August 2013

Innovation and Commercialization Practices - A Qualitative Analysis of Novascan LLC

Shabistan Sheerin
University of Wisconsin-Milwaukee

INNOVATION AND COMMERCIALIZATION PRACTICES - A QUALITATIVE ANALYSIS OF NOVASCAN LLC

by

Shabistan Sheerin

A Dissertation Submitted in

Partial Fulfillment of the

Requirements of the Degree of

Doctor of Philosophy

in Health Sciences

at

The University of Wisconsin-Milwaukee

August 2013

ABSTRACT
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The University of Wisconsin-Milwaukee, 2013
Under the Supervision of Professor Timothy B Patrick

The processes for commercialization of medical devices in healthcare are complex and varied, and it has been difficult to define the ingredients of success. There exists a need to better understand evidence based best practices as there is lack of documented evidence based on best practices for commercialization of medical devices by startups. Commercialization of innovative medical devices in healthcare is in constant demand and the reasons are many fold. Most of the research based startups act as agents of economic development and therefore they need to function more efficiently and effectively. There exists a constant demand from end users to improve medical techniques, results patient experiences and cost effectiveness. However, a large number of strong and commercially viable innovations in healthcare fail to achieve commercialization.

The purpose of this paper is to build a theory. The study examines qualitatively commercialization practices of case study NovaScan LLC, a breast cancer detection device company. Through this single case study, various performances indicators of the commercialization steps followed by the company are identified and findings are presented in the form of theoretical propositions. Extensive literature review and analysis helped in better understanding of the process of commercialization from both healthcare and non-healthcare

perspective. Data gathering, which focused on the above mentioned aim was carried on for nearly over four years, initially as an outsider participant and then in the latter part of study, as an insider participant. The data consisted of observations, informal conversations both via telephone and in-person, using an unstructured interview protocol, field notes, company archives and other historical data. Data collection participants were those institutional officials who were responsible both directly and indirectly for the innovation and commercialization activities at NovaScan LLC. All observations, conversations, field notes, documents and other records have been documented. The analysis for this study involves continuous back and forth linking of theory presented by literature findings and data obtained at NovaScan LLC. For the purpose of data analysis, the data is not coded sentence by sentence; rather it's focused on theme identification based on underlying meaning.

The results verify the impressions of many practitioners in the field of innovation and commercialization of medical devices in healthcare. The findings are presented in the form of seven propositions and also propose a framework of commercialization. These findings are recommended to be tested in future. Various activities related to commercialization process do not happen in isolation with product development in a startup firm like NovaScan LLC. Commercialization strategies are an integral part of development work and are well-aligned with the development process and all stages of development process overlap with each other.

D*edicated to my wonderful parents,*

my loving and supportive husband

And

*To my beautiful, most amazing daughters- Raima and Eliza****!!***

ACKNOWLEDGEMENTS

I wish to thank a number of people for their help, guidance and support throughout the years. First, I want to thank my advisor Dr. Timothy Patrick. He offered unconditional support, advice and guidance from the very beginning and when I was most frustrated. He assured me that I would complete the dissertation. He sacrificed his time with his family and modified his work schedule to critique my dissertation draft. I sincerely thank him for being my advisor and committee chair for his confidence in me. His invaluable inputs on my dissertation allowed me to set forth a brief and concise document. It was his guidance that made me realize the value of a good mentor in life.

Next, I want to thank Dr. William Gregory. He is the founder and chairman board of NovaScan LLC. His invaluable support and advice guided me through the admission to the PhD program, writing the defense proposal to the dissertation defense. I want to thank him for allowing me to work on NovaScan LLC as a case study for the dissertation purposes. He helped and guided me through some difficult times. It was his constant support that kept me on track.

I want to additionally thank the remaining members of the committee, Dr. Sanjoy Ghose, Dr. Janis Eells, Dr. Mary K Madsen and Chancellor Michael Lovell. I am grateful to all my committee members for standing by me in completion of this work .Chancellor Lovell, I can't thank you enough for being there, for your invaluable advice and faith in me. It really helped me going. I feel lucky and blessed to have found mentors in my extremely knowledgeable committee members.

A number of people assisted me during data collection and stay at NovaScan LLC. I want to thank each and everyone associated with the organization for willing to share their insights. I want to let you know that without you this entire thesis would not have happened.

I want to thank all my friends and acquaintances at UWM. I have gathered my motivation seeing you all and you have made my stay at UWM so wonderful. I want to thank the college of health sciences for providing me the financial support throughout .I also want to thank Dean Enwemeka at college of health sciences for his guidance and to thank his staff for arranging meetings with him on short notice. I want to thank Dr. Susan Cashin who advised me to keep my focus on a single case study for this dissertation. She was very instrumental in the choice of my research methods. Special thanks to Lillian Folk for guiding me through the paper work and formalities of the program and Dr. Paula Rhyner and Pat Hayes, thanks to you as well for handling the formalities of the degree work so nicely.

I want to thank all my friends outside UWM, in India and in US for their love and support. I want to express my deepest gratitude to my family. Thanks to my brother and Sister for being there. A thank, full of gratitude to my parents for their unshakeable faith in me, their constant reminders to complete the PhD and raising me to value education and respect people. *Without you Mummy and Papa I couldn't have done it!!*

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Introduction and Background

1.1 Introduction

According to Crossan and Apaydin (2000, p. 1165) “commercialization is an inherent part of innovation. Commercialization is said to be the least developed area of innovation management and that without commercialization the innovation cycle is not complete (Adams, Bessant & Phelps, 2006; Crossan and Apaydin, 2010). Adams et al (2006) actually states that this area of innovation is an urgent need of further development (Simula, 2012). While there is a consensus about the importance of innovation among scholars (Twiss, 1986; Souder, 1987; Chaney, Devinney & Winer Russell, 1991; Cooper, 1993; Patterson, 1998; Dodgson, 2000; Narayanan, 2001; Miller, 2001; Debruyne et al., 2002; Pauwels, Silva-Risso, Srinivasan & Hanssens, 2004; Hsu, 2009), there exists a lack of documented evidence based best practices for commercialization.

A large number of strong and commercially viable innovations in healthcare fail to achieve commercialization. While innovation is incomplete without commercialization, commercialization is not the obvious fate of all innovations.

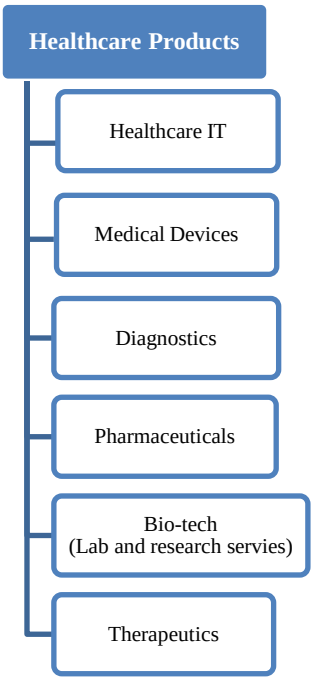


Figure 1.1: Broad Classification of HealthCare Products

Figure 1.1 shows a broad classification of healthcare products. This dissertation is a qualitative, single case study directed to discovering initial evidence for best practices of commercialization of medical device innovations. First, the dissertation describes some meaningful investigative techniques to study specific commercialization practices and the "management" of commercialization within the context of healthcare - Medical Device Innovations. Second, results are described that indicate practices for a successful commercialization of Medical Device innovation.

1.2 Health care Industry

The health care market is one of the most strongly regulated markets. Apart from regulations, there are several other notable differences from other products markets. While purchasing any other non-healthcare retail item or a service in a competitive market, the user is the primary customer, makes the purchasing decision, all appropriate information on the product is provided to the consumer with or without request, and the user is then the payer. However, in the healthcare marketplace, the user is often the patient, and in these cases usually does not make the purchasing decision. The provider and other intermediary institutions, such as pharmacy benefit managers make that decision for the user. The patient does not get all the information and the provider typically gets the detailed briefing and information packages. The patient is not the payer and usually does not know the true price of services and products. The payer is the insurance company or the government.

The healthcare market is highly regulated, starting from the early product development stages to the preparation and dissemination of marketing information, and including the flow of payments, goods, and information. Manufacturers or product developers, therefore, need to pay attention to laws and policies as changes could affect their product development process. Companies must be proactive in monitoring and interacting with legislators (elected representatives) in government and with regulatory agencies. The manufacturers must monitor changes in policy that impact the market and take an active role to educate and inform the drafting of such policy and regulation.

As per the report published by National Academy of Sciences on Small Business Innovation and Research (SBIR), commercialization of the small businesses like the one chosen for the case study analysis described here are a major driver of high-technology innovation and economic growth in the United States, generating significant employment, new markets and high-growth industries. In this era of globalization, optimizing the ability of small businesses to develop and commercialize new products is essential for U.S. competitiveness and it is beneficent in developing better incentives to spur innovative ideas, technologies, and products. *(Charles W. Wessner, Editor, Committee for Capitalizing on Science, Technology and Innovation: An Assessment of the SBIR Program, Policy and Global Affairs; National Research Council of National Academics, Washington, D.C).*

> Regina E. Herzlinger[1], Professor of Business Administration at the Harvard Business School, identifies six forces that can drive or kill the innovation in healthcare sector. The first force is *Industry Players*: the friends and foes lurking in the health care system that can destroy or bolster an innovation's chance of success. The second is *funding* which she describes as the processes for generating revenue and acquiring capital, both of which differ from those in most other industries. The third is *Public Policy*- the regulations that pervade the industry, because incompetent or fraudulent suppliers can do irreversible human damage. The fourth is *technology* that forms the foundation for advances in treatment and for innovations that can make health care delivery more efficient and convenient. The fifth is *customers*, for whom the passive term "patient" seems outdated and the sixth is *accountability* which she describes is the demand from vigilant consumers and cost-pressured payers that innovative health care products be not only safe and effective but also cost-effective relative to competing products. *(Harvard Business Review, 2006).*

[1] *Regina E. Herzlinger (rherzlinger@hbs.edu) is the Nancy R. McPherson Professor of Business Administration at Harvard Business School in Boston. She is the author of "Let's Put Consumers in Charge of Health Care" (HBR July 2002) and the editor of Consumer-Driven Health Care: Implications for Providers, Payers, and Policymakers (Jossey-Bass, 2004). She has written numerous Harvard Business School case studies on health care innovation, which she teaches in her course 'Innovating in Health Care'.*

1.3 Rationale for the Study

This qualitative case study is needed for several reasons. First, a gap exists in the *healthcare* innovation and commercialization literature where there is no clear identification of best commercialization practices. Second, the majority of the literature available has tried to identify commercialization factors quantitatively and even though they intend to present a generalized view, they cannot be generalized with numbers because the innovation and commercialization practices are situation based and hence there is a need to evaluate and focus on the qualitative findings in order to get an in-depth understanding of how the practices are observed. Sapnn, Adams, Souder (1995) used quantitative methods to identify several factors or most frequently used factors to measure effectiveness of commercialization of innovations. However, their study was focused primarily on sponsors, developers and adopters. Previous research on federal transfer programs has usually focused on either the agency or departmental level (Souder1995).

This single case study is based on NovaScan LLC. It explores and identifies the missing approach to successful practices of commercialization of innovations. It describes the most important metrics observed at NovaScan LLC. This may help in identifying differences between the most frequently adopted methods and the evidence based best commercialization practices.

Another reason this study is needed is its focus on common practices of innovation and commercialization of medical devices in healthcare. This research will add new knowledge in terms of highlighting the neglected areas and provide detailed information

on bringing innovations from bench to bedside in a more successful and viable way. Finally, this study may help the future researchers to explore the process of commercialization in other areas of healthcare products in different organizational settings.

1.4 Research Questions

The overall main research question is: ***What practices can be identified as the best practices engaged in the process of commercialization of a medical device innovation*?**

To answer this main question, it's necessary to answer the following questions in regards to the case study

R_1: What activities did technology innovators and researchers perform at NovaScan to initiate the process of commercialization?

R_2: What is the evidence that these approaches are successful?

Any answers to these above mentioned questions presuppose answers to the questions like: what is product innovation? What is commercialization? What defines success and failure in innovation and how are they measured? The answers to most of these questions were found in the literature analysis and guided me to find answers to the main research question.

1.5 Structure of the Dissertation

Chapter one provides background to the dissertation. The objectives and scope are introduced together with the research questions. There is also a brief discussion of the overall structure of the dissertation. Appendix A includes definitions of key terms.

Chapter two reports results of the literature review. The literature search, selection and review methods are discussed. How the method helped me identify core areas and themes around were also discussed. These helped in the data analysis of this dissertation.

Chapter three focusses mainly on the research method and description of the data source and collection. The discussion provides insights as to why qualitative research and analysis method was chosen for this dissertation. In addition a detailed analysis of selection of case study research method and also reasons to why a quantitative scheme would not have worked in the study situation are provided.

Chapter four focusses on the findings of the research. This will include the results obtained by data analysis and literature analysis. This chapter shares details about the case study firm and describes the operational concept of this case study and the strategic commercialization strategy. This part of dissertation focusses on theory for commercialization and continues with the within case analysis.

Chapter five includes propositions that are based on the research findings discussed in chapter four. The propositions are derived from the analysis of the case study, but they are also combined with insights derived from the literature.

Chapter six describes the overall conclusion to this study. It describes how the dissertation contributes to commercialization theory of healthcare innovations and also outlines several related implications. Also discussed are the validity, reliability, and limitations of the study in this chapter and finally, suggestions for future research are made here in this chapter.

Chapter 2

Literature Review

This chapter reports results of review and analysis of voluminous, multidisciplinary literature on innovation, commercialization and technology transfer. Technology transfer is the common link that connects innovations and commercialization processes. The selection of literature was based on the main research question that aims at identifying successful practices of commercializing a medical device innovation.

2.1 Methods

The main research question for this dissertation is: ***What practices can be identified as the best practices engaged in the process of commercialization of a medical device innovation*****?** This helps in getting answers to the following questions.

R_1: What activities did technology innovators and researchers perform at NovaScan to initiate the process of commercialization?

R_2: What is the evidence that these approaches are successful?

Bosewell and Cannon (2010) in their book, *Introduction to Nursing Research: Incorporating Evidence based Practice (2010)* state that there are two methods of searching literature- performing computer search in databases and examining books and periodicals manually. While searching for literature based on the main research question, healthcare specific databases like Cochran and Medline were looked at and then some of the business and management databases were searched for innovation and commercialization.

After searching various databases, only a small number of relevant publications were found. However, the databases did oint towards some of the leading journals. This helped in searching more specifically in their local journal database. Along with these the university based search database system was also used. The electronic search ended in manual search where direct search with the relevant journals was conducted, Allowing

article linking through citations. Out of several articles, the articles that were more specific to innovations and commercialization in healthcare first and then the process of commercialization, innovation and technology transfer more specifically were chosen. The articles were not short listed on the basis of key-words. Rather, a more specific relevance by reading through abstracts and then sometimes the whole article was used. In conducting the literature search it is important to keep a record of the keywords and methods used in searching the literature as these will be used later when describing how the search was conducted (Timmins and McCabe, 2005).

The search included key terms as healthcare innovations, commercialization, technology transfer, success of innovations and commercialization best practices and so on. Literature search on published material since 1980 was conducted. However, it was found that literature published in last ten to fifteen years were more appropriate for analysis. Apart from these, some relevant literature published prior to 1980's were also used.

To reduce the literature to manageable proportions, the literature findings were divided into three main themes-(1) innovation, (2) Technology Transfer and (3) commercialization. The extant literature is reviewed and synthesized to uncover the key emerging themes and to build a framework based on those themes. Since commercialization of innovation serves interest to a multitude of disciplines including management, marketing, entrepreneurship, economics, and other multidisciplinary domains, this literature review captures a more comprehensive view across fields. The shortlisted articles rather than just the abstracts were searched for these three themes.

After removing the overlapping articles from the databases, 90 articles were shortlisted based on the focus exclusively on literature on Innovation and commercialization, from 33 journals across the disciplines of management, strategy, entrepreneurship, economics, and marketing (See Appendix A(a) and A(b)). In terms of distribution of articles across themes, it is worth noting that several articles corresponded to more than one theme.

A set of fundamental conceptual issues, especially the models surrounding innovation in general and with respect to healthcare in particular were examined. Along with the published journal articles, some relevant textbooks, website published articles, blogs and other materials were also used for a detailed analysis.

2.2 Innovation

Innovations are important for technological progress and overall economy and growth in business. They extend our technological capabilities and improve productivity, and also contribute to the wealth of society and high standards of living (Simula 2012). Innovations also increase market share and contribute to the comparative and absolute advantages of a firm (Twiss, 1986; Souder, 1987; Patterson, 1998; Dodgson, 2000; Narayanan, 2001; Simula, 2012).

One of the main issues when discussing the term “innovation” has been its liberal usage by its practitioners. The literature in academia also suffers the same problem. There are often various, different extensions attributed to “innovation”. To clarify this issue in this section, apart from discussing innovations as a process, this section also describes innovations from the healthcare perspective.

2.3 Definition of Innovation

The word innovation has its origins in the Latin word "innovare," which can be translated as "to re-new, to make, or to alter" (Souder, 1987; Narayanan, 2001). Innovation can be defined as the intentional introduction and application within a role, group, or organization, of ideas, processes, products or procedures, new to the relevant unit of adoption, designed to significantly benefit the individual, a group, or wider society(West, 1990). This definition is largely accepted among researchers in the field of innovation (Anderson, et al., 2004), as it captures the three most important characteristics of innovation: (a) novelty, (b) an application component and (c) an intended benefit (Lansisalmi, et al., 2006).

According to Zaltman, Duncan, and Holbek (1973), innovations can be discussed in three different contexts: (1) innovations can refer to an invention and the creative process itself; (2) innovations can refer to the adoption process; and (3) innovations can refer to "..that idea, practice, or material artifact that has been invented or that is regarded as novel independent of its adoption or non-adoption" (ibid., p. 8).

Innovation as defined by United Nations Educational, Scientific and Cultural Organization (UNESCO) is the implementation of a new or significantly improved product (goods or service), or process, a new marketing method or a new organizational method in business practices, workplace organization or external relations (UNESCO Institute for Statistics, 2005).The chart below shows the different classification of innovations defined by UNESCO *(Table 2.1)*.

Table 2.1 Innovation as defined by UNESCO

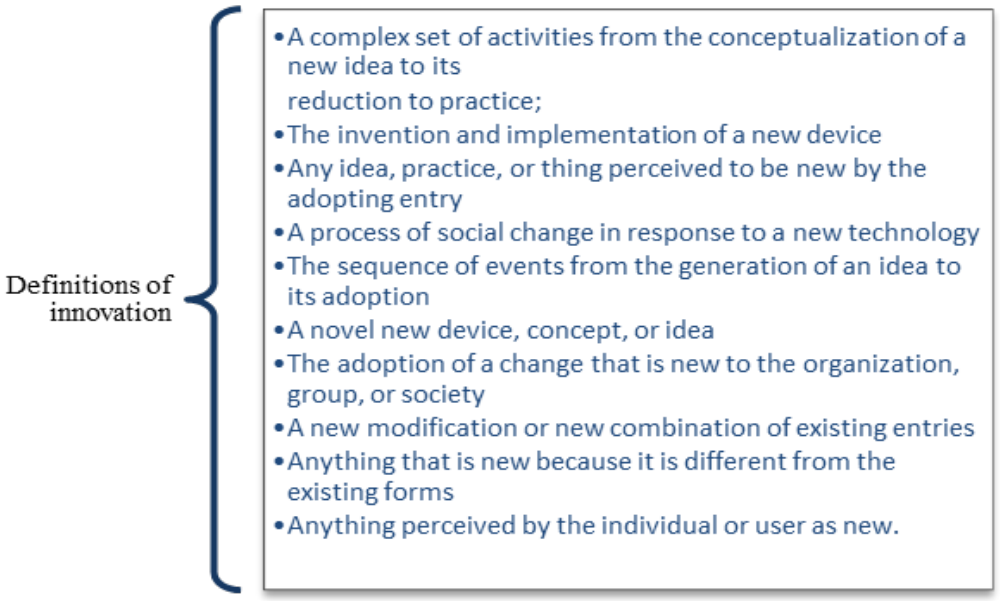


Table 2.2 Various definitions in the field of innovation (Souder, 1987)

There's also a debate on differences between invention and innovation. Inventions and innovations are often confused. Schumpeter (1939) describes that innovations are inventions that are commercialized in the market by entrepreneurs. According to Smith (2006), commercialization is required before an invention can become an innovation. He also notes that in reality, many inventions will never turn out to be innovations. Many authors have tried to define innovation. Table 2.2 lists various definitions in the field of innovation (Souder, 1987). Please see Appendix B for more definitions of innovations. While the collection of definitions is not collectively exhaustive, it does highlight the vagueness of innovation terminology in literature.

2.4 Innovation in Healthcare

> *Innovation in healthcare can be defined as the introduction of a new concept, idea, service, process, or product aimed at improving treatment, diagnosis, education, outreach, prevention and research, and with the long term goals of improving quality, safety, outcomes, efficiency and cost (Omachonu 2010).*

The process of innovation is both complex and multi-dimensional regardless of the industry in which it is being applied. Innovation in the healthcare industry has its own unique challenges. Any attempt to understand the process of innovation in healthcare must begin with an in-depth analysis of its challenges. There are five key stakeholders in the innovation process (Omachonu 2010), and each has its unique and deliberate needs, wants and expectations as shown in Table 2.3.

Stake Holders	Needs, Wants & Expectations
Physicians and Other Care Givers	Improved clinical outcomes, improved diagnosis and treatment
Patients	Improved patients' experience, improved physiological well-being, reduced waiting time, reduced delay
Organizations	Enhanced efficiency of internal operations, cost containment, increased productivity and quality and outcomes improvement
Innovator Companies	Profitability, improved outcomes
Regulatory Agencies	Reduced risks and improved patient safety

Table 2.3 Stakeholders in the process of healthcare innovations and their expectations
Source: Omachonu 2010

It has been suggested that it is difficult to change the behavior of clinicians (Greco and Eisenberg, 1993), current medical practices, and healthcare organizations

(Shortell, Bennett, and Byck, 1998; Shortell et al., 2001) (Litaker et al.,2006). The adoption of healthcare innovations is often regulated by laws, making changes more laborious (Faulkner and Kent, 2001). In healthcare, typical starting points of an innovation process may lead to death, disability, or permanent discomfort (Lansisalmi, et al., 2006). This, together with the clinicians' tendencies to protect their individual autonomy and reputation, can promote a culture of blame and secrecy that inhibits organizational learning and the generation of innovations (Huntington, Gilliam and Rosen, 2000). Furthermore, new practices in patient care are traditionally scrutinized thoroughly in their early development phase so that potentially harmful innovations are not adopted (Faulkner and Kent, 2001).

Any attempt at modeling the process of health care innovation must take into account the key stakeholders as shown in Figure 2.1 (Omachonu & Einspurch, 2010). Healthcare organizations serve six distinct *purposes* – treatment, diagnosis, prevention, education, research and outreach. In serving these purposes, other *parameters* that healthcare organizations must effectively manage are quality, costs, safety, efficiency and outcomes. At the very core of healthcare innovation are the needs of *patients* and the healthcare *practitioners and providers* who deliver care.

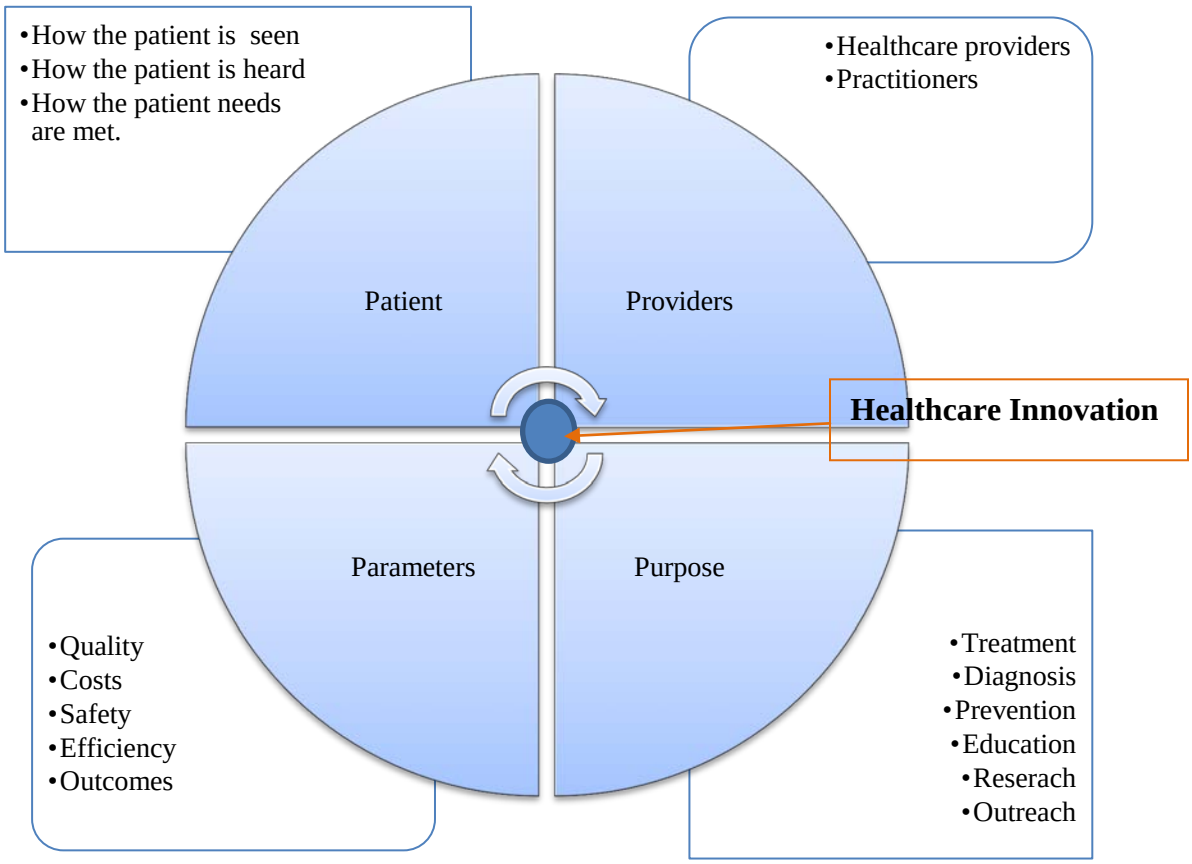


Figure 2.1: Framework of healthcare innovation (Adapted and modified from Omachonu 2010)

Quite often, healthcare organizations arrive at innovation by relying on new or existing information technology. When successful, healthcare innovation focuses on the following three areas the most –

a) How the patient is seen,

b) How the patient is heard, and

c) How the patient's needs are met (Omachonu 2010) (Figure 2.1).

Innovations in healthcare have mostly been stimulated by the patients, healthcare organizations, researchers, physicians, and other healthcare professionals. In some cases, the need for change is forced upon the healthcare organizations by the federal agencies to alleviate healthcare concerns and challenges or by market

competitors. Sometimes the need arises from within the healthcare system. Once the need is identified, the next challenge is to identify procedures of innovation and then it is tested, modified and adopted. On some occasions, for example, a healthcare technology company can develop, test and later market the innovative technology to healthcare organizations. In certain cases, a healthcare innovation company takes what might be an imperfect attempt at innovation from a healthcare organization and refines it into a better product, and then markets it to healthcare organizations.

2.5 Innovation Process Models

There are various innovation models that help firms to create innovations. These models have evolved over the course of time. The main reason for this change is the change in the environment in which innovation takes place (Rothwell 1994). The models discussed here in this section have been found mostly from management books and scientific journals.

According to Professor Joe Tidd of University of Sussex, describes that the early innovation models define innovation as a linear sequence of functional activities.

> He says, "either new opportunities arising out of research give rise to applications and refinements which eventually found their way to the marketplace ('technology push'), or else the market signaled needs for something new which then drew out new solutions to the problem ('need pull', where necessity becomes the mother of invention). However, in real practice successful innovations exist as a combination and interaction of both technology pull and technology push phenomenon". (*Review of innovation models, Imperial College of London 2006*).

Roy Rothwell, a key researcher in the field of innovation management suggested that the innovation process has evolved from simple linear models (characteristic of the 1960s) to increasingly complex interactive models (Figure 2.2). His first generation model stresses technology pull and technology push methods whereas the fifth generation model treats innovation as a more complex, multi-actor process, which requires high levels of integration.

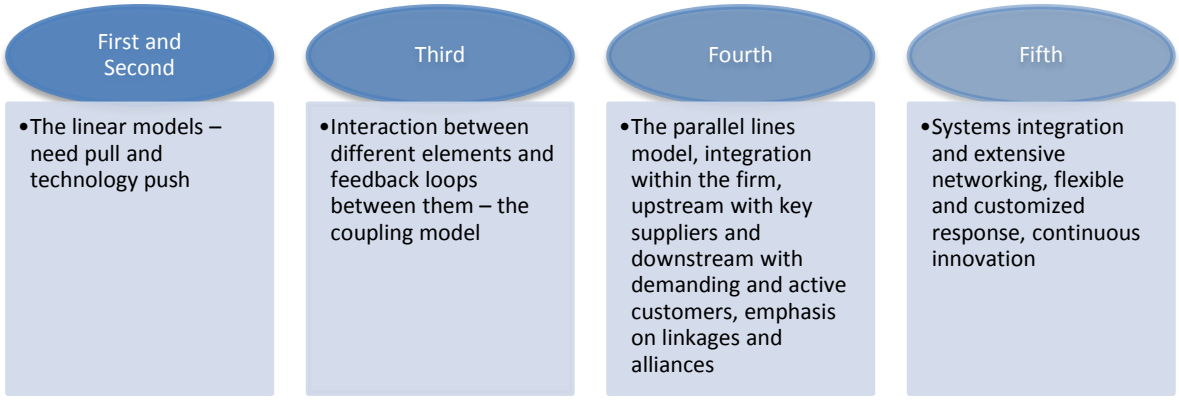


Figure 2.2: Rothwell's five generations of innovation models: Listing generation and its key features

Source: Adapted from Tidd, Bessant and Pavitt, 2005,

According to the technology-push model, the source of new discoveries are within the research and development team and are iterated, modified and eventually applied to products that are left for marketers to promote to potential customers. Technology push assumes that there is a need in the market that requires innovation. So, the customer and market needs are the starting points and initiators for new ideas and requirements and research has more of a reactive role in finding solutions to emerging needs. This constitutes the first and second model suggested by Rothwell. The third-generation model highlights the coupling of functional entities and suggests that innovations are the result of knowledge between research and development, marketing and manufacturing being shared. The interactive, or integrated, model represents the fourth level of innovation and it considers a firm's activities to occur parallel to one another. This model acknowledges that innovation occurs or originates

from different points as a result of concurrent tasks. Finally, the fifth-generation, innovation-process model is a complex set of communication paths and systems integration with strong external networking (Dodgson & Rothwell, 1994; Trott, 2002; Simula 2012).

Cooper (1968) introduced the stage-gate process with distinctive and orderly phases. He prescribed that a given phase can only start if the project satisfied all earlier requirements. This is not only useful to determine if the project should proceed or not, but also to keep track of possible new occurrences during the process. Hartley (2006) argues stages are helpful for conceptualizing the innovation process and determining where drivers and barriers can occur.

Tidd and Bessant (2005) and Jacobs and Snijder (2008) adopted the stage-gate model of Cooper in the implementation phase of their model. During the first phases of idea generation and selection, the phases are less linear and have more feedback loops, while in the later phases, they recommend a more formal and rigid process.

All models start with some form of idea generation or searching for ideas for innovation (Eveleen 2010). Some authors emphasize the openness and acceptance (Nooteboom 2001, Mulgan and Albury 2003, Jacobs and Snijders 2008) and some argue that this is considered to be divergent behavior (Van der Ven et al., 1999).

The next step is to narrow the options down, to make a decision, and to select projects to be purused or not to be pursued (Rogers 1962, Nooteboom 2001, Tidd and Bessant 2005, Jacobs and Snijders 2008). This selection should be based on both the organizational strategy and on the existing portfolio. At this point it has to be judged if

the innovation is potentially lucrative enough (Andrews and Sirkin 2006) and if it is going to increase public value enough (Moore 1995).

The next step is to turn the (selected) idea into some tangible product, process or service (Eveleen 2010). To describe this process, words such as development (Cooper and Kleinschmidt 1986, Van der Ven et al.1999 and Verloop 2004), prototyping Mulgan and Albury 2003), manufacturing (Rothwell 1994) and realization (Andrews and Sirkin 2006, Jacobs and Snijder 2008) are used. Most commonly this phase is known as development and testing phase.

The fourth general step is implementation of newly developed technology or product. Implementation impliers put to work in real word. This phase is called implementation/launch. It entails the preparing of customers and marketing activities. Most authors stop here with their innovation process.

However, some authors (Rogers 1962, Nooteboom 2001, Mulgan and Albury 2003, Tidd and Bessant 2005 and Jacobs and Snijders 2008) include a post launch phase. This entails the sustaining and supporting of the innovation or even re-innovating it and scaling it up. Finally, Mulgan and Albury (2003), Tidd and Bessant (2005) and Jacobs and Snijders (2008), include a phase for feedback. It helps in not only learning about the innovation itself, but also about how the innovation process went. This stage prevents future mistakes and product/technology improvisation.

2.6 Innovation as a Non-Integrated Process

Table 2.4 provides an overview of the difficulties that arise if we take a partial view of innovation (Tidd *et al*, 200).

Innovation Process	Results
Strong R&D capability	Technology which fails to meet user needs and may not be accepted
The province of specialists	Lack of involvement by others and a lack of key knowledge and experience input from other perspectives in the R&D
Understanding and meeting customer needs	Lack of technical progression, leading to inability to gain competitive edge
Advances along the technology frontier	Producing products or services which the market does not want or designing processes which do not meet the needs of the user and whose implementation is resisted
The province only of large firms	Weak small firms with too high a dependence on large customers. Disruptive innovation as apparently insignificant small players seize new technical or market opportunities
Only about 'breakthrough' changes	Neglect of the potential of incremental innovation: with an inability to secure and reinforce the gains from radical change because the incremental performance ratchet is not working well
Only about strategically targeted projects	May miss out on lucky 'accidents' which open up new possibilities
Only associated with key individuals	Failure to utilize the creativity of the remainder of employees, and to secure their inputs and perspectives to improve innovation
Only internally generated	The 'not invented here' effect, where good ideas from outside are resisted or rejected
Only externally generated	Innovation becomes simply a matter of filling a shopping list of needs from outside and there is little internal learning or development of technological competence
Only concerning single firms	Excludes the possibility of various forms of inter-organizational networking to create new products, streamline shared processes, etc.

Table 2.4: Type of innovation processes and its results
(Source: Adapted from Tidd, Bessant and Pavitt, 2005; Tidd, 2010)

Brandbury (1989) also presents an innovation-project model with four phases: (1) Feasibility, (2) Applications, (3) Development and (4) Exploitation. He suggests through this model that first phase is base product innovation and evaluation followed by its consolidation, application product innovation, and evaluation. Then comes the product (may include process as well) development and evaluation leading to its

strategy and data selection, patenting and consultancy, proposal, presentation and negotiation for project adoption (Simula 2012).

Rogers (2003) describes the same innovation process as a series of stages and says that the order of stages may change and that some of the stages can be omitted in certain cases; he also admits that many innovations deviate from this general process flow.

Simula (2012) in a detailed literature review of innovation processes states that Koen et al. (2001) present a similar linear model, in which they divide the innovation process into three phases, i.e. a front-end phase, a new product development phase, and a commercialization phase whereas Padmore, Schuetze, and Gibson (1998) also refer to linear and chain-link models, they ultimately introduce a more cyclical model. Also, Schoen, Mason, Kline, and Bunch (2005) have criticized linear models and propose a cyclical model for innovation development.

2.7 Sources of Innovation

There exists a significant amount of literature on sources of innovation but there is no widely recognized theory exists that provides an exact answer regarding the

Figure2.3: Forces driving innovation (Source: adapted from Sheth & Ram 1987)

origins of innovations. Innovation research have been inconclusive, inconsistent, and characterized by low levels of explanation (Bigoness and Perreault, 1981; Damanpour, 1988; Downs and Mohr, 1976; Kimberly and Evanisko, 1981; Nord and Tucker, 1987; Pennings, 1987; Rogers, 1983). Chaston (2000) illustrates entrepreneurial approach to innovations where the key question to start with is "why not? (Simula 2012) Sheth and Ram (1987) identify four distinct forces responsible for the increasing importance of product and service innovation for organizational survival in the 1990s.

These provide a useful framework for considering drivers for innovation and, are presented in Figure 2.3. These factors driving innovation are intricate and interwoven. Another factor that can be identified as a source of Innovation is firm size. Schumpeter (1939) has suggested that the size of a firm matters and, thus, that larger firms are more innovative. His argument is grounded in the idea that larger firms have

more financial and organizational resources, risk tolerance, and economies of scale for R&D projects and, thus, more chances to provide for more innovation (Simula 2012). However, Narayanan (2001) argues differently. According to Cyert and March (1992), successful firms are the ones that lead to more innovations as they have the required essential funds for innovations. However, Cyert and March (1992) also state that unsuccessful firms can create innovations when they are forced to solve acute problems that they are facing. Palmberg (2004) states that variables of customer demands, market niches, and collaboration with customers that give birth to innovations.

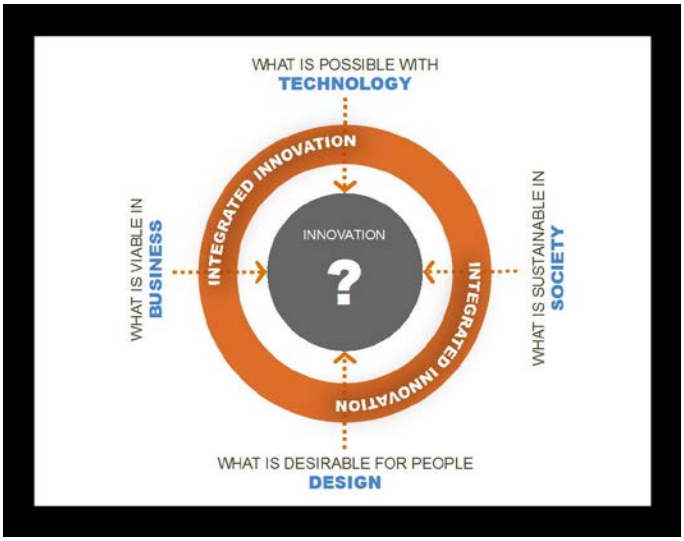


Figure 2.4: A Structured Approach for driving innovations in an organization

(Source "101 Design Methods)

Similarly, new management ideas can lead to overcome the trade-offs between efficiency and profitability (Magnusson & Martini, 2008) and provides a basis for new innovations (Simula 2012). Figure 2.4 is taken from the book "101 Design Methods: A Structured Approach for Driving Innovation in Your Organization" written by Professor Vijay Kumar at University of Illinois. He describes the forces behind

innovation are society, needs business and technology. Any of these factors when lay open to change, might become a reason of innovation (Figure 2.4).

The innovation process (Dosi 1988) is the result of complex activity and it requires a combination of several elements, internal and external to the firm: indeed, it is important to consider not only the organizational and managerial capabilities of individual companies, their investment or the size of the firm, but it is important to consider also a series of external elements, such as the collaboration with other firms or with universities that can improve the internal activity.

Amore and Iorio in a detailed literature analysis of various innovation sources describe that common strand all over the literature on firm strategy and performance is the diffuse utilization of strategic alliances or collaboration at all steps of the innovation process to accelerate innovative activities (Audretsch, 2001; Bagchi-Sen 2004; Terziovsky and Morgan, 2006). In this way firms can improve their competitiveness position by integrating technology in the innovation process and facilitating intra and inter firm knowledge and technology transfer (Amir-Aslani and Negassi, 2006; Boer et al, 2001; D'Amore,R. and Iorio, R.). Deeds and Hill (1996), Freeman (1991), Hagedoorn (1995) analyzed the topic of the relation between firm's rate of new product development and the number of strategic alliances and they concluded that higher levels of expenditures in R&D and scientific ingenuity are positively correlated with higher levels of collaboration. Internal capability and external collaboration have been found to be complements rather than substitutes (Arora and Gambardella 1994; Pisano et al, 1988; Rothaemel, 2001). In particular, Pisano at al., (1988) studied the relationship between in-house R&D and collaboration and they found the two to be complementary,

as in-house R&D capability attracts collaborative partners. Shan et al., (1994) examined the relationship between the number of collaborators and innovative output. They conclude that, while collaboration advances innovation, innovation does not necessarily require collaboration. Schumpeter (1942) as discussed earlier in this section, argued that innovation activity is promoted by large firms on a large scale, Jexkes, Sawers and Stillerman (1958) demonstrated that most inventions arose from individuals or small groups.

Mueller (1962), showed that the major part innovations originated from smaller firm or individuals. According to Damanpour(1992) a smaller firm might be more innovative because of flexibility and ability to accept and effect the change than in a large firm. Kamien and Schwartz (1982) describe that smaller firms are more motivated to innovations as there is a visible impact on the firm's overall performance.

Another source of innovation can be a firm's number of patents. Bound et al.(1984) demonstrated that the number of patents increases at a rate that is less than proportional to firm size and other authors; Acs and Audretsch (1987, 1991), confirm the same results using the number of innovation as an output variable.

Halperin and Chakrabarti, (1987) use the number of a firms scientific publications as source of innovation. Henderson and Cockburn (1996), Mansfield, (1980) showed that larger firms have in some cases an advantage in innovation. There can be several factors that can influence innovation performance.

2.8 Technology Transfer

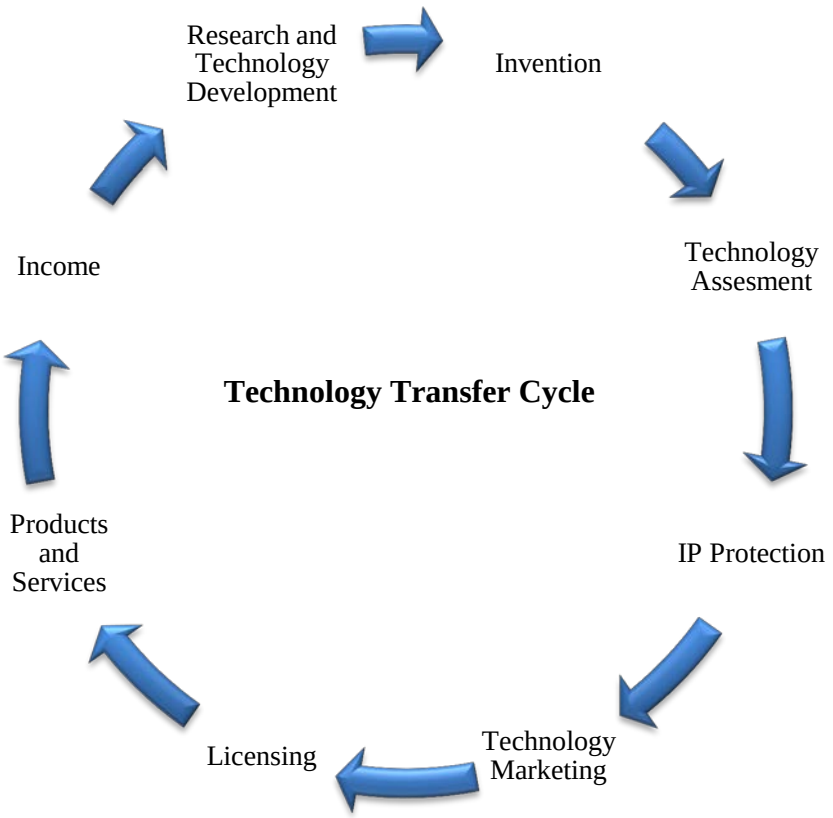


Figure 2.5 Technology Transfer Process

Mansfield (1975) pointed out that, "One of the fundamental processes that influence the economic performance of nations and firms is technology transfer." Technology transfer (TT) is an area of interest not just to business, economists, and technologists but also to other disciplines such as anthropology and sociology (Zhao and Reisman, 1992). For economists, as argued by Mansfield (1975), the focus is on economic growth and achievement of economic goals.

However, from the perspective of business and technologists the main focus of TT is to improve the competitive advantage of firms through the enhancement of

customer value (Ramanathan, 2001). Even though technology transfer is not a new business phenomenon, the considerable literature on technology transfer that has emerged over the years agrees that defining technology transfer is difficult due to the complexity of the technology transfer process (Robinson 1988; Spivey et al.1997). The definitions depend on how the user defines technology and in what context (Chen 1996; Bozeman 2000).

2.9 Definition of Technology Transfer

The term technology transfer can be defined as the process of movement of technology from one entity to another (Souder et al.1990; Ramanathan 1994). The movement may involve physical assets, know-how, and technical knowledge (Bozeman, 2000). Technology transfer in some situations may be confined to the relocating and exchanging of personnel (Osman-Gani 1999) or to the movement of a specific set of capabilities (Lundquist 2003).

Technology transfer has also been used to refer to movements of technology from the laboratory to industry, developed to developing countries, or from one application to another domain (Philips 2002) (Ramanathan 1994). Gibson and Rogers (1994) defined technology transfer as application of information, in a regulating sense where technology is considered as information.

In an analogous disposition economists Arrow (1969) and Dosi (1988) analyzed technology transfer on the basis of the properties of generic knowledge, focusing particularly on variables that relate to product design. Mittleman and Pasha (1997) have attempted a broader definition where they state that technology transfer is the movement of knowledge, skill, organization, values and capital from the point of generation to the site of adaptation and application.

2.10 Technology Transfer Models

Since the early 1970s, considering the difficulties and complexities faced by managers of technology transfer projects, researchers, consultants, and practitioners of technology transfer have been proposing models of technology transfer that could facilitate the effective planning and implementation of technology transfer projects (Ramanathan 2010). Here in this section some of the models proposed from qualitative perspective are discussed. According to Ramanathan in his article "An overview of technology transfer and technology transfer (TT) models", Jagoda (2007) points out that,

> "Qualitative models often have as their objective the delineation of activities involved in managing TT and the elicitation of factors and issues that can influence the success and/or effectiveness of TT. Quantitative models, on the other hand, aim at quantifying parameters of significance in TT and analyzing them with a view towards minimizing goal incompatibility between the transferors and transferees of technology"(Jagoda 2007).

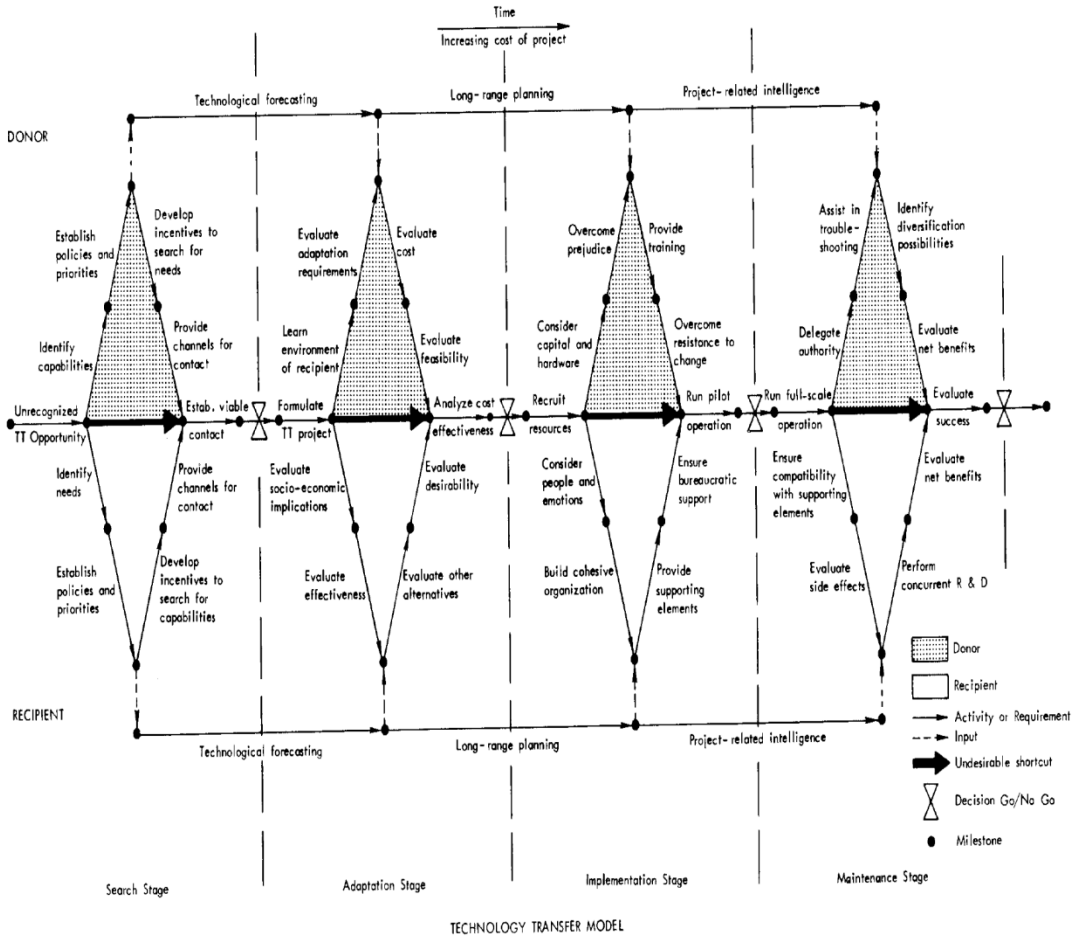
2.11 A Brief Overview of Some Qualitative and Quantitative TT Models

(a) The Bar-Zakay Model: Based on a project management approach, a comprehensive TT model is offered by Bar-Zakay (1970). He divided the TT process into the Search, Adaptation, Implementation, and Maintenance stages. He depicted the activities, milestones, and decision points (go or no-go) in each of these stages as shown in Figure 2.6. The upper half of the figure delineates the activities and requirements of the transferor (referred to as the "donor" by Bar-Zakay) and the lower half that of the transferee or the "recipient." The model uses the term "donor" for the transferor giving the impression that the owner of technology is giving away a valuable asset out of altruistic reasons! This is clearly not the case and the use of such terms must be avoided.

The Bar-Zakay model also suffers from another disadvantage. Jagoda (2007) points out that,

> "The model has limited relevance today since many of the activities, terms, and ideas expressed reflected the setting of the late 1960s to early 1970s, when buyers of technology were mainly passive recipients who depended greatly on aid programs for the purchase of technology. It was also an era when government controls were instrumental in determining the rate, direction, and scope of technology flows" Jagoda (2007).

(b) The Behrman and Wallender Model: Behrman and Wallender (1976) have proposed a seven stage- process for international technology transfer that may be more relevant to multinational corporations. Some of the features of this model are following:



TECHNOLOGY TRANSFER MODEL

Figure 2.6 The Bar-Zakay model of technology *(1970)*

- There is a need for the transferee to be involved right from the beginning in the planning and implementation of a TT project.
- TT project does not end with commencement of production.
- Unless explicit measures are in place to ensure assimilation of the transferred technology, the TT cannot be said to have been successful.

(c) The Dahlman and Westphal Model: Dahlman and Westphal (1981) carried out considerable work in the Republic of Korea and, based on their experience in rapidly industrializing countries during the 1980s, proposed a nine stage process model. However, this model may be regarded as an improvement of the Behrman and Wallender model with great emphasis on transferee involvement at all stages of the technology transfer project. The important lessons that this model presents include the following:

- A TT project is best studied using a sequential process perspective.
- Any TT project should not be commenced without a careful feasibility study since such projects often require heavy resource commitments.
- The transferee should be involved in the planning right from the beginning.
- It is important for transferees to develop sound engineering and project management skills without which the TT process cannot be managed effectively.

(d) The Schlie, Radnor, and Wad Model: Schlie et *al. (*1987) proposed a simple, generic model that delineates seven elements that can influence the planning, implementation, and eventual success of any TT project.

The valuable lessons that emerge from this model are as follows:

- The many changes that have taken place and are taking place in the global business setting today have made it imperative for managers of technology to gain good insights into the transferee environment, transferor environment, and the greater environment when planning and implementing a TT project.
- The choice of the technology transfer mechanism should be based on a sophisticated understanding of the other six elements.

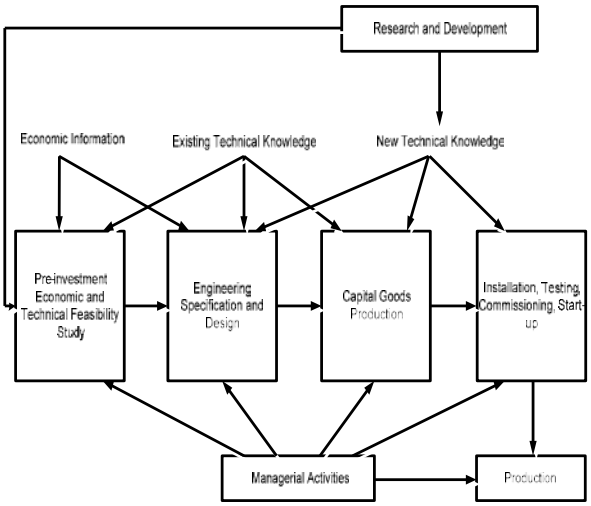


Figure 2.7 The five-phase model of international technology transfer. *(Source: Jagoda 2007)*

(e) The Chantramonklasri Model: The Dahlman and Westphal Model has been further improved by Chantramonklasri (1990 who proposes a five phase model as shown in Figure2.7.

The five phases of this model are as follows:

- Carrying out a pre-investment and feasibility study
- Developing engineering specifications and design based on the feasibility study

- Commence capital goods production based on the engineering specifications and designs that have been developed.
- Commissioning and start-u including comprehensive of the workforce
- Commence commercial production

As in the Dahlman and Westphal Model, the negotiation and assimilation elements are missing from this model as well. The lessons that may be learned in this case are similar to those of the Dahlman and Westphal Model.

(f) Other Qualitative Models of TT: There are several other models that have been developed. However, these will only be described briefly. Lee *et al.* (1988) have developed a longitudinal model of technology transfer based on a study of developing and rapidly industrializing countries. They point out that a transferee firm needs to put in place strategies to be able to go through the stages of acquisition, assimilation, and eventual improvement. As the firm advances technologically, it needs to choose appropriate mechanisms of transfer, depending on the stage of the life cycle of the technology and their own technological capability profile. They also note that the mechanisms chosen by the transferor to transfer technology will depend on the relative newness of the technology, its strategic importance to the transferor firm, and the level of intellectual property protection needed.

Reddy and Zhao (1990), in a model similar to that of Schlie et *al.* (1987) state that any international technology transfer (ITT) project should examine three main components, which they refer to as the home- country component, host-country component, and transaction component. The home country is that of the transferor and

the host country is that of the transferee. The transaction component consists of important business issues such as the pricing of technology, intellectual property protection, payment modalities, potential conflicts, and measures for ensuring effective transfer.

Keller and Chinta (1990) argue that effective TT would be determined by the extent to which the transferor and transferee manage the barriers that impede transfer and strengthen initiatives that facilitate it. The facilitating initiatives refer to the willingness of the partners to adapt their respective strategic and operational postures to ensure a "win-win" outcome. The barriers could be political, legal, social, cultural, economic and technological. They also stress the importance of selecting the correct mechanism to transfer the technology.

The United Nations Industrial Development Organization (UNIDO) (1996) model, in what appears to be an endorsement of the Bar-Zakay approach, suggests that, in the manufacturing sector, once the need for a TT project is established, the steps of search, evaluation, negotiation, contract execution, and technology adaptation and absorption should be followed sequentially to ensure effectiveness.

Durrani et al. (1998) proposed a generic model (Figure 2.8) consisting of five steps:

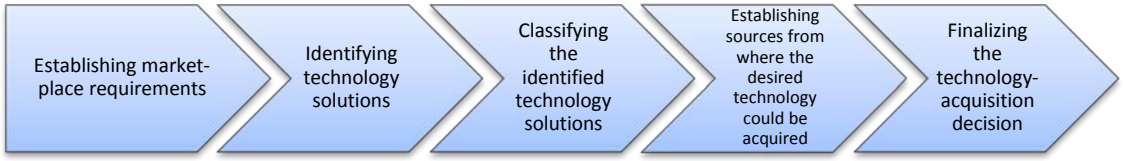


Figure 2.8: Technology transfer model, *Source Durrani et al*.

This model stops with the technology acquisition decision. Its major lesson is that it stresses the importance of establishing the need for a TT project and the need for identifying multiple sources of technology for enabling a better choice of transferor.

Bozeman (2000) has proposed a contingent effectiveness model of TT. While the emphasis is on technology transfer from universities and government laboratories to industry, the model is also relevant to inter-firm TT. This model also stresses on importance of establishing the need for a TT project and the need for identifying multiple sources of technology for enabling a better choice of transferor. Six "out-the-door" measures are proposed. These are market impact, economic development, political benefits, opportunity assessment is a valuable lesson that this model imparts.

(g) A Brief Overview of Some Quantitative TT Models: The literature is sparse when it comes to quantitative models of technology transfer. Some of the more

important models are described briefly. The interested reader may wish to refer to the original publications if further information is sought.

Perhaps the earliest quantitative model is due to Sharif and Haq (1980). This model proposes the concept of potential technological distance (PTD) between a transferor and transferee and argues that when the PTD is either too great or too small between the transferor and transferee, the effectiveness of the transfer is low. It suggests that when a transferee first looks for a potential transferor it is important to look for one with an "optimal" PTD. From a practical point of view, a potential transferor at the firm level may not be willing to easily divulge information that could enable an assessment of the PTD. The greatest value of the model is that it draws attention to the need for incorporating the concept of a PTD in deciding the transferor.

Raz *et al.* (1983) have presented a model of technological "catch-up" that shows how a technology leader, through technology transfer, can assist the rate of technological development of a technology follower. The model examines three phases of growth of a technology follower namely, the slow initial phase with high technological capability gap, the faster learning phase with the decreasing gap, and the catch-up phase when the technological gap is very small or closed. They argues that this type of analysis would enable technology leaders to develop clear policies, based on considerations of competitiveness, security, and other related issues, when entering into TT agreements.

It may be said that the main contribution of the quantitative models is their emphasis on the need for partners in TT projects to develop skills and approaches for better TT planning.

2.12 Laws of Technology Transfer

The transfer of new technology from university laboratories to the private sector has a long history and has taken many different forms. The current national emphasis on this activity, however, can be dated to the 1980 enactment of P.L. 96-517, The Patent and Trademark Law Amendments Act, more commonly known as the Bayh-Dole Act. Appendix C lists the various laws and their inclusions exclusive for TT and applicable to across technological innovations.

2.13 Commercialization

Academic researchers have used innovation and commercialization in the same construct however with the difference in the processes of the two; the two definitions became rather distinct. For a company to be successful, continuous innovations are almost necessary however it is not necessary that every innovation becomes a successful commercialization.

Commercialization is defined as the act or activities required for introducing an innovation to the market (Andrew & Sirkin, 2003; Kelm, Narayanan, & Pinches, 1995; Kwak, 2002; Nambisan & Sawhney, 2007; Narayanan, Pinches, Kelm, & Lander, 2000; Nerkar & Shane, 2007). To commercialize an innovation we is to bring a product into a market and reach the mainstream of the market further than the innovators.

Cooper (1993) defined commercialization as "'the 'back end' of the process, including market launch, production start-up, trial sell, and production". According to Rogers (2003), commercialization can be seen also as "The conversion of an idea from research into a product or service for sale in the market place". There is no generic form of commercialization and therefore there is a fundamental difference between the commercialization of technology and the commercialization of products.

Jolly (1997) provides a good distinction between these two by stating that,

> A technology is essentially a "capability", often a versatile one that can be used in more than one product. Products are occasional embodiments of this capability and mediate the process of bringing it to market and realizing from it. These technology and products, however often have separate existences, following their own competitive logic, converging sporadically.

To commercialize an innovation, activities must start at idea generation and end in product introduction into the market. A detailed analysis of the literature reveals that the journey from one end to the other in this process is far from simple, with the inclusion of innovation protection, transforming the innovation to into product and other critical steps. It is of great importance to perform every activity in a precise manner to achieve success. However, there is no suggested uniform methodology in the literature that could define the process of successful commercialization. Out of every three thousand new innovative ideas, only one gets to become a successful product (Stevens & Burley, 1997). Looking at it from another perspective, it takes three thousand raw ideas to result in one successful product (Stevens & Burley, 1997; Dutta 2011).

2.14 Commercialization of Technology

Successful and innovative technology commercialization (TC) is important for survival in today's competitive markets (Cooper, 2000). Mitchell and Singh (1996:170) view TC as 'the process of acquiring ideas, augmenting them with complementary knowledge, developing and manufacturing saleable goods, and selling the goods in a market.'

Successful TC is multifaceted. It refers to a firm's ability to: (1) develop and introduce a large number of product and process technologies (Zahra and Covin, 1993); (2) create radically new products (Zahra, 1996); (3) expedite the introduction of these new products to the market (Stevens, Burley, and Divine, 1999); and (4) create new knowledge (Leonard-Barton, 1995). These dimensions should be considered simultaneously in order to understand the factors that influence technology commercialization (Zahra and Nielsen, 2002).

Commercialization of technology is often done by private firms (Rogers, 2003). However, the technology embodied in a new product has no value for the firm unless it provides significant new or improved customer benefits, or reduces product costs (Abetti & Stuart, 1988). The commercialization of technology can happen in various ways and the form it takes depends on the competencies of an underlying organization. There are many alternatives that can be adopted to commercialize innovation such as licensing, R&D contracting, partnering, alliances, and joint ventures (Arora & Grambardella, 1990; Kollmer & Dowling, 2004). A firm can market a technological innovation by selling complete patents to external parties (Katz & Shapiro, 1985;

Dodgson, 2000). Another way to achieve technology commercialization is creating a joint venture (Zajak, 1991) or establishing a strategic partnership or alliances (Steele, 1989; Grant, 2002). Joint ventures help a firm share the business risk and combine complimentary assets and resources between two or more firms. However, joint ventures are sometimes hard to manage due to potential conflicts of interest (Simula, 2012).

2.15 Commercialization of Product

Cooper and Kleinschmidt (1990) used the term commercialization to describe trial production and sales, production start-up, and market launch. The focus of this dissertation lies on the commercialization within the context of the product (Medical device) innovation process. The literature on product innovation typically considers product innovation process to comprise three phases: a front-end phase, a development phase and a commercialization phase (e.g., Buckler, 1997; Koen et al., 2001). This type of linear approach with separate activities is also considered by the new product development (NPD) literature, too (e.g., Cooper, 1996; Khurana & Rosenthal, 1997; Griffin, 1997; Schilling & Hill, 1998) (Simula 2012).

The path of commercializing a new product can be complex and may involve heavy risk and unforeseen surprises (Norling 1998). It may require more investment and can be more risky than several other alternatives to commercialization in the sub sections above (Di Benedetto, 1999; Kotler & Keller, 2009). According to Mitchell and Singh (1996), a collaborative relationship is beneficial in the case of the commercialization of complex products. Another factor that may differentiate technology and product commercialization is the capability of a single technology to provide base for different projects and several new products (Parker & Mainelli, 2001).

For example a technological invention to detect breast cancer may be exploited further to detect a pancreatic cancer. The same technology may also be used for doing biopsies in different contexts. Thus, a single project is not sufficient enough to capture the full value of a single technology base. Cook (1997) says that "[it] may not be clear which new technology is the most appropriate to carry the product in future". Thus, a

firm that chooses to commercialize new products has to keep a close eye on technology development because there can be radical changes in technology that make existing products obsolete (Simula 2012).

The time period between an original invention and a commercialized product can be very long. Agarwal and Bayus (2002) studied 30 industrial and consumer innovations in the United State between the years 1849 and 1983. The average time between an invention and the actual commercialization of the product took 29 years. And then, another ten years before sales really took off. The process might have expedited in the recent years however for every medical product it still requires a great deal of time from invention to the actual sale of the product in the market.

2.16 Commercialization of innovation-Success and Failure- A Discussion

The literature on innovation commercialization, especially from the journals with a focus on new product development, has paid significant attention to the process of developing an innovation. Successful product development requires achievement of three objectives: (a) maximizing fit with customer requirements, (b) minimizing time to entry, and (c) controlling development costs. Parallel development processes and coordination between marketing, manufacturing and R&D has not only minimized entry time and controlled development cost but also allows for a fair understanding of customer needs (Clark & 27 Wheelright., 1993; Cohen & Levinthal, 1990; Griffin & Hauser, 1992). This section covers both the success and failure sides of the innovation mainly product related. Success and failure are two sides of the same coin and they are often researched in dyadic setup (Simula 2012).

According to Montoya-Weiss and Calantone (1994), this approach most likely, dates back to the SAPPHO and New Product studies. According to Cooper (1979a), Project SAPPHO was the first study to actually differentiate between the success and failure of new products. Brockhoff and Chakrabarti (1988) state that: “It appears that while technical success is more readily obtained, commercial success is far from being guaranteed” (p. 173). These two dimensions − i.e. the technical and the commercial − are often used to measure success, but Abetti (2000) adds financial success as another dimension that should be investigated. A list of some of the core failure measures that are used by academicians and practitioners alike adapted from Griffin and Page is provided in Appendix G.

According to Cooper (1975), the "failure label" is given to products whose initial sales fell below expectations While Cooper (1975) simply equates financial failure with product failure. Schneider (2004) refers to a study conducted in the consumer goods industry and says that products are failures if they are unable to obtain distribution in the first year of introduction to the market.

Rehn and Lindahl (2011) describe failure in a qualitative case study:

> Thus, the failure was not made up of anything in particular, but by odds and ends, small mistakes and uncertainties, tipping the scale this way and that until the situation careened out of control.

It is evident from this that there really is no specific formula for failure. In order to identify reasons for success comprehensive meta-analyses of product success have been done by several authors (Johne and Snelson (1988), Lilien and Yoon (1989), Griffin and Page (1993), Montoya-Weiss and Calantone (1994), Poolton and Barclay (1998), and Ernst (2002), among others).

Goldenberg et al. (2001) explains that new products that include some familiar attributes are generally the most successful. He identified two main factors predicting success: (1) whether the product provides a solution to a customer's problem, and (2) whether the product fits certain templates that describe changes in regularities during the evolution of the product. A more detailed description and examples of these templates are provided by Goldenberg, Mazursky, and Solomon (1999a, 1999b). On a different note Abetti and Stuart (1988) postulated that it is actually less risky to commercialize a completely new product if compared to a situation where a firm tries to replicate a competitor's product.

According to Levy (1998), there are five factors that are of importance for high-tech firms seeking success: (1) An innovation uncertainty factor, consisting of market, technology, and supply uncertainties for new products; (2) the human factor, i.e. the challenge of recruiting creative professionals capable of creating innovations; (3) an organization factor, i.e.

the capability to create a culture and environment that nurtures innovations; (4) a management competence factor, i.e. the ability to bring in leadership and team spirit; and (5) know-how and know-why factors, which ensure that a firm is doing the right thing in the most efficient way (Levy, 1998). Kulvik (1977) found no single factor but a list of variables that would have been sufficient for success.

Poolton and Barclay (1998), Cooper and Kleinschmidt (2000), Song and Parry (1987), Henard and Szymanski (2001), Cagan and Vogel (2002), Kulvik (1977), Connell et al. (2001) and several authors including the ones listed already in this section and the others not listed, have identified one common thing in the analysis of success of new innovation (product or technology) and that common factor is that there is no single reason but a list of variables that acts as the deciding fate of an innovation.

Chapter3

Research Methods

This chapter focusses on the research methodology and approach for this dissertation. It discusses the research approach used in this study to answer the two research questions.

R_1: What activities did technology innovators and researchers perform at NovaScan to initiate the process of commercialization?

R_2: What is the evidence that these approaches are successful?

The answers to the above questions will help answer the main question-"What practices can be identified as the best practices engaged in the process of commercialization of a medical device innovation". This chapter also discusses the reason to opt for a qualitative case research method over the quantitative methods The chapter also discusses the data sources and the data analysis used.

According to Peter and Olson (1983), there is semantic confusion regarding the variety of philosophical perspectives in science (Simula, 2012). Dewey (1933) outlines a general paradigm of enquiry that underpins the scientific approach, consisting of inductive discovery *(induction)* and deductive proof *(deduction).* According to Dewey, deduction begins with a universal view of a situation and works back to the particulars; in contrast, induction moves from fragmentary details to a connected view of a situation. Through the inductive approach, plans are made for data collection, after which the data is analyzed to see if any patterns emerge that suggests relationships between variables. From these observations it may be possible to construct generalizations, relationships and even theories. Gray D, in his book, 'Doing Research in the Real world' says, "Through induction, the researcher moves towards discovering a binding principle, taking care not to jump to hasty inferences or conclusions on the basis of the data" (2009). This study focusses on the highlighted elements of the research framework shown in Figure 3.1.

3.1 Epistemology

Easterby-Smith et al. (2002) points out that having an epistemological perspective is important as it helps to clarify issues of research design. Crotty's (1998) ideas established the foundation for a research framework. He suggested that there exists a relationship between the theoretical stance adopted by the researcher, the methods used, and the researcher's view of the epistemology (see Figure 3.1).

Ontology is the study of being, that is, the nature of existence and embodies understanding of "what is?" whereas epistemology tries to understand what it means to know. Epistemology provides a philosophical background for deciding what kinds of knowledge are legitimate and adequate.

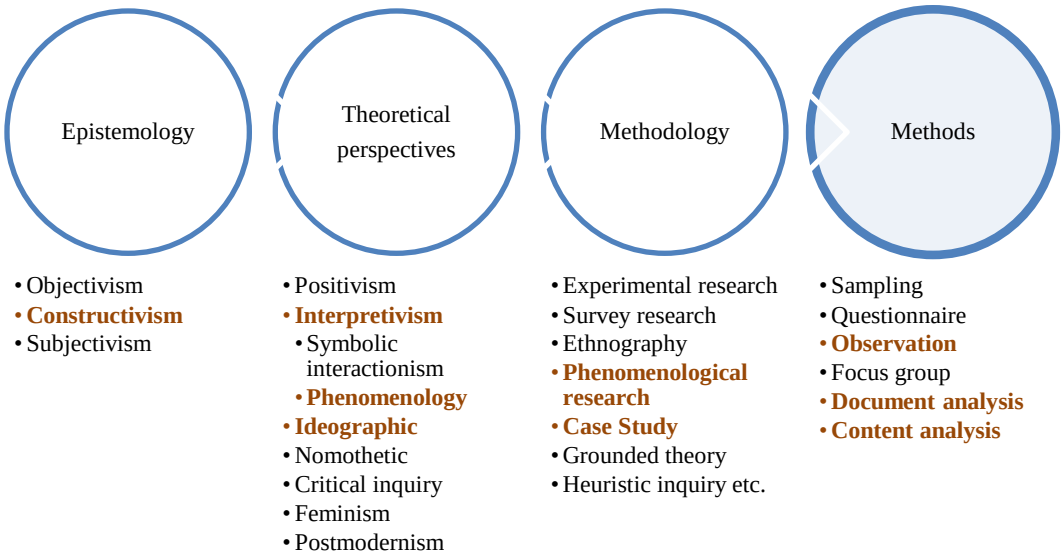


Figure 3.1 Examples within Crotty's knowledge framework**,** *from Crotty, 1998*

Objectivism in epistemology, for example, holds that reality exists independently of consciousness – in other words, there is an objective reality 'out there'. So, research is about discovering this objective truth. A theoretical perspective closely linked to objectivism is positivism**.** The positivist approach can be called *nomothetical*; the idea behind it is that research procedures are formal, structured, and standardized to create empirically observable and experimentally verifiable proofs (Pihlajisto, 1994). Positivism has been described as 'one of the heroic failures of modern philosophy' (Williams and May, 1996: 27).

In contrast to objectivism, constructivism rejects this view of human knowledge that truth and meaning exist in some external world. Constructivism supports that truth and meaning are created by the subject's interactions with the world. Meaning is constructed not discovered, so subjects construct their own meaning in different ways, even in relation to the same phenomenon.

For subjectivism, meaning does not develop from the interaction between the subject and the outside world, but is forced on the object by the subject. Subjectivism is based on a becoming ontology. Using the epistemology of constructivism, this dissertation focused on studying NovaScan LLC.

3.2 Theoretical Perspective

A theoretical perspective linked to constructivism is interpretivism. Yet, while interpretivism and objectivism hold different epistemological positions, both are still based upon a being ontology (Chia, 2002). The world is interpreted through the classification schemas of the mind (Williams and May, 1996). As mentioned above, interpretivism is closely linked to constructivism. Interpretivism asserts that natural reality (and the laws of science) and social realities are different and therefore require different kinds of methods. While the natural sciences are looking for consistencies in the data in order to deduce 'laws' (*nomothetic*), the social sciences often deal with the actions of the individual (*ideographic*).

The "idiographic," approach is applied in this dissertation. The dissertation describes commercialization of healthcare innovation as a social phenomenon rather than a natural science phenomenon (Welch, Piekkari, Piakoyiannaki, & Paavilainen-Mantymaki, 2011).

3.3 Methodology

Insights about innovation, commercialization and technology transfer are obtained through an empirical study of NovaScan LLC. The company was founded in the year 2003 and is developing a technology to detect breast cancer using electrical properties of the human tissue. The technology will be used to detect cancerous tissue within the surgical cavity of a partial mastectomy. More details about this company will be discussed in chapter four and specifics to why this company was chosen as a case study will be discussed in this chapter in the following sections.

Robert Stake classifies case study research into three types:

1. Intrinsic case study (where the interest is to only understand the particulars of the case).
2. Instrumental case study (where the interest is in understanding something more general than the case).
3. Collective case study (where interest is in studying and comparing multiple cases in a single research study).

One of the central pieces of this dissertation is to describe the case study in depth, gather data and seek answers to the research question by abductive reasoning whereby one seeks to explain relevant evidence by beginning with some commonly well known facts that are already accepted and then working towards an explanation.(*Source: Business Dictionary*)

Phenomenological case study research methodology forms the core of the effort. Phenomenology holds that any attempt to understand social reality has to be grounded in people's experiences of that social reality. It expands on more traditional approaches (Peter and Olson 2077).

3.4 Methods

In this research work, several data collection techniques have been used such as personal observations, documentation, audio-visual recordings, document and text analysis and other related contents analysis. This methodology is ideally suited to study TT or commercialization of innovation processes for several reasons that are discussed in this chapter.

This data-collection technique integrates personal conversations with participants and allows the researcher to capture the essence of each experience familiar to the participant (Thompson, Locander, Polio 1989). With this increased amount of information, we can create a better understanding of how the variables are related and further analyzed. Rather than aiming to generalize, the inquiry develops an ideographic body of knowledge that describes NovaScan LLC as an individual case and the case study results are presented in the form of a theory.

3.5 Research Approach

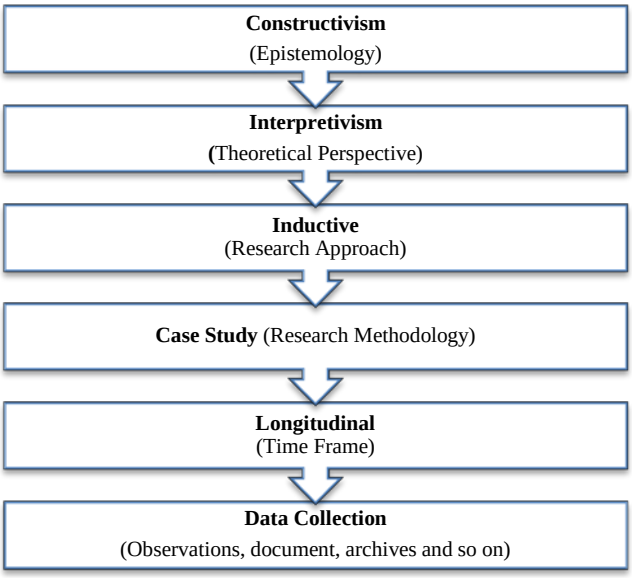


Figure 3.2 Research Approach *adapted from Saunders et. al., 2007*

There are several questions that can be raised around commercialization of innovations in healthcare: can commercialization be identified, described, and measured? (Simula 2012).

The purpose of this study is to provide an answer to the research question by combining the extant literature with the empirical data and by creating variables that characterize commercialization. The body of knowledge derived from the extant literature covers the fields of technology, innovations, technology transfer, innovation management, commercialization and strategy related material (Simula 2012) and the empirical data obtained from the case studied here. Table 3.1 summarizes the qualitative research method for case study analysis.

The constructivism and Instructivism paradigm that acknowledges that there are no absolute realities (Figure 3.2) is used here. The research approach is the inductive research approach and I chose NovaScan LLC is a case study over a longitudinal time frame using various data collection methods. The data collection methods are explained in detail in section 3.8.

Qualitative Research Approach	
Dimensions	Case Study
Research purpose	To describe the case study in depth and answer the research questions
Disciplinary origin	Multidisciplinary including management , medicine etc.
Primary Data collection method	Personal observations, document and content analysis, published interviews, Audio recordings
Data analysis approach	Listing significant statements and identifying meanings, holistic description and search of themes shedding light on the case
Report focus	Rich description of essential context , discussion of themes issues and implications

Table 3.1 Qualitative Research Approach
Source: Adapted from http://www.southalabama.edu/coe/bset/johnson/lectures/lec12.htm

The purpose of phenomenological research as described in various literatures is to gain an accurate understanding of another's experience, to capture in-depth reflections by participants regarding their experience of an identified phenomenon (Creswell, 2007).

A case study explores a phenomenon through one or more cases within a circumscribed setting or context. Therefore, this dissertation utilized a phenomenological approach to explore the practices of innovation and commercialization of breast cancer detection device at NovaScan LLC. While commercialization of all innovations may seem to be the natural and obvious route, this phenomenon is very case specific. The objective of this dissertation is to provide observations and discussion about how it is practiced and whether it will be possible to create a theory based on these observations.

3.6 Qualitative Case Study of NovaScan LLC as a Research Method

This dissertation as discussed in the previous sections uses qualitative research methods for investigation. The qualitative case-study method has a long and respected history in the mainstream management literature. The method is also gaining acceptance, along with other qualitative methods, within the small business and entrepreneurial research community. (Perren 2004).

As Denzin and Lincoln explain:

> Where only statistics, experimental designs, and survey research once stood, researchers have opened up to ethnography, unstructured interviewing, textual analysis, and historical studies. Where "We're doing science" was once the watch-word, scholars are now experimenting with the boundaries of interpretation, linking research to social change, delving into characteristics of race, ethnicity, gender, age and culture to understand more fully the relationship of the researcher to the research. In various disciplines in various guises, this implicit critique of the traditional worldview of science and quantitative methods is taking place. All of these trends have fallen under the rubric of "qualitative research." (Denzin 1994)

Most qualitative researchers would agree with Snider's (2010) observation that numbers impress, but unfortunately, also conceal far more than they reveal. They would also agree with Davis's (2007) observation that "good qualitative research has equaled, if not exceeded, quantitative research in status, relevance, and methodological rigor". Qualitative studies can be traced back to the earlier part of the 20thCentury (Lindlof 1995). Deemed as "soft scientists," qualitative researchers fought to have their methodology recognized and appreciated by the social scientific world (Denzin 1994; Lindlof 1995; Silverman 2000).

Misunderstanding	Restatement
General knowledge is more valuable than context specific knowledge.	Universals can't be found in the study of human affairs. Context-dependent knowledge is more valuable.
One can't generalize from a single case so a single case doesn't add to the scientific development.	Formal generalization is overvalued as source of scientific development; the force of single example is underestimated.
The case study is most useful in the first phase of research process; used for generating hypothesis	The case study is useful for both generating and testing of hypothesis but is not limited to these activities.
The case study confirms the researchers preconceived notions	There is no greater bias in case study towards confirming preconceived notions that in other form of research
It is difficult to summarize case studies into general propositions and theories	Difficulty may be due to properties of realtiy, not the research method

Table 3.2 Five Misunderstandings about case study research, Adapted from Flyvbjerg (2006)

In an interesting discussion of the value of case study research, Flyvbjerg (2006) sets up five "misunderstandings" about case study research, which he then dismantles, substituting a more accurate statement about the issue underlying each misunderstanding. These misunderstandings and their restatements are displayed in Table 3.2.

Yin (2009, p. 19), a recognized leader in case study methods, emphasized that case studies may also be useful for explaining presumed causal links between variables. However, the orientation of qualitative researchers contrasts sharply with that of quantitative researchers on many dimensions. The debate between comparable, case-oriented (i.e. qualitative) research and large-N, variable oriented (i.e. quantitative) research streams has been ongoing and rather extensive (Ragin, 1997). Both methods of research, according to Ragin (1997), aim to "construct representations of social phenomena from evidence" (p. 40). However, the goal of case research is to increase the depth of existing knowledge and the contextual richness of the findings rather than focus on the representativeness of large-N research (Bonoma, 1985). It generates questions that

are answered with an emergent methodology, and works with rich sources of data that requires creativity for its analysis.

Qualitative research, in all of its complex designs and methods of data analysis, is guided by the philosophical assumptions of qualitative inquiry: To understand a complex phenomenon, you must consider the multiple "realities" experienced by the participants themselves—the "insider" perspectives.

As a participant observer at NovaScan, this researcher played the role of an insider since late 2008. More details about the association and involvement with NovaScan LLC are described in the next section and in chapter five. The researcher's role as an insider within the company helped in identifying several aspects that as an outsider it would be difficult to have access to.

Theoretical ideas are important in case study design and are usually developed prior to data collection, since they guide the type of data collected. As Orton (1997) states, "in a study where neither the theory nor the data is fixed, research improvisation works better than research design".

This kind of approach for this dissertation is appropriate because the objective of this dissertation is to identify an emergent theory (Glaser & Strauss, 1967; Eisenhardt, 1989) or phenomenon about commercialization within the context of health care innovations focused on medical devices.

The essence of the case-study method is a research strategy focusing on understanding the dynamics (Eisenhardt, 1989) and investigating contemporary

phenomena in real-life contexts (Yin, 1994). The case study method focusses not so much on statistical generalization as it does on analytical generalization (Yin 1994).

This dissertation was undertaken in health sciences and has been developed with management studies perspectives. Thus it can be linked with the broader category of Social Sciences. The research tradition in these fields has often emphasized the role of drawing conclusions based on deductive reasoning (Bonoma, 1985). The traditional deductive approaches are concerned with developing propositions from current theories and making them testable in the real world, whereas inductive approaches rely more upon a phenomenological or grounded-theory type of an approach where theory is systematically generated from the data (Dubois & Gadde, 2002). The inductive approach is a useful path for scientific learning.

The case-study method is suitable for topics in which existing theories seem inadequate or in which a fresh perspective is needed (Eisenhart 1989). Eisenhardt (1989) and Yin (1994) are in the qualitative world, often referred for justifying case studies as a research method .Their case analysis is focused primarily on theory of positivism. However, there are several other theories available. For example, Stake (1994) advocates a more constructive approach, Burawoy (1998) a more reflexive approach, and Dyer and Wilkins (1991) a more interpretative approach.

The focus area of this dissertation is to identify and uncover the issues and factors underlying the phenomenon of commercialization of medical device innovations in health care. It was found in the previous chapter of literature review and analysis that there exists inadequate information about evidence-based best practices of commercialization.

Such an aim would require using a qualitative research methodology and possibly an interpretive as opposed to a positivist theoretical perspective (Levy 2006).

A number of other disciplines incorporate interpretivist methodologies where the primary assumptions are that:

> "…access to reality (given or socially constructed) is only through social constructions such as language, consciousness and shared meanings. Such interpretive research does not predefine dependent and independent variables, but focuses on the full capacity of human sense making as the situation emerges" (Myers, 1997). (Levy 2006)

A main topic of this dissertation, "identifying practices of innovations and commercialization at NovaScan LLC" is a topic that is best served by the case-study method. Based on the literature review conducted in this dissertation, the researcher does not hesitate to claim that, as of today, commercialization within the context of a new medical or non-medical device is an unclear and an emergent concept (Simula 2012).

3.7 Role as a Researcher

> The qualitative researcher's perspective is perhaps a paradoxical one: it is to be acutely tuned-in to the experiences and meaning systems of others—to indwell—and at the same time to be aware of how one's own biases and preconceptions may be influencing what one is trying to understand. (Maykut & Morehouse, 1994, p. 123)

In qualitative research, the researcher is an instrument as Patton says, "he interacts and collaborates with the participants, and he gathers data by himself". However, in quantitative research, the researcher uses instruments to collect data and does not interact with his participants.

Qualitative research, in all of its complex designs and methods of data analysis, is guided by the philosophical assumptions of qualitative inquiry: To understand a complex phenomenon, you must consider the multiple "realities" experienced by the participants themselves—the "insider perspectives".

The data collection technique was based on the strategy discussed above. This is relevant more as qualitative because it allows researchers to work closely with participants within an organization and collect information pertaining to their personal thoughts and experiences (Yin, 2003; Bonoma, 1985).

In qualitative studies the role of a researcher is very different from that in quantitative research. That is, in a perfect quantitative study scenario, participants act independently of the researcher as if he or she were not there. In correlational studies, the data are collected without regard to the participants or the person collecting the data (Simon 2011).

As a qualitative researcher with full participation in all commercialization activities and programs at NovaScan LLC, even before formal organizational participation, as an outsider, some observations were noted that also contributed towards data collection. In qualitative case study analysis, sometimes a researcher starts as an outsider and then becomes a member of the group. Or the reverse can occur –the researcher starts as a member of a group then becomes a more objective observer (Punch, 1998).

The informal documentation of observations at NovaScan started as early as 2008. The researcher was not an employee of the organization and was not involved formally in any of the company related activities then. Several activities were observed and noted that contributed to the theoretical basis for this dissertation. These ideas were not concrete enough to be identified as proper research questions. However, they helped in formulating a guide to the design of NovaScan study. This approach of generating theoretical ideas is important in case study design and are usually developed prior to data collection, since they guide the type of data collected.

Adler and Adler (1987) identified three "membership role" of qualitative researchers engaged in observational methods:

(a) Peripheral member researchers, who do not participate in the core activities of group members;

(b) Active member researchers, who become involved with the central activities of the group without fully committing themselves to the members' values and goals; and

(c) Complete member researchers, who are already members of the group or who become fully affiliated during the course of the research.

Initially, the observations documented in 2008 at NovaScan were the first category of observational method. Later as a curriculum practicum trainee, data was collected as a complete member researcher. The population for this study consisted of NovaScan employees of which the researcher was one for over five years, starting first as an outsider and then as an insider.

Insider research refers to when researchers conduct research with populations of which they are also members (Kanuha, 2000) so that the researcher shares an identity, language, and experiential base with the study participants (Asselin, 2003). The complete membership role gives researchers a certain amount of legitimacy and/or stigma (Adler & Adler, 1987).The stigma refers to the view of outsiders, who might see this role as creating a heightened level of researcher subjectivity that might be detrimental to data analysis and even collection(Dweyer C, Buckle J. 2009).

A research strategy should involve multiple investigators and visiting the company in teams to increase the confidence of the findings (Pettigrew, 1990; Eisenhardt, 1989). However, due to the nature of the PhD dissertation as an individual assignment, this project was investigated only by the researcher.

However, being an insider is not without its potential problems (Adler, 1990). In Adler and Adler's (1987) discussion of complete member researchers, they suggest that in this "ultimate existential dual role", researchers might struggle with role conflict if they find themselves caught between "loyalty tugs" and "behavioral claims" (Brannick &

Coghlan, 2007, p. 70). Asselin (2003) has pointed out that the dual role can also result in role confusion when the researcher responds to the participants or analyses the data from a perspective other than that of researcher. She observed that role confusion can occur in any research study but noted that there is a higher risk when the researcher is familiar with the research setting or participants through a role other than that of researcher.

Even though these issues have been identified by several scholars, the data collection for this study was mostly unbiased as it was mostly based on observational facts of organizational developments, meeting notes and other company literature facts. It was not dependent on data obtained through personal interviews or structured focus groups. More details on data sources are discussed in the next setion.

3.8 Data Sources and Collection

Levy (1988) used a single-case design for the study at the University of Arizona. Yin (1994) said that single cases may be used to confirm or challenge a theory, or to represent a unique or extreme case. Yin (1994) listed six sources of evidence for data collection in the case study protocol: *documentation, archival records, interviews, direct observation, participant observation, and physical artifacts* and mentioned that all need not be used in every case study (Yin, 1994). In this study formal interviews are not relevant, since the intention is to identify the phenomenon of commercialization as a process and not as a view point.

No single source of data collection has a complete advantage over the others; rather, they might be complementary and could be used in tandem. Thus a case study should use as many sources as are relevant to the study (Tellis, W. 1997). Table 3.3 summarizes some strengths and weaknesses of each type of data collection method.

Following the guidelines of Yin (1994) for using case study as a research method and data collection procedures and Eisenhard (1989) for theory building from case studies, NovaScan LLC was chosen as a case study.

The case study approach typically combines data collection methods such as archives, interviews, questionnaires, and observations (Yin 1989). Other data collection devices are oral histories, and specimen records (behavior recorded through observation). However, the choice of data collection methods is also subject to constraints in time, financial resources, and access. Qualitative research data records are typically quite massive.

Source of Evidence	Strengths	Weaknesses
Documentation	• Stable - repeated review • Unobtrusive - exist prior to case study • Exact - names etc. • Broad coverage - extended time	• Retrievability - difficult • Reporting bias – may reflect author bias • access - may be blocked
Archival Records	• Same as above • precise and quantitative	• Same as above • privacy might inhibit access
Interviews	• targeted - focuses on case study topic • insightful - provides perceived causal inferences	• bias due to poor questions • response bias • incomplete recollection • reflexivity - interviewee expresses what interviewer wants to hear
Participant Observation	• Same as above • insightful into interpersonal behavior	• Same as above • bias due to investigator's actions
Physical Artifacts	• insightful into cultural features • insightful into technical operations	• selectivity • availability

Table 3.3 Strenghts and weaknesses of data collection method
(*Adapted from Application of a Case Study Methodology by Winston Tellis, 1997, (Yin, 1994, p. 80))*

Also, the qualitative researcher is advised to keep fairly detailed records of his or her thoughts, feelings, and behaviors while data are collected. It is important to determine whether or not the researcher is himself or herself a source of bias.

For NovaScan case study, a combination of archives, observation and informal discussions with main emphasis on the first two were main sources of data. Conducting a survey was inappropriate due to the lack of established concepts and indicators. Observation here refers to participant observation as the researcher was recording the observations systematically as an insider. The general questions that were covered during informal discussions are shown in Appendix D.

Participant observation is the process enabling researchers to learn about the activities of the people under study in the natural setting through observing and

participating in those activities. Observations enable the researcher to describe the existing situations under study (Erlandson, Harris, Skipper, & Allen 1993).

As suggested by Bernard (1994), as a participant observer, a rapport was established as an insider with the company professionals and it blended in such a way that the research did not affect the natural setting of people and organizational processes. Then, to be immersed in the data collected by different ways and be able to analyze, the researcher got disassociated from the organizational settings at NovaScan LLC in late December of 2012.

Participant observation is characterized by actions such as having an open, nonjudgmental attitude, being interested in learning more about others, being aware of the propensity for feeling culture shock and for making mistakes, the majority of which can be overcome, being a careful observer and a good listener, and being open to the unexpected in what is learned (DeWALT & DeWALT, 1998). This was used as a strategy for making all the observations and taking field notes by the researcher.

Participant observations contributed the most for data sources and the reason why they were chosen as a primary source of data collection are many fold. Schmuck (1997) describes that this method provides researchers with ways to check for nonverbal expression of feelings, determine who interacts with whom, grasp how participants communicate with each other, and determine the amount of time spent on various activities.

. DeMUNCK and SOBO (1998) provide several advantages of using participant observation over other methods of data collection. These include that it affords access to the "backstage culture"; it allows for richly detailed description, which they interpret to

mean that one's goal of describing "behaviors, intentions, situations, and events as understood by one's informants" is highlighted ; and it provides opportunities for viewing or participating in unscheduled events.

DeWALT and DeWALT (2002) believe that "the goal for design of research using participant observation as a method is to develop a holistic understanding of the phenomena under study that is as objective and accurate as possible given the limitations of the method".

While, DeWalt and DeWalt (2002) add that it improves the quality of data collection and interpretation and facilitates the development of new research questions or hypotheses, they also emphasize on the limitation that male and female researchers have access to different information, as they have access to different people, settings, and bodies of knowledge. However, this was not a concern in this case study (research topic being a gender neutral).

DeWalt, DeWalt, and WAYLAND (1998) pointed another potential limitation of researcher bias. They note that, unless ethnographers use other methods than just participant observation, there is likelihood that they will fail to report the negative aspects of the cultural members. The method of triangulation was used in this study by involving document analysis and informal discussions along with observations to avoid the problem of observation bias.

A primary consideration in any research study is to conduct the research in an ethical manner, letting the community know that one's purpose for observing is to document their activities. DeWALT, DeWALT, and WAYLAND (1998) advise the researcher to take some of the field notes publicly to reinforce that what the researcher is

doing is collecting data for research purposes. The association of the researcher with the case study was based entirely on the proposition of data collection for this doctoral dissertation as curriculum practicum training. This made clear the researcher's intentions from the very beginning of taking field notes and audio recordings. The group members were regularly reminded of the audio recordings.

The data collection for this study was more focused on the processes rather than personal opinions. The researcher promised to preserve the anonymity of the NovaScan LLC participants throughout the final write-up and in field notes to prevent their identification. The field notes taken as a participant observer have been the primary means of capturing the data. These notes include records of what is observed, including informal conversations with people at NovaScan LLC, records of activities and ceremonies and journal notes that were kept on a daily basis.

There are several literature sources that describe the participant observation method and ways to conduct it. Werner and Schoepfle (1987, as cited in Angrosino & dePerez, 2000) focus on the process of conducting observations and describe three types of processes:

1) The first is descriptive observation, in which one observes anything and everything, assuming that he/she knows nothing; the disadvantage of this type is that it can lead to the collection of minutiae that may or may not be relevant to the study.
2) The second type, focused observation, emphasizes observation supported by interviews, in which the participants' insights guide the researcher's decisions about what to observe.

3) The third type of observation, considered by Angrosino and DePerez to be the most systematic, is selective observation, in which the researcher focuses on different types of activities to help delineate the differences in those activities (Angrosino & dePerez, 2000, p.677).

Observation techniques for this study were influenced by the second and the third ways described above where focus was on commercialization activities of the case. The informal discussions and interviews guided the observation task and field notes. To keep the observations systematic and organized, a structured format for taking field notes and narrative reporting was developed for data analysis.

Other researchers have taken a different approach to explaining how to conduct observations. For example, MERRIAM (1988) developed an observation guide in which she compiled various elements to be recorded in field notes. The first of these elements includes observing the surroundings of the setting and providing a written description of the context. Next, she describes the participants in detail and then she records the activities and interactions that occur in the setting. She also looks at the frequency and duration of those activities/interactions and other subtle factors, such as informal, unplanned activities, symbolic meanings, nonverbal communication, physical clues, and what should happen that has not happened. However, considering the research questions of this study, the Werner and Schoepfle (1987) model was chosen.

3.9 Data Analysis

Case study is an ideal methodology when a holistic, in-depth investigation is needed (Feagin, Orum, & Sjoberg, 1991). Qualitative data analysis is mostly inductive—the researcher identifies important categories in the data, as well as patterns and relationships, through a process of discovery. In Qualitative analysis there is often no predefined measures or hypotheses (Crotty 1998).

For this dissertation, before the data analysis, all observations, documents, journal entries field notes and indirect interviews were documented and then transcribed. This transliterating allowed to become acquainted with the data (Reissman, 1993). For the purpose of data analysis the data is not coded sentence by sentence, rather it is focused on theme identification based on the underlying meaning. The analysis for this study also involves continuous back and forth linking of theory and data. This kept the focus on relevant literature (review method of literature has been discussed in the previous section) and then compare gaps in literature and also interact between the data and literature. Langley (1999) recommended this iterating process between theory and data during the analysis of data.

For the thematic analysis, step by step guidelines have been followed as suggested by Braun and Clarke (2006). They recommend the word guidelines to highlight the flexibility of this qualitative analytic method.

These guidelines are:

(1) Familiarizing yourself with your data,

(2) Generating initial codes,

(3) The researcher read throughout each transcript to immerse in the data,

(4) Reviewing and defining themes,

(5) Producing the report.

In addition to the above, the triangulation method advocated by Yin (1994) and Denzin (1978) is also used. They emphasized on combining different sources of evidence and shifting between analysis and interpretation. For this study, several data sources such as internal reports, presentations, brochures, news, industry reports, annual reports, company web pages, informal discussion descriptions, notes have been used along with observations as the main data source (Simula 2012).

3.10 Validation Strategies

As the area of qualitative research increases, social and behavioral scientists critique on the validity of studies that use such methodology. Thus, qualitative researchers utilize various validation strategies to make their studies credible and rigorous (Creswell & Miller, 2000). Credibility for this study was achieved using the validation strategies of triangulation, researcher reflexivity and rich observation and description. Bulmer states 'qualitative researchers try to achieve validity not through manipulation of variables but rather through their orientation and the study of the empirical world' (Bulmer, 1979).

The observation data will be triangulated with the various other forms of data that were collected in this study (i.e., interviews, documents, reflective journal entries and field notes). As a basic foundation to achieve this, the researcher ensured that: (a) the case study research question is clearly written and (b) case study design is appropriate for the research question; (c) purposeful sampling strategies appropriate for case study have been applied; (d) data are collected and managed systematically; and (e) the data are analyzed correctly (Russell, Gregory, Ploeg, DiCenso, & Guyatt, 2005).

Stake's (1995) "critique checklist", is used in this study to assess the quality of the report. This criteria checklist includes the following:

- Is the report easy to read?
- Does it fit together, each sentence contributing to the whole?
- Does the report have a conceptual structure (for example, themes or issues?)
- Are its issues developed in a serious and scholarly way?
- Is the case adequately defined?
- Is there a sense of story to the presentation?

- Are headings, figures, artifacts, appendixes, and indexes used effectively?
- Has the writer made sound assertions, neither over-nor under-interpreting?

Chapter4

Research Findings-Case study of NovaScan LLC

This chapter illustrates the case study for this dissertation. Researched here are backgrounds of the company chosen (NovaScan LLC), how its technological innovation of the Electrical Property Enhanced Tomography (EPET) took the form of two different medical devices and how they went from early innovation stage to the more formal commercialization stage. Following this description, this chapter includes a within case analysis of the case study. There are two case products discussed in this chapter. Pictures of both the case products are available in Appendix E.

4.1 Company Background

NovaScan LLC was founded in 2003 to commercialize breast cancer detection technology. Though initially it was formed as a limited liability company for the purpose of conducting research on the electrical properties of tissue, and then to develop a commercial product which uses this technology. The founders, Dr. William Gregory, Dr. Christopher Gregory and Larry Wells, developed the technology at UW Milwaukee in collaboration with the Aurora Health Care in Milwaukee, WI. NovaScan is the exclusive licensee for patents related to this technology from WiSys, a division of WARF (Wisconsin Alumni Research Foundation). NovaScan's mission is to develop and commercialize products using electrical properties to evaluate the health of human breast tissue.

The company is in the early prototype stage of the development of a commercial product which is based upon its prior research. Since 2003, the company's research and business operations have been funded by individual investors, awards from Wisconsin Governor's business plan contest, institutional investor like Aurora Healthcare, Department of Commerce loans(Loan 1:TVF FY06_12397; Loan 2:TVF FY10_20259), and federal National Science Foundation (NSF) grants for both phase I and phase II (Grant number-1058413).

The company is currently funded solely with grant funds and investors' money. It has no commercial products on the market and no income from the sales of products, services, or licenses. Current revenue from grants comes from the federal NSF grants. The company received National Science Foundation Small Business Incentive Research (SBIR) Phase I, Phase Ia, Phase II and a Phase IIb grants for this research for a total of

$2.3 million, including external matching funds. NSF officials during a review presentation made by NovaScan LLC have recommended to National Institute of Health (NIH) for additional funding. This will provide a NIH match of up to $3 million to fund a FDA Pivotal Trial for approval to market in the USA.

Figure 4.1 describes the lineage of the company. It shows various milestones it has achieved and the awards and grants it received along its commercialization path since its inception to 2011. Post 2011, the company has expedited its commercialization activities with some more strategic partnerships, initiating a pilot study of the device and searching for funding options from individual and institutional investors apart from federal grants.

While federal grants will fund the development of a functional prototype, individual and institutional investors and possible NIH grants will fund the FDA trials, marketing, and manufacturing start-up. It is expected that FDA trials will take place in Year 2016-17, and that a commercial product will be introduced in 2018.

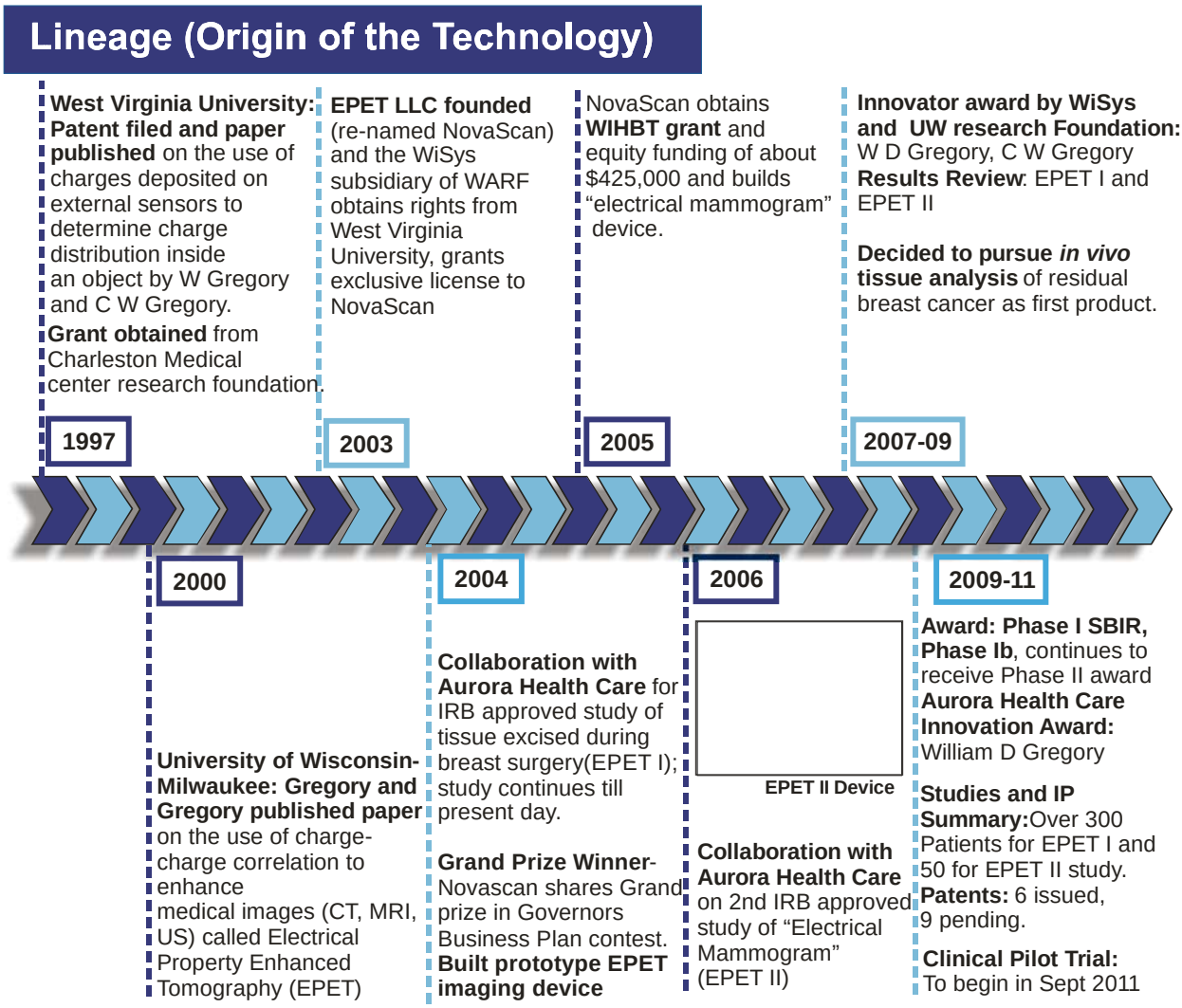


Figure 4.1 Company Background,
Source: NSF SBIR Ph II 2012 poster presentation, NovaScan LLC

4.2 Organizational Structure

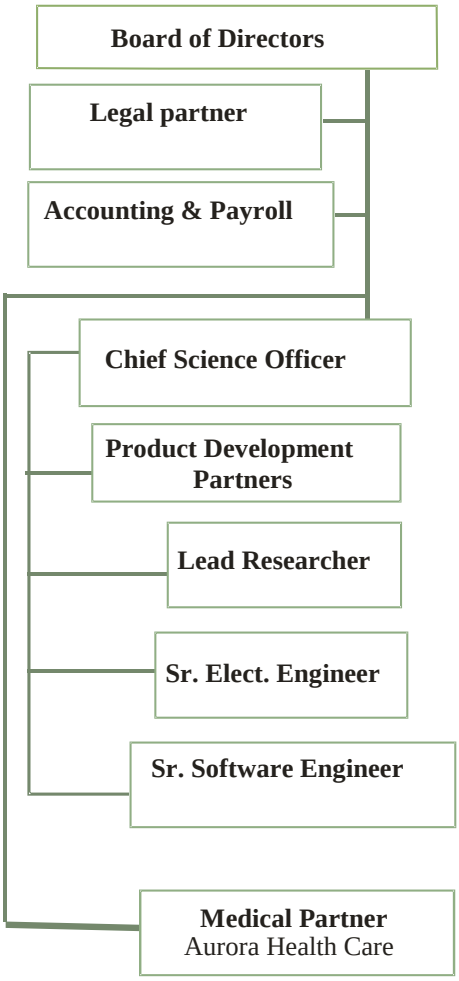


Figure 4.2 Organizational chart - NovaScan LLC

The company operates on a traditional corporate structure used by small firms. The stockholders elect the board of directors, responsible for the overall operations of the company. The board of directors appoints the officers of the company who are responsible for the day-to-day operations. William D Gregory, (PhD, Physics, Massachusetts Institute of Technology) is the founder of the company and is currently the Chief Science Officer and Chairman of the board of directors. Wisconsin based Aurora Healthcare System is an investor and collaborator with the company.

Aurora has provided NovaScan with tissue samples, access to personnel for evaluating the use of the technology in selected operational schemes, guidance for product development, use of their IRB procedure, use of laboratory space, and has invested funds into the company. Figure 4.2 shows the strategic role employment structure followed by NovaScan LLC.

At present the role of CEO is played by the Chief Science officer, Dr. William D Gregory. However for effective operations, NovaScan is searching for a board member or CEO with successful experience in the medical device field in attracting angel and later-stage investors, taking a prototype through to commercialization, and eventual sale of the company. The company also identified position of an advisor or board member who is well-connected to the angel investor and venture capital community to benefit flow of funds in the organization.

The company made a strategic partnership with a Minneapolis based Product Development Company that not only assisted in developing the first prototype but also will be developing other improved versions of the prototype for FDA trials. This collaboration will help NovaScan achieve product development for FDA approvals and commercialization .This collaboration eliminated the need for an advisor who would assist in the process of obtaining FDA approval for the product. It will help NovaScan in commercialization of their devices get them fully International organization of Standardization (ISO) certified. They will also assist in obtaining CE mark in European Union. NovaScan has some more strategic alliances with the following:

- **Wisconsin Alumni Research Foundation** (WARF) for patenting and patent portfolio management

- **Michael Best Friedrich Law Firm** for legal advice. Firm members attend companies Board of Director meetings, maintain the corporate records and review the contracts and agreements
- **EWH Accounting**- Payroll, tax management, monthly balance sheet preparation, year-end compilations

The researcher was initially associated with the company during 2008 to 2010 on the University of Wisconsin, Milwaukee research grant and then later joined the company as a curriculum practicum trainee (CPT). The association with the company was solely for the purpose of working on this dissertation. The CPT contract ended at NovaScan in December of 2012. Since the disassociation the researcher has worked on documentation and organization of the collected data to present the findings in the form of this thesis. Under no circumstances the researcher held any authority to approve or disapprove of the NovaScan products. The association was entirely academia based.

4.3 The Case Product (1)

4.31 Electrical Mammogram

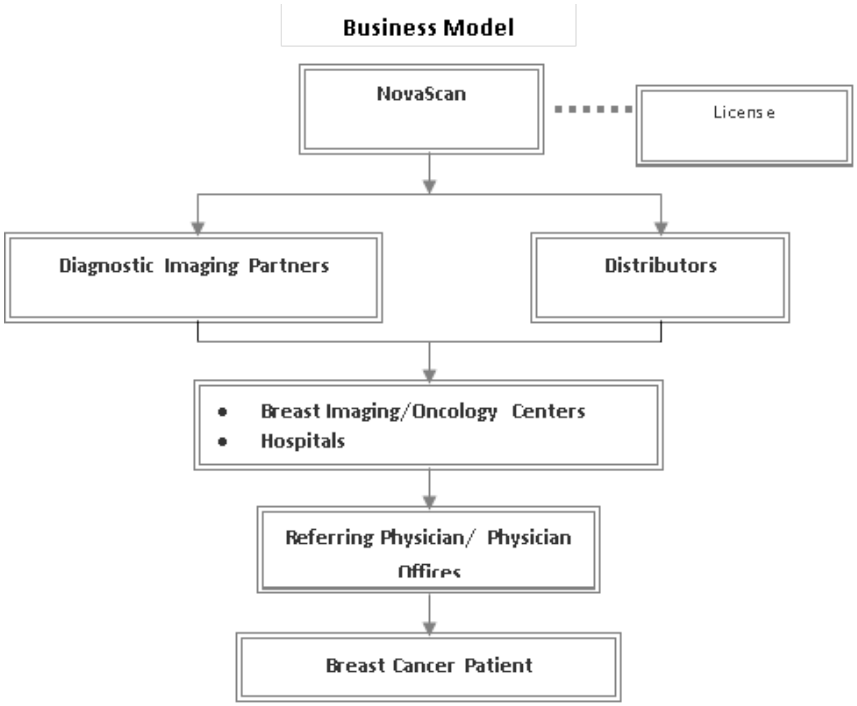


Figure 4.3 Business Model for NovaScan Imaging Technology
(Source: NovaScan Business Plan 2004)

NovaScan's imaging products will be based on Electrical Property Enhanced Tomography, or EPET. According to NovaScan LLC, EPET is an in vivo technique that can be used to identify various structures within the interior of an object (e.g. the human body). Because each tissue has unique electrical properties, EPET can be used to identify different tissues with the goal of distinguishing malignant from benign tumors. NovaScan's system utilizes a geometrically shaped array of electric field sensors positioned around an object of interest (e.g. breast).

These sensors measure the formation of charges on the boundary layers of different tissues over a range of electromagnetic frequencies. The charges on the boundary layers relate directly to the dielectric and conductivity coefficients of the material being scanned, allowing the unique electrical properties of the tissue to be measured. By performing these measurements, diseased (cancerous) areas can be distinguished from healthy tissues.

4.32 Value Proposition

By providing better screening and earlier detection, the product will increase the 5-year survival rate of breast cancer patients and reduce the costs associated with the diagnosis and treatment of breast cancer. NovaScan's direct consumer for this imaging product is the diagnostic imaging companies and/or distributor partners. They will be provided with a unique breast cancer detection tool that they can deploy as a marketplace differentiator and drive new sources of revenue. According to NovaScan LLC, this will ensure improved oncology screening and staging.

4.4 Case Product (2):

4.41 FastPath ™ Surgical Probe

The FastPath ™ surgical probe referred to here as case product (2) is the company's first official product. The basis of technology remains the electrical properties of human tissue. The NovaScan Probe will provide breast cancer surgeons a tool to (a) determine if there are cancer cells remaining in the surgical cavity in real time during surgery, and (b) determine if excised tissue has clear margins during surgery in the surgical suite.

Surgeons must now send excised tissue to the pathology lab for preparation and analysis, a procedure that can take 20-30 minutes, while the patient remains under anesthesia. Final analysis of excised tissue can often take 24-28 hours, which would require an additional surgery if the margins are not clear. The NovaScan Probe makes this analysis in seconds.

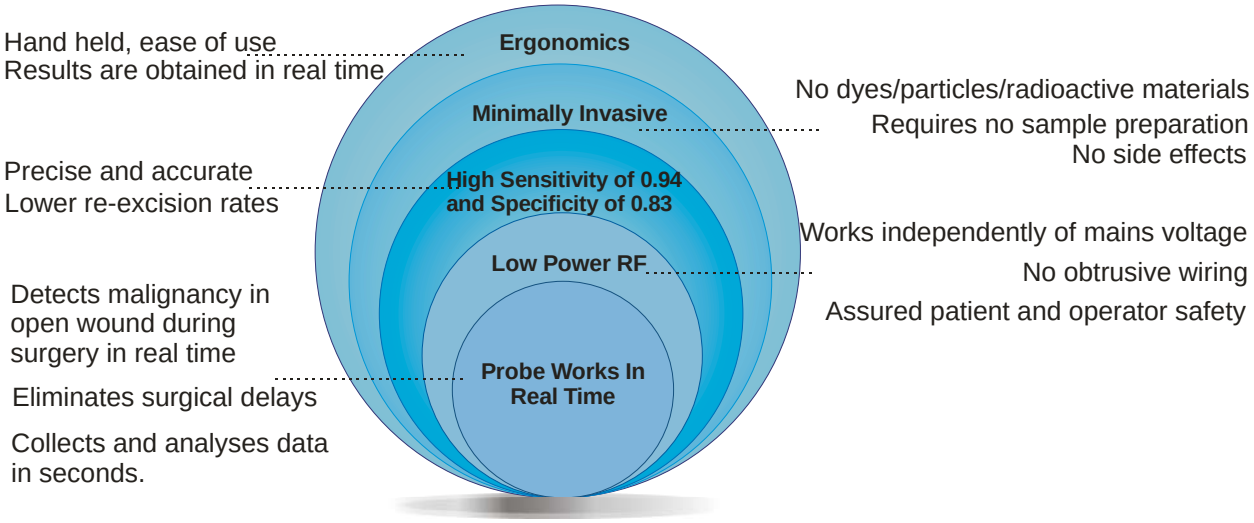


Figure 4.4 NovaScan's FastPath™ surgical probe value proposition
Source: NSF SBIR Ph-II 2012 poster presentation, NovaScan LLC

4.42 Opportunity Identification-Market Drivers for the FastPath™

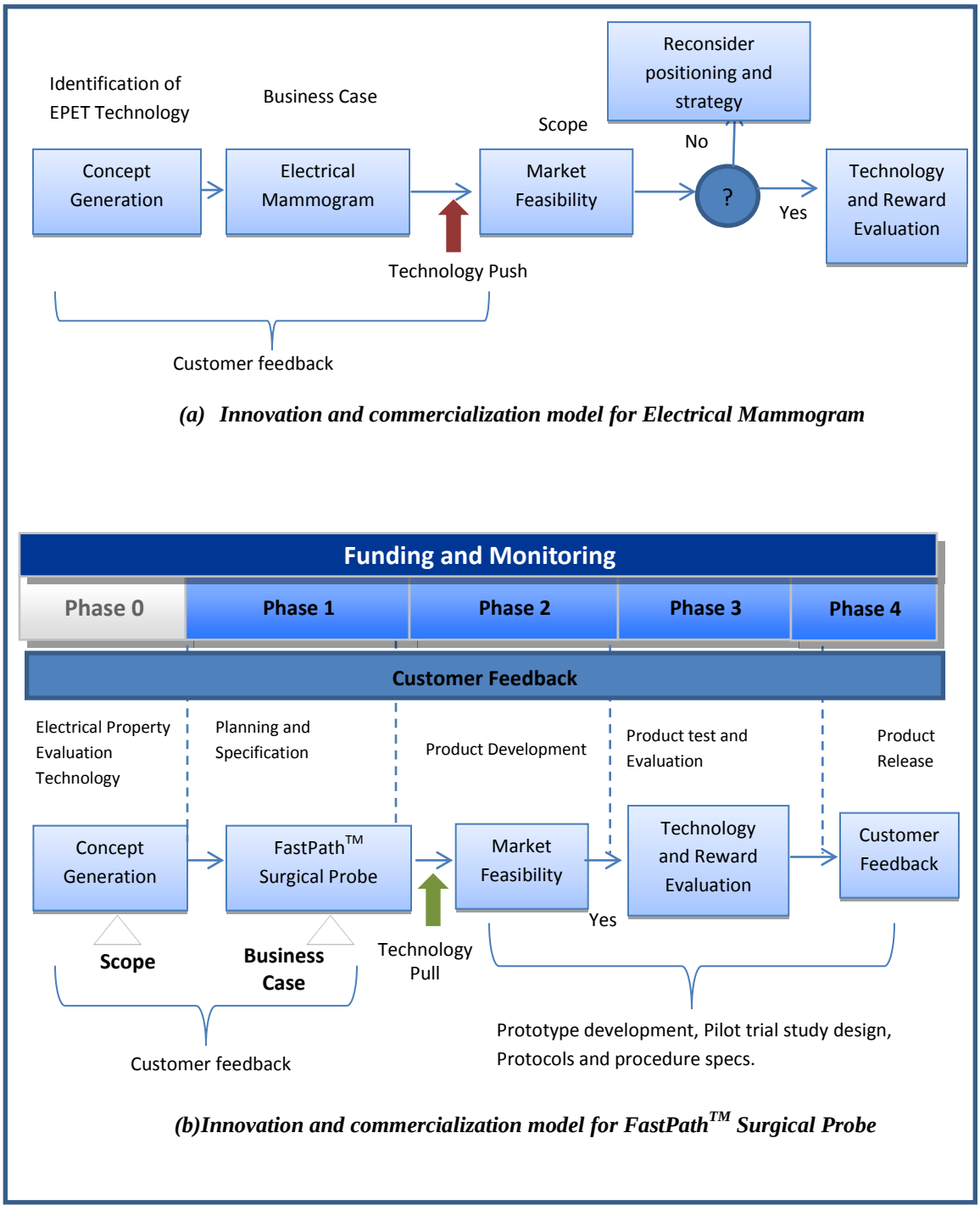
While NovaScan was trying to push their electrical mammogram technology to the potential consumer who were physicians and surgeons in a hospital setting, it was identified through several interviews an discussions that while the technology seems very promising, the need of the hour was a cancer detection device that could help identify cancer tissues real time and eliminate the repeat surgeries. NovaScan's efforts in this direction are discussed in detail below and in section 4.5.

The companies breast cancer collaborators guided NovaScan towards improvising their FastPath™ prior to the imaging device so that this hand held tool can be used in the surgical cavity to determine if all of the cancerous cells have been removed and that the surgical cavity is cancer free. NovaScan LLC claims this will help not only reduce the number of repeat surgeries but also minimize the follow up treatment of chemotherapy as well, the company claims. As a strategy NovaScan LLC rather than moving on the technology-push path, decided to move towards the technology-pull path which seemed profitable and a better business sense.

Martin, Michael J.C. (1994) in his book Managing Innovation and Entrepreneurship in Technology based Firms defines technology pull and technology-push the following way:

> A technology push implies that a new invention is *pushed* through R&D, production and sales functions onto the market without proper consideration of whether or not it satisfies a user need. In contrast, an innovation based upon market pull has been developed by the R&D function in response to an identified market need. (Martin, Michael J.C., 1994).

4.5 Opportunity Assessment and Commercialization Activities of NovaScan LLC



(a) Innovation and commercialization model for Electrical Mammogram

(b)Innovation and commercialization model for FastPath™ Surgical Probe

Figure 4.5 NovaScan's Commercialization models

The company was formed as a limited liability company in 2003 for the purpose of conducting research on the electrical properties of tissue, and then to develop a commercial product which uses this technology. Initial research was focused specifically on developing an electrical mammogram which would be used in conjunction with existing x-ray mammography. This research proved successful in detecting cancerous cells to a far higher sensitivity and accuracy than traditional x-ray mammography. The research also showed that this technology was very applicable to differentiate various cell types, for example, distinguishing cancerous cells from benign cells. This indicated that the technology could be used to successfully avoid many of the biopsies that are undertaken just to be sure that cancerous cells are not present. As shown in figure 4.5(a) a business case was prepared based on the technological research success data .Based on the initial research success, the company officials decided to touch base with the consumers to assess the market for electrical mammogram.

> "While we had heard of the work of Steve Blank only recently (at the May 2012 NSF Phase II meeting), we inadvertently did exactly what he teaches, but with one twist: we spent several years acquiring data so we could present a full menu of possibilities to our audience. And, also as suggested by Blank, we found it advisable to PIVOT*** when our personal top choice of a 'first marketable device' was not supported by our customer interviews. The process to arrange visits, make a presentation, record feedback and sift through all of the comments took 18 months", said Chief Science Officer, Dr. William Gregory of NovaScan LLC.

*** Eric Ries coined this business model iteration loop – the Pivot. Pivoting" is when you change a fundamental part of the business model. (One of the Pivot's positive consequences for the startup team is realizing that a lack of scalable revenue is not the fault of Sales or Marketing or Engineering departments – and the solution is not to fire executives – it's recognizing that there's a problem with the assumptions in the initial business model.) *Source: Why Startups are Agile and Opportunistic – Pivoting the Business Model, April 12, 2010 by Steve Blank (Fig. 4.8).*

There were surprising results from the market assessment and contacts with hospitals. It was found that though the electrical mammogram technology was very promising, it still wasn't the need of the hour. The hospital surgeons needed a device that could use this technology in breast cancer surgery. Apart from consumer feedback there were several other barriers identified like first and foremost the regulatory and then the list of well-established competitors. Many large well established firms (such as GE and Hologic with x-ray mammograms, MRI and US devices) dominated the breast screening market. And even though NovaScan device was superior in every way to the x-ray based technology, the medical community was not willing to shift from the well known technology. It would be a fight to get to market suggesting that such a device would be more of a technology push.

Choosing the better business sense, NovaScan shifted its focus to development and commercialization of the surgical probe that continues on this path today (Figure 4.5(b)).

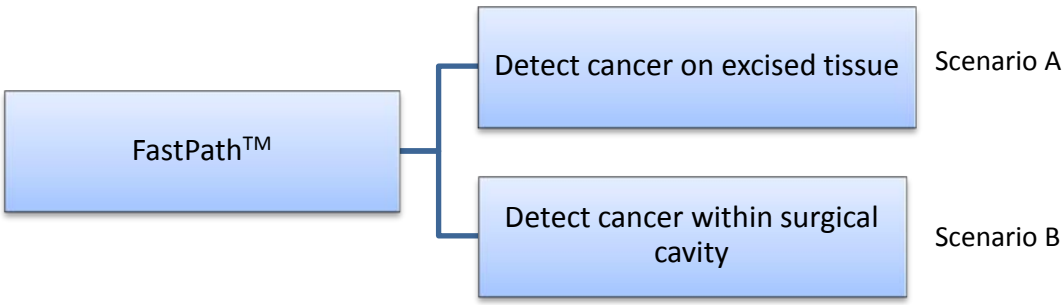


Figure4.6 Usage scenarios of the FastPath™ surgical probe

The company is in the early prototype stage of the development of a commercial product which is based upon its prior research. Figure 4.5(b) describes the process of

commercialization of FastPath™ surgical probe. As per the diagram, it has accomplished most of phase 1, part of Phase 2 and is also working towards entering phase 3. The company strategically delayed the development of electrical mammogram and have plans to revisit the electrical mammogram market only after the FastPath™ probe has achieved most of the phase 4 (Figure 4.5(b)).

Another strategic decision that NovaScan took was to split the usage scenarios to expedite the regulatory approval and product launch process(Figure 4.6) While the company has extensive research data available on excised tissue they decided to market the probe in *Scenario A* – where it will be used to examine the tissue removed during a Breast Conservation Therapy procedure (a partial mastectomy or lumpectomy) to determine that no cancer exists within a safe distance from the margin of the excised tissue (defined as 3-4 mm by most surgeons) and then later as *Scenario B* – where it will be used for testing the tissue within the surgical cavity to find any residual cancer(Figure 4.6).

During phase I a first version of the hand held probe, the alpha prototype, was developed while working on size of the device and electronics simultaneously. During later part of phase I another modified version of device was developed with a better sensitivity and technical programming and they called it the beta prototype. During phase 2 Novascan made a strategic collaboration with a Minneapolis based product development company that could help Novascan progress towards development of Gama prototype while simultaneously working on various protocols and requirements for submitting it to FDA for Pilot trial approvals. This collaboration streamlined the development process. As per the diagram shown in Figure 4.5, the research team decided

to take improved prototype from latter part of phase 2 and begin testing in the surgery suite with both the first (A) and second (B) scenarios (Figure 4.6) discussed earlier. This step will help them develop a metric to characterize the medical value of the probe. The beta prototype was put to rigorous testing with a feedback mechanism to incorporate improvements suggested by the physician team members and the feedback will be incorporated into the final gamma prototype that will be submitted to FDA for Pre-Market approval.

As of July 2013, the company for its product FastPath^{TM} surgical probe has an International Organization of Standardization (ISO) approval for use on humans. This probe that can be used in sterile or non-sterile conditions to scan tissue for breast cancer was tested during a continuation of the products current IRB studies and is ready for first marketing in Europe. At the end of the European Union introduction of the probe the company will begin the FDA Pivotal Trial process to obtain US marketing approval. As a strategy, NovaScan plans to start the process of commercialization of the electrical mammogram device as a follow-on product to the surgical probe.

4.6 Product Market Launch

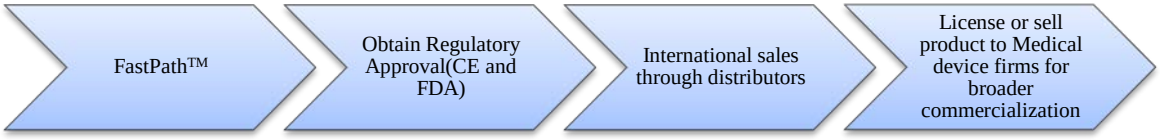


Figure 4.7 FastPath™ surgical probe market launch steps

At first the Pilot Study results will be used to apply for outside United States regulatory approval, notably in Europe for a CE mark. Then the results will be shared with FDA while negotiating on a plan for the Pivotal Trial as a necessary part of the application for a Pre-Market Approval (PMA). The National Science Foundation grant has funded the development and testing of the initial prototype of the surgical device. However, for FDA trials, marketing, and manufacturing of the product, a funding of $3 million in future revenue from individual and institutional investors will be sought. It is expected that FDA trials will take place in 2016-17, and that a commercial product will be introduced in 2018.

The strategic alliance with the Devicix will help NovaScan achieve outside United States (OUS) regulatory approval and start with early OUS sales. This will help decrease the demand for high external investments for the Pivotal Trial. Without the OUS sales the company has to look for heavy investments to start with the Pivotal trial in US.

4.7 Role of Competition in Product Launch

The competitive landscape for NovaScan is not too complex as there aren't many players in the market for detecting cancer tumor margins. The only direct competitor for NovaScan is Dune Medical systems. They are in their Pre-Market Approval stage and that makes them ahead of NovaScan. However, Novascan has a competitive edge in terms of cancer detection capability over the Dune device. As mentioned earlier the Dune device is slightly ahead in the approval and market launch than NovaScan and this lead of the Dune device will help generate the market for NovaScan surgical probe. The fact that FastPath™ surgical probe measures both in the wound, and on the excised lump, will be a strong factor in competition with Dune. Nonetheless, NovaScan cannot delay the commercialization process as it might lose on the market pull and demand. Table 4.1 shows the comparison of features of NovaScan FastPath™ with Dune's device that they call as Margin Probe™.

Feature	NovaScan's FastPath™	Dune's Margin Probe™
Scan surgical cavity	Yes	No
Scan shavings	Yes	No
Saline or gels	Yes	No
Touch only (no vacuum)	Yes	No
Avoids spatial avg. errors	Yes	No
Works in hetero samples	Yes	No
Can sense deep and close	Yes	No
Scan Lump or Partial Mastectomy	Yes	Yes
Likely to get PMA late 2012, early 2013	No	Yes

Table 4.1 Feature comparisons of NovaScan FastPath™ with Dune's Margin Probe™.

4.8 Within Case analysis

> "Our first thoughts had been to use this EPET technology for an electrical mammogram. In fact, we built such a device and tested it in a small study (N=50) at the Aurora Health Care hospitals in Milwaukee.The results of this small study were exceptional- no errors in identifying cancer from benign breast disease.And even though our device was superior in every way to the x-ray based technology, the medical community seemed loath to change from an older, well known technology. It would be a fight to get to market."- Dr. William Gregory,CSO NovaScan LLC.

Several researchers have suggested that it is difficult to change the behavior of clinicians (Greco and Eisenberg, 1993), current medical practices, and healthcare organizations (Shortell, Bennett, and Byck, 1998; Shortell et al., 2001). The NovaScan innovators and researchers spent several years acquiring data to give its consumers a detailed idea of functional possibilites however their personal top choice of a 'first marketable device', in this dissertation referred as case product(1), was not supported by the customer interviews.

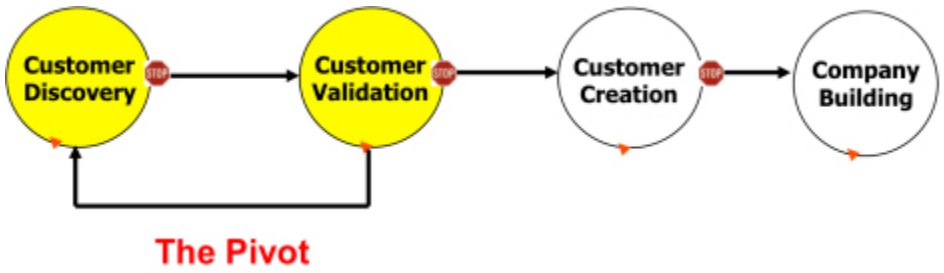


Figure 4.8 *Source: Why Startups are Agile and Opportunistic – Pivoting the Business Model, April 12, 2010 by Steve Blank*

NovaScan founders arranged visits with physicians, made presentations, recorded feedback and sifted through all of the comments. It took 18 months to firmly realize that there was something wrong with the initial business model (Figure 4.3). Their contacts

with surgeons and oncologists resulted in the discovery that a device that would solve the 'residual cancer' problem using same technology would be more meaningful. That led NovaScan reconfigure some part(s) of their model. Figure 4.9 is a graphical representation of NovaScan's approach with a difference that they did not form the company after pivoting rather they pivoted within the same company with a different product approach.

Case Product	**Electrical Mammogram**	**FastPath™ Surgical Probe**
Technology	EPET	EPET
Product Uniqueness	Accurate detection of cancer tissues in imaging mode	Detects cancer real time during surgery Safety Hand held device Physicians requirement
Product Driver	Technology Push	Technology Pull
Radicallity	Technology	Market Technology
Target Market	Hospitals, Clinics	Breast surgery Centers Hospitals
Customer base	Not established	Mostly established

Table 4.2 Product feature comparisons

New practices in patient care are traditionally scrutinized thoroughly in their early development phase so that potentially harmful innovations are not adopted (Faulkner and Kent, 2001).Looking at the product value proposition of the NovaScan hand held surgical probe technology, safety has been a great USP (Unique Selling Proposition). While there have been some technologies available for detecting residual cancer, none promises to be free from side effects NovaScan surgical probe is free from any side effects and it uses no injectable dyes or external radioactive or non-radioactive agents. This property attracted a lot of attention from the stakeholders.

For most healthcare innovation the stakeholders are patients, provider's parameters and purpose (Figure 2.1). The NovaScan hand held surgical device provides

the patients with precise, lower re-excision rates and helps surgeons detect malignancy in the open wound during surgery in real time. It also, provides time reduction and several solutions to the existing breast conservation surgical procedure. This technology assures both patient and operator safety. As mentioned by Steve Blank, the path to success is connectivity with consumers; NovaScan has been in touch with all its consumers from very early stages.

Moreover, while there were numerous competing technologies being studied to solve this problem detecting residual breast cancer during surgery, real time, there are only a handful that are being commercialized. In fact, as of today, only one company , Dune Device has survived and is near to obtaining a Pre-Market Approval (PMA). for a device that is inferior to the NovaScan device (see Table 4.1).

Professor Joe Tidd of University of Sussex at London claims that the early innovation models define innovation as a linear sequence of functional activities. He says either new opportunities arising out of research give rise to applications and refinements which eventually found their way to the marketplace (‘technology push’), or else the market signaled needs for something new which then drew out new solutions to the problem (‘need pull’, where necessity becomes the mother of invention).NovaScan’s modified business model can very easily relate to this approach.

Roy Rothwell, a key researcher in the field of innovation management suggested that the innovation process has evolved from simple linear models (characteristic of the 1960s) to increasingly complex interactive models (Figure 2.2). His first generation model stresses on technology pull and technology push method whereas the fifth concept sees innovation as a more complex, multi-actor process, which requires high levels of

integration. NovaScan's FastPath™ Surgical Probe business model is seen basically as a technology pull method however it's more complex in nature. It involves more strategic collaborations, customer feedbacks, raising funds etc. The company has developed a large suite of software programs, electronic circuitry and electrode configurations that will be tried during the Pilot Study. This Pilot Study is a pre-Pivotal Trial study. The probe prototype will be tested in real settings for several performance parameters. Based on the feedback, the probe will go through changes, replacements and alterations necessary to bring the device to market.

To achieve this, apart from being a promising functional device, the company must have the regulatory approval to enter the market. "The FDA approval, whether the less onerous 510K or the full PMA, will be the most important hurdle we must achieve to enter the market", says Dr. William Gregory. He said that this is intimately tied to the market projections and the strategy we use to commercialize the device. The strategy is to attempt a much less expensive 510K if a predicate device is available (such as the Dune device or earlier bio-impedance devices from companies such as T-Scan). The company plans to seek sufficient capital to pull together manufacturing and sales using strategic partnerships wherever possible.

Case Product	Success factors
FastPath™ Surgical Probe	Technology Pull
	Performance Parameters
	Consumer' requirements of such a device
	Investments in the promising technology
	Strategic Partnerships
	Competitors landscape
	Customer reviews
	Safety features of the device
	Strong research team

Table 4.3 FastPath™ Surgical Probe success factors

As shown in Table 4.3, there are several factors that may contribute to the successful commercialization of the FastPath™ Surgical Probe. As discussed in the earlier sections of this chapter, this product was developed keeping in mind the demand from the breast surgeons. The interviews with the end users helped company focus on need analysis of the technology as well as the product. The confirmation from the end users regarding need in the current market gave stimulus for further research and development of the product. The extensive research revealed the performance parameters discussed earlier (Figure 4.3). The initial technological success helped raise some money from grants, awards and investments from friends and family. It also paved the way for strategic partnership and investment for Aurora Healthcare.

A detailed review of the competitor landscape revealed that there wasn't any direct threat to the NovaScan's technology and the potential, based on its functional parameters and safety promises was very high (Table 4.1). Another important factor for NovaScan's commercialization success would be its strong research team. The value of human resource can never be underestimated.

Chapter 5

Propositions for Managing Innovations and Commercialization

This chapter includes propositions that are based on the research findings discussed in chapter four. The propositions are derived from the analysis of the case study, but they are also combined with insights derived from the literature. The chapter presents seven propositions and a framework of commercialization based on the literature review and research findings.

While the propositions can be read as general managerial suggestions, they are not intended to represent any ideal, law like guidelines. These propositions represent the researcher's best effort, based on the literature and case study, to summarize what has been learned during the research process. In other words, while the propositions are formulated in a relevant and practical form, they should be considered as mere recommendations and the basis for theory. As mentioned in previous sections as well, the aim of this study is not to create statements of generalizations of facts.

5.1 Commercialization Process

Proposition (1) *Identifying critical steps of commercialization early in the processes are important to the success of commercialization.*

Successful product design and development requires the ability to take a concept and translate the technology into useful, patentable, commercial products by formulating a sound road map. The desired outcome of every such practical healthcare product research is to identify a viable and less trodden path for introducing research based innovations from the laboratories to the clinics and the bed side.

While commercialization-related tools such as a *Business Plans, Gantt Chart* were often in place at NovaScan LLC, neither maps nor descriptions of the commercialization process or other documentation concerning commercialization existed in the early part of their product development. However, a more strategic commercialization plan was put in place while applying for the National Science Foundation SBIR Grant. This helped company re-identify its focus areas and target. Critical steps to successful development and commercialization of a healthcare product are: invention, patenting, planning early prototyping, and developing and implementing the commercialization of profitable medical product innovations. There is a need to develop a comprehensive and practical overview of the steps and challenges early on in the research and developmental stage to successfully develop and commercialize a product. This finding is in line with the findings of Prebble et al. (2008) that there is little understanding of the actual decision making that goes on when designing a commercialization process.

While it is not possible to generalize, it seems quite likely that many research based small firms lack clear commercialization processes. However, the firm under study viewed the commercialization process as an important topic but did not put it into practice early on. This led to Proposition 1, *Identifying critical steps of commercialization early in the processes for success of commercialization.*

5.2 Test Market- Internal Field Trials

Proposition (2) *First field trials play an important role in commercialization, especially when commercializing a technology intensive product.*

According to Deming (1988),

> A consumer can seldom say today what new product or new service would be desirable and useful to him three years from now, or a decade from now. New product and new type of service are generated, not by asking the consumer, but by knowledge, imagination, and innovation, and risk, trial and error on the part of the producer, backed by enough capital to develop the product or service and to stay in business during the lean months of introduction. (Deming, 1988)

While the above statement was targeted at the non-healthcare business, the idea can be applied to the healthcare industry as well. The above statement does indicate that customer may be ignorant of his own wants and needs and therefore the customer interaction during the new product development and commercialization processes may take a back seat. Despite the clear statement above, which devalues the consumer as a source of ideas, Deming (1994) seemingly contradicts himself later on when he claims, "An educated customer may have a firm idea about his needs, what he would wish to purchase. He may be able to specify his needs so that a supplier may understand them".

NovaScan's first thoughts were to use the EPET technology for an electrical mammogram. To move further in the development they built the device with some intial funding and conducted tests in a small study (N=50) at the Aurora Health Care hospitals in Milwaukee. The results of this small study were exceptional- no errors in identifying cancer from benign breast disease. And even though company claims that the device was

superior in every way to the x-ray based technology, the medical community did not accept this technology over the well known technology of mammograms.

However, the positive outcome of this interraction with the physicians and breast cancer surgeons (*consumer*) was the demand for the hand held surgical probe to detect cancer real time while operating in the surgical suite. The EPET technology could be easily applied to this hand held device as well and based on this need based analysis NovaScan shifted its focus from electrical mammogram to the development of the surgical probe.

This shift meant a more promising evidence based solution to an existing problem of detecting breast cancer in the surgical cavity real time and a big leap to successful commercialization. This led to formulation of my Proposition (2): *First field trials play an important role in commercialization, especially when commercializing a technology intensive product.* Various articles seem to promote the holistic role of consumer in the innovation process. And the insights derived from the case study approves of this approach of involving consumer early in the process.

5.3 Consumer Testimonials

Proposition (3) *Positive consumer references and testimonials recommending a particular product play an important role in the commercialization*

Deming (1994) claims that,

> An educated consumer may have a firm idea about his needs. What he would wish to purchase. He may be able to specify these needs so that a supplier may understand them (Deming, 1994).

The case study on NovaScan demonstrates that the consumer, even though not the originator of technology, can contribute useful ideas to an innovation process. In other words, a consumer may very well know what he or she wants, without knowing exactly how to achieve or implement those desires. Like in NovaScan case study the surgeons and physicians carved out the need of the hand held surgical device. It shows that while consumer understanding is important, it is even more important to be able to pinpoint and solve the problems a consumer is having. In cases where a consumer cannot express her or his needs and wants, it is much more difficult for a developer to come up with a product that meets those needs and desires.

This led to defining Proposition (3): *Positive consumer references and testimonials recommending a particular product play an important role in the commercialization.*

As the diffusion of innovation theory (Rogers 2003) indicates, there are only a limited number of innovators and early adopters. Therefore, a firm is better-off in finding those innovative consumers as early as possible. NovaScan identified the group of surgeons

and physicians that helped in developing a more desired product from the same EPET technology early on.

In addition, external opinion leaders play a crucial role in convincing potential future consumer. It is important to use testimonials and reports from industry experts to pave the way for a new product. This can be seen as one of the most important commercialization-related tasks and helped NovaScan in raising funds for the company (both through federal grants and external investors).

5.4 Product Launch Within the Organization

Proposition (4) *Implementing an internal product launch can be an important prerequisite for a successful commercialization.*

The management of internal information flows and knowledge management in general are much easier tasks to organize in a small startup firm than in a large corporation with several divisions around the globe. Larger firms view internal training and preparations as very important. A small firm may not need specific internal launch practices because the information is easy to spread. However, at NovaScan, even though the FastPath™ was not officially launched as a prototype, the company has plans to introduce a test batch within the hospital it is affiliated with. The surgeons will be allowed to use it and provide feedback. This will help as a test market for the device and any flaws and discrepancies witnessed by the surgeons in the first hand use will be easy to fix before a full-fledged launch.

Lambert and Slater (1999) provide an example from the airline industry in which Southwest Air's modest expansion outperformed People Express's aggressive product introduction strategy. This illustrates that speeding a product to market is not always the best option. Lempres (2003) argues that while firms may have fine-tuned their processes as effectively as a fast production line, they also may have become so rigid that they cannot adapt to market changes. The solution is to foster flexibility and to try to keep the process dynamic and information-based. It is better to postpone a launch if product is not ready (Lempres 2003).

5.5 Role of Strategic Alliances

Proposition (5) *Successful commercialization requires a strong and competent facilitator or strategic alliances*

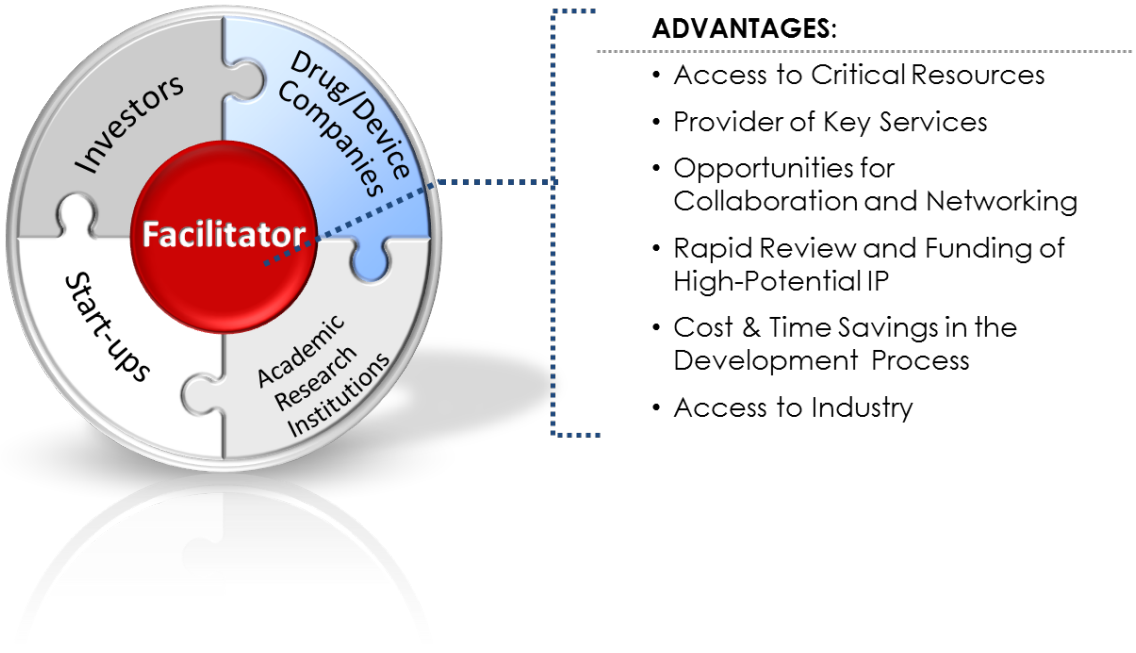


Figure 5.1 Facilitator's role in the process of innovation to commercialization
(Source: Shabistan Sheerin, IATI BioMed Conf 2013(Israel))

Identifying a facilitator early on in the process helps research based organizations to have access to critical resources like it may help in licensing, linking to product development agencies, research design, review of various protocols, access to industry, opportunities for collaboration and networking. It also helps in getting regulatory

approvals. This process of identification of this central agency (may be operated by a single man or another company) can help save on time in the development process and streamline resource allocations.

NovaScan LLC saw this position as quite important not only for ensuring the technical functioning of a product, but also from the commercialization point of view. To fulfill this role they made few strategic tie ups. One was with Aurora hospitals that helped them in identifying and keeping constant contact with their real consumers. This also helped them in running the device through various testing phases at their hospital facility in Milwaukee.

Second important strategic tie up of NovaScan LLC was with Devicix, a Minneapolis based company that is helping them develop the real product. This company is also facilitating NovaScan in development of various protocols necessary to achieve the regulatory approval, not only for US, but also for European Union markets. The importance of this role has also been discussed in Chapter 2 (literature review).

5.6 Contribution of End Users in the Design Stage

Proposition (6) *Product design discussions with end users should initiate in early stages of development for a successful commercialization.*

Donald A Norman in his book, the design of everyday things (2002) narrates a problem identified by a designer (Name Unknown),

> We often know the product too well to envision how people will use it and yet we are separated from the end users by multiple layers of corporate bureaucracy, marketing, consumer services etc. These people believe they know what their [consumers] want and feedback is limited by the filters they impose. If you accept the problem definition from these outside resources without a personal investigation you would design an inferior product regardless of your best intentions. If this initial hurdle is overcome you are only half way home.

Identifying real end users and holding discussions regarding product and technology helps in defining direction for a successful product. It can define the need and improve the design of the product simultaneously.

NovaScan LLC presented their early data to physicians and surgeons and sought feedback on the viability of devices on their patented EPET technology. While the company wanted to introduce an electrical mammogram, the users defined need for for a device that would solve the 'residual cancer' problem. That was a discussion that led the company to shift its focus to a more need based innovation and commercialization. The need analysis revealed a market for the hand held surgical device suggesting an opportunity for a successful market launch.

Apart from helping in identifying need, the discussions with end users also helped the company shape their product. The requirement of the hand held device forced the company to shrink the size of technology that could fit into nothing larger than that of an electrical tooth brush.

(Appendix E)

Repeat meetings and discussions with the surgeons helped them work on form and human factors. The surgeons could share issues of using devices in surgical suite . This helped in identifying both ergonomic and technical concerns. The availibilty of these inputs from the very early stages of development helped NovaScan in a speedy development and elimination of cost of repeated rengineering again and again of the functional prototype. When the first functional prototype was developed by NovaScan, it had included almost all the consumer led feedbacks already .

5.7 Availability of Funds

Proposition (7) *Availability and management of funds ensures availability of timely resources for commercialization.*

NovaScan planned its business and started off as a small startup with self-funding. Self-funding or bootstrapping is still the most common and safest approach for startups (Zwilling, 2013). Zwilling also recommends accumulation of funds before starting off with the business.

NovaScan raised the next round of funds from friends and family investments. They applied for business plan contests and other business grants. This source is a major focus these days due to government initiatives to incentivize research and development. In Figure 4.1 of Chapter Four, the timeline and availability of funding resources is described. Many startups also use Crowd funding method which is an online fund raising strategy. People are requested to make donations, preorder in case of an already developed product for some equity or other reward. NovaScan still being in the early stage of actual product development did not use this method. Loan is also a way of keeping funds in place. NovaScan applied for some short term loans from the local state agency.

The company had a strong strategic plan for management of resources from the very early stages. They generated funding from varied sources recommended by the practitioners in the field. This helped company stay afloat even during the slow research and development progress stage of commercialization.

5.8 Framework of Commercialization

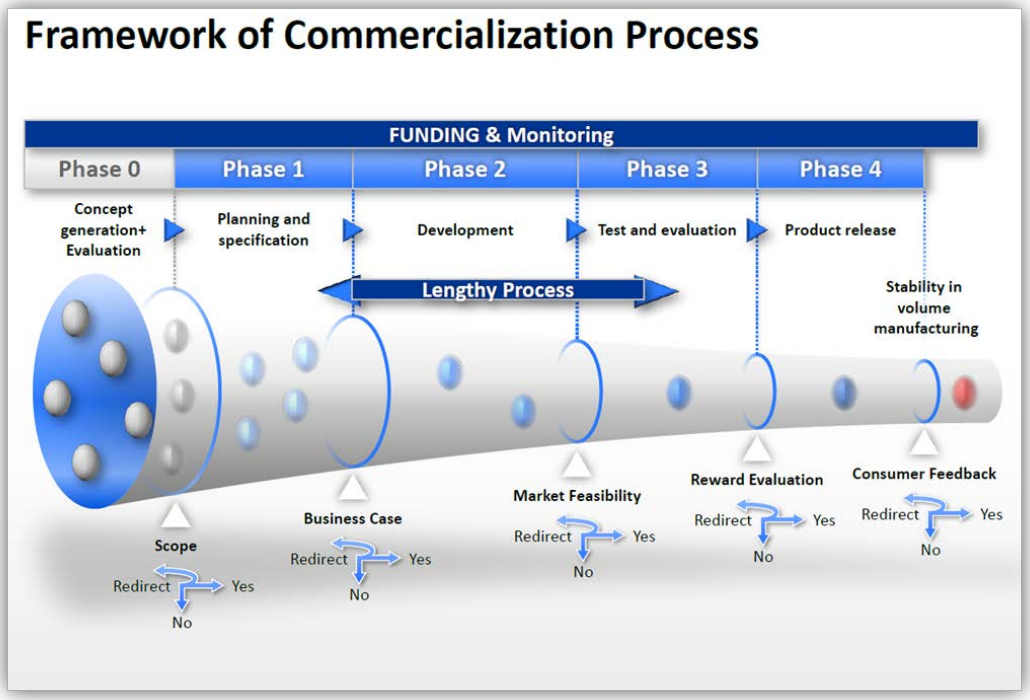


Figure 5.2 Suggested Framework of commercialization (An integrated scheme with product development**)**
(Source: Sheerin S, Patrick T, IATI BioMed Conf 2013(Israel))

Souder and Sherman (1994) used the term concurrent commercialization. They used it to describe a situation where the start of the production ramp-up phase and the go-to-market phase overlap. However, Simula (2012), in a comparison of Business to Business commercialization, identifies concurrent commercialization as a much broader concept that starts already from the ideation phase. The key point here is that the commercialization process does not happen in isolation with product development in a startup firm. Like at NovaScan LLC, commercialization strategies are an integral part of development work and are well-aligned with the development process, rather than as a separate step. For small start-up firms such as NovaScan LLC, this type of commercialization is perhaps an easier way to work because there is not a need to

communicate between the different organizational units. Naturally, larger, established firms such as GE or Phillips need to spend more effort on getting all the relevant employees on the same page regarding the new product.

It is worth mentioning that similar ideas have been presented in the extant literature. For instance, Newell et al. (2009) critique the traditional linear innovation process and state that most innovations actually do not happen in such a manner. Instead, they consider innovation to be a complex, iterative, and interactive process (Newell, 2009). Several articles also point out that product marketing and product-launch planning need to be synchronized and overlaid on top of product development (Copper, 1993; Soni & Cohen, 2004).

According to Nevens et al. (1990), the commercialization process should be considered as starting from the point of concept generation and cover all organizational functions. Similarly, according to Holt (1983) and Cooper (1993) the planning for introducing the product on the market should occur at the same time as the technical planning (Simula2012).

Based on the literature review, and the NovaScan case study, it is suggested that commercialization should be seen differently than the traditional linear model described in literature. The case revealed that, in reality, it is quite difficult to separate product innovation into distinct ideation, development, and commercialization phases. Thus, traditional linear models hardly do justice to real product innovation processes. In light of this shortcoming,

The commercialization framework presented in Figure 5.1 draws together the theoretical and the empirical findings of this dissertation. Commercialization and product

development are processes that work hand in hand and run simultaneously is the main idea depicted in the figure.

The bigger umbrella supporting the commercialization activities through and through is the availability of funds. The phase of prototype development, testing and evaluation is the lengthiest process in commercialization of a healthcare product innovation. It is this phase that seems very critical as cost of developing trial study is very high and at the same time very elaborate and time consuming especially for devices or technologies in healthcare. (Following the guidelines of the FDA regulatory procedures)

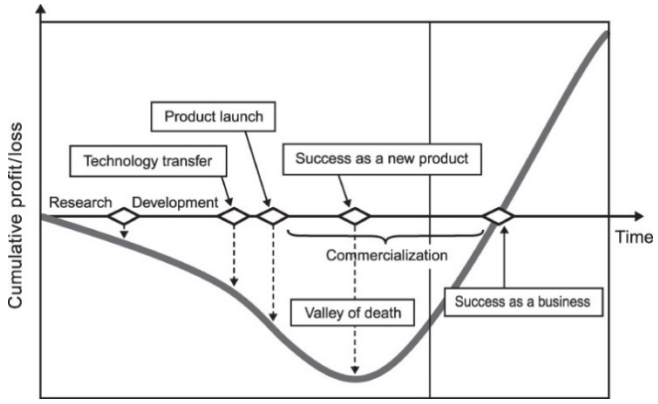


Figure 5.3 Valley of Death
(Source: Zwilling M, *10 Ways For Startups To Survive The Valley Of Death,* 2013)

Sometimes lack of funding results in the difficulty of covering the negative cash flow in the early stages of a startup, before their new product or service is bringing in revenue from real consumer (Zwilling, 2013).This stage is termed as *Valley of Death* (Figure 5.3). Management of funds, early commercialization strategy and identification of the facilitator or strategic alliances early on can help companies keep from falling into this and achieve an early recovery in case of a fall (Zwilling, 2013).

Chapter 6

Conclusions

This final chapter describes the study's contributions to theory and its contributions to practitioners. It also discusses the validity, reliability, and limitations of this study. Finally, opportunities for future studies are described.

6.1 Novel Contributions of this Dissertation

This dissertation is a contribution towards new knowledge for innovators, researchers, academicians and other practitioners of innovation and commercialization. This knowledge covers ways research based small firms developing medical devices can move ahead from innovation to a successful path to commercialization. The study discussed in this dissertation examines qualitatively commercialization practices of NovaScan LLC, a breast cancer detection device company. Through this single case study, various performance indicators of the commercialization steps followed by the company are identified and findings are presented in the form of theoretical propositions and a theoretical framework of commercialization. Extensive literature review and analysis contributed to a better understanding of the process of commercialization from both healthcare and non-healthcare perspectives.

A literature gap exists in terms of understanding how the commercialization of innovations in technology based industries can determine commercial success or failure (Chiesa and Frattini, 2011). The focus of the Chiesa and Frattini study was the non-healthcare consumer market. They emphasize on further exploration that the industrial market needs to be studied more closely. Based on the detailed literature review conducted for this dissertation it can be said that there is a research gap in terms of understanding how commercialization activities can determine success in the healthcare medical device market. This dissertation aims to understand these gaps in the light of the actual work in real settings performed by innovators and researchers during the commercialization process. Since the dissertation purpose is to build a theory, the

findings do not aim to close the gaps. Rather the purpose of this study is to provide a theoretical framework based on those gaps that need testing in further studies.

The desired outcome of any new product development effort is timely commercialization of a profitable product (Griffin and Hauser, 1996). Commercialization is considered a desired outcome of new product development (NPD). While there is commercialization whenever there is a new product, commercialization may not be the obvious fate of all new products.

The study of NovaScan LLC for the purpose of this dissertation revealed several important aspects that need attention in the commercialization process. The importance of cross-functional teams in the new product process has been documented and discussed widely (Nonaka, 1990; Aaby & Discenza, 1993; Hutchings & Knox, 1995; Song, Thieme, & Xie, 1998; Kono, 2005; Prebble, Gerrit, & de Groot, 2008). Researchers have found that when firms utilize a cross-functional team, they increase the quality of the product (Song et al., 1998), the success rate of the project (McDonough III, 2000), the success rate of new products (Cooper, 1994; Valle & Avella, 2003), and they also improve the launch success of the new product (Kono, 2005).

However, it takes time, resources, and leadership skills to build consensus between different units in because managers need to navigate between diverse opinions and objectives (Song et al., 1998).While these statements have been made in regards to the non-healthcare products, the extant literature review and research findings concerning NovaScan LLC makes it possible to say that in a setting of medical device innovation and commercialization, the process of commercialization has to be synchronized and more

integrated. This approach has been suggested in sub section Eight of Chapter Five of this dissertation as a framework of commercialization The idea presented is that commercialization practices do not happen in a linear non-integrated way, (as traditionally considered) in the field of medical device innovations. These commercialization practices are synchronized and integrated together from the conception of the idea to the time it reaches its end user. This statement is based on the observations made at NovaScan LLC and the literature analyzed.

Ruokolainen (2008) studied a start-up firm in the software industry and noted that the first consumer reference is especially important for companies trying to enter a competitive business-to-business market for complex products, where it may be impossible to convince a potential customer of the product's value without evidence that it functions well in the real world. The importance of testimonials is valid in the case of NovaScan LLC as well however in the medical device industry substantial evidence of functional parameters is what builds the testimonials. The testimonials from the physicians and surgeons paved NovaScan LLC's path to funding.

The statement made by Ruokolainen is an important aspect of the software industry and can be extended to the medical device industry as well. This has been reported in this dissertation as Proposition Three in Chapter Five. The Propositions Two and Three of Chapter Five emphasize the importance of both consumers and their testimonials. The findings in this study and the analysis of literature helped in framing all the seven propositions. These propositions are an effort to fill in the literature gap focused on consumers.

The literature on product innovation considers the product innovation process to be comprised of three phases: a front-end phase, a development phase and a commercialization phase (e.g., Buckler, 1997; Koen et al., 2001). This type of linear approach with separate activities is embedded in various articles in the NPD literature, too (e.g., Cooper, 1996; Khurana & Rosenthal, 1997; Griffin, 1997; Schilling & Hill, 1998) (Simula 2012).This study represents one of the first attempts to assemble empirical data about the commercialization activities of small startup firms in the field of developing medical devices in healthcare.

Jalkala (2009) as reported by Simula (2012) studied the phenomenon of consumer reference marketing. She states that, "While [consumer] references are typically considered an important marketing and sales tool, the academic literature has paid very little attention to the phenomenon". As evident, the statement is made with respect to marketing and sales. Since sales and marketing are an integral part of commercialization activities for any technology or product, it can be stated that the same lack of studies applies to commercialization. Gaps in the literature have been discussed in detail in Chapter Three. The emphasis on consumer references is very limited in the extant literature.

According to Rogers (2003), "the presence of an innovation champion contributes to the success of an innovation in an organization". Identifying such a champion early on in the process helps research based organizations to have access to critical resources such as licensing, linking to product development agencies, research design, review of various protocols, access to industry and opportunities for collaboration and networking.

The relevant gap in the literature is that there is no uniform evidence based best practice methodology reported in the literature that defines the process of commercialization of healthcare medical devices. Since the purpose of this dissertation is to build a theory; it does not aim to completely fill this gap identified in the literature. The dissertation has developed propositions and a theoretical framework based on literature findings and empirical data collected from the NovaScan case study. These findings should be tested in future follow up studies. This focus on the identification of evidence based commercialization practices will also contribute to the body of knowledge in this field. Forthcoming studies can verify the validity of the propositions and the theoretical framework developed. If the proposition and theoretical framework presented in this dissertation hold true then they may be incorporated in other marketing and new product development. Thus, this study is a novel contribution to the attempts to assemble empirical data about the commercial activities of small startup firms in the field of developing innovative medical devices in healthcare.

6.2 Implications and Relevance to Industry

This study aims to fulfill the academic requirements for the PhD dissertation and has some practical relevance for practitioners. They may benefit from the case study presented here because it can provide some ideas for the commercialization of other products (other than breast cancer detection device).

The propositions presented in Chapter Five, are not intended to prescribe standard guidelines. As Numagami (1998) says, "*There is only a very slight chance, if any, of being able to discover an invariant law that will be useful in suggesting what managers should do to adapt to the future course of events"* (Simula 2012).

In addition, because the research is based on a single case study and was not carried out from the perspective of the population at large, it would be misleading to generalize the findings to any particular population. Therefore, these propositions should be interpreted with caution. These propositions need to be studied and verified in future research work. However, if the propositions hold true, they can provide some stimulus for practitioners to apply them in the future.

The focus of this study was to emphasize the activities that NovaScan LLC had engaged in, since inception of EPET Technology to the development of their first prototype and the direction they intend to take in future for developing their final product. The propositions of Chapter Five can be considered as the basis for a theoretical approach that can improve the chances for the commercial success of a new medical device. These propositions will help practitioners to keep focus on some of the evidence based successful activities.

According to Rogers (2003), “The innovation process does not always begin with a perceived problem or need. A considerable degree of serendipity may occur”. While Rogers’s statement is accepted here it is also recognized that, sometimes timing plays a very critical role as well. Timing in conducting need analysis, timing in writing business plans, timings in doing competitor analysis and so on. An understanding of timing may play a crucial role in conducting various activities.

6.3 Reflections on Research Questions

The main research question "**What practices can be identified as the best practices engaged in the process of commercialization of a medical device innovation?**"

As discussed in the earlier sections, to understand better this main question in context to the case study, it was divided it into following parts:

***R1**: What activities did technology innovators and researchers perform at NovaScan to initiate the process of commercialization?*

***R2**: What is the evidence that these approaches are successful?*

The single case study presented here in this dissertation and the case analysis of that company aimed at providing answers to the above mentioned research questions. In addition the propositions presented in Chapter Five and the conceptual framework for a more collaborative and integrated commercialization also aimed at providing an answer to the questions.

Any answers to these above mentioned research questions presupposed answers to the questions like: what is product innovation? What is commercialization? What defines success and failure in innovation and how are they measured? The answers to most of these questions were found in the Chapter Three via an extensive literature review. This led to find answers to the main research question. The literature review in section 2.1 to 2.8 and the further discussion of success and failure covered in section 2.16 provide answer to the question, "what is the role of success and failure in innovation and how are they measured?" The literature review in section 2.13, 2.14 and the discussion in chapter 5 provided answers to the question, "what is commercialization. Finally, the within case

analysis provided answer to the questions, ***R1:*** *What activities did technology innovators and researchers perform at NovaScan to initiate the process of commercialization?* And ***R2****: What is the evidence that these approaches are successful?*

6.4 Validity, Reliability and Replicability Issues

Qualitative researchers utilize various validation strategies to make their studies credible and rigorous (Creswell & Miller, 2000). Credibility for this study was achieved using the validation strategies of triangulation, researcher reflexivity and rich observation and description.

The first validity procedure was prolonged engagement in the field (Creswell & Miller, 2000) or what Merriam (1998) calls "long-term observation".

For the purpose of this dissertation, NovaScan LLC was studied for more than four years both as an outsider initially and then as an insider later on. During each of these observation procedures, there was consistent contact with the company and its progress. Association with the case study NovaScan LLC for this length of time allowed some preliminary findings and then a thorough follow up through observations and interviews (Creswell & Miller, 2000). Therefore, the length of the case study and the consistent contact lends credibility to the researcher's perceptions of this experience.

In addition to prolonged engagement in the field, another important validity procedure of triangulation was used (Creswell, 1998). Merriam (1998) defines triangulation as "using multiple investigators, multiple sources of data, or multiple methods to confirm the emerging findings" (p. 204).

Denzin (1984) identified four types of triangulation: *Data source triangulation*, when the researcher looks for the data to remain the same in different contexts; *Investigator triangulation*, when several investigators examine the same phenomenon; *Theory triangulation*, when investigators with different viewpoints interpret the same

results; and *Methodological triangulation*, when one approach is followed by another, to increase confidence in the interpretation.

Data triangulation method was used (Creswell & Miller, 2000) especially on three forms of data: observations, unstructured and informal interviews, and documents. The informal interviews were conducted with several participants (Creswell & Miller, 2000) of NovaScan LLC. The process of triangulation was used to seek convergence in the data and to confirm or disconfirm emerging categories and themes (Creswell & Miller, 2000). Categories or themes that emerged in the within-case analysis were compared with literature findings. If a category did not hold true across cases and literature, it was generally deemed to be unreliable. The outcomes are presented in the form of propositions and that forms a theory basis for future research studies.

Finally, the validity procedure of thick description is used. This procedure of writing gives the reader a sense of being there and to capture the essence of the experience (Creswell & Miller, 2000). This is an important feature in case study design that is presented to the reader through the case description.

Joppe (2000) defines reliability as: "...The extent to which results are consistent over time and an accurate representation of the total population under study is referred to as reliability and if the results of a study can be reproduced under a similar methodology, then the research instrument is considered to be reliable". Embodied in this citation is the idea of replicability or repeatability of results or observations.

Reliability and replicability are clearly problematic in case studies. Numagami (1997) points out that it is hard to meet the reliability criterion in its most literal sense because Whatever documentation a researcher devises, the ultimate quality of the

research findings from qualitative approaches ought to vary with his or her social and conceptual skills because what can be obtained from, for example, interviewing, seems to be dependent more on human and contextual factors of the particular research project than is the case with other data gathering techniques .

However, the same dilemma is also present in surveys. According to Numagami (1998), a language system evolves over time and the wording used in questionnaires may propagate different meanings, too.

In any event, as Remenyi at al. (1998) point out, with a phenomenologist approach it can be argued that “all situations and organizations are different and thus the same results cannot ever be obtained again,

Because so much depends on the researcher's personality and approach, a case study is difficult to repeat.

Lincoln and Guba (1985) states that: "Since there can be no validity without reliability, a demonstration of the former [validity] is sufficient to establish the latter [reliability]”.

6.5 Limitations of the Present Study

Commercialization can be seen as a complex phenomenon (Simula 2012). One could enter into an endless conceptual debate about whether commercialization should be considered as a sub-category of marketing or as a sub-category of the new product development process instead of defining it as a separate concept. As there are hardly any exact concepts in literature, it is impossible to provide a solid argumentation against these kinds of claims. Empirical material is used in this dissertation to support the argument for considering commercialization differently.

There can be several sources of bias in case studies. Jones and Stevens (1999) argue that an analysis of failure probably provides a more useful lesson for managing innovation. The failure part was discussed in the literature review. This case, however, focuses primarily on success, which naturally can be seen as a bias in this study.

Rogers (2003) says, "Serendipity and accidental aspects of the innovation-development process are unlikely to be fully reported in research publications written by the inventors and researchers." In this study while full attention to detail was given and the steps of innovations and commercialization at NovaScan LLC were studied in stages of development to eliminate the possibility of losing any piece of information. However, it would be unrealistic to ignore the possibility of missing and failing to report at least some such information.

Another cause of concern can be selection of number of cases to be included in the study. This dissertation is based on a single case study. The study of innovations and commercialization in the light of more complex situations and at more than one case study may have resulted in a different output.*

Eisenhardt and Graebner (2007) explains that,

> Multiple-case researchers retain only the relationships that are replicated across most or all of the cases. Since there are typically fewer of these relationships than there are details in a richly observed single case, the resulting theory is often more parsimonious (and also more robust and generalizable) (Eisenhardt and Graebner , 2007).

More cases could have been included by approaching additional firms. However, with case studies the typical criteria regarding sample size is irrelevant (Yin, 1994). In other words, adding a few additional cases does not increase the statistical relevance of the study. Thus, the choice of a single case study seemed adequate.

The amount of required observation data and interviews are also questions to which there is no exact answer and different opinions exist in the academic literature. The guiding principle is to gather enough information so that theoretical saturation** is achieved (Johnson, 2002). Another limitation of this dissertation is the number of participants in this study. NovaScan had a total of six employees including full time and part time. Had there been more people working at NovaScan LLC, more informants would have contributed to the study and would have provided support to the case more strongly. But at the same time, the amount of time spent as a participant observer provided a deeper understanding of both relevant and irrelevant details pertaining to this case, adding more insight as such.

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* It could have been a never-ending story; there are numerous firms with successful products.

** The issue is impossible to verify in reality. The point of saturation is also always difficult to determine objectively.

6.6 Suggestions for Future Research

There has to be a better way – find it. - Thomas Edison

Theory validation follows theory building (Simula 2012). The qualitative method was suitable for this study, but quantitative research could take place next in order to test whether or not the propositions presented in Chapter Five are valid.

This study was only able to study innovation and commercialization practices of a single case, NovaScan LLC. The company is currently in the process of conducting pilot trial study after establishing and conducting the proof of concept study. It is also preparing for the next Pivotal trial for FDA approval. A next study would be to continue the investigation until the market launch of their hand held device for detection of cancer during surgery. That future study would be of more in-depth in nature and the researcher would be able to follow the whole life cycle of that product.

For the purpose of this dissertation the regulatory procedures and the role of patents are not included in the process of commercialization. Regulatory procedures require consideration from the early stages of inception, get more attention when conducting studies on real humans, and even more so for getting FDA approvals. These successes of such studies also attract venture investments. The future study can include these aspects for a more thorough investigation.

Another source of innovation can be the number of patents. Bound et al.(1984) demonstrated that the number of patents increases at a rate that is less than proportional

to firm size and other authors; Acs and Audretsch (1987, 1991), confirm the same results using the number of innovation as output variable. Henderson and Cockburn (1996), Mansfield, (1980) showed that larger firms have in some cases an advantage in innovation.

In the field of innovations and commercialization, patents also play an important role. However, for the purpose and scope of this study they are not included in the research questions of this dissertation and its boundaries. However it is recommended that this aspect be applied in future research projects.

Cui et al. (2011) suggest avenues for future research related to the launch of new products and states that,

> The important role of managers' perception of market conditions also highlights the need to study the behavior of new product managers. Perception of market conditions is formed within the context of the managers' individual knowledge and experience, and influenced by their personality traits and management style. (Cui et al., 2011)

The same idea could be applied to study of innovation and commercialization as well. At NovaScan LLC, the inventor was the chief science officer, also performed responsibilities of the chief executive officer (CEO) and was also chairman of the board. He also played the role of a new product manager in the company. It is also recommended for future research to study the role of innovator who plays different roles in the process of commercialization.

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APPENDIX A
(a)

Journals	Number of Articles
Journal of Management Reviews	1
Journal of Marketing	7
European Journal of Marketing	1
Journal of Business Industrial Marketing	1
Journal od Product Innovation Management	22
Journal of Business	2
Journal of Strategic Management	7
Engineering Management Journal	1
Journal of Management Studies	2
Journal of Innovation Management	3
Journal of Technology Transfer	5
Journal of Marketing Research	10
Academy of Management Journal	2
New England Journal of Medicine	1
Journal of Business Venturing	3
Rand Journal of Economics	1
Quarterly Journal of Economics	1
Journal of Business Research	2
Journal of Marketing Theory and Practice	1
Journal of Food and Engineering	1
International and Small Business Journal	1
Journal of Consumer Marketing	1
Journal of Knowledge Transfer	1
Journal of Research in Marketing	1
Journal of Consumer Research	3
Journal of Business and Industrial Marketing	1
Journal of Service Research	1
Journal of Pharma World Research	1
Australian Journal of Management	1
Journal of Medicine	1
European Journal of Innovation Management	1
International Journal of Innovation and Technology Management	2
Engineering Management Journal	1
Total	**90**

APPENDIX A (b)

Journal	Study
Journal of Management Reviews	Adams,R,Bessant,J., & Phelps, R. (2006).
Journal of Marketing	Cook, H., E. (1997).
	Crawford, M. C. (1977).
	Doney, P., & Cannon, J. (1997).
	Goldenberg, J., Barak L., & Muller E. (2002).
	Massey, G. R., & Kyriazis, E. (2007).
	Peter, J. P., & Olson, J. C. (1983).
	Ruekert, R.W. & Walker, Jr. O. (1987).
European Journal of Marketing	Cooper, R. G. (1980).
Journal of Business Industrial Marketing	Calantone, R. J., & Di Benedetto, A. (2007).
Journal of Product Innovation Management	Calantone, R. & Rubera G. (2012).
	Chiesa, V. & Frattini, F. (2011).
	Cooper, R. G., & de Brentani, U. (1991).
	Cooper, R. G., & Kleinschmidt, E. J. (1986).
	Cooper, R. G., & Kleinschmidt, E. J. (1987a),
	Crawford, M. C. (1984).
	Crawford, M. C. (1992).
	Danneels, Erwin (2004).
	Griffin, A., & Hauser, J. R. (1996).
	Griffin A., &Page,A.L. (1993).
	Griffin, A., & Page, A. L. (1996).
	Johne, A. F., & Snelson, P. A. (1988).
	Kleinschmidt, E. J., & Cooper, R. G. (1991).
	Martin, E,. Ginn, M. E., & Rubenstein, A. H. (1986).
	Meyers, P. W., & Athaide, G. A. (1991).
	Micheal, K., Rochford, L., & Wotruba, T. R. (2003).
	Michalek, J. J., Feinberg, F. M., & Papalambros, P. Y. (2005).
	Ottum, B. D., & Moore W. L. (1997).
	Rackham, N.(1998)
	Reid, S. E., & de Brentani U. (2004),
	Rein, G.L. (2004),
	Saunders, J., & Jobber, D. (1994).
Journal of Business	Knight, K. E. (1967).
	Chaney, P. K., Devinney, T. M., & Winer Russell, S. (1991).

Journal of Business and Industrial Marketing	Calantone, R. J., & Di Benedetto, A. (2007).
	Schmidt, J.B. (1995).
Journal of Strategic Management	Christensen, Clayton M. and Bower, Joseph (1996).
	Zhang, Q., & Doll, W. J. (2001).
	Connor, T. (1999).
	Lieberman, M. B., & Montgomery, D. B. (1988).
	Makadok, R. (1998).
	Mascarenhas, B. (1992)
	Mitchell, W., & Singh, K. (1996).
Engineering Management Journal	Schoen, J., Mason, T. W., Kline, W. A., & Bunch, R. M. (2005).
Journal of Management Studies	Crossan, M. M & Apaydin, M. (2010).
	Wolfe, R. A. (1994).
Journal of Innovation Management	Eveleen,C.(2010)
	Cozijnsen, A. J., Vrakking, W. J., & van Ijzerloo, M. (2000).
	Kim, J., & Wilemon, D. (2002).
Journal of Technology Transfer	Dort, R. C. (1987).
	Lundquist, G., 2003.
	Mayer, S. and Blaas, W., 2002.
	Reisman, A., and Lining Zhao(1991)
	Reisman, A(1989)
Journal of Marketing Research	Golder P. N., & Tellis, G. J. (1993).
	Griffin, A. (1997).
	Chandy R., Hopstaken, B., Narasimhan, O., & Prabhu J. (2006)
	Chandy, R., & Tellis, G. J. (1998).
	Eliashberg, J., & Robertson, T. S. (1988).
	Goldenberg, J., Mazursky, D., & Solomon, S. (1999a).
	Henard, D. H., & Szymanski, D. M. (2001).
	Griffin, A. (1997).
	Moore, M. J., Boulding, W., & Goodstein, R. C. (1991).
	Shankar, C., & Krishnamurthi (1998).
Academy of Management Journal	Eisenhardt, K. M., & Graebner, M. (2007).
	Golden, B. R. (1992).
New England Journal of Medicine	Greco, P. J., and J. M. Eisenberg. 1993
Journal of Business Venturing	Harmon, B., Ardishvili, A., Cardozo, R., Elder, T., Leuthold, J., Parshall, J., et al. (1997).
	Markman, G. D., Phan, P. H., Balkin, D. B., & Gianiodis, P. T. (2005).
Rand Journal of Economics	Katz,M., & Shapiro, C. (1985).
Quarterly Journal of Economics	Klemperer, P. (1987).

Journal of Business Research	Lai, W. (2011).
	Rehn A., & Lindahl, M. (2011).
Journal of Marketing Theory and Practice	Mazumdar, T. Sivakumar, K., & Wilemon D. (1996).
Journal of Food and Engineering	Morrissey, M.T. and Almonacid, S., 2004.
International and Small Business Journal	Perren, L., & Ram, M. (2004).
Journal of Consumer Marketing	Ram, S., & Sheth, J.N. (1989).
Journal of Knowledge Transfer	Reisman, A.
Journal of Research in Marketing	Rodriques Cano, C., Carrillat, F.A., & Jaramillo F. (2004).
Journal of Consumer Research	Rogers E.M. (1976).
	Sheppard, B., Hartwick, J., & Warshaw, P.R. (1988).
	Thompson, C. J., Locander, W. B., & Pollio, H. R. (1989).
Journal of Business and Industrial Marketing	Calantone, R. J., & Di Benedetto, A. (2007).
Journal of Service Research	Sharma, M., Kumar, U., & Lalande, L. (2006).
Journal of Pharma World Research	Singh, A., & Aggarwal, G. (2010).
Australian Journal of Management	Cooper, R. G., & Kleinschmidt, E. J. (2000),
Journal of Medicine	Greco, P. J., and J. M. Eisenberg.
European Journal of Innovation Management	Kim, J., & Wilemon, D. (2002).
International Journal of Innovation and Technology Management	Omachonu, V. K. and N.G. Einspruch. 2009
	Omachonu, V. K. and N.G. Einspruch. 2010
Engineering Management Journal	Connell, J., Edgar, G.C, Olex, B., Scholl, R., Shulman, T., & Tietjen, R. (2001)

APPENDIX A (b)

APPENDIX B
Definition of Innovations in various Literatures

Afuah 1998
Innovation is the use of new knowledge to offer a new product or service that customers want. It is invention + commercialization.

Betje 1998
Innovations are new things applied in the business of producing, distributing and consuming products or services

Boer and During 2011
Innovation is the creation of new product-market-technology-organization-combination

Bradbury 1989
Innovation is therefore a creatively initiated process which is then developed and progressed to a definable goal by the application of further creativity allied to logical analysis and work organization in which the creative element continually introduces 'change' as a 'horizontal shift' in the logical progression of the chain

Crawford and Di Benedetto 2006
Innovation refers to the overall process whereby an invention is transformed into a commercial product that can be sold profitably.

Crossan and Apaydin 2010
Innovation is production or adoption, assimilation, and exploitation of a value-added novelty in economic and social spheres; renewal and enlargement of products, services, and markets; development of new methods of production; and establishment of new management systems. It is both a process and an outcome

Dodgson 2000
Innovation includes the scientific, technological, organizational, financial, and business activities leading to the commercial introduction of a new (or improved) product or new (or improved) production process or equipment.

Freeman and Soete 1997
The first commercial application or production of a new process or product

Hult 1983
Innovation is a process which covers the use of knowledge or relevant information for creation and introduction of something that is new and useful

Knight 1967
An innovation is the adoption of a change which is new to an organization and the relevant environment

Morton 1971
Technological innovation is the process of perception or generation of relevant science and its transformation into new and improved products and services for which people are willing to pay

Myers and Marquis 1969
Innovation is not a single action but a totol process of interrelated sub processes. It is not just the conception of a new idea, nor the invention of a new device, nor the development of a new market. The process is all these things acting in an integrated fashion.

Narayanan 2001
Innovation refers both to the output and the process of arriving at a technologically feasible solution to a problem triggered by a technological opportunity or customer need.

Padmore & et. al. 1998
An innovation is any change in inputs, methods, or outputs which improves the commercial position of a firm and that is new to the firm's operating market

Parker 1980
Innovation involves the birth of a new idea, often an invention, together with its successful progression to a new material, process, product or system. It implies a discontinuity and a radical change in the way a company should be managed.

Pessemier 1977
The act of introducing something new or novel (making an addition to the things previously available)

Robertson 1967
Innovation has been defined as a process whereby a new thought, behavior, or thing is conceived of and brought into reality

Rogers 2003
Innovation is an idea, practice, or object that is perceived as new by an individual or other unit of adoption

Rogers and Shoemaker 1971
An innovation is an idea, practice, or object perceived as new by an individual

Schumpeter 1939
Setting up a new production function

Scott and Bruce 1994
Innovation is a process involving both the generation and implementation of ideas

Souder 1987
Innovation refers to a high-risk idea that is new to the sponsoring organization, and which the organization believes has high profit potential or other favorable commercial impacts for them.

Trott 2002
Innovation = theoretical conception + technical invention + commercial exploitation

Trott 2002
Innovation is the management of all the activities involved in the process of idea generation, technology development, manufacturing and marketing of a new (or improved) product or manufacturing process or equipment

Van de Ven 1986 Innovation has been defined as the development and implementation of new ideas by people who over time engage in transactions with other within an institutional context

APPENDIX B

APPENDIX C
Laws of Technology Transfer

Stevenson-Wydler Technology Innovation Act 1980 (Public Law 96-480)	• Focused on dissemination of information. • Required Federal laboratories to take an active role in technical cooperation • Established Offices of Research and Technology Application (ORTA) at major Federal laboratories. At many laboratories and agencies, these are simply called technology transfer offices. • Established the Center for the Utilization of Federal Technology (in the National Technical Information Service)
Bayh-Dole Act of 1980 (Public Law 96-517)	• Permitted universities, non-profit organizations, and small businesses to obtain title to inventions developed with governmental support. • Allowed Government owned, Government operated (GOGO) laboratories to grant exclusive licenses to patents.
Trademark Clarification Act of 1984 (Public Law 98 620)	• Primarily pertains to non-Department of the Interior laboratories, such as Department of Energy National laboratories (many of which are Government-owned, Contractor-operated-GOCOs). • Permitted decisions to be made at the laboratory level in Government owned, Contractor operated (GOCO) laboratories regarding the awarding of licenses for patents. • Permitted contractors to receive patent royalties for use in R&D, awards, or for education • Permitted private companies, regardless of size, to obtain exclusive licenses. • Permitted laboratories run by universities and nonprofit institutions to retain title to inventions within limitations.
Federal Technology Transfer Act (1986)	• Made technology transfer a responsibility of all Federal laboratory scientists and engineers. • Mandated that technology transfer responsibility be considered in Federal laboratory employee performance evaluations. • Defined a new kind of collaborative agreement to encourage Federal laboratory and private sector partnerships: the Cooperative Research and Development Agreement (CRADA). • Established royalty sharing for Federal inventors (15% minimum) and set up a reward system for other innovators. • Chartered the Federal Laboratory Consortium for Technology Transfer (FLC). • Provided specific requirements, incentives and authorities for the Federal laboratories. • Empowered each agency to give the director of GOGO laboratories authority to enter into cooperative R&D agreements (CRADAs) and negotiate licensing agreements with streamlined headquarters review. • Allowed laboratories to make advance agreements with large and small companies on title and license to inventions resulting from Cooperative R&D Agreements (CRADAs) with government laboratories. • Allowed directors of GOGO laboratories to negotiate licensing agreements for inventions made at their laboratories. • Provided for the exchange of GOGO laboratory personnel, services, and equipment with research partners. • Made it possible to grant and waive rights to GOGO laboratory inventions and intellectual property.
Executive Orders 12591 and 12618 (1987): Facilitating Access to Science and Technology	• Promoted the commercialization of Federal science and technology.
Omnibus Trade and Competitiveness Act of 1988 (Public Law 100 418)	• Placed emphasis on the need for public/private cooperation to assuring full use of results of research. • Established centers for transferring manufacturing technology. • Established Industrial Extension Services within states and an information clearinghouse on successful state and local technology programs. • Changed the name of the National Bureau of Standards to the National Institute of Standards and Technology and broadened its technology transfer role. • Extended royalty payment requirements to non-government employees of Federal laboratories. • Authorized Training Technology Transfer centers administered by the Department of Education.
National Competitiveness Technology Transfer Act 1989 (Public Law 101-189)	• Granted GOCO laboratories opportunities to enter into CRADAs and other activities with universities and private industry, in essentially the same ways as highlighted under the Federal Technology Transfer Act of 1986 for GOGOs. • Allowed information and innovations brought into, and created through, CRADAs to be protected from disclosure. • Provided a technology transfer mission for the nuclear weapons laboratories.
American Technology Preeminence Act 1991 (Public Law 102 245)	• Extended the Federal Laboratory Consortium (FLC) mandate, removed FLC responsibility for conducting a grant program, and required the inclusion of the results of an independent annual audit in the FLC Annual Report to Congress and the President. • Included intellectual property as a potential contribution under CRADAs • Required the Secretary of Commerce to report on the advisability of authorizing a new form of CRADA that permits Federal contributions of funds. • Allowed laboratory directors to give excess equipment to educational institutions and non-profit organizations as a gift.

The National Technology Transfer and Advancement Act of 1996	• Guarantees a Cooperative Research and Development Agreement (CRADA) industrial partner the option to choose an exclusive license to the resulting invention in a field-of-use. • Clarifies that agencies may use royalties to hire temporary personnel to assist in CRADA or related projects. • Gives first $2,000 of royalty income to the inventors and increases an inventor's maximum royalty award to $150,000 per year. • Allows laboratories to use royalties for related research in the laboratory. • Refines the laws concerning excess scientific equipment

APPENDIX C

Source: Technology Transfer Handbook for the U.S. Geological Survey2003

APPENDIX D

Informal discussion and General questions

What does commercialization mean? What kind of activities and critical events happened since inception at NovaScan LLC?

What kinds of problems were encountered since inception?

Why do you think the technology and the product based on this technology will be successful?

What kind of benefits the product provide for consumers

Who are the consumers for NovaScan's products?

What is the most difficult thing for NovaScan to commercialize its products?

What do surgeons feel about the EPET Technology?

What was the consumer's role during the product development?

What kind of problems you encountered while trying to sell the concept of electrical mammogram to the surgeons

Did you take notes and carry further discussions based on surgeon's feedback?

Have you seen cases where a product, which seems like a failure right after the introduction has become successful later on?

Did the product change from the original during the development?

Is the product customized based on customer requirements?

What kinds of criteria were considered before a decision to develop FastPath™ surgical probe?

Who were the main actors during that?

Was it easy to convince consumers that the product will work as promised?

Could you please describe briefly the market and special characteristics of it?

Was there enough funding available for the research and prototype development?

What were the sources of funding?

How did you come up with the name for the product and what were the things related to that?

What do you think are the most important activities that ensure a product to become successful?

Is there any internal competition between this product and other products?

Are there any strategic partners? What are their roles?

Who decides about the product development changes?

What will be the main main things behind the success of commercialization of surgical probe?

When do you expect the launch?

Do you monitor the technical readiness on a regular basis?

What kind of regulatory procedures the surgical probe will have to undergo?

How expensive would these regulatory approvals will be?

When will the company be ready for the FDA trials?

The strategic alliances that company made with Aurora and Devicix, how productive is it for NovaScan LLC

What does the term “commercialization” means at NovaScan LLC?

Is commercialization process mapped or described at NovaScan LLC?

- IF YES: Is it stand alone process or a part of other main process?
- IF NO: Should it be perhaps describe?

How many times do you follow with you consumers for product feedback and so on?

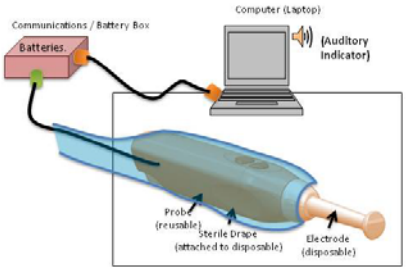
APPENDIX D

APPENDIX E

Case Product (1) Electrical Mammogram

THE DEVICE: A hand held surgical instrument to allow real-time detection of cancer in the surgical cavity, or on the excised lump.

Actual FastPath™ probe



Design features of the FastPath™ surgical probe

Case Product (2) FastPathTM surgical probe

APPENDIX E

APPENDIX F

This list describes several factors that may need consideration before market launch of a product. The list is just illustrative. Some of the items are not necessarily needed and there can be items that are missing. (This information is based on the extant literature and author's own experience.)

- Product (and service) brochure (printed and online versions) describing features function and benefits.
- Audience specific data sheets with more technical description of a product
- Posters / banners
- Name & branding
- White paper(s) / leaflet(s)
- Exhibition stands and demos (+ company specific marketing material, handouts, gifts, takeaways etc.)
- Review articles by magazines, newspapers analysts etc.
- Customer testimonials
- Letter/certificate of compliance (proof that a product meets standards, regulations, directives etc.)
- Video clips about a product and its usage
- Visual aids i.e. pictures, 3D images, virtual tours/demos etc.
- Roadmap
- Product specific website (where all the above mentioned items can be viewed or downloaded)
- Samples (either the product samples or test samples i.e. output of usage of a product)
- Distribution plan and channel selection
- Tradeshow, event and seminar plan & calendar
- PR activities (press tour / analyst coverage)
- Action plan for social media presence
- Non-disclosure agreements
- Licensing agreements
- Prototypes or physical mock-ups if a product is still under development
- Packaging & artwork
- Press release material
- Press tour plans
- Webinars/seminars
- blog pages / on-line forums
- Advertising material & campaigns
- Sales process descriptions

APPENDIX G
Literature findings-Reasons of commercialization failure

Ignored or misinterpreted market research	Calantone and Cooper (1981), Kotler and Keller
Misunderstanding of customer needs	Cooper (1976), Jain (2001), Leadbeater (2006),
Small size of potential market	Jain (2001)
Changing market requirements not understood	Parker and Mainelli (2001)
Competitors' aggressive actions	Kotler and Keller (2009)
Incorrect positioning	Crawford (1977), Kotler and Keller (2009), Rehn & Lindahl (2011)
Stronger competition than expected	Cooper (1975)
No clear differentiation	Jain (2001)
Market newness to the firm	Calantone and Cooper (1981), Kotler and Keller
Product newness to the market	Calantone and Cooper (1979)
Ineffective advertising or lack of selling and promotion resources	Calantone and Cooper (1979), Kotler and Keller
Misdirected marketing efforts	Cooper (1975), Lee and O'Connor (2003a)
Insufficient distribution support or lack of channel partner motivation and incentives	Kotler and Keller (2009); Hill (1988), Berggren
Product focus crowded on customer needs	Rackham (1998)
Prototyping neglected	Rehn & Lindahl (2011)
Poor product launch advertising strategy and communication with customers	Lee and O'Connor (2003b)
Special characteristics of culture and market not understood	Sheth and Ram (1987)
Unexpectedly high development costs	Crawford (1977), Kotler and Keller (2009)
Low return on investment	Jain (2001)
Wrong price	Cooper (1975), Crawford (1977),

No differential advantage	Calantone and Cooper (1979)
Late in the market	Jain (2001)
Too early in undeveloped market	Grayson (1984), Jain (2001)
Timing failure	Udell and Hignite (2007)
Inadequate selling efforts	Calantone and Cooper (1979)
Lack of network effect	Lee and O'Connor (2003a), Rehn & Lindahl (2011)
Lack of product uniqueness or superiority	Cooper (1975), Crawford (1977)
Poor design or poor prototype testing	Jain (2001), Calantone and Cooper (1979)
Product not working correctly or otherwise flawed	Cooper (1975), Crawford (1977), Jain (2001), Folkes and Kotsos (1986), Calantone and Cooper (1979), Rehn & Lindahl (2011)
Bet on the wrong technology	Carroll and Mui (2008)
The newness of production process	Mishra et al. (1996)
Lack of organizational support	Grayson (1984), Crawford and Di Benedetto (2003), Jain (2001), Rackham (1998), Calantone and Cooper (1979)
Lack of R&D resources and skills	Calantone and Cooper (1979)
Enthusiasm crowded on facts	Crawford (1977), (Grayson(1984), Rehn & Lindahl (2011)
Product lacked a champion	Crawford (1977)
Poor fit with the organizational culture	Dipak Jain (2001)
Company politics	Grayson (1984), Crawford (1977), Jones and Stevens (1999)
Lack of sharing and using market information	Crawford (1977), Hill (1988), Calantone and Cooper (1979)
Management losing course of action	Grayson (1984), Boulding et al. (1997), Carroll and Mui (2008), Biaylogorsky et al. (2006)
"Sliding to failure" i.e. the series of decisions that slowly pushed the project towards a slide and that accelerated until failure was inevitable. Projects might thus slide rather than fall into failure — muddle up in a manifold of ways.	Rehn & Lindahl (2011)
Companies trapped in their own thinking and traditions	Leadbeater (2006), Dundas and Richardson (1980)

SHABISTAN SHEERIN

sheerins@outlook.com

PROFESSIONAL SUMMARY

- Product research, design and business development professional who can lead the investigation of various domains for innovation opportunities. Over 10 years of experience in product design, research and development.
- Dedicated professional accomplished in concept development, feasibility analysis and highly passionate about developing strategies for commercialization of innovations.
- Strong and significant experience in advanced level market research and communications combined with data collection and analysis.
- Specialist in driving and delivering consumer as well as medical product design and research, road map development for moving research from labs to the market.
- Proficient in Business plan writing and National Science Foundation SBIR Grant Proposals.
- Experienced in startups, investor relations and direct company representations in trade shows, seminars and conferences.
- Proficient in Medical device regulations and requirements for market introduction (FDA and CE).
- Significant experience in working with International development teams for design and development, marketing of products- US, Europe, Middle East and Asia.
- Skilled and experienced in overseas vendor development and management.
- Experienced in creating curriculums, planning courses ,grading, instructing and guiding students
- Result driven effective team leader with exceptional interpersonal skills, looking forward to a challenging career advancement opportunities.

EDUCATION

PhD. Health Sciences
Dissertation: Product innovations and commercialization — 2013
University of Wisconsin, Milwaukee

MS- Industrial Design — 2001
Indian Institute of Technology, New Delhi-India

BS- Electrical Engineering
Faculty of Engineering and Technology, New Delhi-India — 1999

EMPLOYMENT HISTORY

Teaching Assistant- College of Health Sciences, University of Wisconsin — 8/22/2011 — 6/1/2013
Milwaukee, WI

Product and Business Development Intern, NovaScan LLC — 10/1/2010 — 12/31/2012
Milwaukee. WI

Technology Transfer Intern, UWM Research Foundation — 2/1/2010 — 8/30/2011
Milwaukee, WI

Adjunct Instructor, College of Eng. And Applied Sciences, UWM — 9/1/2010 — 8/30/2011
Milwaukee, WI

Assistant Design Manager, VIP Industries Ltd. — 6/14/2004 — 12/30/2006
Mumbai, India

Team lead- Sr. Industrial Designer, Timex Group
Noida, India — 6/2/2001 — 5/30/2004

Chief Design consultant, Symphony Designs
New Delhi, India — May 2000 to April 2002

AWARDS AND HONORS

- Year 2009-2010, Chancellor's Graduate Student Award, University of Wisconsin-Milwaukee
- Year 2008-2009, Chancellor's Graduate Student Award, University of Wisconsin-Milwaukee.
- Year 2000-2001, Industrial sponsorship by Timex Watches USA for Master's Program at IIT Delhi.