

Challenges in Medical Device Commercialization

Nik Tehrani, PhD

International Technological University
2711 N 1st St. San Jose, CA 95134

Abstract:

There are multiple obstacles that need to be overcome prior to commercializing technologies: (1) new technology must add real value over existing approaches, (2) getting investors and funding, (3) the feasibility stage, (4) high risk and expense of creating marketable products, (5) high costs of clinical trials, (6) the gap between academic researchers and business communities, and (7) Smartphone technology security (wireless technology). Disconnect between scientists and healthcare professionals have contributed to the technological lag seen in medical care. There is gap between academic researchers and business communities when it comes to commercialization, mainly due to high risk, expense and time of creating marketable products (Scanlon & Lieberman, 2007). The process in which medical devices go from early concept through to commercialization requires a complex multidisciplinary structure. Inventors need to establish product requirements, the intended application and material requirements, the device's intended duration of use, and the materials from which the device will be made. Prior to commercialization, product tests must be conducted to ensure stability, design verification, process validation, FDA approval, safety and regulatory clearance. IDEA Labs (Innovation, Design, and Engineering in Action) has created a biomedical design and entrepreneurship incubator that connects clinicians to share their clinical problems with students from multidisciplinary backgrounds and work in teams to develop innovative health solutions. Designers, engineers and scientists work closely with medical practitioners, healthcare providers and patients to determine product function, health benefits and regulatory viability.

Keywords — Medical device commercialization, product testing, clinical trials, technological lag, IDEA Labs, Scientists and healthcare professionals disconnect.

I. INTRODUCTION

Overcoming commercialization challenges for new medical technology necessitates cross-industry support. Basic requirements for creating new medical devices include securing intellectual property rights to safeguard the value of innovation [1]. Inventors, especially those looking to maintain existing research and medical appointments, must understand their end goal in commercializing a device as this advises the types of partnerships and investments they should seek [1]. Assembling a full-service team of internal and

external experts with unique skill sets, with expertise ranging from quality to regulatory, clinical, laboratory and manufacturing is necessary [2]. Inventors need to establish product requirements, the intended application and material requirements, the device's intended duration of use, and the materials from which the device will be made [2]. Prior to commercialization, product tests must be conducted to ensure stability, design verification/validation, process validation, safety and regulatory clearance [2]. It is necessary to maintain focus on a current project and avoid

parallel opportunities [1]. Finally, the product must have various regulatory approvals, such as the FDA.

Scientists need more knowledge of product commercialization. Business entrepreneurs have to look for successful ways to conduct effective communication with academic researchers in order to transform patented ideas as well as novel discoveries into marketable and profitable healthcare products. The process in which medical devices go from early concept through to commercialization requires a complex multidisciplinary structure. The lengthy time to introduce new biotechnology, healthcare developments and medical devices to market is due to huge financial and resource investment, in-depth research, and clinical trials [3]. Product engineers may not generally visit a hospital or healthcare facility to become acquainted with real-life medical problems they could address with innovation, and clinicians do not always have a way to communicate with product engineers to solve daily clinical challenges they encounter [3]. Bringing a new medical breakthrough product to market, especially a product linked to a Smartphone is a lengthy and costly process often requiring animal and human clinical testing and regulatory approval.

High risk and expense of creating marketable products

For scientific and technical innovation within the medical device industry, it is essential to clearly understand the clinical need, market potential and technical risks [3]. This requires extensive technology and science management, clinical trials, substantial testing, and regulatory control [3]. Defining technical feasibility without knowing preliminary function or demonstrating early test data can be extremely expensive, and time consuming. Thus, the medical sector must seek to reduce such costs and speed up time to market by decreasing inherent risks at the feasibility stage of development, preferably before excessive investment.

New Technology Must Add Value

New technology must offer value beyond existing technology. For example, chemical sensors are the greatest commercialization challenge due to their sensitivity. Chemical specificity is required if the sensors themselves are to provide greater value. Sensors are fragile and susceptible to interference because they can detect a single type of chemical among a superfluity of others in perspiration, blood, saliva and tears. During this feasibility stage, designers, engineers, and scientists need to work closely with medical practitioners, healthcare providers, and patients to determine product function, health benefits, and regulatory viability [3]. If a product fails to make it through clinical approval and market adoption, there is a significant loss of investment and time.

Investors and Funding

Gaining reliable funding is not easy. Investors may be wary of technology changes. Individuals in the medical field may have already invested in technologies which compete with innovations [4]. Investors may not understand how disruptive new technology can be, and that this technology is safe, low cost, and non-invasive. Some investors may have concerns about the steps required for bringing medical technologies to the market.

Clinical Trials and the FDA

The Food and Drug Administration (FDA) requires clinical trials before any new product can be commercialized [5]. Clinical trials (clinical studies) test potential treatments using human volunteers to determine if they ought to be approved for use in the general population. Treatments include drugs, medical devices, or a biologic, such as a vaccine, gene therapy, or blood products. Prior to human testing, potential treatments are tested on laboratory animals for toxicity. Clinical trials are intended to answer research questions using a protocol which determines study procedures. Products can be tested to find how they compare to standard

treatments or to no treatment at all. Clinical teams of health care professionals monitor and assess participants in hospitals or research centers during and after each phase of a trial.

At present, some clinical trials can cost about \$12 million to run from beginning to end. Although costs can be lowered significantly, this field is relatively new requiring quality and effectiveness assessments. The medical community expects innovators to demonstrate clinical relevance through publication of research and clinical trials.

Gap between Academic Researchers and Businesses

Many new products that fail do so due to failure of innovators to understand real users' needs. [4]. Many products do not get past the prototype stage because the clinical requirements, nor those of the patient, have been considered. Changing the culture of commercializing medical device/technology among academic researchers and increasing communication between students, clinicians, product engineers, and scientists is one solution[7] offered by IDEA Labs[8].

IDEA Labs/Engineers and Developers

Healthcare professionals may identify problems or inefficiencies but may not have the time or skills to resolve them. Medical product engineers may not have access to a clinical environment. This disconnect has contributed to the technological lag seen in medical care. One solution is IDEA Labs (Innovation, Design, and Engineering in Action) which has addressed this problem. IDEA Labs has created a biomedical design and entrepreneurship incubator that connects clinicians to share their clinical problems with students from multidisciplinary backgrounds and work in teams to develop innovative health solutions[8]. IDEA Labs are student-driven, collaborative entrepreneurial spaces which allow developers to compile a clinical problem database and develop prototyping facilities. Promising ventures are linked to design and

entrepreneurial competitions, accelerator platforms, venture capital and angel investor networks, and other funding sources that drive clinical projects toward implementation[8].

Smartphone Technology Security (Wireless Technology)

Sensor technologies that transmit vital signs data are emerging so rapidly they will most likely disrupt the medical industry[4]. Smartphone technology can be used to monitor patients with long-term health conditions[6]. Apps and add-ons allow Smartphones to change how chronic diseases are diagnosed, treated, and managed.

Smartphone apps that monitor data can be uploaded to the cloud for sharing, however, they need to be reliable and not misinterpret sensor collected data[4]. This non-invasive clinical tool can manage chronic diseases outside of the clinic. Software systems, such as Artificial Intelligence (AI), can improve the overall predictive value of each unique data set coming in.

The medical device industry requires regulation, so it is crucial for innovators to validate security for their medical device[4]. Innovators, regulators and users must collaborate to avoid risks of these technologies[4]. Security regulations are needed due to continuous monitoring from sensors in non-medical settings that glean confidential data for sharing. The question arises as to whom should be allowed to access the monitored data and is the data secure from hackers. Appropriate legislation for regulation of Big Data must be required to remain current with technologies while concurrently preserving patient privacy [4].

FDA Challenge

Getting FDA approval for a new medical device can be time-consuming and very expensive. Many medical device companies feel that the FDA needs to speed up the process to keep foreign competitors from getting their innovations into the marketplace first. U.S. hospitals may see patients seek foreign

cutting-edge treatments that domestic hospitals do not offer[9]. On the other hand, the FDA's approval process is criticized for various shortcomings that could endanger patients who might be given a defective implantable device, for example [9].

With the passage of the Medical Device Amendments of 1976, the FDA is to categorize all medical devices as Class I, II, or III, with III representing the most potentially harmful class, such as implantable devices[9]. A Pre-market Approval (PMA) application for an innovative device can be submitted, in which case a clinical trial or similar study is required. Alternatively, a PMA notification indicates that a new device is similar to one already on the market. In this case, detailed scientific information about effectiveness and safety is not required[9].

Conclusion

Bringing a new medical device or drug to market is a lengthy and costly venture for scientists and innovators, and must undergo rigorous testing and clinical trials prior to obtaining FDA approval. Prior to commercialization, product tests must be conducted for stability, design verification/validation, process validation, safety and regulatory clearance. Pre-Sub FDA submission can speed up the process by learning about policies, procedures, requirements, and the forms required for the FDA approval process. Until IDEA Labs was created, many design engineers were unaware of certain health care issues due to a lack of exposure to medical settings and procedures, while clinicians had no way to communicate medical needs to engineers who could address certain problems with innovation. IDEA Labs was designed to connect medical and non-medical personnel to bridge that gap.

There are multiple obstacles that need to be overcome prior to commercializing these technologies which include: (1) new technology must add real value over existing approaches, (2) getting investors and funding, (3) the feasibility stage, (4) high risk and expense of creating

marketable products, (5) high costs of clinical trials, (6) the gap between academic researchers and business communities, and (7) Smartphone technology security (wireless technology). Challenges of the gap between academic researchers and business communities in raising capital, must be overcome.

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