cincinnati, and the University of Michigan. It is one of only three such Centers in the country. The mission of the NCAI program is to provide an integrated, systematic, and comprehensive approach to the translation of early stage biomedical innovations from the research laboratory to commercial development and successful deployment to patients. Funded with grants totaling over \$12.5 million from the National Heart, Lung and Blood Institute (NHLBI), the NCAI provides project funding, expert project management guidance and a program for educating and mentoring researchers, clinicians and developers. Projects are related to the prevention, diagnosis and treatment of heart, lung, blood and sleepdisorder conditions across the range of diagnostics, devices, and therapeutics. The NCAI center is managed in close conjunction and by the same operational staff as GCIC. Cleveland Clinic was also awarded \$1.5 million in support for the Center from the Ohio Third Frontier program.

### Lessons Learned

Many lessons have been learned over the course of GCIC's engagement with hundreds of potential commercialization opportunities.

**Focus on a specific clinical area**. GCIC is focused on the diagnosis and treatment of cardiovascular disease. While a huge market and diverse within itself, it nevertheless has boundaries that help to define our area of involvement. Having a well communicated focus instructs clients and supporters as to the domain of the organization and helps to establish criteria for program implementation. Further, it enables hiring staff with specific relevant expertise. An important lesson is that you need to know what you

don't want to do as much as you need to know what you do want to do. This also helps in targeting and qualifying prospects/clients for engagement.

Leverage a core strength. Having a specific area of focus in one thing, having an area of focus where there is a well known, established, and leverage-able strength facilitates promotion, attraction, and recognition to enhance program success. GCIC was established by Cleveland Clinic which has a near century old history of innovative healthcare delivery, and has been ranked the number one U.S. hospital in cardiac care 22 years in a row by U.S. News and World Report. Clients seek out GCIC in significant part due to the affiliation with Cleveland Clinic.

**Secure sufficient funding to enable a long view**. The Ohio Third Frontier program showed extraordinary vision in awarding a \$60 million five year initial grant to establish GCIC. With that level of resources and operational horizon, GCIC has been able to establish programs with longevity; business-appropriate timelines; statewide, national and international awareness; and the ability to follow and stay involved with our portfolio companies to enhance their probability of success. We have been able to focus on the business of economic development rather than the business of fund raising for ourselves, meanwhile making investments that will establish a return to the organization for sustainability.

Hire industry-experienced staff. Closely linked to having a specific area of focus is having staff that is experienced in the business of commercialization in that field. Being a cardiovascular focused company, recruitment of staff targeted the cardiovascular industry. Although the management and technical staff is lean - comprising only five full-time employees - the team represents over 60 years of directly related product development, business development and marketing experience along with 24 issued patents in the field and dozens of product introductions. This experience is offered as a resource to the portfolio companies to help them make wise product development and business decisions, and to avail of referrals to prequalified resources in areas such as clinical, regulatory, reimbursement, and intellectual property strategy. The result is acceleration of product development schedules and avoidance of common pitfalls.

## **GCIC 10-Year Anniversary**

**Establish and rely on advisory boards**. Despite the deep industry experience of the staff, GCIC established external advisory boards to help guide and govern the process of making funding decisions. The composition of the boards – representing cardiovascular clinical and academic medicine, venture capital, medical industry, and economic development constituencies – brings added perspective and even broader experience to the process, while at the same time helping to shield the process from bias or influence.

### Establish selective and business-practical programs.

Technology based economic development, measured by business success and successful commercialization of product, must confront the present day challenges of scarce funding, virtual organizations, pressure to meet milestones, and challenging regulatory requirements, to name a few major issues. Program organization, funding criteria, funding mechanisms, and business expectations must be practical in order to enhance a company's probability of success. The programs must be highly selective, and commercialization focused in order to achieve desired outcomes.

Set goals, measure results, and be willing to adjust. GCIC was established with specific metric goals for the number of companies created/attracted in Ohio and the number of new jobs created or retained. The organization has exceeded every one of those goals as companies that received funding and business support have progressed through their growth stages. Relentless pursuit of achieving those goals has kept programs and activity focused, encourages constant review of what is working and what needs adjustment, and helps to identify new approaches or opportunities to fit a changing environment. For example, we learned that the initial concept of attracting companies to the state that were expanding established businesses was not realistic in a recession economy, so the focus shifted to identifying earlier stage foreign companies that sought to enter the U.S. market. We also began to target companies that could provide needed business support to the growing cluster of medical products developers. The result has been the attraction of 17 companies to establish new operations in Ohio though direct influence of GCIC's activities.

### Advantages of Multi-Institutional Collaboration

A key attribute of the GCIC program is that it encompasses a statewide, multi-institutional collaborative of clinical and academic centers and regional economic development organizations to serve as origins and scouts for commercialization opportunities. Further, the involvement of multiple institutions brings specialized resources and expertise in areas that may not be readily available in a single organization. Such cross institution collaboration is unusual, if not unique, in technology commercialization, and requires constant reinforcement of fair and unbiased processes for engagement. GCIC conducts regular and frequent outreach visits to all of its partners to work collaboratively in identifying and nurturing commercialization prospects. And when ready to be considered for funding assistance, these prospects are evaluated on merit criteria, not origin. GCIC has worked hard to establish and sustain a reputation of being "non-denominational" and transparent in this way in order to promote effective participation and collaboration among the diverse partners. For example, representatives of all the partner institutions sit on the Commercialization Advisory Board, and a representatives of the Ohio Third Frontier Program are welcome to attend board meetings as part of this open engagement philosophy. With this collaborative participation and input, the program will continue to identify and bring forward new technologies for commercialization, thereby assuring a rich pipeline for economic growth and success.

### <u>Summary</u>

Visionary in concept, committed in purpose, dedicated in focus, broad in reach, collaborative in work, practical in approach, and transparent in process, the Global Cardiovascular Innovation Center stands apart in creating technology-based economic development. Serving as both a catalyst and a magnet for new business in Ohio, GCIC is contributing significantly to building a thriving and sustainable biomedical industry cluster within the state. GCIC is recognized worldwide as a model for advancing commercialization, and delivering innovative cardiovascular technology to the marketplace. The result benefits the economy of the State of Ohio and the wellbeing of patients worldwide.

### **Acknowledgments**

GCIC acknowledges the generous support of the Ohio Third Frontier Program; our institutional partners, Cleveland Clinic, Case Western Reserve University, University Hospitals, the Ohio State University, University of Cincinnati, and University of Toledo; and our economic development partners BioOhio, BioEnterprise, Team Northeast Ohio, and the Fairfax Renaissance Development Corporation for their participation, support and contribution to the current and future success of mission.

