UNITED STATES EXPERIENCE

TITLE OF THE EXPERIENCE:
Global Center for Medical Innovation

Country: United States

Institution: Georgia Institute of Technology, Saint Joseph's Translational Research Institute, Piedmont Healthcare, Georgia Research Alliance

Type of Institution: Public/Private

Webpage: www.devices.net

Related Principle: 6. Promote a **simpler, more stable and efficient institutional and regulatory framework** for business and investment, by increasing transparency in government, the rule of law, promoting competition in our markets, and ethical conduct in the interactions between the public and private sector

Context

The Global Center for Medical Innovation (GCMI) is an independent, not-for-profit organization that has launched the Southeast's first comprehensive medical device innovation center. GCMI is bringing together core members of the medical device community, including universities, research centers, clinicians, established device and drug companies, investors, and early-stage companies, with the goal of accelerating the commercialization of innovative medical technology.

GCMI was founded by four of Georgia's leading research and healthcare organizations: Georgia Institute of Technology, Saint Joseph's Translational Research Institute, Piedmont Healthcare and the Georgia Research Alliance.

The U.S. Commerce Department's Economic Development Administration (EDA) played a critical, catalyzing role in helping to assemble and connect these founding organizations. As a result of this strong public-private collaboration, GCMI received a $1.3 million EDA investment to help build and equip the center and, through the EDA-led, multi-agency i6 Challenge, which is designed to strengthen regional innovation ecosystems by rewarding innovative ideas that accelerate technology commercialization and new venture formation, GCMI secured an additional $1 million to help implement three major initiatives to accelerate the development and commercialization of next generation medical devices and technology.

In the Southeast, a strong clinical and research community produces a significant amount medical device technology innovation and intellectual property. Historically, most medical device startups in the region migrate to Boston, Minneapolis and the Bay Area because of limited venture capital in the region and, more importantly, there is an absence of specialized development and manufacturing facilities. GCMI fills this early commercialization gap and has been positioned as a Southeast resource that will retain locally developed technologies and attract innovation from other parts of the US and abroad.

Objectives

GCMI's main objective is to accelerate the development and commercialization of next-generation medical devices and medical technology that can save lives and improve quality of life. To do this, GCMI works with four key segments of innovators: (1) universities conducting medical device research, (2) clinician entrepreneurs (3) startup medical device companies lacking prototyping, manufacturing and testing infrastructure, and (4) established medical device companies requiring independent development, prototyping and testing of their device innovations. These segments see a number of advantages and benefits through GCMI:

- Cost-effective development and pilot cGMP manufacturing;
- Access to state-of-the art equipment and validated cleanrooms;
- Existing knowledge in technical expertise;
- Independent Testing & Validation; and,
- Ideal Geographical Location.

Relevance

A critical mass of knowledge, clinical centers, and engineers exists in the Southeast. However, innovation generated from these resources has not translated to an equally strong medical device industry. GCMI is positioned to help innovators overcome the hurdles associated with bringing new medical technologies from the bench to bedside. The presence of GCMI's medical device development and manufacturing center in Atlanta is promoting the growth of the Southeast's medical device industry by keeping technology in the region and attracting interest from other parts of the country. GCMI has developed a network of intellectual property lawyers, biomedical engineers, regulatory and reimbursement experts, clinical research organizations and investors and is providing a platform for collaboration and product development. We expect that his development platform will allow the steady movement of new medical technology from the laboratory into the healthcare market, which will attract investors, industry and help build a stronger regional medical device industry.

Implementation

GCMI provides valuable capabilities and services to medical device innovators that have previously not existed in one facility in the Southeast region. First, the Center is providing design, engineering and product development expertise. While GCMI has technical expertise on staff, the Center is contracting with a range of consultants with very specific development expertise. This allows GCMI to build project teams on a case-by-case basis based on the technology or knowledge required.

Second, GCMI launched the MedTech Innovation Education Series earlier this year. Held over four quarterly sessions, the Series is designed to provide creative clinicians, surgeon entrepreneurs and academic researchers with an overview of the commercialization process and a forum to discuss ideas with experienced medical device innovators and successful entrepreneurs. The Series brings together the best and brightest from all of the GCMI founding institutions and others that the Center is working with.

Finally, the Center is working with venture capital groups, strategic investors and grant resources to match existing projects with potential sources of funding.

Distribution of tasks

All activities are managed by the GCMI management team with the input of the Center's Board of Directors, which is comprised of leadership from each of the founding institutions.

Achievements and results

Over the past year, GCMI has positioned itself as a core resource for medical device commercialization throughout the Southeast region. The Center is in discussions with a number of innovative universities and healthcare systems in Tennessee, Alabama, South Carolina and Florida to develop programs that provide development expertise and support commercialization. An average of 50 clinicians, researchers and local entrepreneurs have been participating in this year's Education Series, which the Center will rollout to larger groups throughout the network in 2013.

GCMI officially opened in April 2012 and has kicked off a handful of product development and projects across a range of medical specialties and stages of commercialization, including:

- cGMP Cleanroom Manufacturing & Prototype Development. Startup company has begun cleanroom production for commercialization in Europe and Latin America with a goal of pursuing FDA clearance in 2013.
- Clinical Trial Coordination. An ophthalmologist based in Atlanta has developed a new diagnostic device with our partners at Georgia Tech. GCMI will be prototyping and facilitating the clinical trial of this device.
- Regulatory Guidance. GCMI efficiently identified regulatory resources for two startup companies in with general surgical and health-IT technologies. One startup is working on a 510(k) submission and recently raised their Series A. The founders have also been attending GCMI's education sessions.
- Design & Engineering. GCMI is working on two design & engineering projects – one is an elderly assist device and the other is a new catheter technology. There are a number of other device development projects in the pipeline, including: custom orthopaedic devices, custom surgical tools, spinal implants and safety syringes.

Unexpected achievements

While GCMI was not created to serve as a medical device incubator, we have seen a great need for short term "incubation" in the late stages of the commercialization process, particularly around cleanroom manufacturing and clinical trials. Often at this stage, a startup may have everything that they need to launch a technology except the funding necessary to build facilities or make long-term contract manufacturing commitments. However, the Center is now providing space and resources to a new startup that will soon begin commercialization in Europe and South America while they pursue FDA market clearance – GCMI is serving as a springboard for commercial launch. By leveraging the facilities and quality systems at the Center, the startup recently received ISO 13485 certification and will begin shipping product in the 4th Quarter.

GCMI did not anticipate using internal resource to facilitate clinical trials. However, GCMI facilitate a clinical trial for a new diagnostic device this fall, which will help support funding and commercialization milestones for the startup organization. The Center has been hosting tours and meetings for the startup to demonstrate capabilities to potential strategic partners and investors. The startup should close initial round of funding by the end of September 2012.

GCMI was launched with the goal of being a key medical commercialization resource for the Southeast region. There has been tremendous interest from healthcare systems, research universities and training centers around the region – Georgia, Alabama, Tennessee, South Carolina and Florida – in building formal collaborations and partnerships with healthcare systems, research universities, and training centers to support innovation.

Experience and Sustainable Results

GCMI has the resources and capabilities required to sustain, reproduce and expand upon these results. The Center's business model is based on a combination of project revenue, membership fees, and development grants. The Center was founded with Membership fees from the four founding institutions and launched with several federal and state grants, including the prestigious Department of Commerce i6 Challenge Grant. The Center's core product development operations will be supported by ongoing project revenue. In addition, institutional and partner membership fees will provide resources for critical start-up costs and support of broad member services. Finally, GCMI will seek opportunities to add medical device development services through future development grants.

Capacity to replicate and potential for exchange

Education Series. GCMI launched the MedTech Innovation Education Series in February 2012 with a session on "Concept Development and Analysis", followed by a session in May on "Intellectual Property", and one in September on "Regulatory, Quality Assurance and Reimbursement in the Development Process." The 2012 Series ends in November with a final session on "Funding and Exit Strategies".

Technical Assistance. GCMI's model for sustainability is built around fee-for-service product development, prototyping and small-scale cGMP manufacturing services. GCMI's systems, policies and procedures support a replicable model for quality technical assistance across a broad range of products.

Human, operational and institutional capacities

GCMI welcomes the opportunity to share experiences with other countries that are members of the RIAC. The Center regularly hosts tours and meetings to discuss background information and lessons learned. In addition, GCMI is open to exploring unique ways of supporting medical device development and commercialization in other countries.

Modalities to replicate the exchange

a. Information sharing
b. Expert visits
c. Technical tours
d. Videoconference

Good practices and concrete lessons

Communication. Regular communication – both formal and informal – among all supporting institutions is critical to the success of a medical device commercialization center, particularly during the startup phases. Institutional goals and objectives vary from organization to organization, and these must be understood by Center management to successfully support commercialization activities.

Education. Successful medical device commercialization depends on a strong framework and understanding of the process. An education initiatives provides innovators with both a framework and network to have greater opportunities for success.

Network Development. Successful medical device development requires the careful coordination of many different experts from intellectual property, product development, regulatory through clinical trials and market launch. It is not cost effective to have all of these resources within the Center – building a formal network of credible experts is key to financial viability and efficiently using valuable resources that already exist in the community.

Experiences and subjects to learn from other RIAC members

GCMI would be interested in understanding the regulatory and healthcare economics environments in the RIAC member countries, as well as understanding clinical trial resources.

Key persons involved in the design, implementation, and evaluation

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