Developing Accessible Telehealth Technology

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Introduction

Telehealth technology faces many barriers to success in the commercial marketplace. This paper discusses the approach taken by Med Graph, Inc. (MGI) and the Technology Transfer Rehabilitation Engineering Research Center (T^2RERC/AZtech) to bring an accessible Life Improvement Portal to the commercial marketplace using consumer input, federal development funds, and university based field testing.

DEVELOPING ACCESSIBLE TELEHEALTH TECHNOLOGY

Diabetes and the Life Improvement Portal

Diabetes is a growing healthcare concern in the United States and in Canada. According to statistics from the American Diabetes Association, in 2002 diabetes was listed as the sixth leading cause of death in the U.S. and is a contributing factor in the deaths of approximately 41,500 Canadians each year (Candian Diabetes Association, 2007). Exacerbating the situation for people with diabetes are the increased risks of developing complications, including loss of vision, kidney failure and nerve damage. MGI is developing a Glucose Monitoring System that will be accessible to people with vision and hearing disabilities. The Glucose Monitoring System will work in conjunction with a Life Improvement Portal to collect, store, analyze, and track glucose readings for people with diabetes. The LIP will allow physicians to immediately access this critical health information via the central server, helping to avoid complications from fluctuating glucose levels. Users can also access the central server to view their glucose status and take control of their health. The central server and the LIP have two-way communication, to notify both parties if glucose levels are dangerously high. While this telehealth technology meets a critical need in the marketplace, there are many barriers to successful commercialization of the GMS and other telehealth

devices for people with disabilities. In order to successfully address these barriers, MGI formed a partnership with the Technology Transfer Rehabilitation Engineering Research Center (T^2RERC)
and its commercial partner AZtech. This partnership is unique in that it takes the innovation potential of a small company and links it to the proven process for successful commercialization of small market devices developed by the T^2RERC at the University at Buffalo.

Identifying Valuable Partners

Small businesses often lack the internal resources to develop a product without assistance from outside parties (Bauer, 2003). As a result, developing key partnerships is

critical to the success of research and development efforts. While building these relationships creates additional investments of time and money, this initial investment is well worth the effort. It is important to approach the question of partnerships in a systematic way to determine which partnerships will have the greatest impact on the likelihood of commercial success. By benchmarking potential medical device development partners at the beginning of the LIP development effort, MGI was able to identify and approach the most suitable companies within the Western New York area. Key parameters to consider include everything from basic contact information and company size and growth to patent history, willingness to partner, and potential for future collaboration (i.e. is the company willing to license technology that was developed externally?). MGI also considered costs associated with forming potential development partnerships. MGI was able to use these benchmarks to prioritize a list to of potential development partners.

University and public resources were also benchmarked. Partnerships were formed with prestigious universities in the area who had skills in software and hardware development, resource generation expertise, and experience in the successful transfer and commercialization of rehabilitation and medical technology. US universities have strict rules regarding technology development and ownership based upon Federal legislation. Small Business should be intimidated, however. Universities only have title to new intellectual property developed within the university system. If the small business already owns the intellectual property, most universities have mechanisms by which small business can contract for development of this technology using university facilities and expertise that it not subject to university ownership. Universities are key partners when developing technology in the rehabilitation and medical fields where clinical trials are key components of commercial viability. Without a partner who has the expertise and resources necessary to properly evaluate the impact of an intervention or tool on the population of people who will be using it as a medical intervention, the potential for licensure and reimbursement will be severely impacted.

A number of community partners that specialized in resource generation and a medical network were also identified. These key partners allowed MGI to leverage resources within Western New York so that questions and concerns regarding the development of the LIP could be quickly addressed and resolved. For example, a community organization that specializes in the identification of funding sources allowed MGI to ensure that resource generation could be completed. The Medical network facilitated the identification of key professionals to participate in focus groups. Without these partners, the R & D process becomes more difficult and costly while small businesses rush to bring partners in who do not understand the goals of the project.

Leveraging Public Funds: Using Small Business Innovation Research Grants

As stated previously, R & D efforts in small business can be significantly delayed by the lack of financial resources. This shortfall makes it difficult to pursue development of innovative technology as it will not immediately bring much needed financial resources to the company's coffers. Therefore, the identification and pursuit of public funds, while time consuming, can be invaluable to the long-term success of small business. In the United States, the federal government has made funds available to small business via competitive Small Business Innovation Research (SBIR) grants that can be used to bring in much needed funds for research and development (R & D) (Department of Education, 2004; Zyn Systems, 2002). There is some variation amongst programs, typically however, the SBIR program is funded in three phases.

- Phase I: Supports feasibility research with awards up to $100,000 for a six month time period.
- Phase II: Supports research and development of new technologies proved feasible in Phase I with awards up to $750,000 for a period of up to two years. In order to compete for Phase II funding, a company must have received a Phase I funding.

- Phase III: Entails commercialization of the new technologies funded through the first two phases. No monetary support is provided by the federal government to the small business concern during this time period. Activities should be financed using company funds or outside investor funds (Small Business Administration (SBA), 2001).

The SBIR grant requires identification of the need for the product and a specific target market that will benefit from its use. This establishes that a device from this research has utility and is worthy of public investment. The generation of a specific work plan that details the work to be carried out, time frames for completion and staff assignments ensures that the company can complete the R & D effort within the grant period. Finally, a budget as to how public funds will be used helps to ensure feasibility of each phase of the project. These requirements not only prove to the funding agency that the small business concern has a well defined work scope, but also that they have considered the technical and financial barriers that must be overcome. These are key components to success of any R & D effort. The pursuit of public funds requires companies to take the time to define a work plan and identify markets and customers; this is highly beneficial to small companies planning to undertake research and development efforts whether or not they receive public funding.

There are many other sources of public funds available for companies who wish to develop innovative products. In the United States, grant opportunities are listed in the Federal Register that can be accessed via a daily email from FEDREGTOC-L@LISTSERV.ACCESS.GPO.GOV or it is publicly available at the following website: http://www.gpoaccess.gov/fr/index.html. The Small Business Funding Centre located in Ottawa, Ontario, Canada has many valuable links to information and resources available on their website at http://www.grants-loans.org/index.php for Canadian Companies.

Collecting Primary and Secondary Consumer Input:

Every technology must travel through a virtual "Valley of Death" to gain a spot in the commercial marketplace (Auerswald & Branscomb, 2003). Even if a company is able to move their technology successfully through this landscape, product success often depends as much on its functionality and presentation as it does on the underlying technology. Device usability plays a major role in what product consumers are willing to invest in even when health and function can be vastly improved by an underlying technology (Lane, Usiak, Stone, & Scherer, 1997). Consumer input allows a company to ensure that the parameters it uses to define the functions and features of a new product will not only meet the needs of the intended consumers, but will also exceed their expectations for basic functionality.

In the case of the LIP, MGI's customer base is people who have diabetes and the medical professionals that support them. Access to new user segments in the disability arena can be very difficult to obtain. The partnership with the T^2RERC/AZtech created a mechanism for not only accessing these markets, but also a proven process for gathering meaningful data on how best to obtain confirmation of a technical direction for the LIP and specifications for improvement of the device beyond the initial prototype. T^2RERC/AZtech has a database of people with disabilities established over the 12 years of working to collect and evaluate user data for the T^2RERC. Recruitment of doctors and medical students was completed via a network of medical professionals established by the company.

The focus group process includes a concept definition or Alpha Group during the initial funding of the SBIR grant. This group provided confirmation of technical design features that the company had considered for the initial prototype design. Ideas that the group provided as to where current systems were lacking will help to ensure product differentiation in the commercial marketplace. The group also provided information on features and functions that MGI's customers desired for the commercial product. Beta focus groups, that provide confirmation and refinement of the original design, will be conducted during Phase II of the SBIR grant. The Alpha group also allowed MGI's patient and doctor customer base to share ideas and brainstorm around issues that were important to both of them. This atmosphere

created an invaluable resource when problem solving for the prototype product, these solutions will be validated during the Beta focus groups.

Conclusion

There are many barriers to commercial success for any new product that is introduced into the commercial marketplace. Failure at any one of many critical points in the development effort will mean the end of the potential product line (Lane, 2003). Small companies must consider each of the landmarks to commercial success and ensure that they are sufficiently equipped to address each of them as they arise. The process of innovation and commercialization is extremely risky, but by leveraging the resources available to a company, the path can be made less perilous. The major benefit of partnerships is the contribution of partners' unique expertise. The company brings technical and engineering expertise. The university brings a familiarity with the niche markets that serve people with disabilities, collecting and utilizing end-users information in building effective technology tools, and in linking companies with access to resources for clinical trials and protection of human subjects. The medical professionals and product consumers bring their unique experiences with existing tools and knowledge of industry needs that will ensure the long-term success of the development effort. With each focusing on individual strengths, a better commercial product is assured.

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