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If You Build It, They Will Come: How to Establish an Academic Innovation Enterprise

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The rapid growth of minimally invasive, image-guided intervention has redefined the procedural management of multiple disease entities. The process of innovation which has characterized the growth of interventional radiology can be best described as "needs-based," whereby practicing interventionalists identify unmet clinical needs and subsequently invent solutions to achieve desired technical and clinical outcomes. Historically, catheters and other percutaneous devices were developed with rudimentary manufacturing techniques and subsequently translated to patients with relatively little regulatory oversight. Since then, the resources required and financial costs of interventional technology development have grown exponentially. Fortunately, advances in software development, new methods of rapid prototyping, and commoditization of hardware components have made in-house engineering feasible once again. This has created an opportunity for academic medical centers to translate their research into testable prototypes in humans sooner and at reduced costs, and academic interventional radiology divisions are now leveraging these developments to create collaborative centers of innovation. This article describes five such organizational formats for collaboration and innovation in the academic setting, describing the structure, opportunities, requirements, and caveats of each model.
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Introduction

The rapid growth of minimally invasive, image-guided intervention has redefined the procedural management of multiple disease entities. Percutaneous delivery of a therapeutic device or bioactive agent to an anatomically deep target under precise image-guidance is the result of significant technological advancement across multiple fields. The evolution of sophisticated radiologic imaging, novel manufacturing techniques for custom-building guidewire-catheter systems and other devices, and improvements in materials science and chemical engineering, have enabled the precise and controlled delivery of therapeutic agents to exact anatomical sites of disease. Historically across many industries, new technologies often stemmed from basic science discoveries, with practical applications for their use found secondarily. The process of innovation that has characterized the growth of interventional radiology and its related disciplines, however, is best described as "needs-based," in which practicing interventionalists identify unmet clinical needs and subsequently invent targeted solutions that best achieve desired procedural outcomes.

Historically, percutaneous devices and interventional procedures were developed with rudimentary manufacturing techniques and short, relatively unregulated paths to use in patients at the bedside or in the angiography or interventional suite compared to present times. Since the 1960s, the process of medical device development has undergone multiple layers of governmental, institutional,

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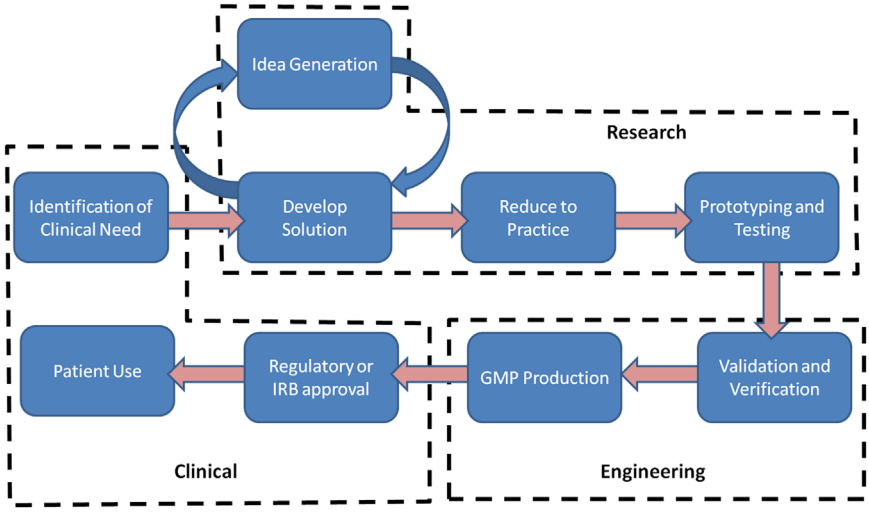

Figure Workflow and key components on the path to solving a clinical need with new technology or devices. (Color version of figure is available online.)

and medicolegal regulation. These changes have resulted in significant cost pressures and lengthy development periods for the translation of new technologies for patient use, in part driving the innovation process away from academic institutions and into the sphere of commercial industry.

The Figure illustrates a simplified workflow of how ideas are translated into devices or technology. In the time of Charles Dotter or Seldinger, research and engineering stages of the development process were commonly performed within the hospital or academic center and in many cases, by the physician themselves. The regulatory barrier to patient trials was lower, and the overall cost and resource requirement to complete inhuman testing were also lower. The United States Food and Drug Administration (FDA) formalized the 510(k) process in the late 1970s, and the Center for Device and Radiologic Health was not made a separate entity till 1982. Since then, the resources required and financial costs of each step of this process have grown exponentially. Fortunately, simplified computer aided design software, new methods of rapid prototyping, and commoditization of hardware components have together reduced the costs associated with the research stage to a fraction of those in previous decades. These changes have now created an opportunity where the research leading to the first prototype can be performed inhouse within hospitals and academic medical centers. IR divisions are taking advantage of these developments by creating collaborative centers of innovation. This article describes 5 such organizational formats for collaboration and innovation in the academic setting, describing the structure, opportunities, requirements, and caveats of each model.

The Embedded Scientist or Engineer Model

Engineers or scientists can be recruited to facilitate innovation and development activities within an IR service of an academic center. Addition of members with a technology background to an IR service can provide value at multiple levels as they can contribute to every step of the innovation process, from needs identification to clinical trials of the technology. Some form of this model has been implemented in IR services across the country, including Memorial Sloan Kettering Cancer Center, University of Wisconsin Madison, National Institutes of Health, University of Minnesota, University of Miami, and the University of California at San Francisco.

Opportunities

Close integration of engineers and scientists within the clinical team can create unique synergies that will not just enhance innovation but also improve clinical activities. An integrated innovation team will create an environment for cross-pollination of ideas and peer learning. Conventionally, engineers and scientists operate from silos of their laboratories or companies, limiting direct and continuous interaction with other members of their team. Bringing together technology and clinical experts in a common space will increase sharing of ideas and enhance the problem solving process. This can be beneficial especially for early stages of development, as the alternate viewpoints afforded to a multidisciplinary team will improve the concept generation and ideation processes. Inhouse development till the idea is mature for manufacturing will provide greater control over intellectual property. An inhouse innovation team can also troubleshoot critical flaws at the early stages of a project, limiting issues that could potentially prove fatal at a later stage of development.

Requirements

IR specializes in a variety of procedures, organ systems and procedures. A theme or narrow focus of work will prove useful for smaller innovation teams at the outset. At larger