

## **Innovation: Going from meeting clinical needs to product and service development**

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The Criterion Health Management Briefing Series provides resource materials that allow quick overviews of the major factors influencing the industry as well as reference sources for more intensive investigation.

### **Tapping talent, fostering innovation**

Technology transfer, translational research, and knowledge transfer are not central activities for human services' practitioners. Generally these terms relate to transforming research knowledge into products or services. However, the main idea of this briefing is that the providers of clinical services are already innovators. Taking the innovation from meeting the need of an individual client to the development of a new product or service is a reasonable extension.

Not-for-profit organizations seldom can commit the resources to engage directly in research and development. A policy of fostering and supporting innovation is a Board decision. A Board may support a culture of innovation if it understands its value, i.e., that drawing on the talent of its employees can contribute to the organization's success and that innovation is consistent with the mission.

The first task is to identify a need or opportunity. The second is how to address the need.

**Identifying a need or opportunity.** Clinicians address clients' problems daily. Together, clinicians and clients are the primary resources to identify and prioritize needs and opportunities. Focus groups of providers and/or clients are relatively easy to set up and can be invaluable. The key is to ask, depending on the service population, open-ended probe questions that will provide useful ideas. For example: "What have you done recently while working with one of your clients that might be effective for others to use in their work with clients?" "As a client receiving services, what are your unmet needs?" "If you could go to the store or go online, what do you wish you could buy that would improve the quality of your life or the life of someone you care about?"

The bigger challenge is what to do next as it becomes an applied research project. Someone has to do the work. It may be the time to establish a partnership for innovation.

**Partnership for innovation.** The most immediate challenge for the not-for-profit, once there is a commitment to innovation and potential opportunities are identified, is to move forward. The challenge is: How? Partnering with an organization that has the resources to move from an idea to a product or service is one way to proceed. They might be a for-profit company, an institution of higher education, or a combination of both. The goal is access to personnel and resources. The nature of the relationship will depend on the goals for the innovation. For example, systematically testing a clinical practice to determine its efficacy might be a good master's thesis or doctoral dissertation that can be developed in conjunction with a faculty member at a local university. However, developing and evaluating a new product might take the commitment of several people, engineering skills, intellectual product protection, and several years. Both examples call for partnerships. Any approach requires the not-for-profit's commitment and involvement.

**Next steps.** Who is going to do the preliminary work to determine if the potential innovation is truly innovative? A review of existing products/services and relevant literature is essential. If the organization does not have the internal resources, there are several options available

### **One avenue to innovation: The SBIR/STTR approach.**

The Federal Small Business Innovation Research, SBIR, programs and Small Business Technology Transfer Research, STTR programs provide early stage research and development funding for small businesses. Each federal agency, for example, National Institutes of Health, Department of Education, National Science Foundation, has to provide approximately 2.5% of its extramural funding for these programs, which amounts to approximately \$2 billion/year. All SBIR/STTR programs are structured essentially the same. Phase I – 6 months, establish feasibility, \$100,000; Phase II – 2 years, research and development, \$750,000, Phase III – Commercialization, no funding. Every state has an Office to support the development of SBIR proposals and many provide additional support, especially for Phase I recipients.

The key requirements for the SBIR are that the applicant be a for-profit small business with 500 or fewer employees, for Phase I no more than 33% of the budget can be for consultants or subcontracts, and the Principal Investigator must be employed at 50% time by the small business. For an STTR, which focus more on research, there must be a formal involvement of a research organization and up to 50% of the budget can be used for subcontracts and consultants.

A not-for-profit might approach the SBIR process with a small business partner, or the not-for-profit might establish a for profit small business entity.

One caveat. SBIRs are highly competitive. And innovation is essential. Even though a good idea meets a need, it might still not be viewed as innovative. Also, the time from proposal submission to project start date is usually 9-12 months.

### Other avenues to innovation

Institutions of higher education can provide multiple mechanisms to support innovation. The most obvious is a consulting relationship with a faculty member. However, advanced undergraduate and graduate students working with the direction of a faculty member may be able to obtain course credit or meet other requirements through work on an innovation project. Colleges and universities are increasingly concerned with “community engagement.” Partnerships with not-for-profits are one way to engage. Challenges of partnerships with academic institutions include the academic calendar driving the availability and deadlines for students and faculty, intellectual property rights, and, of course, the business relationship.

Internal support can go a long way. A not-for-profit might commit to allocating the resources to undertake innovation internally. However a more cost-effective approach might be to establish a partnership with an organization, e.g., a small business. The partnership can provide access to the specialized resources to collaborate with the not-for-profit first to evaluate the innovation and then to proceed to move forward with further development. The key to success is that the relationship is collaboration and not simply “outsourcing.”

Funding whether through internal allocation or from external sources is the bottom-line concern. If innovation in one form or another is not a budget item, even the smallest project requires new or reallocated funding. At one end is major grant support such as the SBIR program. However, the resource needs for an innovation project may require only a modest reassignment of responsibilities. Except for personnel, other budget expenses will depend on the nature of the project. A donor might help with the purchase of project specific equipment or other support to launch a project. Local corporations and foundations are potential resources.

### Other considerations

- If the innovation involves collecting data from human subjects who are not staff of the organization working in the service associated with the innovation, the services of an Institutional Review Board (IRB) for the protection of human subjects may be required. For example, a group of staff clinicians brainstorming as an expert panel would not require IRB review, however, a focus group of clients might.
- Intellectual property protection is a corollary of innovation. For written materials it may entail copyright; if there is a unique name trademark protection may be appropriate; and if it leads to a new device, patent protection is appropriate. The category of “trade secret” is probably not likely to occur. It is essential that any undertaking that involves innovation determines the intellectual property options that might apply. Intellectual property primers are readily available. There are two sides to intellectual

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property, one is to protect what one is developing; the other is not to violate existing intellectual property.

Once there is “public disclosure,” for example, presentation to a group of people outside the organization, the possibility of patent protection becomes difficult. If patent protection or other Intellectual Property protection is anticipated, a Non Disclosure Agreement should be used.

### Criterion Health’s examples

- Criterion, in partnership with a major not-for-profit provider of services to those with disabilities, has obtained SBIR support from the National Institutes for Health and the National Institute for Disability and Rehabilitation Research to design and develop two innovative pieces of durable medical equipment. Both are patent protected. The intent is to license the technology for manufacturing and marketing.
- Criterion in partnership with a community mental health center has developed and evaluated psycho-educational programs for individuals with depression, adolescents at risk because of family members dealing with substance abuse and/or serious mental illness, character building, as well as others.
- Criterion in partnership with a community mental health and health center has developed an innovative set of training and support materials to implement the integration of behavioral health into primary care.

### Resources

- **Human Subjects Research Primer.** A Google search of – Primer Protection Human Subjects – will access several useful background documents, typically in Power Point format. The National Institutes of Health Office of Extramural Research has extensive resources at: <http://grants.nih.gov/grants/policy/hs/index.htm>
- **SBIR programs in general.** The parent organization is the Small Business Administration, SBA. Their site is: <http://www.sba.gov/aboutsba/sbaprograms/sbir/index.html>. However, the guidelines, deadlines, and procedures are different for each Federal Agency. Therefore a Google search of, for example, NIH SBIR will take you to the specific information at: <http://grants.nih.gov/grants/funding/sbir.htm>

Each state has an office that supports SBIR/STTR projects. A Google search of the state name and SBIR should eventually get you to the right office. These offices are typically within an economic, business, or technology development center or office for the state.

- **Intellectual Property.** The United States Patent and Trademark Office at: <http://www.uspto.gov> is a valuable resource. It is also the place to search patents and trademarks. Putting something like “primer intellectual property”

into a Google search will provide various discussions of IP. Patent law is a specialization that may not be available in smaller communities.

- **Non Disclosure Agreement (NDA).** Once you start discussing possible innovations, it is essential to protect the ideas from “theft.” This is particularly true for discussions with anyone who is not a member of your organization, but is also relevant within the organization. The point is that you do not want to give away your ideas unwittingly before there is proper protection. A NDA–non-disclosure agreement– does this for you. For participants in, for example, a focus group, Criterion Health has used a single page NDA; however, for discussions with manufacturers a longer, more detailed NDA is used. If your organization does not already have an NDA, models are readily available via a Google search.
- **Working with universities. NCET2,** National Council of Entrepreneurial Tech Transfer (<http://ncet2.org>) is an organization of entrepreneurial universities focused on university startups. A non university organization might find the web site useful for some of the resources available and also to use to open a discussion with a potential university partner.
- **Technology transfer. KT4TT,** Center for Knowledge Translation for Technology Transfer at the University of Buffalo (<http://kt4tt.buffalo.edu>) is a good general purpose resource for innovation and development.