

GLOBAL CARDIOVASCULAR INNOVATION CENTER

Final Grant Report

January 2020

A photograph of a globe and a stethoscope on a blue background. The globe is in the foreground, showing the continents of North and South America. The stethoscope is positioned behind the globe, with its chest piece on the right and its tubing curving around the globe. The background is a solid, light blue color.

GCCIC

Bringing High-Impact Cardiovascular Innovations to the Market

ACKNOWLEDGEMENTS

Cleveland Clinic acknowledges the generous support of the Ohio Third Frontier Program, the Ohio Development Services Agency, the State of Ohio and its citizens; our institutional partners, 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 the GCIC mission.

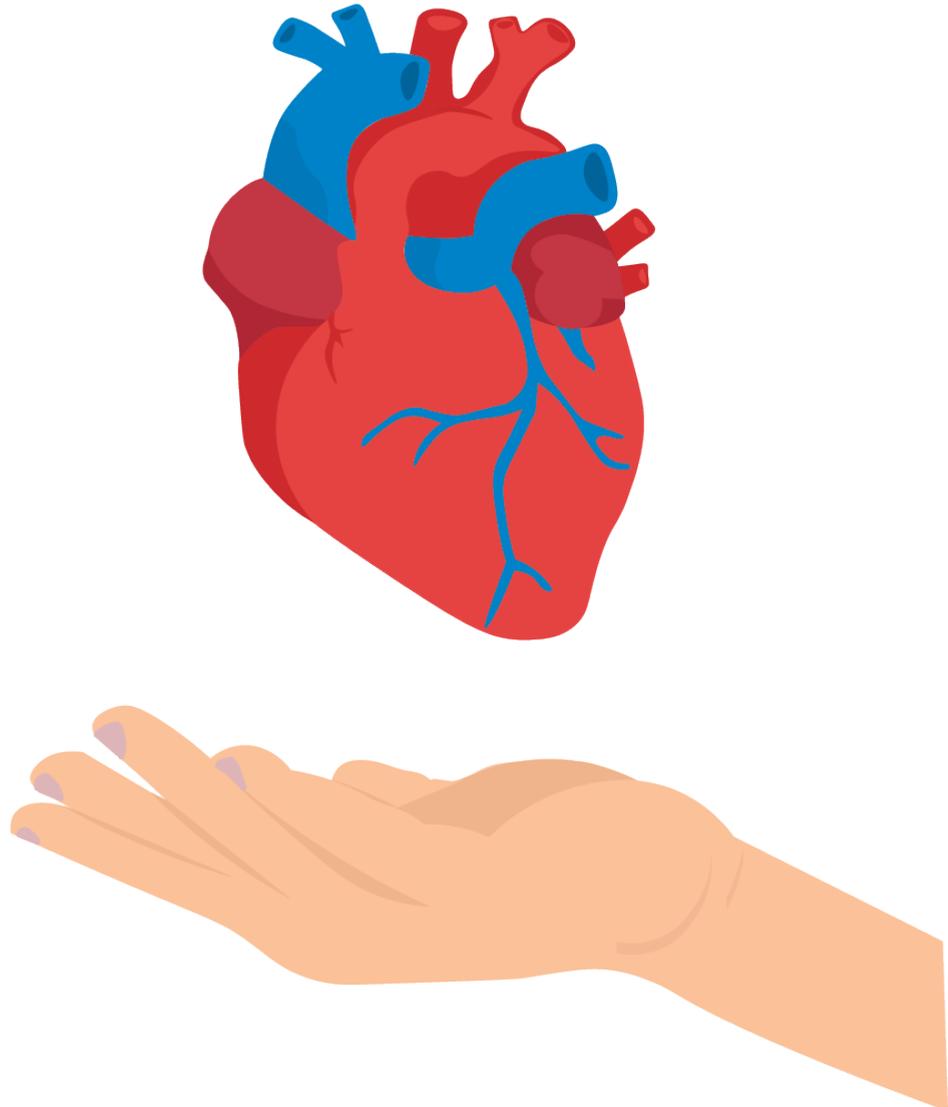


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Dear Colleagues,

On behalf of Cleveland Clinic and the entire Global Cardiovascular Innovation Center (GCIC) team, I am proud to present this final grant report for the Ohio Third Frontier funded Wright Mega-Center of Innovation Program (TECH 07-024).

Founded in 2007 with support from an unprecedented \$60 Million funding award to Cleveland Clinic from the State of Ohio, GCIC is the sole Wright Mega-Center of Innovation in the Ohio Third Frontier program. The purpose was to establish a center of excellence that would clearly define Ohio as an international leader in the research and commercialization of a technology platform that would have a substantial, measurable, and sustainable impact on the State's economy. Leveraging the world-class position of Cleveland Clinic – consistently ranked in the top 5 of best hospitals by U.S. News and World Report, and number 1 in heart care for 25 years in a row as of 2019 – GCIC's mission was established to be an international leader in developing, incubating, and commercializing cardiovascular technology.

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 and opportunities.

Over the past 12 years, GCIC has fulfilled that mission and far exceeded goals on all fronts through programs to provide technology development funding, industry-based commercialization expertise, new company incubation facilities, business development and company attraction support, and resources for the testing, validation, and training in the use of new technologies – all for the diagnosis, treatment, and management of cardiovascular disease.

This report summarizes the accomplishments of the GCIC programs and profiles a number of the companies that are developing the new technologies that are making a difference in patient care worldwide.



Sincerely,
MARK LOW
Managing Director, GCIC

ABOUT THE GLOBAL CARDIOVASCULAR INNOVATION CENTER

THE GLOBAL CARDIOVASCULAR INNOVATION CENTER (GCIC) IS A...

product development and commercialization accelerator made possible through a \$60 million grant from the State of Ohio's Third Frontier Program. GCIC is focused on developing, incubating, and commercializing innovative cardiovascular technology and facilitating economic development in the State of Ohio. Founded in 2007, the organization is led by Cleveland Clinic and partners with leading clinical and academic institutions, industry, and economic development organizations to support new product development and commercialization. Significantly, with 60 technologies funded through the program to-date, 28 have successfully reached the clinical evaluation stage or are now commercially available for the diagnosis, treatment or management of cardiovascular patients worldwide. www.gcic.org.

The consortium is made up of Cleveland Clinic, Case Western Reserve University, University Hospitals of Cleveland, The Ohio State University, the University of Cincinnati, and the University of Toledo, along with state-wide economic development partners BioOhio, BioEnterprise, and Team Northeast Ohio.

GCIC manages four core programs to support product and economic development based on cardiovascular technologies:



TECHNOLOGY DEVELOPMENT, COMMERCIALIZATION ACCELERATION

A program to formally solicit, evaluate and to fund candidate projects, and to provide engagement with a staff of industry-experienced product developers to efficiently and effectively advance technologies towards commercialization.



BUSINESS ATTRACTION

A program offering financial incentives and local access to resources for companies to establish new businesses in Ohio and grow the cardiovascular cluster.



NEW COMPANY INCUBATION

Operating and managing a newly constructed incubator facility for start-up companies and support service companies to help grow the regional ecosystem.



PRECLINICAL INVESTIGATION CAPABILITIES

Operating a state-of-the-art preclinical facility for sponsored research, product validation, and procedure training.



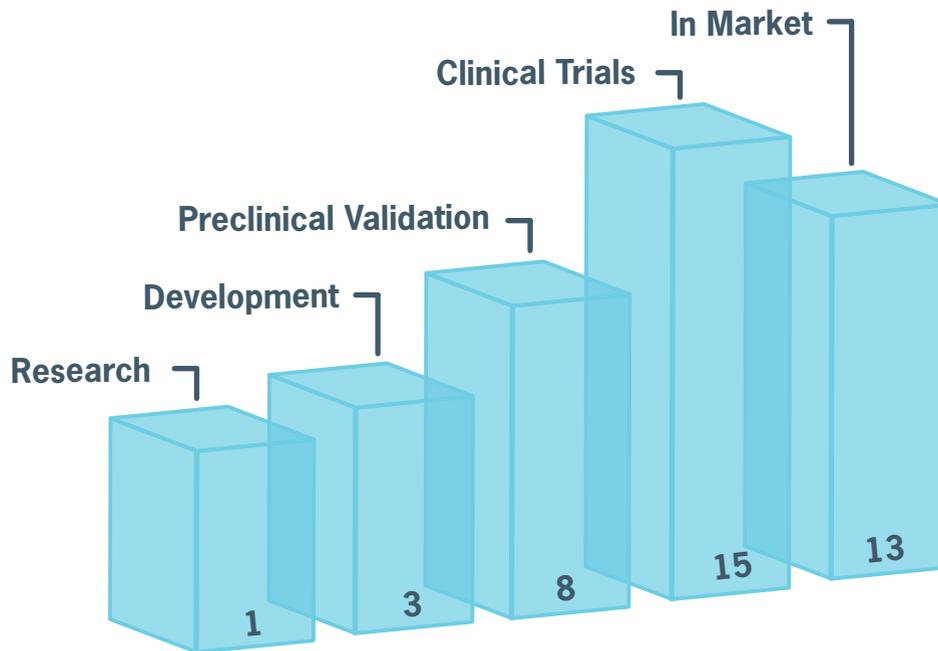
GCIC CELEBRATED ITS 12TH ANNIVERSARY OF OPERATIONS IN 2019

During that time it has far exceeded the metrics originally established for the program, contributing to significant growth and success in both cardiovascular innovation and Ohio economic development.

Since its founding in 2007, the program grew and took on added responsibility. An earlier established Ohio Third Frontier-funded initiative, the Atrial Fibrillation Innovation Center (AFIC), was brought under the GCIC umbrella, and the program extended its reach into cultivating early stage technologies by becoming one of three NIH Heart, Lung, and Blood Institute funded Centers of Accelerated Innovations in the U.S. Together the programs continue to provide even broader support and resources to cardiovascular research and development.

TECHNOLOGY DEVELOPMENT AND COMMERCIALIZATION ACCELERATION

PROGRESS OF 60 TECHNOLOGIES FUNDED



With the goal of creating or attracting 40 companies and creating 850 associated jobs, nearly half of the original state grant was earmarked to provide seed funding for early stage Ohio-based companies. Using a periodic request for proposals (RFP) process to solicit and qualify project applications, GCIC formally evaluated over 230 candidate projects. Funding recommendations were made by members of an external Commercialization Advisory Board which was comprised of leaders from the cardiovascular scientific research and clinical community, venture capital funds, and the cardiovascular industry. The combined evaluation perspectives incorporated clinical need, mechanisms of action, market opportunity, business and finance, and channels to market which altogether contributed to assess the probability of commercialization success.

A total of 60 projects have been funded, all of which then had the benefit of working closely with members of the GCIC product development staff to gain access to design, development, clinical, regulatory, finance, manufacturing, marketing, and distribution expertise in order to accelerate development. The result thus far is a significant success rate with 13 projects (22%) having been introduced into the market, 15 (25%) following closely in human clinical trials stage, and 12 (20%) progressing through earlier development stages, for an overall progression rate of 67%.

CLEVELAND HEARTLAB (QUEST DIAGNOSTICS)

Jake Orville



Cardiovascular diagnostic testing company Cleveland HeartLab works to aid clinicians in identifying risk, and reducing occurrence of, cardiovascular events. Cleveland HeartLab was established in 2009 to commercialize cardiovascular biomarker technologies born out of Cleveland Clinic's Lerner Research Institute. With the help of initial grant funding from GCIC, Cleveland HeartLab was not only able to get its founding three products to market, but continue to develop new offerings. Today the lab offers a range of FDA approved diagnostic tests for inflammation, advanced lipid measurement, metabolic disorders, vitamin and supplement levels, genetic makeup, and other cardiovascular disease triggers.

In 2017, Cleveland Heart Lab was acquired by New Jersey-based medical testing laboratory, Quest Diagnostics. With intent to establish a "national center of excellence" in cardiometabolic disorders at the Cleveland HeartLab location, Quest took another huge step toward its ultimate goal of uncovering the hidden risks of heart disease.

In connection with the acquisition, Quest Diagnostics and Cleveland Clinic finalized a strategic collaboration with the intent to speed commercialization of emerging cardiovascular diagnostic technologies. Through their deal with Quest, the company has been able to further the reach of its innovative technology made possible, in part, by GCIC years ago.

Says former Cleveland HeartLab CEO, Jake Orville, ***"We were frequent customers of the advice and support of GCIC. There was continuous interaction over the course of 10 years, from assistance with product concepts to development to regulatory to reimbursement procedures. The validation the [GCIC] grant provided in our early stages allowed us to attract eventual follow on investors."***

CARDIOINSIGHT TECHNOLOGIES

Charu Ramanathan, PhD

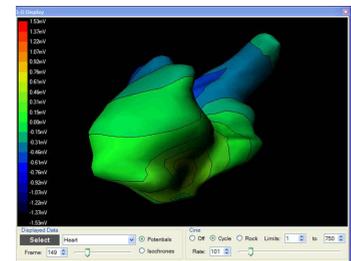


With its founding in 2006, CardioInsight Technologies, a Case Western Reserve University medical device company, developed a new approach to improve the mapping of electrical disorders of the heart. Originally dubbed the ECVUE system, CardioInsight's technology provided the unique opportunity for advanced cardiac mapping and non-invasive characterization of abnormal heart rhythms outside the EP lab. This innovative solution was supported in its early stages by GCIC.

CardioInsight was awarded three funding awards from the GCIC program – in 2008, 2010, and 2012. The first grant was to help develop a piece of technology that would eventually be incorporated into the product, the second was to enhance the capability of the product via a new feature, and the third was a convertible note investment to support final development of the technology for commercialization. The technology that emerged from these grants established a valuable market player, gaining CE mark and FDA approval in 2014.

CardioInsight was acquired by Medtronic in July of 2015 after having grown from 15 to around 40 individuals in four years. The company became part of the atrial fibrillation solutions business in the cardiac rhythm and heart failure division and the product was renamed the CardioInsight™ Noninvasive 3D Mapping System. To date, the technology has been used on more than 1,600 patients in Europe and the United States and featured in more than 120 peer-reviewed manuscripts, abstracts, and presentations.

Says co-founder Charu Ramanathan, PhD, of GCIC's involvement in the company's early days, ***"It was very impactful. The vehicles which we got funded were both software technology, so the grants helped us test these concepts."*** Dr. Ramanathan also referenced the rigor of the GCIC grant application process: ***"The due diligence process was very helpful to get focused on the technology and the features for the product. I remember it being difficult and thought-provoking – effectively helping us think more critically about what it was we were trying to accomplish."***



NANOFIBER SOLUTIONS / VASCULAR GENESIS

Jed Johnson, PhD



Founded in 2009, Nanofiber Solutions, LLC is a regenerative medicine company focused in the production of scaffolds for organ and tissue regeneration. Developing a new class of implants with unrivaled performance, Nanofiber Solutions' technology is revolutionizing tissue engineering. Meeting complex clinical requirements in both human and veterinary medicine, the company's extensive research experience comes in part by way of the GCIC and NCAI programs.

Nanofiber Solutions has benefitted from multiple engagements with GCIC and NCAI to enable development and validation of the technology, and progress towards commercialization. In 2007, at the very beginning of the GCIC program, an award was granted to James Lee, PhD and John Lannutti, PhD at The Ohio State University to support electrospinning of biodegradable nanofibers for various vascular device applications. In its first funding round in 2014, NCAI supported a project to develop tissue engineered vascular grafts – an extension of the technology first supported by GCIC years prior – at Nationwide Children's Hospital in Columbus in conjunction with Nanofiber Solutions.

Though one entity at the time of the 2014 engagement, 2016 saw the creation of five subsidiary companies: RenovoDerm, Atreon Orthopedics, Tarian Medical, eLum, and Vascular Genesis. With focus on everything from hernia meshes to neurovascular embolization devices, the bank of IP formed across various clinical focus areas made Nanofiber Solutions – the parent company – desirable to outside investors.

Funding later awarded by GCIC in 2016 would invest directly into one of Nanofiber Solutions' subsidiaries, Vascular Genesis. Positioned in the vascular conduit replacement market with its line of synthetic scaffold products with self-healing capabilities, Vascular Genesis is lowering the risk of rejection, infection, and stenosis.

Over the timespan of involvement with GCIC and NCAI, Nanofiber Solutions has grown, formed a number of subsidiary companies, quadrupled its number of employees, progressed various applications of the technology through preclinical, clinical, and regulatory phases, and has introduced various applications into the market. According to co-founder Jed Johnson, PhD, GCIC's funding was crucial to the company's basic research and development – a stage at which acquiring investor funding is difficult. Jed also spoke highly of the initial panel of GCIC judges, stating **“the feedback from both clinicians and investors on the panel was extremely useful – it is essential that a developing company understands the perspectives from all interested parties.”** Now four years after their most recent grant award, Nanofiber Solutions and Vascular Genesis are continuing to diversify their portfolios and advance their revolutionary products to serve patients everywhere.



ENABLE INJECTIONS

Mike Hooven



Headquartered in Cincinnati, Ohio, Enable Injections is a medical device company developing on-body drug delivery devices that allow patients to self-administer high-volume, high-viscosity therapeutics.

With their flagship product, enFuse®, Enable Injections is on a mission to enable safe and effective user-administered subcutaneous delivery of therapeutics outside of a healthcare facility. Through collaboration with biopharma companies, Enable Injections' goal is to allow portfolio diversification and an improved patient experience.

In 2010 – the earliest stages of the business – Enable Injections was staffed with 5 employees working on an initial technology concept with no pharma partners and just a few rented offices. Having undergone a very small seed round of funding from Cincinnati Children's Hospital and a few other select investors, the company had raised less than one million dollars.

Leveraging familiarity with Cleveland Clinic and applying for the GCIC grant in 2010, Enable Injections secured the funding essential to launch the company toward growth. Now employing 140+ people in a 40,000 square foot building, Enable Injections has raised nearly 80 million dollars to date. Though its products are investigational at this time, the enFuse® platform is well-developed. The company has entered into development and commercialization contracts with several well-known pharmaceutical and biotech companies including Sanofi, Genentech, and Eli Lilly.

As stated by CEO Mike Hooven, ***“GCIC was one of our earliest investors and their investment played a key role in developing the company. The grant provided absolutely critical funding that was used to bring on the people and secure the resources we needed at that stage. The GCIC board was very supportive and having them as an investor greatly assisted future fundraising.”***



VENTUREMED

John Pigott, MD



VentureMed is a developing medical device company with a tool to revolutionize the artery prep process for angioplasty or the application of drug coated balloons. Funded in its early stages by a GCIC grant, VentureMed's FLEX Vessel Prep™ System is now on the market, making a difference in the lives of patients.

The FLEX Vessel Prep™ System is an over-the-wire, flexible, retractable sheathed device designed to prepare an ideal vessel environment to facilitate angioplasty. The system predictably modifies and scores plaque with control to prepare lesions via a dual mechanism of action combining longitudinal micro-incisions with radial force expansion.

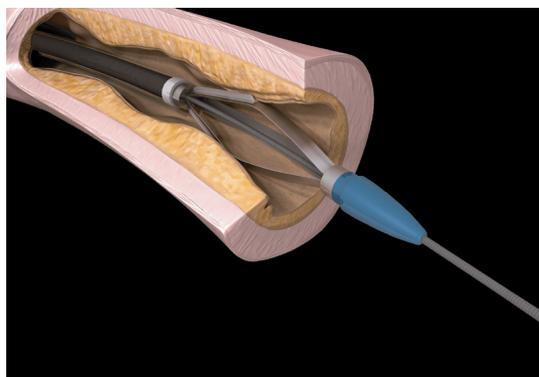
When introduced to GCIC in 2012, the VentureMed group was pre-commercial and pre-revenue, having just finished their design validation for the FLEX product. On staff were a CEO and a CMO, with all other specialty positions contracted. Though a capital efficient startup, the company was limited to a friends and family round of funding.

Today, VentureMed has a full-grown operation with nearly 20 employees headquartered in Toledo, Ohio. Supported by a CEO, CMO, CFO, Sales Team and more, their flagship product has been commercialized in both the United States and Europe. With GCIC funding, VentureMed's leadership was able to grow the company to a point that lead two well-known VC investors to organize a crucial round of Series A funding. VentureMed expects to undergo another round of funding in the near future to support increasing commercialization and marketing efforts, as well as the preparation of the FLEX platform for additional indications.

In Q1 of 2020, VentureMed will have five active clinical trials or registries – four in the US and one in Europe. Using the device, VentureMed has treated over 2000 patients with excellent clinical results. This patient impact metric is most important for the company – ***“we are committed to improving the lives of the patients we treat,”*** said CMO John Pigott, MD.



Dr. Pigott credits both the funding and the experience brought by the GCIC grant for their ability to grow to the point they are today. ***“I think the thing that made us a better company early on was going through the rigorous process of applying and presenting to the GCIC panel for the award. Their mandates made our presentation much crisper – when we got to VCs, pitching our worth was something we were comfortable with. The GCIC gauntlet brought a lot of refinement to the process, and for that we thank them.”***



NEW COMPANY INCUBATION



WITH SUPPORT FROM THE GCIC STATE GRANT,

and in collaboration with the neighboring Fairfax Renaissance Development Corporation, Cleveland Clinic constructed a new incubator/accelerator building to attract and support a growing population of new product development and services companies.

Conveniently located adjacent to the Cleveland Clinic main campus, the incubator offers 50,000 square feet of prime, state-of-the-art lab and office space, which currently provides operational space for 23 companies, 8 part-time tenants, plus Cleveland Clinic's business development, Innovations, and Ventures organizations. Configured to accommodate the latest in technology development, the facility is open to companies seeking short-term or longer-term, full-time or part-time occupancy to meet their strategic needs at competitively attractive lease rates. Tenants enjoy customizable laboratory facilities for new product research and development activities, flexible and furnished office space, high speed fiber network and Wi-Fi access, large meeting rooms with video conferencing capability, and have convenient access to all of GCIC's business support services.

Ground-breaking for the new building took place in early 2009 and operations started in May 2010. Since opening, the facility has been consistently at or near full occupancy. Clients include both start-up companies developing proprietary technologies, and service companies that provide business support such as regulatory, quality, and clinical trial services.

THERMALIN DIABETES

Rick Berensen, JD



Founded in 2010, biotechnology company Thermalin was established to disrupt the insulin therapy market. Through re-engineering insulin molecules for increased stability and selectivity, Thermalin has been able to overcome the limitations of existing insulin products. Thermalin's new formulations of these molecules fuel state-of-the-art delivery devices and systems with the power to transform lives: transformations that include lower burden of insulin use, increased patient adoption of/adherence to insulin therapy, improved outcomes, and lower cost of Type 1 Diabetes (T1D) and Type 2 Diabetes (T2D) care.

Thermalin approached the GCIC Incubator in 2010, via their connection with an existing tenant. A connection that would allow the company's first employee to work in borrowed space until additional staff arrived. As the staffing ramped up, Thermalin solidified their company presence by leasing one lab and one office. Evolving over the years to follow the science that led them, the company has grown to eighteen employees that occupy four labs, one office, and one large shared office workspace within GCIC.

Thermalin quickly noticed that evolving science requires evolving capabilities. Upon discovering the molecules they needed were hard to access, the company began developing their own at GCIC. Through creation of a GMP facility in the building, Thermalin developed novel protein therapies that would ultimately lead to the capture of a large investment round with multinational pharmaceutical company Sanofi. Through the years, Thermalin has benefited from a deep relationship with GCIC management, allowing them to reconfigure their space as needed. Rick Berensen, JD, CEO, Thermalin Diabetes, notes, ***"This type of flexibility is crucial to biotech companies that are led by where the science takes them. The quality of the facility and the ability to bring in equipment needed to advance the company to the next stage allows for continued progress."***

The healthy partnership between building management and its tenant companies has been crucial to Thermalin's success, allowing the company to utilize their capital where they need it most — developing the science.

DIASOME

Robert Geho



Diasome is a small, Cleveland-based pharmaceutical company focused on the development of more effective insulin. Working to reduce the amount of insulin needed to regulate blood sugar, Diasome's technology leverages a never-before-seen feature: a nano-sized carrier system additive, taking injected or oral insulin directly to the cells of the liver where it is primarily received.

Diasome became a resident of the GCIC facility when it first opened its doors over 10 years ago. The company was seeking attachment to a larger organization to provide both infrastructure and credibility – even if only through proximity. Enter a turn-key opportunity, GCIC. The incubator facility provided support, wet labs, dry labs, office spaces, telephone systems and other shared lab services that are not always available to startups on a tight budget. From both a business operations and technology development perspective, Diasome was very early stage, working in the underexplored space of diabetes drug development.

Upon moving to GCIC, Diasome's footprint included one office and two labs, though over time its configuration has changed. Today, the company has two labs and a large office space, allowing business operations to communicate efficiently and effectively to drive the company forward. Diasome is currently venture backed with support from high networked families with passion for Type 1 Diabetes and JDRF.

Daily interactions and open dialogue with the facility management team allowed flexibility during Diasome's residence. As the company grew, shrunk and grew again, they were able to find exactly what they needed with the mindfulness and flexibility of GCIC.

Says Robert Geho, CEO, on the relationship Diasome and GCIC have built, ***"The big thing is the awareness from the building management that companies that do this kind of work have peaks and valleys as they develop – it's not a straight line. You can have all the best plans and be thrilled when things go exactly the way you think, but the real winners are the ones who can survive when it doesn't go as planned. Having an open, engaging relationship with the management where you can be honest about your ups and downs helps tremendously. This is a system that is very conducive for getting things done. It's a business that recognizes the ins and outs of startups, and adapts accordingly."***

BUSINESS ATTRACTION

IN ADDITION TO SUPPORTING THE FORMATION AND GROWTH OF NEW COMPANIES WITHIN THE STATE,

attracting new companies to Ohio is an important element of GCIC's mission. The GCIC program and the resources it brings have significantly influenced companies – both domestic and international – to expand or relocate their operations in Ohio to pursue their business objectives. A central geographic location, rich human and technology resources, and favorable business finance and tax structures make Ohio a desirable and supportive state for new business location. Over GCIC's lifespan a total of 28 companies have either temporarily or permanently established new operations in Ohio, acknowledging GCIC as a major factor in their decision.

These companies represent a broad geographic mix, including international companies from Belgium, China, Ireland, Israel, New Zealand, Japan, and domestic companies from Indiana, Michigan, Minnesota, New Hampshire, North Carolina, Oregon and Pennsylvania. They vary in size from one or two person offices, to a division of a major multinational medical device firm that acquired a GCIC funded start-up and continues to grow the operation in Ohio. Some are companies developing proprietary products for first introduction into commerce, some are international companies establishing Ohio as their base of operations for entering the U.S. market, and some are service providers that are catering to the technology development, clinical trial, or regulatory strategy needs of companies all across the U.S. from their location in Ohio.



PROXY BIOMEDICAL, INC. / VISCUS BIOLOGICS LLC

Peter Gingras



Viscus Biologics is an original design manufacturer (ODM) that designs, develops and manufactures native polymer components and medical devices. Making truly custom products for their clients, Viscus Biologics takes their products all the way from early concept, through regulatory filing and manufacturing.

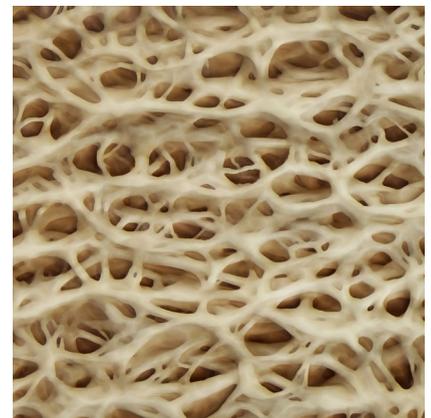
With a desire for growth, Peter Gingras, Executive Director of Proxy Biomedical, Ltd. of Galway, Ireland, decided to set up a subsidiary in Cleveland, Ohio in 2009. Gingras, a graduate of Case Western Reserve University, felt the familiar network of Cleveland Clinic and the abundance of life science companies in the surrounding area made Cleveland a compelling location. With support from a company attraction loan from GCIC, Proxy Biomedical, Inc. established operations in Cleveland.

Viscus Biologics was established in 2012 as a joint venture with product technology from Proxy Biomedical and the company moved into the GCIC incubator facility.

Partnering with and leveraging the knowledge of Cleveland Clinic physicians, the company has developed products including FibermarX™, a radiopaque tissue marker visible in standard imaging, and VitanatiV, a platform of native polymers, soluble collagen and bioinks. XenoMEM™, the company's third product, is an FDA-cleared porcine peritoneal membrane for advanced wound care.

After four years in the GCIC incubator with office, lab space, and a small production clean room, Viscus recently graduated to a 15,000 square foot facility of their own. Viscus Biologics' work with GCIC has translated to jobs, as well as revenue for the state of Ohio. They currently employ approximately 15 people in their new facility and hope to grow that number in the coming year.

Said Gingras of the company's time at GCIC, ***"In the right environment, with the right people and infrastructure, you can develop some very compelling solutions."***



GENAE AMERICAS

Bart Segers



Contract research organization genae was founded in Belgium in 2005. Responsible for designing, monitoring and analyzing clinical trials for manufacturers of medical devices, as well as offering research, regulatory and safety services to the medical industries, genae is helping bring better products to market faster. Since 2005, the company has grown to encompass nearly 110 employees worldwide, with locations in Antwerp, Frankfurt, Zurich, New York, Tel Aviv, and Cleveland.

In genae's early days, the company noticed a trend of US-based customers with a desire to deploy in the European market. It became immediately clear that to understand US regulatory processes and properly service their US-based clients, genae would need boots on the ground.

"When you decide to move to the US, it is hard to know where to start – East Coast or West Coast?" said Bart Segers, genae Co-Founder and CEO. Leveraging an existing relationship with Case Western Reserve University in Cleveland, the company began to look for its new location in the state of Ohio. ***"We were lucky to be there [GCIC] early."***

At the start of operations in 2010, genae Americas had one project manager in Cleveland. For three years, this individual worked to set up shop, make initial contacts with local customers, and hire additional employees. According to Segers, the GCIC staff was integral to genae growth at this time. With the help of GCIC, the company made new connections, secured business services and legal counsel, grew to 19 staff members, and learned to navigate the market in Cleveland.

Under one roof, with near-daily contact, the genae and GCIC teams grew close. ***"The GCIC staff helped to introduce us to other potential companies to work with,"*** said Segers. ***"They are truly ambassadors, not just for GCIC but for the other organizations throughout their network."***

REGULATORY & QUALITY SOLUTIONS

Maria Fagan



Since its founding in 2008, Pittsburgh-based Regulatory & Quality Solutions has been on a mission to improve people's lives through the success of medical device, in-vitro diagnostic, and combination product companies. While a lofty goal, it is one R&Q works every day to achieve via the regulatory and quality services it provides to companies around the world. Helping bring innovative solutions to market and keeping them there, R&Q's suite of consulting services include regulatory expertise, quality system development, design assurance, product quality control, post-market surveillance and remediation solutions.

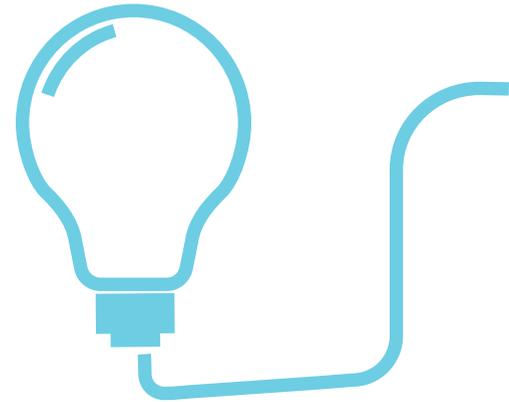
Though founded in Pittsburgh, R&Q opened an office in GCIC after introductions to BioEnterprise, GCIC, and a forgivable loan offered through the GCIC Company Attraction Program in 2011. With 5 initial staff members, R&Q set to work further expanding its offerings in the Midwest. GCIC was a natural fit for the company, as there were many other startups in the building to offer services. The building also provided ample space for collaboration and meeting with clients.

Said Maria Fagan, CEO of R&Q, ***"The management team [at GCIC] was very engaged in helping its startups. They introduced us to a lot of potential clients."***

R&Q fulfilled their grant requirements in 2017, and currently employs 19 Ohio residents – a jump from the original five in 2010. The company generated over \$2.6 million in Ohio revenue in 2018 and still operates their Ohio business out of the GCIC facility.

PARTNERING FOR INNOVATION SUCCESS

No program of the scope and ambition of GCIC can accomplish its objectives without significant engagement of partnerships. The Center was founded as a consortium of academic, clinical, and economic development partners, led by Cleveland Clinic. GCIC has also grown by co-managing or partnering with other innovation programs in order to expand the reach and resources available to the programs.



ACADEMIC AND CLINICAL PARTNER INSTITUTIONS

Six institutional partners comprise the core of the consortium. Individually, they are among Ohio's leading academic, research and medical centers, recognized as hubs of innovation and discovery and leaders in cardiovascular disease research and care. In addition to being the sources of many of the technologies evaluated by GCIC for development, they provided clinical perspectives to complement one another and technology expertise for product innovation.



ECONOMIC DEVELOPMENT PARTNERS

GCIC'S ECONOMIC DEVELOPMENT PARTNERS PROVIDE INVALUABLE SERVICES AND SUPPORT

for the new businesses formed and supported by the program. Working together with GCIC, the group leverages combined resources and networks to enhance business attraction, formation and acceleration, as well as in some cases being a source of follow-on development funding.



ATRIAL FIBRILLATION INNOVATION CENTER (AFIC)



Pre-dating GCIC, the State of Ohio awarded Cleveland Clinic a \$23 Million Ohio Third Frontier Grant (TECH 05-066)

in 2005 to establish the Atrial Fibrillation Innovation Center with the objective to accelerate the pace of AF technology development and commercialization in Ohio. The grant enabled AFIC to build a state of the art dedicated preclinical research and development facility at Cleveland Clinic, equipped with specialty surgical, imaging, and measurement systems ideal for both electrophysiology research and broader cardiovascular product development.

In 2008, the AFIC facility merged under the GCIC program and continues its operation to this day on a sustained cash flow positive basis, long after the original AFIC grant period ended. Incorporating the preclinical facility into GCIC expands the capabilities offered to both internal researchers and to external sponsored research customers for product evaluation, procedure development and physician training across a wide diversity of clinical application areas.



NIH CENTER FOR ACCELERATED INNOVATIONS (NCAI)



NIH Center for Accelerated Innovations
at Cleveland Clinic

Success of the GCIC program has also resulted in broader opportunity for program expansion and growth. Based in large part on the successful institutional relationships established by GCIC and the demonstrated commercialization outcomes of the program, Cleveland Clinic successfully competed for a NIH award to establish a NIH Center for Accelerated Innovations (NCAI) in 2013. The NCAI-Cleveland Clinic, www.ncai-cc.ccf.org, includes partnering institutions Case Western Reserve University, The Ohio State University, Cincinnati Children's Hospital Medical Center, the University of Cincinnati, the University of Michigan, and Northwestern University. It is one of only three such Centers in the country, and the only one between the coasts.

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 \$14 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 sleep-disorder conditions across the range of diagnostics, devices, and therapeutics. The NCAI center is managed in close conjunction with 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 Industrial Research and Development Center Program (IRDCP grant TECG20140286).

While the GCIC funding program evolved early on to target company-based projects that had the potential for economic development growth and investment returns for program sustainability, the NCAI program targets earlier stage projects that are still being conducted within academic research institutions. Since both programs focus largely on cardiovascular clinical indications they are highly complementary. There are a number of examples now where earlier stage projects at the academic partner institutions received NCAI funding, have been spun-out to form companies, and have gone on to receive continued development funding from GCIC.

OUTCOMES AND ECONOMIC IMPACT

Ohio's excellence in biomedical research and development served as the launching pad for GCIC's efforts in establishing new companies, attracting existing companies to the state and expanding the cardiovascular technology community. 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 & SUCCESS



Formally evaluated over 230 technologies and provided funding totaling \$24.6M for development of 60 innovative cardiovascular products.



Supporting 47 different companies and 8 research institution-based projects throughout the state.



Resulting in 28 new products in the market or currently being evaluated in clinical trials where they are serving the diagnostic and therapeutic needs of patients worldwide.

IN BUSINESS ATTRACTION



17 new businesses attracted to and continuing operations in Ohio, plus 11 additional attracted companies operated in Ohio on a temporary basis, bringing new key design, manufacturing, and business resources to the state

IN PRODUCT DEVELOPMENT & 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, currently home to 23 full-time and 8 part-time tenant companies, with 8 other companies having graduated to expand and grow their businesses, still in Ohio.



RESULTING IN SIGNIFICANT NEW EMPLOYMENT AND INVESTMENT

1275 new jobs to-date in companies funded, attracted or incubated by GCIC.



Greater than \$1.2 Billion in follow-on funding and M&A transactions secured.

IN AN INVESTMENT PORTFOLIO EXPECTED TO YIELD RETURNS FOR PROGRAM SUSTAINABILITY

As of December 2019

\$3.65M in commercialization funding convertible notes with 9 companies.

\$6.1M in equity investments in 8 companies.

\$1.94M in realized cash returns from 3 company investments.



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

BEST PRACTICE IMPLICATIONS

Many lessons have been learned over the course of GCIC's engagement with hundreds of potential commercialization opportunities. **Key best practices include:**

HAVE A SPECIFIC AREA OF FOCUS



GCIC has been 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 the 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 the organization needs to know what it does not want to do as much as what it does 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 25 years in a row by U.S. News and World Report. Two other Ohio based partner institutions are in the top 25 of the ranking. Clients seek out GCIC in significant part due to the affiliation with Cleveland Clinic and these partner institutions.



SECURE SUFFICIENT FUNDING TO ENABLE A LONG VIEW



The Ohio Third Frontier program demonstrated significant vision in awarding a \$60 million grant to establish GCIC. With that level of resources and a long 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 portfolio companies to enhance their probability of success. We have been able to focus on the business of product and economic development rather than the business of fund raising for ourselves, meanwhile making investments that will establish a return to the organization for sustainability.

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 tight 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. GCIC kept such a practical approach forefront in consideration of opportunities and requirements for funding and attracting companies to the program.

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 organization, 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 80 years of directly related product development, business development and marketing experience along with dozens of product introductions into the market. This experience is offered as a resource to the portfolio companies to help them make wise product development and business decisions, and to benefit from referrals to pre-qualified resources in areas such as clinical, regulatory, reimbursement, and intellectual property strategy. The result has been acceleration of product development schedules and avoidance of common pitfalls.



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 – brought added perspective and even broader experience to the process, while at the same time helping to shield the process from bias or influence.

SET GOALS AND MEASURE RESULTS, BUT 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 far exceeded those goals as companies that received funding and business support have continued to make progress through their growth stages. Relentless focus on achieving those goals has kept the programs and activity on track, encouraged constant review of what was working and what needed adjustment, and helped to identify new approaches or opportunities to fit a changing environment. For example, we learned that the initial concept of attracting to the state companies 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 28 companies to establish new operations in Ohio through direct influence of GCIC’s activities.



ESTABLISH BROAD PARTNERSHIPS AND COLLABORATIONS



A key attribute of the GCIC program is that it encompassed 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 brought specialized resources and expertise in areas that may not have been readily available in a single organization. Such cross institution collaboration is unusual, if not unique, in technology commercialization, and required constant reinforcement of fair and unbiased processes for engagement.

GCIC conducted 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, those prospects were evaluated on merit criteria, not origin. GCIC 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 sat on the Commercialization Advisory Board, and a representative of the State Department of Development regularly attended board meetings as part of this open engagement philosophy.

SPREAD THE WORD

GCIC promotes its programs and success through a variety of venues. In addition to conventional website, press release and promotional literature vehicles, and regular quarterly reports to the State of Ohio, perhaps the most significant communication of GCIC’s programs and success is through attendance and podium presentations at key medical and economic development conferences. GCIC team members attend major cardiovascular scientific and industry meetings throughout the U.S. and internationally to promote and recruit interest in the growing Ohio cardiovascular industry cluster. We are regularly asked to present our commercialization programs, best practice processes, and results providing worldwide recognition of the program.



ESTABLISHING THE BASE FOR CONTINUED INNOVATION

Through lean operation and selective decision making, the original \$60 Million state grant has sustained the GCIC programs for 12 years. The outcomes measures, though taking longer than originally projected, were all achieved and surpassed. The ultimate outcomes have far exceeded expectations on a dollar for dollar basis.

In order to establish a basis for program sustainability, GCIC switched from making funding awards as grants to funding in the form of convertible promissory notes or direct equity investment in 2012. As of December 2019, Cleveland Clinic has received cash proceeds from three GCIC investments, holds equity in 8 GCIC funded companies, and holds convertible promissory notes with 9 additional companies on active GCIC funded projects. Proceeds are being held as a GCIC Evergreen Fund for future mission-oriented use.

At this time the GCIC commercialization funding program is paused, pending evaluation of new market needs and opportunities and realizing further returns on the funding investment portfolio. Personnel support continues via internal Cleveland Clinic funds, and other grant sources. The incubator and preclinical facilities programs continue, self-funded by operating income.





THE GCIC AND NCAI OPERATIONS TEAM

Over the 12 year grant period the GCIC operational team has been a lean organization, averaging only 10 full time employees supported by the state grant, plus 2 additional product development directors during the period of NCAI parallel operations.

ADMINISTRATIVE

Mark Low
Managing Director
2007 — 2019

Susan Bernat
Director, Operations and Finance
2007 — 2014

Jennifer Mate
Sr. Accountant
2008 — 2010

Matt Stegmeier
Financial Analyst
2010 — 2011

Judy McAnally
Administrative Coordinator
2008 — 2012

Veronika Dwyer
Administrative Coordinator
2012 — Present

Joseph Rich, JD
Director, Governance
2011 — Present

PRODUCT DEVELOPMENT

Shubhayu Basu, PhD
Sr. Director, Devices
2008 — 2013

Eugene Jung
Sr. Director, Devices
2008 — 2014

Kelly Emerton, PhD
Sr. Director, Devices
2014 — 2016

Marwan Berrada
Sr. Director, Devices
2014 — 2018

Ramasamy Sakthivel, PhD
Sr. Director, Life Sciences
2014 — 2015

Suguna Rachakonda, PhD
Sr. Director, Life Sciences
2015 — Present

Vara Prasad Josyula, PhD
Sr. Director, Life Sciences
2018 — Present

Thomas Kadavy
Sr. Director, Devices
2019 — Present

PRECLINICAL PROGRAM OPERATIONS

Laura Konczos
Program Manager
2005 — Present

Jackie Kattar
Administrative Coordinator
2007 — Present

Bill Kowalewski
Veterinary Technician
2008 — 2018

Mark Hancock
Veterinary Technician
2018 — 2019

Mary Lachowski
Veterinary Technician
2019 — Present

THE GCIC/NCAI OPERATIONS TEAM

INCUBATOR OPERATIONS

Kimberley Davenport

Program Manager
2009 — 2014

Laura Konczos

Program Manager
2014 — 2019

Scott Sparks

IT Systems Administrator
2013 — Present

Dan Giczkowski

Manager, IT Systems
2007 — Present

Jeanne Sanford

Receptionist
2018 — Present

Kaitlin Guice

Administrative Coordinator
2018 — Present

Julie Carter

Administrative Coordinator
2014 — 2018

Sara Hantak

Receptionist
2011 — 2013

Elise Derbin

Receptionist
2013 — 2014

Amber Owens

Receptionist
2014 — 2018

Heather Lenix

Receptionist
2010 — 2012

BUSINESS DEVELOPMENT

Michael Austriaco

Sr. Director, Business Analytics
2010 — Present

Thomas Sudow

Director, Business Development
2007 — 2016

Joseph Barone

Project Management Associate
2007 — 2010

GCIC BOARD OF DIRECTORS

Steve Nissen, MD

Chairman, GCIC Board,
Former Chairman,
Cardiovascular Medicine,
Cleveland Clinic
2007 — Present

Paul DiCorleto, PhD

V.P., Research and Sponsored
Programs, Kent State University;
former Chair, Lerner Research
Institute, Cleveland Clinic
2007 — Present

Keith Kerman, MD

Operating Partner and Senior
Advisor, The Riverside Company;
former Managing Director,
Primus Venture Partners
2007 — Present

John Rice, PhD

Managing Director, CincyTech
USA; former Managing Partner,
Triathlon Ventures
2007 — Present

Frank Samuel

Former Ohio Third Frontier
Science and Technology Advisor
2007 — 2014, Deceased

Adele Gulfo

Former President and General
Manager, Pfizer, USA; former
VP, Business Development and
Innovation, AstraZeneca
2007 — 2012

Chris Coburn

Former Executive Director,
Cleveland Clinic Innovations
2007 — 2013

COMMERCIALIZATION ADVISORY BOARD

Keith Kerman, MD, Chairman

Operating Partner and Senior Advisor, The Riverside Company; former Managing Director, Primus Venture Partners

William T. Abraham, M.D

Professor of Medicine, Physiology and Cell Biology; former Chief, Division of Cardiovascular Medicine, The Ohio State University

Dorothy Air, PhD

Former Associate Sr. VP, Entrepreneurial Affairs, University of Cincinnati

Mike Bunker

CEO, Cryothermic Systems, Inc.; former Managing Director, Early Stage Partners

Paul DiCorleto, PhD

Vice President for Research and Sponsored Programs, Kent State University; former Chair, Lerner Research Institute, Cleveland Clinic

Bob Easton

Chairman, Bionest Partners

Paul W. Erhardt, PhD

Professor Medicinal & Biological Chemistry, College of Pharmacy & Pharmaceutical Sciences; Director Center for Drug Design & Development (CD3), The University of Toledo

Peter Fitzgerald, MD, PhD

*Director, Center for Cardiovascular Technology Stanford University Medical School
Managing Partner and Co-Founder, Triventures*

Patrick Fortune, PhD

Former Partner, Boston Millenia Partners

Jan Garfinkle

Founder and Managing Director, Arboretum Ventures

Jeff Gold

Independent board member and advisor, former Venture Partner, Longitude Capital

Reggie Groves

Former CEO, Reva Medical, Inc.; former Vice President, General Manager, Cardiac Rhythm Disease Management, Medtronic, Inc.

Steven Gullans, PhD

Former Managing Director, Excel Medical Ventures

John Mack

Vice President and General Manager of Cardiac Surgery, Medtronic, Inc.

Steven Nissen, MD

Former Chair, Department of Cardiovascular Medicine, Cleveland Clinic

Matt Pollman, MD

Cardiologist, Medical Industry Executive, Entrepreneur; Founder, Guided Interventions

Daniel I. Simon, MD

President, UH Cleveland Medical Center; former Chief, Division of Cardiovascular Medicine

Immanuel Thangaraj

Managing Director, Essex Woodlands Health Ventures

D. Geoffrey Vince, PhD

Chair, Department of Biomedical Engineering, Cleveland Clinic Lerner Research Institute

Dennis Wahr

Former President, CEO, Co-Founder, Lutonix

Lee Wrubel, MD

Former General Partner, Foundation Medical Partners



BOARD CHAIRMAN'S MESSAGE

Dear Colleagues,

The Global Cardiovascular Innovation Center is proof that great things are possible when clinical, research and business enterprises pool their energies. Over the twelve years that the Center has been actively pursuing its mission, GCIC has infused Ohio with fresh energy and exciting opportunities as we have achieved significant results in business formation, attraction, expansion, and retention.

These business ventures represent potential advances in the diagnosis and treatment of patients with cardiovascular disease – and many of these breakthroughs have become commercially available to extend a patient's life, improve quality of life or help physicians deliver treatment more efficiently. Fueled by the aging of the population and the rise in chronic diseases that accompanies that demographic shift, patient demand for safer, less invasive treatments, more sophisticated imaging for earlier diagnosis and more effective drug therapies will drive continued innovation in the field, and GCIC will continue to be part of the equation.

I know that you share my enthusiasm as GCIC builds on the accomplishments of the past 12 years and continues to shape a brighter future for patients, businesses and the great state of Ohio. Thank you for your interest, investment, and imagination.



Sincerely,

STEVEN NISSEN, MD

Chairman, GCIC Board of Directors
Former Chairman, Cardiovascular
Medicine, Cleveland Clinic

APPENDIX

GCIC STATE GRANT METRICS PERFORMANCE

■ Grant Target*
■ Total as of December 2019

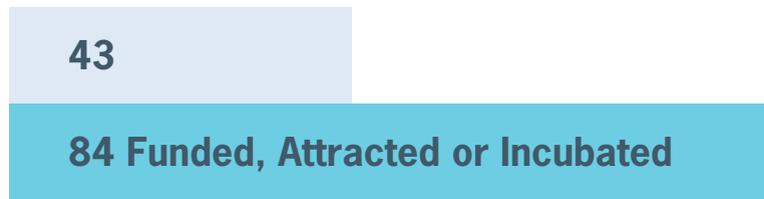
149%
of Target

Job Creation



195%
of Target

Venture Capital Backed and Recruited Companies



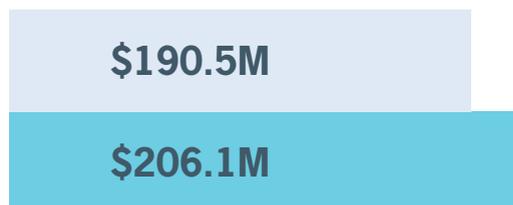
488%
of Target

Seed and Venture Capital Invested



108%
of Target

Cost Share Reported



A complete final financial report is being submitted to the State separately.

*Grant Period. Start: February 2007. End: Extended to December 2019.

GCIC COMMERCIALIZATION FUNDING AWARDS SUMMARY

Company Name	Funding Dates	Projects	Location	Classification	Funding Type	Current Development Stage
Advanced NanoTherapies	Dec-2019	SupraLimus Drug Coated Balloon	Cleveland, OH	Interventional Device	Convertible Note	Development
Akebia	Dec-2007	HPTPB Inhibitor therapeutics for the Treatment of Peripheral Artery Disease	Cincinnati, OH	Drug Development	Grant	Clinical
Arterioocyte	May-2007 July-2008	Clinical Development of Autologous Marrow-Derived CD133 Cells for Treatment of Chronic Myocardial Ischemia	Cleveland, OH	Regenerative Medicine	Grants	Clinical
Athersys	May-2007 July- 2008 Sep-2011	MultiStem as Therapy for Chronic Heart Conditions	Cleveland, OH	Regenerative Medicine	Grants	Clinical
Atricure	Mar-2010	Robotic Toolkit Platform for Atrial Fibrillation and Stroke Prevention Procedures	Cincinnati, OH	Surgical Devices	Grant	Marketed
Blue Ash Therapeutics	Sep-2009	Azimilide Clinical Development for FDA Approval and Commercialization	Cincinnati, OH	Drug Development	Grant	Discontinued
CardioCeption	Sep-2009	Development of CardioPatch for Acute MI	Cincinnati, OH	Drug Development	Grant	Discontinued
CardioInsight	Jul-2008 Mar-2010 Apr-2012	Real Time Non-invasive Guidance of Therapy for Cardiac Arrhythmias	Cleveland, OH	Electrophysiology	Grants, Convertible Note	Marketed
CardioStar	Jan-2009	Non-invasive Blood Pressure Monitor	Cleveland, OH	Vital Signs Monitoring	Grant	Discontinued
Case Western Reserve U. / Simon	May-2007 Sep-2009	GP Ib Alpha Inhibitors for Prevention of Heart Attack, Restenosis, and Vasculitis	Cleveland, OH	Drug Discovery	Grant	Pre-Clinical
Cell Targeting	May-2007	CellDirect™ - Directed Stem Cell Homing	Cleveland, OH	Regenerative Medicine	Grant	Not Known
Clear Catheter Systems	Dec-2007	Pleuraflow Chest Tube Clearance Technology	Bend, OR	Surgical Devices	Grant	Marketed
Cleveland Clinic	Mar-2011	The Interactive Visual Health Record	Cleveland, OH	Healthcare IT	Grant	Discontinued
Cleveland Clinic / DiCorleto	May-2007	TNF2 Inhibitors for Inflammatory Diseases	Cleveland, OH	Drug Discovery	Grant	Discontinued

GCIC COMMERCIALIZATION FUNDING AWARDS SUMMARY

Company Name	Funding Dates	Projects	Location	Classification	Funding Type	Current Development Stage
Cleveland Clinic / Fukamachi	May-2007	Mitral Annular Remodeling	Cleveland, OH	Heart Valve Products	Grant	Discontinued
Cleveland Clinic / Mihaljevic	May-2007	Minimally Invasive Fiberoptic Cardioscopy	Cleveland, OH	Image Guided Surgery	Grant	Discontinued
Cleveland Clinic / Navia	May-2007	Myo Ring Annuloplasty Device to Treat Mitral or Tricuspid Valve Regurgitation	Cleveland, OH	Heart Valve Products	Grant	Development
Cleveland Clinic / Navia	May-2007	Dry/Crimped Storage of Bioprosthetic Heart Valves for Minimally Invasive and Percutaneous Delivery	Cleveland, OH	Heart Valve Products	Grant	Clinical
Cleveland Clinic / Rezaei	May-2007	NeuroActive Stent & NeuroActive Catheter Stimulation Device	Cleveland, OH	Cardiac Neurostimulation	Grant	Clinical
Cleveland Clinic / Silverstein	May-2007 Sep-2009	CD36 Inhibitor Targeting in Atherosclerosis, Diabetes and Metabolic Syndrome	Cleveland, OH	Drug Discovery	Grant	Discontinued
Cleveland Clinic / Smith	May-2007	Mini-Mixed Flow Cardiac Assist Pump	Cleveland, OH	Cardiac Assist	Grant	Pre-Clinical
Cleveland Clinic / Wu	May-2007	Corin Assay for Congestive Heart Failure	Cleveland, OH	Diagnostic Assay	Grant	Research
Cleveland Heart	Jul-2008	Left Ventricular Assist Device	Cleveland, OH	Cardiac Assist	Grant	Pre-Clinical
Cleveland HeartLab (PrognostiX)	May-2007 Dec-2008	Cardiac MPO and Dysfunctional HDL Diagnostic Test Development	Cleveland, OH	Diagnostic Assay	Grant	Marketed
Cryothermic Systems	Apr-2012	Cardiac Arrest Cooling System	Cleveland, OH	Therapeutic Hypothermia	Grant	Marketed
Enable Injections	Apr-2012 Apr-2016 Sep-2017 Oct-2018	On Body Drug Delivery System	Cincinnati, OH	Drug Delivery	Grant Convertible Note Equity Invest.	Clinical
Enhale Medical	Dec-2019	VytaSom Obstructive Sleep Apnea System	Cleveland, OH	Interventional Device	Convertible Note	Development
EXCMR	Jan-2009	MRI Compatible Exercise Test Treadmill	Columbus, OH	Exercise Device	Grant	Clinical
Hemex Health	Jun-2017	Development of Advanced Malaria and Sickle Cell Diagnostic Product	Portland, OR	Diagnostic Device	Convertible Note	Clinical

GCIC COMMERCIALIZATION FUNDING AWARDS SUMMARY

Company Name	Funding Dates	Projects	Location	Classification	Funding Type	Current Development Stage
ICHOR Vascular	Aug-2016	Percutaneous Embolectomy System for Lower Limb Reperfusion	Toledo, OH	Interventional Device	Convertible Note	Marketed
Infinity Angioplasty Balloon Co.	Aug-2016	Infinity Balloon Development and Preclinical Studies	Toledo, OH	Interventional Device	Convertible Note	Pre-Clinical
Interventional Imaging	Dec-2007	RF Ablation Catheter for MRI Guided Pulmonary Vein Ablation (CWRU Technology)	Cleveland, OH	Interventional Devices	Grant	Discontinued
Ischemia Care	Mar-2011	Blood Test for Cardioembolic Cause of Ischemic Stroke	Oxford, OH	Diagnostic Assay	Grant	Marketed
Juventas Therapeutics	May-2007 Apr-2012 Oct-2013 May-2015 Sep-2017	SDF-1 for Treatment of Congestive Heart Failure and Myocardial Infarction	Cleveland, OH	Regenerative Medicine	Grant Equity Invests.	Clinical
Minimally Invasive Devices	Mar-2010	Floshield - Endoscope Lens Cleaning Apparatus for Cardiovascular Use	Columbus, OH	Surgical Devices	Grant	Marketed
Mitria Medical (CCF)	Dec-2019	Transcatheter Mitral Valve Repair Technology (Subvalvular Spacer)	Cleveland, OH	Interventional Device	Convertible Note	Development
Navis Medical	Dec-2007	Variable Control Guidewire System	Cleveland, OH	Interventional Devices	Grant	Discontinued
Ohio State University / Lannutti	May-2007	Electrostatic Spinning of Biodegradable Nanofibers	Columbus, OH	Tissue Engineering	Grant	Preclinical
PeriTec	May-2007 Jul-2008	Development of Peritoneal Tissue Lined Stent	Cleveland, OH	Interventional Devices	Grants	Discontinued
Quality Electroynamics	Dec-2007 Mar-2011	32-Channel Detector and Ultrahigh Field MRI Arrays for Diagnosing Heart Disease	Cleveland, OH	Imaging	Grants	Marketed
Securus Medical	Mar-2011 Aug 2016	Esophageal Thermal Mapping System for Cardiac Catheter Ablation	Boston, MA	EP Procedure Monitoring	Grant Equity Invest.	Clinical
Sense Diagnostics	Aug-2015 Nov-2018	SENSE Brain Hematoma Detector	Cincinnati, OH	Diagnostic Device	Grant Convertible Note	Clinical

GCIC COMMERCIALIZATION FUNDING AWARDS SUMMARY

Company Name	Funding Dates	Projects	Location	Classification	Funding Type	Current Development Stage
Sensible Medical	Jan-2009	Non-invasive Congestive Heart Failure Monitoring System	Tel Aviv, Israel	CHF Monitoring	Grant	Marketed
Tatara Vascular	May-2015	Coronary Guidewires Development Project (Whitlow Wires)	Cleveland, OH	Interventional Device	Convertible Note	Clinical
TheraVasc	Sep-2010	Clinical Development of Sodium Nitrite Reformulation for Diabetic Patients with Peripheral Arterial Disease	Cleveland, OH	Drug Development	Grant	Clinical
Toad Medical	Apr-2013	TAG Brace for Aiding Healing of Plantar Ulcers	Washoe Valley, NV	Orthotic Brace	Grant	Not Known
TRIM-edicine	Oct-2013	Development of MG53 as a Therapeutic Agent	Columbus, OH	Therapeutic	Convertible Note	Pre-Clinical
Vascular Genesis	Aug-2016	Tissue Engineered Vascular Graft for Vascular Access	Columbus, OH	Interventional Device	Convertible Note	Pre-Clinical
VasoStar	Jan-2009	Chronic Total Occlusion Crossing Guidewire	Cleveland, OH	Interventional Device	Grant	Discontinued
Vectorious Medical	Nov-2014 Oct-2019	Left Atrial Pressure Based Management for Chronic Heart Failure	Tel Aviv, Israel	CHF Monitoring	Convertible Note Equity Invest.	Clinical
VentureMed	Oct-2012	Flex Scoring Catheter - First in Human Project	Toledo, OH	Interventional Device	Convertible Note	Marketed
VitalStream Health	Jul-2008	The Virtual Hypertension Clinic	Cleveland, OH	Remote Vital Signs Monitoring	Grant	Discontinued
Xact Medical	Jul-2018	Fast Intelligent Needle Delivery (FIND) System:	Springboro, OH	Interventional Device	Convertible Note	Development
Zehna Therapeutics	Dec-2019	Development of a Small Molecule Therapeutic for Cardiovascular Diseases (TMAO)	Cleveland, OH	Therapeutic	Convertible Note	Development
ZIN Medical	May-2007 Jul-2008	BioWatch Ambulatory Cardiac Monitoring and PT/INR Remote Monitoring System	Cleveland, OH	Remote Vital Signs Monitoring	Grants	Inactive



Cleveland Clinic

Every life deserves world class care.