Scientific Commercialization: From Bench to Bedside

...a researcher's guide to improving grant applications for advancing concepts to products through the NIDDK SBIR and STTR Programs

presented to

Dr. Marva Moxey-Mims

National Institute of Diabetes and Digestive and Kidney Diseases

by

The Johns Hopkins University

MBA Capstone Project, May 2012

Professor Michael Tumbarello

Authors: Helen Kim, Timisha Porcher, Satabdi Raychowdhury
Avni Shah, J. Tiffany Slayton, and Stan Zhang

Disclaimer

This document was developed in response to an academic assignment that can enable researchers to understand and apply business processes and principles to improving their success in receiving grant funds from NIDDK. This Guide is designed for scientific researchers like you, who may have conceived an invention that you believe has commercial potential. The goal of this project is to provide an easy-to-comprehend and informative overview of the "concept-to-commercialization" process. Please note that the policies, procedures and legal issues of commercializing inventions differ among universities, private sector and government organizations. Therefore, you should consult your respective intellectual property and technology transfer offices for compliance information and specific procedures. While this Guide is an introduction to the scientific commercialization process, it is not all-inclusive. Additional resources are provided in the appendix for those seeking a comprehensive treatment of this topic.

About the Authors

Sponsor:

Dr. Marva Moxey-Mims

Dr. Moxey-Mims is currently the Deputy Director of Kidney, Urologic and Hematologic (KUH) Clinical Research; the Director of Pediatric Nephrology & Renal Center Program, Division of Kidney, Urologic, & Hematologic (DKUH) Diseases; and the Director of the Applied Kidney Small Business Innovation Research (SBIR) Program, DKUH.

Members:

Project Director: Michael Tumbarello:

Mr. Tumbarello is a Senior Professional Instructor at the Johns Hopkins Carey Business School. He is a seasoned executive and a successful entrepreneur with proven expertise in strategic management, marketing, business analysis and product development. He leads the Masters in Business Administration (MBA) Strategic Management Capstone course, and oversees the successful delivery of capstone projects from participating MBA students. Mr. Tumbarello holds an MBA from New York University, and a Masters of Management from the University of Dallas.

Project Manager: Tiffany Slayton

Ms. Slayton is a Technical Writer for the Department of Transportation and a senior MBA student at Johns Hopkins Carey Business School. Ms. Slayton brings adaptive leadership skills to foster teamwork and innovation from prior experience running a small business, while her in-depth knowledge in project management and technical writing provides the foundation for this project. Ms. Slayton holds a Bachelors of Arts in International Relations from Mount Holyoke College and is an alumna of the Defense Acquisition University.

Financial Planning & Analysis: Timisha Porcher:

Ms. Porcher is a Financial Management Specialist at National Institute of Health and an MBA student at Johns Hopkins Carey Business School. Ms. Porcher is an expert in the field of quantitative financial analysis; her past experience in credit planning, loans and business financial continuity offers accurate quantitative modeling and assessment for start-up businesses. Ms. Porcher holds a Bachelors of Science in Finance and Marketing from University of South Carolina-Columbia.

Technical Review, Research & Feasibility Study: Stan Zhang

Mr. Zhang is a Senior Architect at Verizon Communication Corporation and an MBA student at Johns Hopkins Carey Business School. Mr. Zhang has over 20 years of industry experience in Information Technology and Telecommunication Operation. He is an expert in data networking; focusing on Voice Over IP and SIP product set. He has designed, developed and deployed data infrastructure and call-center solutions for Fortune 100 companies across the country. He holds the industry distinguished Cisco Certified Internetwork Expert (CCIE) certification from Cisco Systems and Bachelors of Science in Information Telecommunication System from University of Maryland University College.

Medical Research & Review: Helen Kim

Ms. Kim is an MBA student at The Johns Hopkins Carey Business School. Ms. Kim works in the Department of Radiation Oncology and Molecular Radiation Sciences under the Johns Hopkins School of Medicine as an Assistant Research Program Manager in the Clinical Trials Office. Her role serves in overseeing regulatory and data management for various cancer research trials, including multi-center, pharmaceutical, cooperative group, and Investigator initiated protocols. Ms. Kim has experience with Investigational New Drug (IND) submissions and has helped receive Food and Drug Administration (FDA) approval for several trials for her department.

Marketing Research & Analysis: Avni Shah

Ms. Shah is a student at Johns Hopkins Carey Business School. She is pursuing her MBA and a Masters in Information Technology (IT). Ms. Shah is working as a manager at Accenture and has been with the firm since September 2006. She has knowledge and experience in the full systems implementation lifecycle; specifically involved within the analysis, testing and deployment phases. She is currently a project manager for the implementation of a global supply chain management system at the Catholic Relief Services in Baltimore, MD. She is an alumna of the University of Maryland, College Park.

Financial & Policy Management: Satabdi Raychowdhury

Mrs. Raychowdhury is a Grant Manager for the Fogarty International Center at the National Institutes of Health (NIH) and an MBA, Finance student at the Johns Hopkins Carey Business School. Her work experience consists of Financial Reporting, Financial Research Compliance and Budget Analysis at Johns Hopkins University. In her current position as Grant Manager at NIH, she Implements and supervises International Grant Portfolios. Mrs. Raychowdhury holds a Bachelors of Art in English from the University of Calcutta, Kolkata, India and a Master of Arts in History from University of Burdwan, Burdwan, India; in addition, Mrs. Raychowdhury holds a Bachelor of Science in Information System and Business Administration from the University of Baltimore.

Acknowledgements

We want to take this opportunity to thank these individuals for their advice, contribution and support. Without them, this project could not have been successfully completed.

Professor Mike Tumberallo
Dr. Jayanthi Chandra
Dr. Bruce Molitoris
Dr. Rob Ivkov
Dr. Romit Majumdar
Ms. Christina Doty
Ms. Elizabeth Good
Mr. Cesar Salas

Table of Contents

1.0 Overview

1.1 Purpose

This document is a resource that details the core business concepts, strategic planning, analysis and execution required to bring an idea, process or invention, referred to as a 'concept', from initiation to commercialization. The theme of this Guide, "From Bench to Bedside", explains and illustrates the processes of scientific commercialization in medical research and life sciences sectors.

This Guide is intended for members of the research community who seek to develop and deliver a product borne from a concept or theory. NIH and the Centers for Disease Control (CDC) define "commercialization" as "the process of developing markets, and producing and delivering products for profit (whether by the originating party or by others)." In this Guide, "commercialization" applies to both government and private sector markets.

The desired outcome is for you, the investigator, to:

- Understand the requisite steps that may be required throughout the commercialization process
- Increase your understanding of the commercialization process from a business perspective
- Develop and include a robust Business Plan with your Small Business Innovative Research (SBIR) or Small Business Technology Transfer (STTR) grant application
- Provide high quality SBIR/STTR application submissions to NIDDK that will improve your probability of receiving funding awards to permit further development of your concept
- Increase the success rate of transitioning concepts into commercially available products

Two additional tools accompany this Guide: a Pamphlet that summarizes key elements of this Guide, and an Automated Presentation in the Prezi format covering highlights of processes explained in this Guide.

1.2 Scope

Creating this commercialization resource required thorough research of many different areas of the life science industry. It was important for us to become extremely knowledgeable about the industry and commercialization pathway to be able to deliver the most comprehensive and accurate product to you. However, because product development is so diverse, there cannot be a standard, single approach to the bench to bedside process. As a result, this document hopes to serve as a helpful example in navigating you through the course. The steps we identified within the scope of work include:

- Evaluating the invention to determine feasibility and success
- Identifying and determining a market 'niche'
- Citing pros and cons of funding and partnering through grants, personal funding, venture capitalists, angel investors and other parties
- Methods of raising the necessary funds for commercialization
- Obtaining patent rights
- Understanding University Technology Transfer Offices and their services
- Knowing the importance of complying with legal and ethical policies such as any conflict of interests
- How to apply for FDA approval
- Identifying tools for marketing, product development and commercialization

2.0 Quick Guide – Bench to Bedside Initial Steps

2.1 Process Flow

The process flowcharts on the following pages (Figure 2-1, Figure 2-2 and Figure 2-3) provide an overview of the initial steps you, as the investigator, may take after discovering your concept has commercial potential. These steps address the activities, research and analysis required to prepare an action plan that should compel you and potential employees to support the concept's commercialization process.

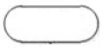
Important: At a high level, these process flowcharts provide an example of how a concept might progress from discovery to the initial stage of commercialization. This process will vary according to the unique requirements of concept development and the relationship between the investigators, universities and investors.

Process Elements:

Predefined Process: Represents the performance of a series of related procedures, activities or steps taken within the flow of events.

Procedural Step: Represents a single activity, action or step taken.

Decision: Represents points where decisions are made. This shape highlights a decision made in the previous procedure in flow diagram. The condition to be met at the decision point is: yes or no.



Terminator: Represents the end to the flow of events and identifies where the event ends.

Continued on next page

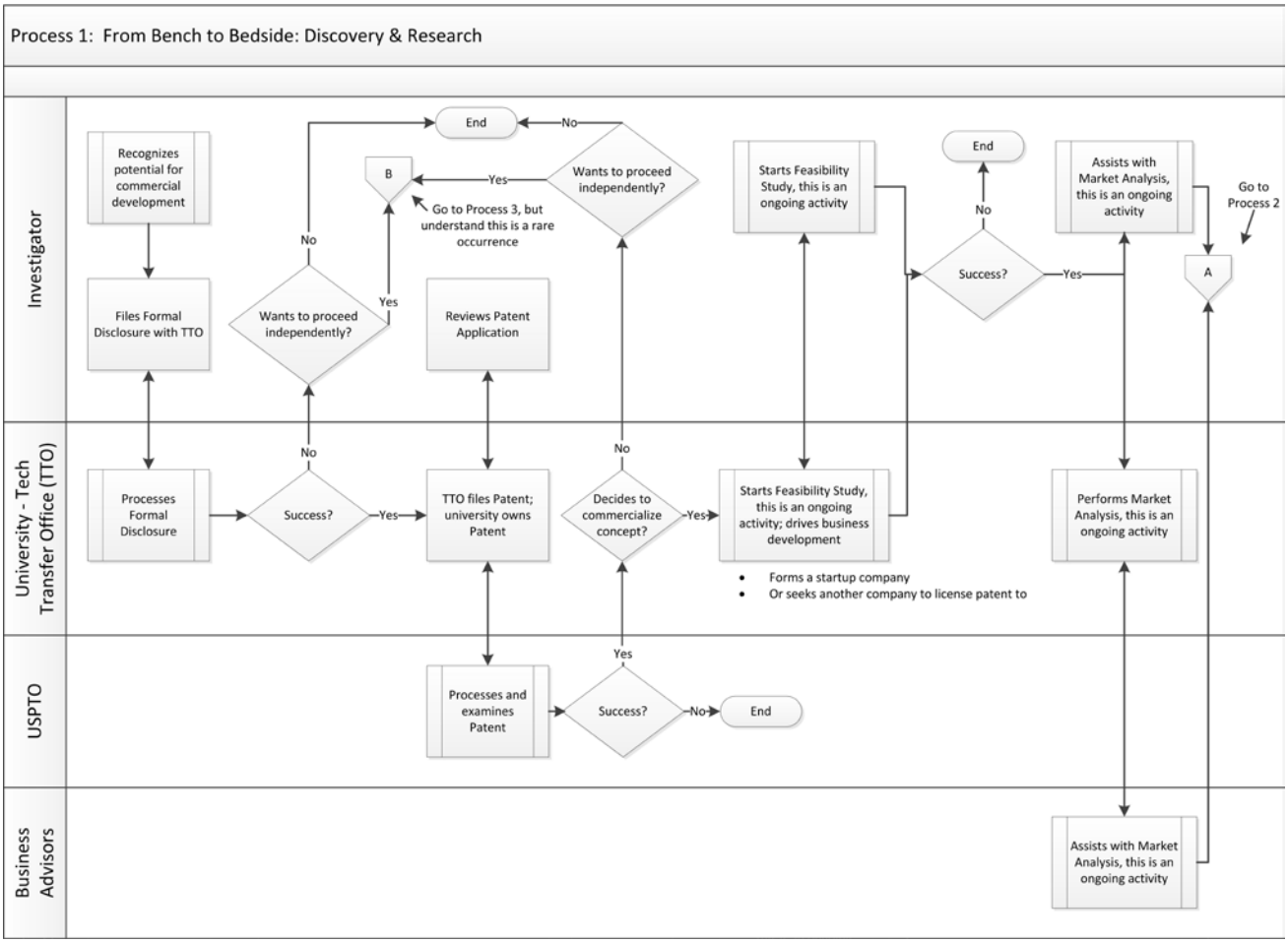


Figure 2-1: Process Flowchart (Discovery & Research)

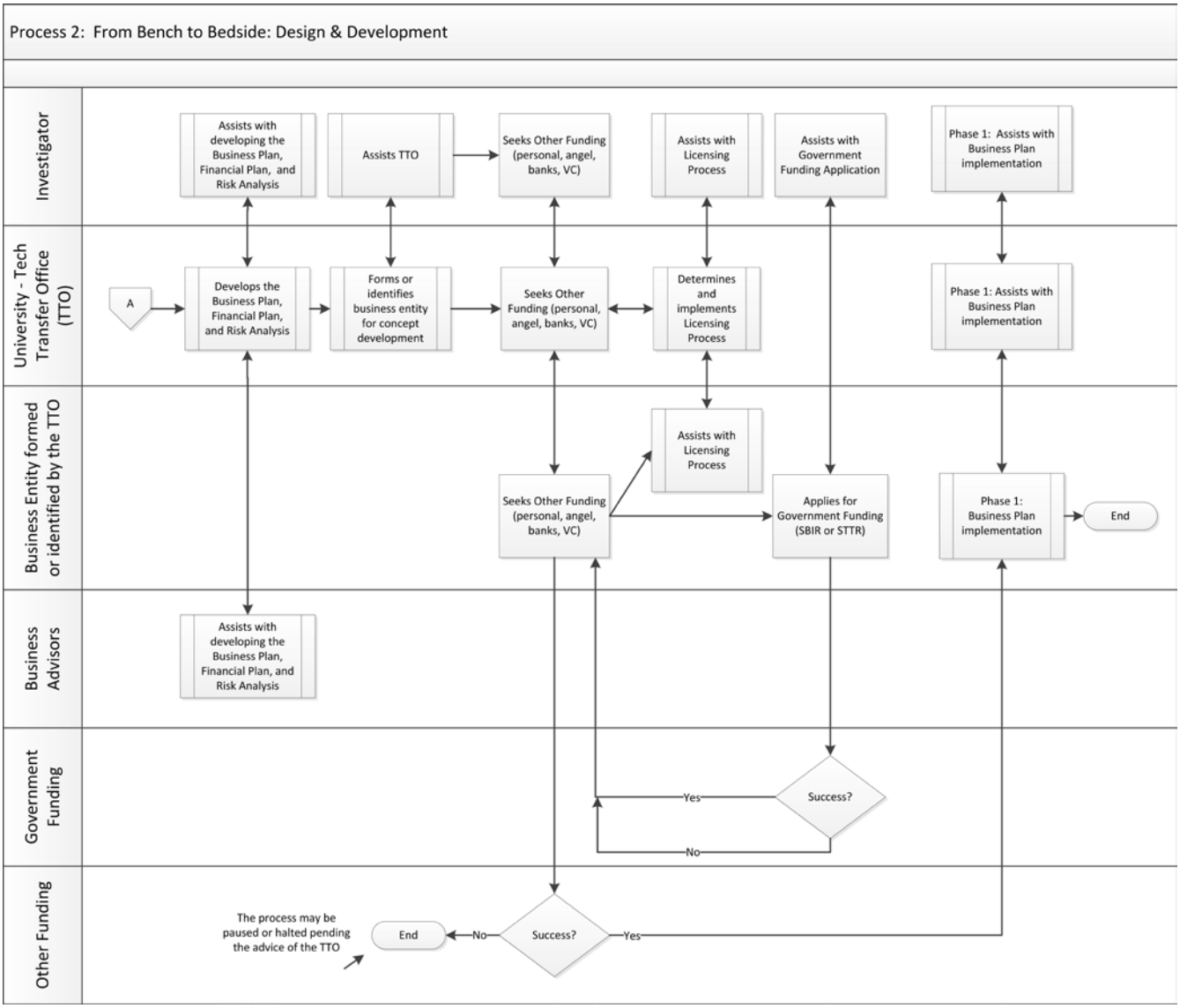


Figure 2-2: Process Flowchart (Design & Development)

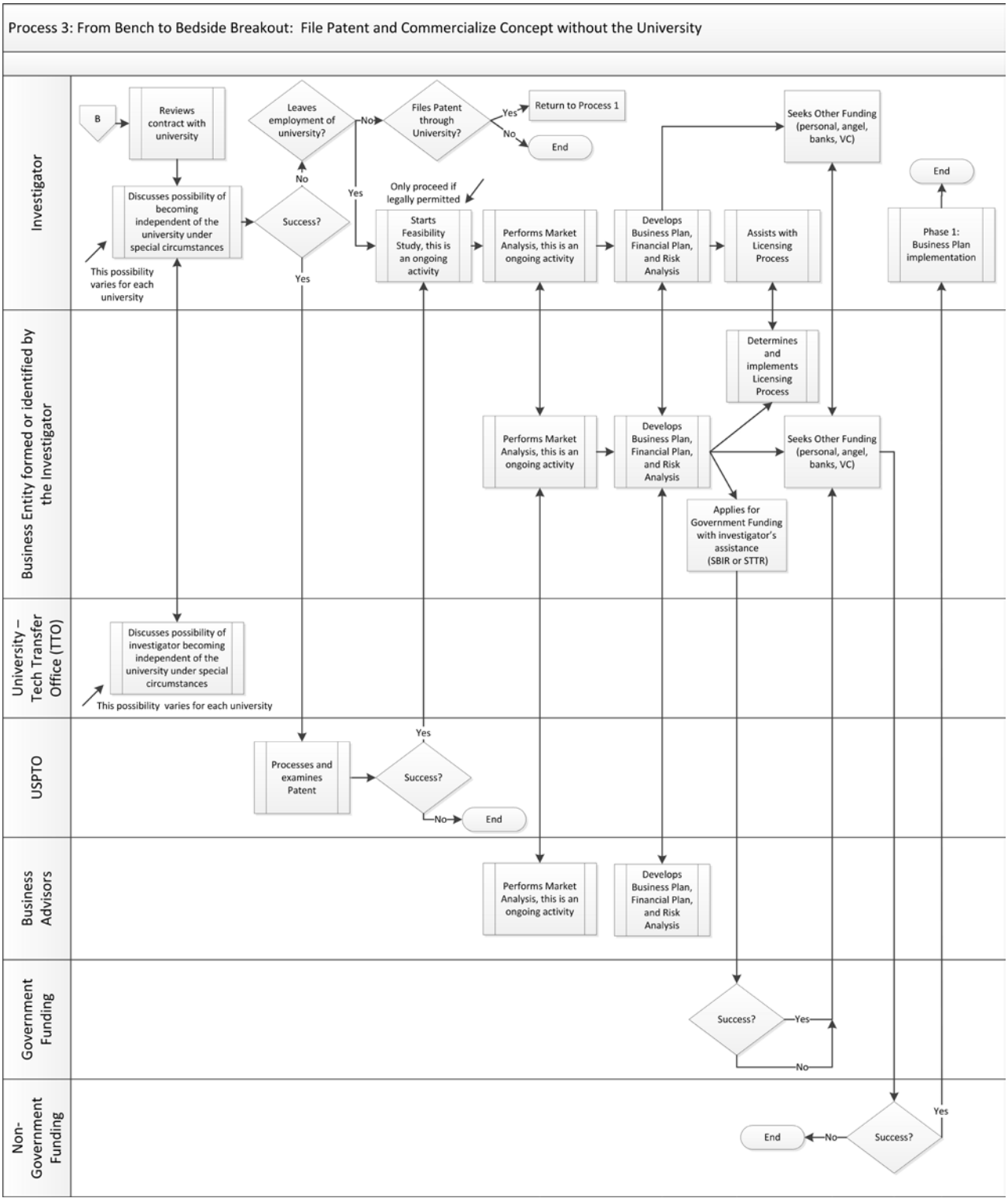


Figure 2-3: Process Flowchart (Commercialize Without the University)

2.2 Step-Action Table

The table below provides a written description of the process flow listed above.

Important: At a high level, this Step-Action Table provides an example of how a concept might progress from discovery to the initial stage of commercialization. This route will vary according to the unique requirements of concept development and the relationship between the investigators, universities and investors.

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>1</td><td>Discovery: You, the investigator, realize you concept has commercial potential.

You should know: “Concept” refers to inventions, ideas and processes.

Important: If possible, do not publish your concept before filing for a patent. Publishing is considered to be “any verbal, written, PowerPoint presentation” to those who have not signed a non-disclosure agreement. This requirement is often challenging because the academic community encourages and rewards publishing events.</td></tr>
<tr><td>2</td><td>Protect Intellectual Property (IP): Contact your university’s Tech Transfer Office (TTO) to:
File a formal invention disclosure form
Proceed through the TTO’s formal disclosure process
<table><tr><th>If</th><th>Then</th></tr><tr><td>The TTO decides to file for a patent,</td><td>Go to Step 3.</td></tr><tr><td>The TTO decides not to file for a patent,</td><td>You will end the process, or, in rare cases, explore the possibility of being independent of the university. This possibility will vary according to university policy and employee contracts.</td></tr></table>For Purposes of Clarification: The instruction sequence in this Step-Action Table assumes you, the Investigator, are working with your TTO. However, if you are independent of the TTO, these steps could be similar as they point to best practices in business analysis and development.</td></tr>
</table>

Continued on next page

2.2 Step-Action Table (continued)

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>3</td><td>
The TTO Files a Patent Application with the United States Patent and Trade Office (USPTO): It will be for a Provisional or Non-Provisional Patent; this will lock in the date of filing as the priority date. It is internationally recognized as a valid filing event.

Provisional Patent:
▪ Inexpensive compared to the Non-provisional Patent
▪ Minimal risk, will not be published
▪ Does not require a lot of detail
▪ Expires in one year, but the date can be extended

Non-Provisional Patent:
▪ Costly
▪ Formal process
▪ Will be published and reviewed by the USPTO
▪ Takes 2-5 years to issue, the patent is pending during this time

An example of the Patent Application process:
▪ The university submits the Patent Application
▪ The investigator reviews the Patent Application
▪ The university will own the Patent

<table>
<tr><th>If</th><th>Then</th></tr>
<tr><td>The TTO decides to commercialize the concept,</td><td>Please refer to Section 3.4 for more details. Go to Step 4.</td></tr>
<tr><td>The TTO decides to not commercialize the concept,</td><td>You will end the process, or, in rare cases, explore the possibility of being independent of the university. This possibility will vary according to university policy and employee contracts.</td></tr>
</table>
For Purposes of Clarification: The instruction sequence in this Step-Action Table assumes you, the Investigator, are working with your TTO. However, if you are independent of the TTO, these steps could be similar as they point to best practices in business analysis and development.
</td></tr>
</table>

Continued on next page

2.2 Step-Action Table (continued)

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>4</td><td>Research: You will work with the TTO to start the Feasibility Study; this is an ongoing activity throughout the commercialization process. Please refer to Section 3.3 for more details.

<table>
<tr><th>If</th><th>Then</th></tr>
<tr><td>The result is favorable,</td><td>Go to Step 5.</td></tr>
<tr><td>The result is not favorable,</td><td>The process ends or is paused until you and the TTO are ready to proceed again.</td></tr>
</table>
</td></tr>
<tr><td>5</td><td>Research: You will work with the TTO to perform a Market Analysis; this is an ongoing activity throughout the commercialization process. Please refer to Section 3.7 for more details.

You should know: Business Advisors can also assist with this process. Resources for locating Business Advisors are discussed in this document.</td></tr>
<tr><td>6</td><td>Design & Development: You will work with the TTO to develop the Business Plan. The Business Plan includes a Financial Plan and Risk Analysis. Please refer to Section 4.1 for more details.

You should know: Business Advisors can also assist with this process. Resources for locating Business Advisors are discussed in this document.</td></tr>
<tr><td>7</td><td>Design & Development: The TTO forms or identifies a business entity to commercialize the concept. This business entity could be, for example, a startup company or an established company that licenses the Patent.</td></tr>
</table>

Continued on next page

2.2 Step-Action Table (continued)

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>8</td><td>
Design & Development: You, the TTO, and the business entity will seek funding; this is an ongoing process determined by the financial demands of the commercialization process. Please refer to Section 5.0 and Section 6.0 for more details.

It will vary according to the unique requirements of concept development, the business entity, the investigators, the universities and the investors.

<table>
<tr><th>If</th><th>Then</th></tr>
<tr><td>Seeking a Government grant,</td><td>The business entity applies for SBIR or STTR grants. Additional funding will still be required either immediately or eventually.</td></tr>
<tr><td>Securing funding from other sources; these sources may include personal sources, angel investors, bank loans and/or Venture Capital (VC),</td><td>The business entity, the investigator and/or the TTO may need to seek funds from other sources. The process of commercialization may proceed regardless of whether or not a grant is secured.</td></tr>
<tr><td>Funding is not secured funding from other sources or you do not secure enough funding from all sources,</td><td>The commercialization process may end or be paused until the business entity or you or the TTO are ready to proceed again.</td></tr>
</table>

Important: This activity will vary according to the unique requirements of concept development and the relationship between the investigators, universities and investors.
</td></tr>
<tr><td>9</td><td>Design & Development: Begin Phase 1 of the commercialization process by implementing the Business Plan.</td></tr>
</table>

3.0 Discovery & Research

3.1 The Objective

The United States (U.S.) is the world's leader in life science Research and Development (R&D). Since our culture thrives on innovation, it is not surprising that we house some of the best academic institutions around the world. Within the U.S., the largest industry is the healthcare and pharmaceutical business. Despite its size and position of being the leader in the life science industry, the U.S.'s scientific and commercial productivity has declined. The industry is consolidating, profit margins are shrinking and healthcare costs are rising. The U.S. accounts for approximately one third of the world's investments in R&D with the federal government investing the largest amount into the R&D projects conducted by universities and colleges. It is in the societal best interest to encourage commercialization of innovations. The objective of this guide is to cultivate technological innovation by strengthening the pool of qualified health and behavioral science researchers, and to promote and encourage the small business community to participate in the R&D needs of the country.

3.1.1 The Hard Truth

Unfortunately for entrepreneurs and investors, the reality is that most new businesses fail. According to the research conducted by Shikhar Ghosh, a senior lecturer at Harvard Business School:

> "If failure means liquidating all assets, with investors losing most or all the money they put into the company, then the failure rate for start-ups is 30-40%. If failure refers to failing to see the projected return on investment, then the failure rate is 70- 80%. If failure is defined as declaring a projection and then falling short of meeting it, then the failure rate is a whopping 90-95%."

Pharmaceutical innovation is also becoming increasingly risky, costly and inefficient. Within the Life Science sector, 90% of new drugs fail to get to the market. McKinsey & Company estimates in its 2010 perspective on pharmaceutical R&D report, the average cost of bringing a new drug to the market is between $800 million to $2 billion. However, despite the challenges associated with commercializing life science research, the rewards can be life changing. Successful research can lead to disease eliminating medicine, new procedures and significant financial returns for the research organization(s) involved. These reasons encourage the need to provide additional tools and education to researchers to assist in successfully transferring technology to the market.

3.1.2 Technology Commercialization Defined

Technology transfers for viable commercial products are an important goal for universities and federal laboratories. Previously, these entities preferred to transfer their technology to big commercial partners whom have better resources to further develop the technology into a widely marketable product. But, that trend has changed. Now, universities and federal laboratories are increasingly gaining an interest in creating start-up companies for their technologies. This is because it's believed there may be more incentive for these types of businesses to focus towards commercializing the technology. A start-up company must be highly motivated to succeed due to the high risks involved, so it will likely expend all of its resources to meet the end goal.

3.1.3 Technology Commercialization Process

Typically, there is a multi-step process in commercializing inventions from universities or non-profit research institutions. Unlike pharmaceutical companies, these institutions are primarily engaged in basic research so they often lack the resources to bring their concepts to the market.

The Tech Transfer Office (TTO) is an excellent and valuable resource for university faculty and researchers. You, as the researcher, will need to work with the TTO when finding a discovery that shows commercial potential. The office is composed of specialists with scientific backgrounds who work in licensing, business development, new venture funding, intellectual property, and various legal matters. The TTO obtains intellectual property protection for new discoveries and markets them for commercial use. This is done either through licensing to existing companies or creating new start-up companies. An overall depiction of the described process is shown in figure below.

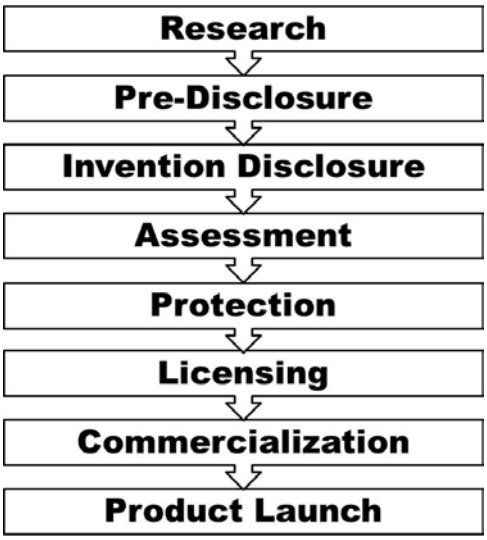


Figure 3-1: Technology Commercialization Process

Continued on next page

3.1.3 Technology Commercialization Process (continued)

Research: Laboratory and research facility experiments often lead to new discoveries and inventions (also referred to as 'concepts' in this document). An invention is defined by law as any useful process, machine, composition of matter (new material), or any new or useful improvement of the same. The work done during the process usually involves many individuals and not just one researcher.

Pre-Disclosure: Pre-disclosure is any early action taken by an investigator to contact the TTO for discussions regarding his or her invention or concept. The dialogue can include guidance, evaluation and protection procedures specific to the technology.

Invention Disclosure: Invention Disclosure is the written notice of invention submission to The Tech Transfer Office. This is a confidential document that records the invention so the options for commercialization can be evaluated and pursued. Depending on the type of discovery that has been made, there are several disclosure forms which are required for submission.

Assessment: Assessment refers to the period in which the investigator and the Technology Manager in the TTO:

- Review the invention disclosure
- Conduct patent searches (if applicable); and
- Analyze the market and competitive technologies to determine the invention's commercialization potential.

This initial assessment varies in time but usually takes about a month to complete. The manager in the TTO office will present the invention at a meeting of at least a technology manager, patent attorney, head of start-up support, and an investment fund manager. The evaluation process leads to strategy development on whether to focus on licensing to an existing company or creating a new business start-up. Sometimes the Technology Transfer office needs to wait until the investigator has more data available to support the invention.

Protection: Protection is the process of securing an invention. Patent protection begins with the filing of a patent application with the U.S. Patent and Trademark Office and, when appropriate, any foreign patent offices. Once a patent application has been filed, it will typically require several years and thousands of dollars to obtain issued U.S. and foreign patents. Other protection methods include copyright, trademark, trade secrets, and contractual use restrictions.

Continued on next page

3.1.3 Technology Commercialization Process (continued)

Licensing: A license agreement is a contract between the university and a company in which the rights to a technology are licensed, without relinquishing ownership, for financial and other benefits. A license agreement can be used with a new start-up business or an established company. When used, this agreement allows the university to maintain its commitment of providing the benefits of the research to the public while requiring the company to diligently develop the product at the same time. The university typically receives an initial licensing fee (the amount varies depending upon the stage of the technology's development and whether the company is a start-up or a well-established company), payments as the company achieves certain development milestones, and royalty payments when the company starts selling products. However, the non-monetary rewards of an invention reaching the market are often more significant than the financial considerations alone. For more information about licensing, please refer to Section 6.0.

Commercialization: The Licensee continues to cultivate the technology by going through the product development phase. Details on this 4 step process are as follows:

1) **Pharmaceutical Development:** The goal of pharmaceutical development is to develop novel or improved innovative high quality pharmaceutical products in a cost-effective way and to continue to support those products throughout their life cycle.

2) **Preclinical Testing:** At the preclinical stage of drug development, an investigational drug is tested extensively in the laboratory either in cell culture or in small animals to ensure that it is safe to administer to humans. Testing at this stage usually takes multiple years and provides valuable information about the chemical composition of the drug, its formulation, its manufacturing process, and how it will be used first in human subjects.

Continued on next page

3.1.3 Technology Commercialization Process (continued)

3) **Clinical Testing:** Testing of an investigational new drug (IND) in human requires submission of information about the drug and application to FDA. Subsequently, an institutional or independent review board (IRB) approval of the protocol is required to make sure the study will be conducted ethically. They will also monitor all signed informed consents from prospective volunteers, which is a requirement to conduct a clinical study. Clinical testing is performed in Phase I, Phase II and Phase III stages with increasing number of patients.

   a. **Phase I Clinical Study:** Phase I study is carried out on healthy volunteers to verify safety and tolerability of the candidate drug in humans. The study is performed on 20 to 100 volunteers in six to nine months to evaluate the safety, tolerability, Pharmacokinetics (mechanisms of absorption and distribution), and Pharmacodynamics (mechanisms of action and the effect of dosing) of administered drug.

   b. **Phase II Clinical Study:** Phase II studies are conducted on 100-300 patients and may last from 6 months to 3 years. In this study, investigational drug or placebo containing no drug are administered to randomly divided subjects to determine the safety and effectiveness of the drug in treating the condition. A Phase II study can be single blinded (patients do not know who is getting drug and who is getting placebo) or double blinded (patients and researcher both do not know who is getting the drug and who is getting placebo) to eliminate the bias of testing.

   c. **Phase III Clinical Study:** Phase III study is performed in a larger scale and typically involves 300-3000 patients. The goal of this trial is to test the effectiveness and safety of an investigational drug. They are usually multi-centered, randomized and blinded clinical trials. Phase III studies are very time consuming, costly to run, and difficult to manage. But, the goal of these trials is to help predict how the consumers will respond to the drug if it is sold in the market, which is obviously imperative.

Continued on next page

3.1.3 Technology Commercialization Process (continued)

4) **Regulatory (New Drug Application/Marketing Authorization Application):** After a successful phase III clinical trial, a new drug application is submitted to the FDA for marketing approval. This application contains documents describing manufacturing procedures, formulation details, shelf life and labeling of the drug for treatment.

If the Licensee is a start-up company, then the investigator can and should be involved in the commercialization process to ensure success. But, if the Licensee is an established company, then there are no requirements for the investigator to assist in the product development. However, the company may want the investigator's participation, as he or she has an intimate knowledge of the product. They may offer sponsorship for research in the investigator's lab or engage the inventor as an independent consultant.

3.1.4 Product Launch

After receiving FDA approval, the drug can be produced in large scales for distribution into the market. The manufacturing facility should be inspected and certified by FDA inspectors, and production should be carried out following good manufacturing practice (cGMP) to ensure safety and efficacy of the drug. Once the drug is created and properly labeled, it is ready for consumers to purchase in the market.

3.2 Identify the Concept

In general, university technologies are embryonic and achieving proof-of-concept is one of the biggest challenges. As a result, a large proportion of the technologies developed at the universities or federal laboratories do not see the light of commercialization. According to the Johns Hopkins Technology Transfer 2010 Annual Report, there were 409 invention disclosures, which led to 159 licenses and 19 start-ups. However, prior to proof-of-concept, recognizing a good start-up opportunity is also important to validate the idea. Unfortunately, it is not an easy task and the best commercialization strategy is often not clear. A big hurdle in licensing the technology to a start-up company is its chronically tenuous financial position. The ability to secure future capital to develop the technology in a timely fashion is not always known. Therefore, it is important for Bio-entrepreneurs to be motivated, knowledgeable, and skilled in all capacities.

Continued on next page

3.2 Identify the Concept (continued)

The goal for starting up a company is to identify and develop smart, fundable opportunities that can eventually create a sustainable and profitable business. For that purpose, a technology has to meet the following criteria to be a start-up opportunity: The technology has to fill a market need

- The market for the product is large and there is growth opportunity for the market
- Ideas has to be novel and smart so that it can be patented and is marketable
- In the long-term, a competitive product or product pipeline can be developed based on a strong platform technology portfolio
- Faculty inventors should be interested in commercializing their inventions and amenable to entrepreneurial guidance
- Licensing to an existing company should be discouraged

In general, The Tech Transfer Office has the manpower and tools to analyze these criteria and is ready to assist faculty inventors in this valuation.

3.3 Perform a Feasibility Study

The Tech Transfer Office conducts a Feasibility Study to analyze the viability of an idea. This investigation thoroughly examines all potential issues and assesses the probability of business success; therefore, it should be done before the Business Plan. The goals for performing a Feasibility Study are:

- Provides focus to the project and outline alternatives
- Narrows business alternatives
- Discovers new opportunities through the investigative process
- Identifies reasons not to proceed
- Enhances the probability of success by identifying and mitigating risks in the early stages of development
- Provides quality information for decision making
- Helps to secure funding for concept development
- Provides documentation that the business venture was thoroughly investigated

The Feasibility Study is a critical step in the business assessment process, but is not a part of the business plan. It addresses the question of business venture viability. A feasible business venture is one where the business will generate adequate cash-flow and profits, withstand the risks it will encounter, remain viable in the long-term and meet the goals of the institutions.

3.3.1 Why it may not work

Your concept may not pass the “sniff test” for one or more of the following reasons:

- The technology is still in its early stage and it needs to be further refined.
- There is lack of a niche market for the new technology.
- There are similar technologies out there in the market, which may bring intense competition and diminish chances for survival.
- Start up business is risky since there is no proven formula for success.
- Start-up business would be very costly and VCs may not be interested in funding.

3.3.2 Why it may work

The new innovation may work for one or more of the following reasons:

- This innovation will result in new product development not present in the market.
- It will lead to an increased demand in associated products already used in the market.
- The market segment for this product will grow decently or rapidly in future.
- It would lead to a very cost effective product.
- The technology is superior to the technology available in the market. So, it has a very good possibility of capturing increased market share and may replace the old technology.

3.4 Protect IP and Start Business Planning

Every invention must be protected before disclosure so that others cannot copy and receive benefits without paying any royalties to the original inventor (you). At a large non-profit institute, the TTO is responsible for evaluating the new technology or device made by an investigator. However, smaller institutes may contact law firms, which provide services to protect the invention. Once the TTO sees a commercialization potential of the technology, it will proceed by securing an intellectual property right of the invention known as a patent. An initial patent application is provisional and may last up to one year. During this time, you may improve the technology or initiate business planning. Before the expiration of the provisional application, you must file for a full patent application which will give you rights to exclude its use by others. This type of patent may take up to several years to receive but will provide up to 20 years of protection by the United States Patent and Trademark Office (USPTO). There will be more details on patents to follow.

3.5 Visit the Technology Transfer Office

Some of the roles and responsibilities provided by the Tech Transfer Office have been presented thus far. However, in the subsequent sections, the resources and services available to you through this group will be further discussed.

3.6 File for a Patent

The Patent Application process is a formal request to the United States Patent and Trademark Office (USPTO) to obtain a patent for the invention described in the filed application (note: again, the 'invention' is also referred to as the 'concept' in this document). This application contains detailed a description of the invention, its function (claim), and filing date.

According to USPTO, there are three distinctive types of patents: Design, Plant and Utility.

The Design patent consists of the visual ornamental characteristics embodied in, or applied to, an article of manufacturing. The difference between design patent and utility patent is: a 'utility patent' protects the way an article is used and works, while a 'design patent' protects the way an article looks.

The Plant patent is a patent granted to an inventor for a newly discovered and asexually produced a unique variety of plant, other than a tuber propagated plant or a plant found in an uncultivated state.

The Utility patent as described previously is a patent that protects the way an article is used and works. This new invention can be a new and useful machine, manufacture, process, or a new and useful improvement, and in this case a new composition of matter, such as drug.

3.6.1 Why is a Patent Necessary?

A successful patent application is essential for the commercialization of a new invention. Patents provide investigators with Intellection Property (IP) protection for the duration of the patent, which is for a period of up to twenty years from the date of the Patent Application filing. A successful Patent Application will offer you, the investigator, the following benefits:

- Allows the ability to establish a strong presence and position in the market
- Provides revenue through licensing and royalties
- Attracts investments to market and develop the new product
- Increases bargaining power during negotiation
- Provides up to 20 years of protection from patent infringement

---

3.6.2 Patent Application Process

The Technology Transfer Office (TTO) files a Patent Application with the United States Patent and Trade Office (USPTO). It will be for a Provisional or Non-Provisional Patent; this will lock in the date of filing as the priority date. This application is internationally recognized as a valid filing event.

Provisional Patent:

- Inexpensive compared to the Non-provisional Patent
- Minimal risk, will not be published
- Does not require a lot of detail
- Expires in one year, but the date can be extended

Non-Provisional Patent:

- Costly
- Formal process
- Will be published and reviewed by the USPTO
- Takes 2-5 years to issue, the patent is pending during this time

An example of the Patent Application process:

- The University submits the Patent Application
- The Investigator reviews the Patent Application
- The University will own the Patent

Although this process seems complicated, there are several key steps you can take that will streamline this complex procedure. As the primary investigator, it is important for you to identify these issues and proactively address them by answering the following questions on the patent application:

- What does your invention do?
- Have you disclosed this invention in any public places, meetings, classroom, conference, or class training?
- What patents and trademarks protect your intellectual property?
- To whom do they belong?
- When do they expire?
- How can they be used to impede potential competitors?
- Do other patents exist that could prevent or inhibit you from successfully entering the Market? If so, do you know who holds them, when they expire or if you could license them?

As an investigator, it is your responsibility to identify the key attributes of your invention, discover its uniqueness and protect it from public disclosure. More often than not, patents were rejected by USPTO after discovery of public disclosure by the inventor/originator in public seminars or speaking engagements.

Continued on next page

3.6.2 Patent Application Process (continued)

The key to a successful Patent Application is to determine the novelty of the invention, establish its uniqueness and be flexible during the application process – this is why it is important to announce your discovery to the TTO. The TTO within each university and college provides investigators with guidelines and assistance to bring the invention to market. It often has in-house patent groups that can review the invention to determine its potential. Therefore, it is crucial to reach out to them at the embryonic stage in-order to ensure success.

Based on information from the USPTO website, Figure 3-2 on the following page illustrates a detailed flow process for obtaining a patent for a specific invention.

Continued on next page

3.6.2 Patent Application Process (continued)

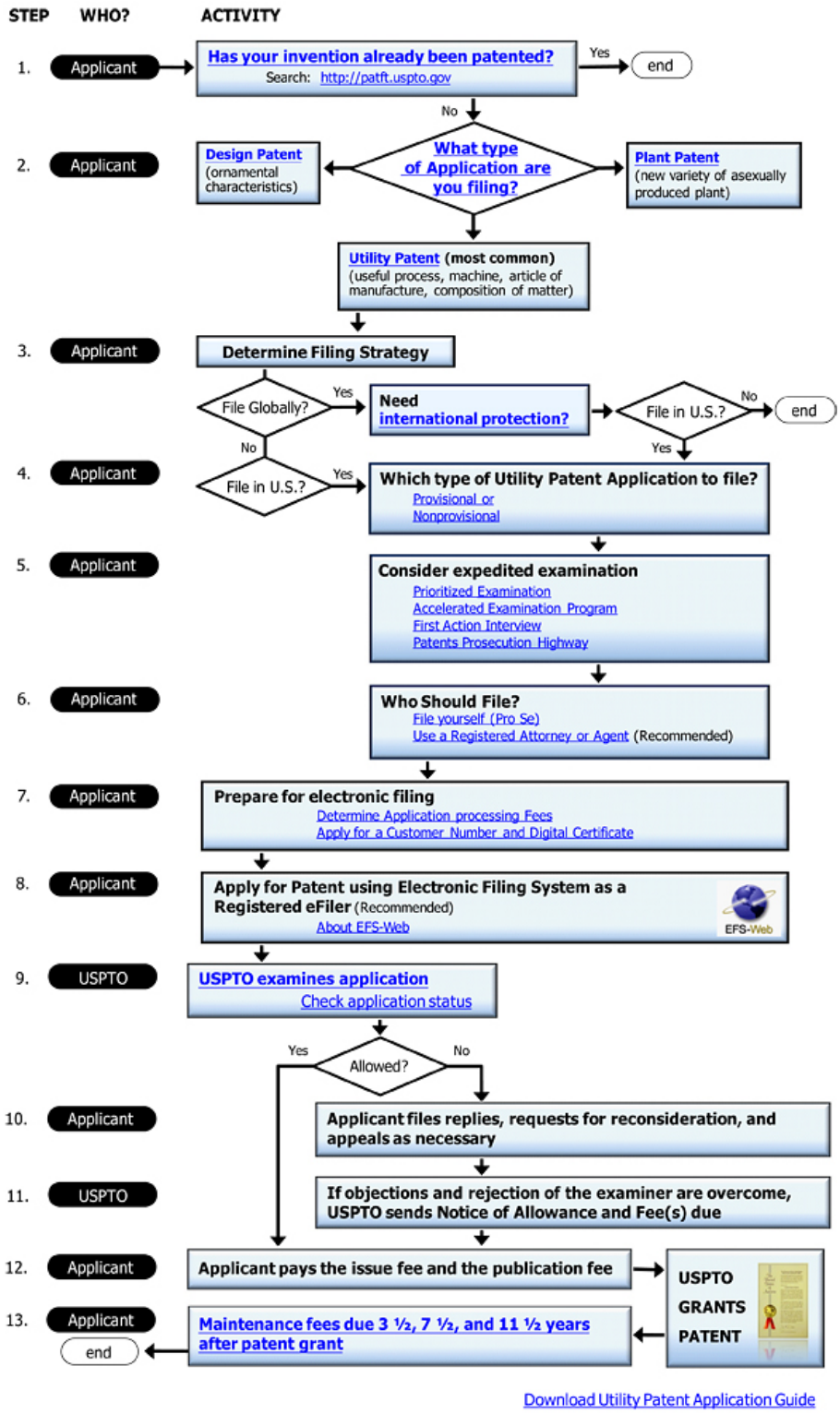


Figure 3-2: Patent Application Process (Source: USPTO)

3.6.3 Seek Legal Advice

Policies on conflicts of interest are inherent to every academic institution to ensure academic integrity and objectivity is not compromised. Naturally, these policies may different from one institution to another. Therefore, consult with your Tech Transfer Office when considering financial and/or fiduciary interests with outside entities. They will be able to guide you to the appropriate resource, such as an Outside Interests Office or similar working group, who will make certain you are in compliance with your institution's guiding principles. Interests include, but are not limited to, consultant work, personal financial interest, fiduciary responsibility, or research work involving a product for which you are named an inventor on a related license.

An Outside Interests Office should have a Review Committee whose objective is to protect the school and its faculty, staff and students from situations which involve risk. These risks may include: research safety and conduct; use of university resources for private financial gain; and the adverse impact personal outside interests can have on those in leadership roles. This office will generally assist with the following activities:

- Review disclosures and identify conflicts of interest
- Assess your professional commitment as an employee of the institution
- Determine whether the particular outside arrangement is acceptable or unacceptable per your responsibilities to the institution
- Provide feedback and management recommendations
- Review licensing applications

It is advisable to contact your Outside Interests Office as soon as you recognize potential to work in or develop interests outside of the institution. Doing this early in the process is recommended because it can alleviate or dismiss future hurdles which may arise.

3.7 Perform Market Research

Market research is an integral part of the discovery process that identifies your potential market through existing resources available both publically and privately. There are two specific types of market research: primary and secondary.

Primary Research: Primary research requires time-consuming surveys, face-to-face, in-depth interviews, or focus groups with participants/subject matter experts. This form of research allows the investigator to gather more industry-specific data from participants within the target segment. You are getting this research from the proverbial 'horse's mouth.'

Continued on next page

3.7 Perform Market Research (continued)

Secondary Research: Secondary research consists of publications, industry journals, professional articles, government data, census data and educational institution research data. For example, the University of Michigan conducts key monthly surveys that gather consumer spending and saving behavior as well as the degree of optimism on the state of the economy; this is compiled into the Consumer Sentiment Index. The Consumer Sentiment Index is monitored by manufacturers, retailers, banks and the Federal Reserve to determine inventory capacity, lending activity and interest rate.

The key take-away from these two different research methods is the underlying cost associated with primary verses secondary research. Primary research is time consuming and expensive, it also requires significant amount of resources and expertise to conduct proper interviews that extrapolate valuable and relevant information. Secondary research is inexpensive and can be done quickly and efficiently. Unfortunately, secondary research does not provide enough data to form an action plan; therefore, most companies use secondary research data to draw a framework for in-depth interviews and focus group studies.

3.7.1 Macro Environment

The Macro environment consists of external factors that are uncontrollable, but impact the organization's decision-making, performance and strategy. As the principle investigator, it is important for you to identify these on-going external factors and mitigate or minimize any potential impact they pose to your invention.

These external factors consist of economic, demographic, legal, social condition, geopolitical, technical and governmental changes. For example, in August 9, 2001, former President Bush enacted Human Embryonic Stem Cell Policy that restricted federal funding of stem cell research unless specific criteria are met. This severely reduced investigator’s ability to experiment, discover and treat diseases using embryonic stem cells. On March 9, 2009, President Obama issued Executive Order (EO) 13505 that revoked the restriction set forth by previous administration. It is important to understand these changes when discovering, applying and researching your invention, so that you can identify how these macro environmental factors can impact your research and go-to-market strategy.

Continued on next page

3.7.1 Macro Environment (continued)

In order to understand the macro environment, we need to understand PEST (as shown below).

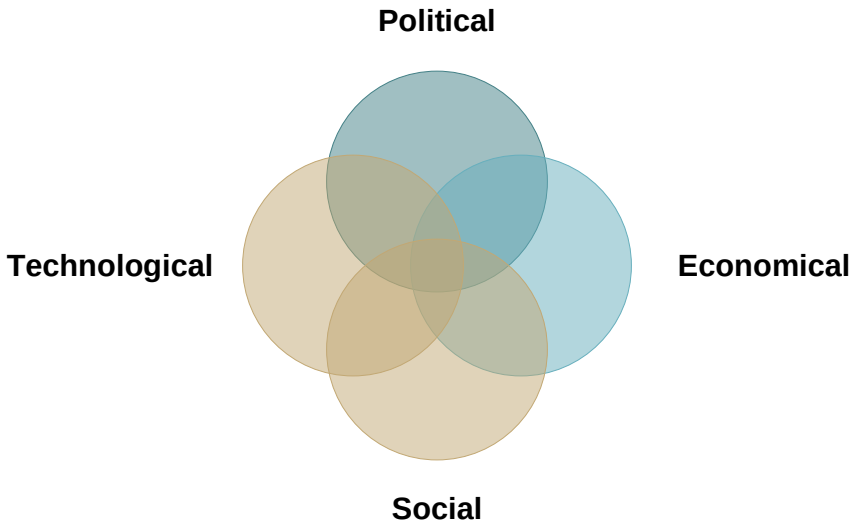


Figure 3-3: PEST

Political: Political factors come in many different flavors: tax changes, labor policies, environmental mandates and as previously discussed, and restrictions based on political party agendas. As the primary investigator, you must understand the impact of these political changes and how they can affect your business now and in the future.

Economical: Interest rate, economic cycles and global monetary fluxes can impact your investment, borrowing cost, expansion and growth plan. These changes can happen slowly over several years, or in a matter of days. For example, one of the major costs for the airline industry is the price of jet fuel, which is directly tied to the price of crude oil. If the price of oil skyrockets, what can an airline industry do to mitigate the increased cost?

Social: Green initiative, safety awareness and aging population, these social factors can affect business strategies and decisions. For example, Japan has one of the oldest workforces in the world. It is also facing a shortage of young workers in the construction field. In order to fulfill these positions, companies must offer higher wages to attract younger workers.

Technological: Personal computers, the Internet boom and the dot com bust left us with the imprint of a technology revolution, which created one of the most efficient workforces ever. You must take advantage of technological advancement because it can create a barrier to entry which will protect you and hinder your competition, enhance and streamline your production, and develop new innovation through collaboration.

3.7.1.1 Market Attractiveness

Market attractiveness is generally used to measure the total potential of revenue generated within that particular sector of industry. In order to determine the total potential of revenue, these attributes below must be evaluated.

Market size: Market size represents the total market volume of the identified product; this is one of the primary attributes of market attractiveness.

Market growth rate: Market growth rate identifies the total potential of market. A high market growth rate provides barriers to product substitution and increases the expansion of overall market.

Market profitability: Market profitability offers the investigator a general overview of product profitability under standard market conditions. High market profitability offers faster return-on-investment.

Pricing trends: Pricing trends provide the investigator an indicator of the strength of product pricing; a negative pricing trend indicates weakness in the offered product category.

Entry barrier: Barriers to entry provide the product with a certain level of protection from new entrants. A high barrier to entry requires a higher degree of capital expenditure to establish the market presence for new entrants.

Strength of demand: The strength of demand creates the demand curve that measures product demand within a specific industry. A higher strength of demand creates increased revenue and also provides a reference point for supply curve.

3.7.2 Micro Environment

The Micro environment consists of factors involve organization's immediate area of operation, which can directly impact its performance and decision. Figure 3-4 below illustrates the three key factors that influence the micro environment: Customers, Competitors and Core competencies.

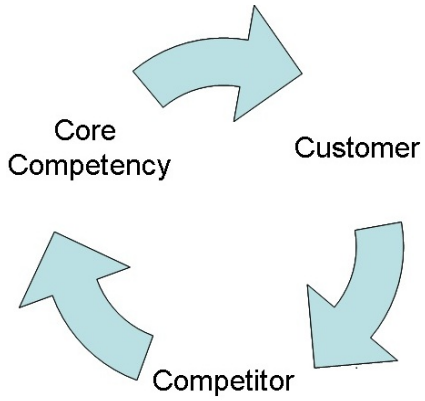


Figure 3-4: 3 Cs

These 3 Cs are the foundation within micro environment, in-order to establish successful market presence and develop market share within the industry, you must analyze these three key factors.

Customer: Customers are essential to a thriving business; they represent the building blocks in creating a successful enterprise. Customers represent the building blocks in creating a successful enterprise. The more customers you have, the greater will be your market share and revenue.

Competitor: If customers are the building blocks in creating a successful, thriving business, then competitors are the road blocks. If you do not take care of your customers, then your competitors will - and that is what you would expect from your competitors. In order to defend your market share, you must identify and understand your competitors.

Core Competency: According to Sun Tzu, author of *The Art of War*, 'If you know your enemies and know yourself, you will not be imperiled in a hundred battles; if you do not know your enemies but do know yourself, you will win one and lose one; if you do not know your enemies nor yourself, you will be imperiled in every single battle.' Once you have identified your competitors, it is important to know yourself. What are your strengths, weaknesses, opportunities and threats (SWOT)? The SWOT analysis is the fundamental tool to discover your core competencies. It allows you to assess and leverage your strengths and mitigate your weaknesses - while identifying opportunities within your market place and defending yourself against potential threats. The SWOT analysis tool is widely available through online resources.

3.7.2.1 Other Micro Environmental Factors

Customer, Competitors and Core competencies are the three most important micro environmental factors; however, there are other micro environmental factors that will impact business success. Figure 3-5 below provides an overview of the relationship between them.

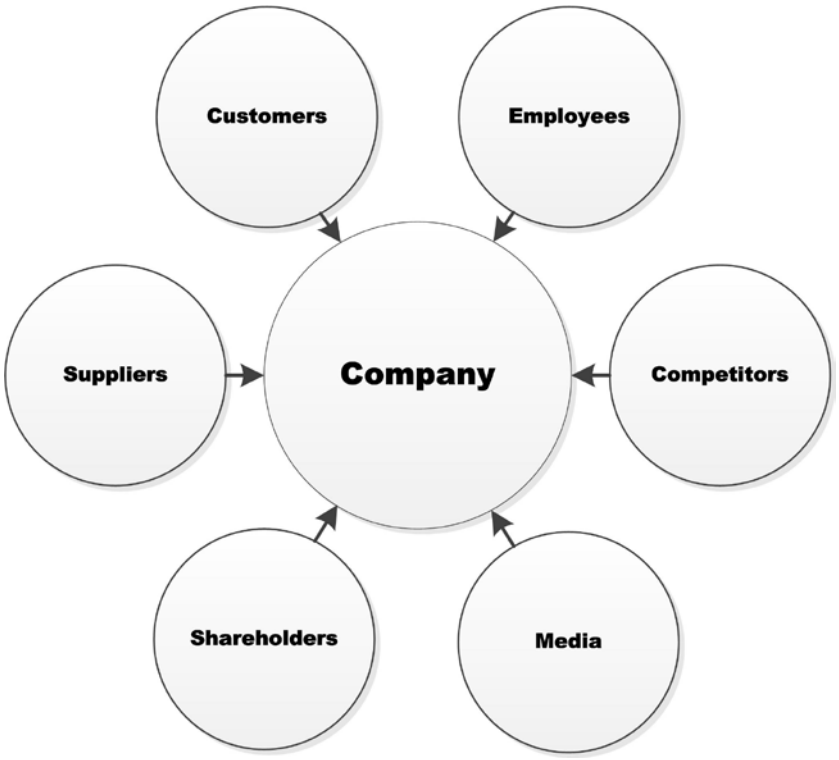


Figure 3-5: 3 Cs and Other Micro Environmental Factors

The company's core competency is the driving force for the remaining contributing factors. Customers and competitors will have the greatest impact to the overall market share and revenue; however, employee, suppliers, shareholders and media will also affect the overall direction and strategies implemented.

Employees: Employees are the foundation for a successful company; they are the heart and soul of the business: take care of your employees and they will take care of your customers. While innovation and creativity are the differentiating factors between you and your competitors, your employees will be the driving force behind this innovation and creativity.

Continued on next page

3.7.2.1 Other Micro Environmental Factors (continued)

Media: Media plays a major role in corporate and product branding. An increase to product and company awareness will correlate to an increased market share; which will also increase revenue. However, the reverse also holds true; negative publicity or fallout could severely damage or cripple the company. For example: In October 1982, Tylenol was the leading pain-killer in the country with approximately 37% of the market share. Unbeknownst to Johnson & Johnson, someone had tampered with the bottle and placed cyanide in the capsules; this amount of cyanide was 10,000 times the dosage needed to kill a human. Media caught-on to the story and spread like wildfire. As a result, Johnson & Johnson's market share plummeted from 37% to just over 9%.

Shareholders: Shareholders offer financial support to the company, but sometimes they become a hindrance. Shareholders are focused on the success of the company; such as increased revenue and profit and decreased cost; which in-turn can increase their stock value. Unfortunately, some shareholders are only focused in stock value and they do not share company's vision or future. Pressure from these types of shareholders can negatively impact corporate strategy and direction.

Suppliers: Suppliers provide the raw material for the company. Although suppliers have the least impact to the overall success of the company, without proper supply chain in place, a company cannot meet the customer's demand.

3.7.3 Competitive Analysis

Competitive Analysis is the process of identifying and examining companies in your market area or sector of industry that are established providers of products or services which compete with your business for a share of the market.

Conducting a Competitive Analysis for both for-profit and not-for-profit ventures should be undertaken because your competitors could be in either or both categories. If you believe your concept or product is so unique that it does not have competition, you are likely to be wrong. Emerging technologies and start-ups enter market sectors that nearly always have established sources of products and services that are accepted by consumers. Some are "good enough" to deny a better product's acceptance, while other competitive products have matured to yield cost and distribution advantages, licensing and regulatory status, and branding recognition of end-users.

Continued on next page

3.7.3 Competitive Analysis (continued)

An intensive examination of your major competitors is the foundation of a Competitive Analysis. For example, some competitors may have well-established offerings while others may have emerging technologies of their own that will challenge your offering. Remember to be thorough, for some investors who specialize in a particular market segment will often know your chief competitors, sometimes better than your Competitive Analysis reveals. If you decide to limit your analysis to a few competitors, you should justify why these few competitors were chosen for analysis, and identify discriminating factors that distinguish your offering from theirs. The analysis should focus on what your competitors offer; how they operate and behave in their competitive landscape against others (e.g., will one of your competitors buy your concept, IP and organization); and how you will develop a competitive advantage that positions your concept or product in a clearly beneficial arrangement that will differentiate you from your competitors.

The Competitive Analysis identifies your competitors' strengths, weaknesses and vulnerabilities in a way that enables you to formulate a comparison matrix that illustrates how you will meet their challenges and overcome their established market position with your concept or product. When properly constructed, the Competitive Analysis is as much an offensive strategic view as it is a defensive strategic outlook that assists in building your strategic plan. It also serves as a gauge to measure, monitor and maneuver your performance against your competitors during the crucial phases of commercialization and market penetration.

The data gathered for your Competitive Analysis should not be based on notions, speculation or anecdotal evidence; it must be based on a rigorous collection of facts, behavioral observations and empirical data of your competitors. Resources used to gather competitive information include stockholder reports, press releases, tradeshows and trade journals, technical papers, distributing partners, end-user surveys, government reports (e.g., investigative and regulatory filings), patent filings and subject-matter experts.

While the Competitive Analysis can be summarized in textual fashion, it is often illustrated in a matrix of competitors that compare or contrast their strengths, weaknesses, core competencies and performance against your own. Your competitive matrix should include:

- A concise definition of the industry you are entering (the example below uses Implantable Therapy for Transient Radiological Immunity)
- Your major competitors (the example uses notional companies ABC, DEF, GHI…)
- Your customers and their requirements and/or expectations (evaluation factors)
- The vital factors that determine success in your market segment (evaluation factors)
- How well each competitor performs to factors relevant to the business segment
- Whether or not your concept or product fills gap in the market that your competitors are not filling; this can be included with appropriate justification

Continued on next page

3.7.3 Competitive Analysis (continued)

For example, if your product is a new device that provides an automatically controlled dose of medication for radiological immunity by preventing cellular damage to first responders who enter areas of high radiation, this factor could be considered as a discriminating factor in your competitive matrix. However, you must consider that your competitors offer conventional medications for pre-treatment and post-treatment, the side-effects of which are mitigated by your new product. The factors for each competitor can be numerically rated against yours to produce the competitive matrix; or they can be situated on a table according to their scores and yours to show the organization and product in the most favorable situation/location for success. This example is illustrated in the following Sample Competitive Matrix, Figure 3-6:

Competitors Compared to ABC's Product

Evaluation Factors	DEF	GHI	JKL	MNO	STU	ABC
• Market Share	5	1	3	2	0	0
• Product Maturity	3	4	2	5	1	4
• Brand Recognition	4	2	3	1	0	0
• Customer Benefit	1	4	5	2	3	5
• Side Effects	1	3	4	2	X	5
• Pre-treatment Cost	1	2	3	5	4	4
• Post-treatment Cost	4	1	2	3	3	5
• Life Cycle Cost	1	4	2	3	X	5
• Dose Stability	2	1	4	5	3	5
• Dosage Effectiveness	2	1	3	4	4	5
• Medical Intervention	2	3	4	1	5	4
• Distribution Partners	5	3	4	2	1	1
➢ Ranking Score	2.58	2.42	3.25	2.92	2.00*	3.58

Competitive Matrix: Implantable Therapy for Transient Radiological Immunity
Ranking: 1 = lowest/weak; 5 = highest/best; Score/12 equally weighted factors

* Incomplete data on STU from lab trials and beta tests; product pending approval

Figure 3-6: Sample Competitive Matrix

In this example of ABC's Competitive Analysis, an emerging company, STU, received a "0" as did ABC because neither had Market Share of Brand Recognition as start-ups without sales. STU was also given "X" because no data was available on Side Effects or Life Cycle Cost. The companies are rated from 1 to 5 to against ABC, and averaged by Ranking Scores.

3.7.4 Decision Gates

The Product Development Institute has created a 'Stage Gate' system to apply to the proposed process of moving a concept to commercialization. In essence, a 'Stage' relates to the phases in the process where work is executed by you, the investigator, your colleagues and/or other stakeholders. Deliverables are created as the outcome of the work performed in each phase and analysis.

The 'Gate' is the decision point. Deliverables are analyzed against a set of established criteria (or a checklist). Depending on the success of meeting your checklist, you can prepare for the next stage by deciding to either move forward, stop the concept at the particular phase, or re-evaluate/re-shape your strategy before taking the next step. In addition to identifying the criteria and deliverables, be sure to use the financial evaluation tools during your analyses.

As a precursor to using this model, identify who will make decisions at each gate. Concurrence from decision-makers should be received prior to moving forward to the next phase. Figure 3-7 below illustrates a high-level application of Decision Gates to the process presented in this Guide:

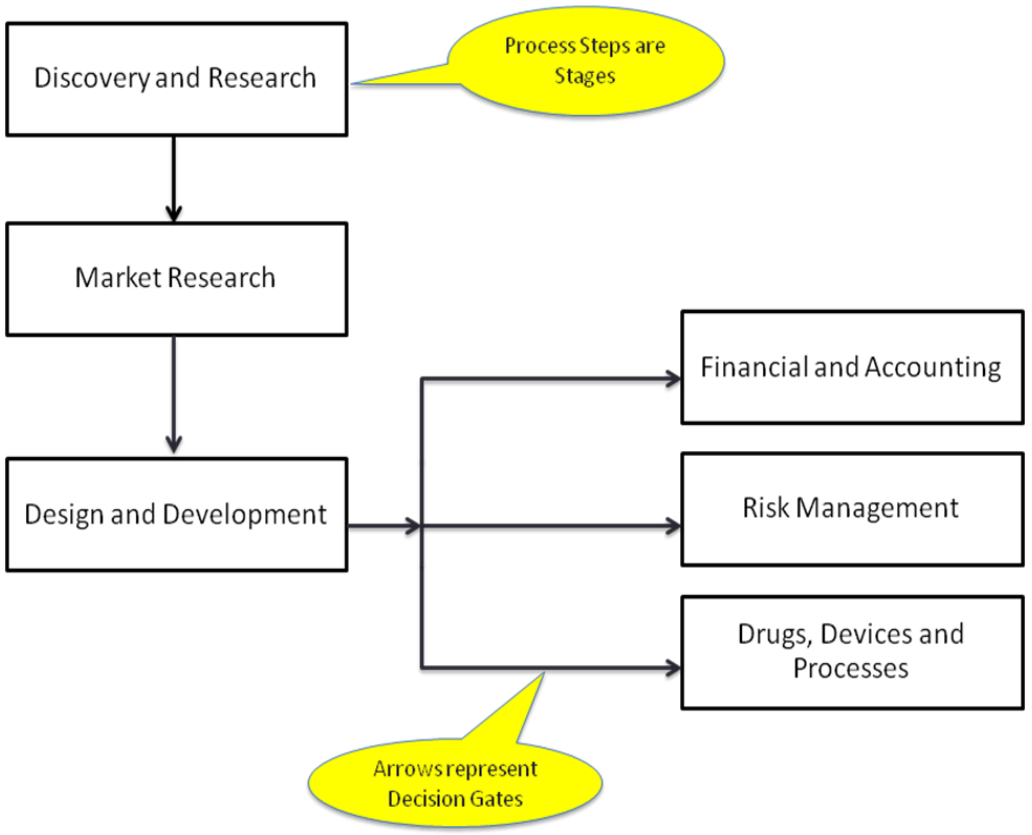


Figure 3-7: High-level application of Decision Gates

Continued on next page

3.7.4 Decision Gates (continued)

The activities that are performed in each phase of the process are detailed in the sections of this document. The collective output produces deliverables such as clinical trials and related results, prototype descriptions and related analyses of prototypes, and process descriptions. Upon completion of each phase, demonstrate your objectives were met by comparing that phase's output to your criteria for success.

The criterion refers to the checklist of items and measurement of success may be quantitative or qualitative. For example, in a clinical trial, steps and success rates must meet Government mandates. For a process, the measurement may be determined by a customer satisfaction survey or the time it takes to complete processes. Therefore, you must develop the criteria/checklist for each phase in order to assess the decision points that permit you to pass through the Gate, and move to the next stage.

Note that the first three phases in the figure above are the most important Decision Gates due to the amount of work executed within each; these are also sequential phases. The next three phases may occur in parallel; however, the output and analysis from any of these may lead to a decision to stop or hold the project until additional work is completed.

The Nature Publishing Group provides a Decision Gate guideline for non-clinical drug development. In this guideline, the authors define the two most important Decision Gates as being 1) the ability to administer the drug to humans, and 2) the marketability of the drug. In this example, the first Decision Gate depends upon clinical proof-of-concept studies and results; and the second Decision Gate depends upon multiple stakeholders; such as Government health regulators and clinical investigators.

For additional resources, please refer to the Appendix: Resources for Investigators.

3.7.5 Networking

"It's not what you know, it's who you know." Effective networking is essential to business development because it involves building relationships with others. These relationships, in turn, build trust and confidence in both you and your business; subsequently, others feel a sense of loyalty to you. This type of relationship is built over time, and it is fundamental to business development. In today's high-paced and virtually-connected business society, networking online is as important as networking in person. It provides your personal brand or your business a presence.

Networking through the Internet can be accomplished using these various web tools and sites:

- LinkedIn. It is your profile of record, including a personal and business bio. It is an excellent networking arena.
- RSS reader. How can you network with others online if you are not aware of what others are talking about? RSS reader, which stand for Really Simple Syndication, is a group of web feed formats used to publish frequently updated works, such as blog entries, news headlines, audio, and video in a standardized format.
- Blogs. This can be an excellent resource to grow professionally and from a business development standpoint.
- Twitter. Twitter is possibly the single biggest personal branding tool since the television. Twitter provides a powerful information network and relationship building tool.
- Facebook. Facebook enables one to enhance their relationships with close business associates.
- Google+. No one has a firm grip on where Google+ is headed; however, there is no question it's here to stay and is going to influence search and discovery of information and people.

For additional resources including books on networking strategies, please refer to the Appendix: Resources for Investigators.

4.0 Design & Development

4.1 Develop the Business Plan: What is a Business Plan?

The Business Plan formally details your business goals, why they are attainable and how they will be executed. It includes a cover page; summary; mission statement; milestones; market analysis; competitive analysis; business development strategy; details about products and services; marketing and sales strategy; operations plan and financial plan.

Investors are your target audience because the Business Plan is a key to securing initial and subsequent rounds of funding. It provides the mechanism through which investors determine how and why the commercialization process of your concept is worth their investment. The process of writing the Business Plan will enable you to communicate a compelling strategy for your concept as it applies to consumer demand and the competitive market. It also provides a track and milestones for you and your investors to follow in the early stages of business development.

Completion of the Business Plan helps you develop two presentations that summarize your product and business objectives: Executive Summary (1-2 pages) and a 30-60 second “elevator pitch” (a verbal statement of purpose conveyed in the length of time it takes to ride an elevator). The Executive Summary is a component of the Business Plan. The elevator pitch can be a combination of your Mission/Vision Statements and the Executive Summary. These pitches are useful communication tools for recruiting managers, directors and employees to your business.

4.1.1 Why is a Business Plan needed?

Commercializing a concept requires more than scientific brilliance. The Business Plan requires you, the investigator, to be aware of all of the mechanisms that allow your concept to reach a broader audience.

When executed successfully, your Business Plan will convince investors that your concept’s commercialization plan is well-researched, viable and meets a legitimate need. Also, the this working document bridges the gap between business and science because it presents your concept in terms investors will understand, regardless of their scientific background.

Continued on next page

4.1.1 Why is a Business Plan Needed? (continued)

The Business Plan identifies the steps needed to bring your concept to commercialization; this includes the action plan, identification of required resources, and milestones of what you expect to reach over the next several years. Once your strategy is identified, you will be able to allocate your resources according to a strategic priority. It should efficiently answer the questions:

- What is the concept, product or service; including the evidence that suggests it will be viable?
- What is required (time, resources, and strategy) to develop and implement the commercialization of your concept, product or service?
- How will development be staged; including milestones and risk mitigation?

Important: Consider the Business Plan to be a living, strategic document that is reviewed and updated regularly because it details your action plan and pinpoints your milestones. Use it to identify and maintain a schedule for meeting milestones and implementing alternate strategies if milestones cannot be met. Remember that without a clearly defined strategy, businesses are not easily able to recalibrate their direction and commercialization plans when difficulties arise.

4.1.2 Who writes the Business Plan?

Typically, the Business Plan is written or outsourced by the founder of the business/concept or the owner(s) of the new company. It can also be written by professional writers or business consultants. If you are writing or assisting in writing the Business Plan, many resources are available to guide you. The initial step is to consult with your TTO. Second, you can seek the council of your academic institution's librarian for resources about market, industry and competitive analysis.

Best Practices: Remember your audience includes readers with scientific and non-scientific backgrounds; keep your Business Plan simple and focused; be objective; continually review and revise the document as needed.

Mistakes to Avoid: Do not submit a rough draft of the Business Plan; use outdated financial or industry comparisons; or exhibit a lack of understanding with financial information.

For additional resources, please refer to the Appendix: Resources for Investigators.

4.2 Business Plan Structure

Business plans vary in their structure based on the needs of the plan and the industry it applies to. A sample structure is detailed below. It incorporates universally applied components as well as components that are specific to the health industry.

- Cover page
- Executive Summary
- Mission Statement & Vision Statement
- Concept (also known as the Product)
    - Description – what it is
    - Why is it unique?
    - Who will need it?
    - Why will they need it?
- Market Analysis
    - Market overview
    - Market changes
    - Market segments
- Target Market
    - Target market size
    - Customer characteristics
- Competitive Analysis
    - Competitive landscape
    - Changes in the industry
- Marketing Strategies
- Patents & Trademarks
- Property & Facilities
- Research & Development
- Government Regulations
- Insurance & Taxes
- Organization & Management
- Risk Factors
- Financial Projections

4.2.1 Cover Page

The Cover Page catches the attention and interest of investors at first glance by presenting a one-page summary of the Business Plan's critical components. Key points when developing the Cover Page include:

Headline: Briefly conveys what your concept is and why it is newsworthy. Writing a Headline may seem like a simple task, but the challenge lies in the effect it has on the reader. The measure of effectiveness is in the reader's response and whether or not their response matches your objectives. Remember that some of your investors may not have the scientific background to understand extremely technical language. Ask people in your field, related fields and unrelated fields if your Headline would cause them to want know more about your concept. Additionally, ask them what they think the Headline is trying to say. If they say they want to know more, be sure it is because their understanding of your Headline accurately perks their interest; not because they are confused. In essence, your Headline should objectively convey what is game-changing about your concept, and it should compel your audience to want to continue reading.

Company Name: Remember that while you must include your company name, it is not as important as the Headline. Therefore, it does not have to be the most prominently displayed text on the Cover Page.

Company Summary: A paragraph that describes your business and what it proposes to do over the next five years and a brief description of your industry, if applicable, related industry trends.

Concept and competition: Briefly describe your concept and how it will be accessible to consumers after it is commercialized. Identify the resources required (such as financing, approvals, suppliers) to bring your concept to commercialization, and the competition your concept currently faces.

Management: List several key people in your management team, and include a brief description of their backgrounds and the skills they will apply to your business; this is to convince investors that your Management team is uniquely capable of implementing your concept's commercialization process.

Also include: Table of Contents; contact information; the date; industry category or market; the word "CONFIDENTIAL;" your logo (optional); current business stage; copyright notice; funds requested and collateral; and financial data.

Important: The Cover Page is oftentimes the first impression investors have of your business.

4.2.2 Executive Summary

After the Cover Page, the Executive Summary is the next opportunity to catch the attention of your investors and convince them your concept is worthy and ready for commercialization. Potential investors will often request a copy of the Executive Summary before they decide they are interested in the Business Plan. The Executive Summary can also be used to convince potential managers and employees to join your company.

The Executive Summary is written after the Business Plan is complete. It is a one or two-page summary of your concept-to-commercialization strategy. It discusses the opportunity, concept, market, competition, intellectual property, management team, use of funds to-date, funds being requested and how they will be used, and exit strategy.

The introduction of the Executive Summary can also be used as your "elevator pitch" (a verbal statement of purpose conveyed in the length of time it takes to ride an elevator). The elevator pitch answers the following questions:

- What is your business name?
- What is the problem your concept solves and how many people have this problem (what is the market segment)?
- What is your concept and how does it solve this problem?
- Why are you and your company qualified to solve this problem and commercialize your concept?
- What is your realistic summary about the potential profitability of your business?

Investigate effective and ineffective elevator pitches to ensure your pitch is effective. The introduction should also include the current status of your commercialization effort, funding-to-date, and your required next-phase of funding. Also, memorize and practice your elevator speech so it results in a natural and concise delivery to investors.

The remainder of the Executive Summary will summarize the key points of your Business Plan. As discussed above, these points generally condense the opportunity, your concept, the market, competition, intellectual property, management team, funds used to-date, funds requested, plans for using requested funds and your exit strategy.

The closing statement of the Executive Summary is as important as the introduction. It should tell investors why they should continue reading your Business Plan, and it should compel them to want to continue.

Important: The effectiveness of the Executive Summary can determine if potential investors will read the remainder of your Business Plan. Writing the Executive Summary will also clarify your "elevator pitch." Memorize and practice your "elevator pitch" so it is easy to convey to all audiences.

4.2.3 Mission Statement & Vision Statement

Essential components of the Business Plan include concise statements on your business' mission and your vision of its values, growth, customers and contributions. While both statements are results-oriented, they have different purposes.

Mission Statement: Describes your business purpose and strategy; how it performs, and how your customers are regarded. The process of developing your Mission Statement begins with a short version (as few as two to three sentences, but sometimes more) of your business' strategic purpose; this is best captured from a customer's view. In general but assertive terms, a mission statement addresses the following questions:

- What does our organization do? Consider your central purpose and/or key deliverables at a high-level.
- Who do we serve? Ask yourself who are your customers, end-users and/or beneficiaries.
- What are our primary objectives? You need to define the key metrics to measure your success.
- How do we do it? Include characteristics that differentiate your product and your company's strategy from competitors.

Vision Statement: Describes your view of how the business will serve its customers; how it will grow and sustain its place in the market; its core values; your customers' values; and how your stakeholders will benefit. Begin by concisely defining your vision. Then, develop strategies that will inspire your organization to implement your vision. Revisit your Vision Statement to improve its precision and to ensure that your strategies are well-aligned with your vision and mission. After your Vision Statement is complete, revisit your Mission Statement to confirm that it complements your vision.

Important: Do not underestimate the importance of Mission and Vision Statements. They will provide guidance during difficult phases, and milestone reviews.

4.2.4 Concept (also known as the Product or Invention)

The Concept section of the Business Plan describes your concept in both technical terms, for investors with a scientific background, and non-technical terms, for investors that do not have a scientific background. It should efficiently answer the questions:

- What is your concept?
- Why is it unique?
- Who will need and why will they need it?
- What void will it fill in the current market?
- How will it be produced?
- How will it be used by end-users?

For more details, please refer to Section 3.2.

4.2.5 Market Analysis

The Market Analysis section describes the Market Demand for your concept, product or service. According to "Marketing Management" by Philip Kotler and Kevin Lane Keller, Market Demand is the "total volume of a product that would be bought by a defined customer group in a defined geographical area in a defined time period in a defined marketing environment under a defined marketing program." The Market size is determined by the total annual sales of products that meet the customer's specific need. Key action items in performing a Market Analysis include:

- Describe the industry; include current and future industry trends
- Detail how your business fits into this industry; include barriers to entry
- Identify the Market size, growth rate, and the competition within the Market
- Identify Market Segments that could need your business
- Describe your business' competitive advantage

The Market is influenced by: its size and growth rate; the nature and price of your concept, product or service; the expertise of the sales force; frequency of product switching; and the nature of the competition.

Important: The size and growth rate of the Market can be indicators of future profitability. Be careful not to overestimate the potential Market penetration of your concept, product or service. If you do not identify similar concepts, products or services within your Market, examine similar Markets, or similar concepts, products or services.

For more details, please refer to Section 3.7.

4.2.6 Target Market

The Target Market section identifies and describes the market that will purchase your product. According to "Marketing Management" by Philip Kotler and Kevin Lane Keller, the Target Market is the "part of the qualified available market the company decides to pursue." The Target Market portion of your Business Plan should efficiently answer these questions:

- How large is Target Market?
- How fast is it growing?
- How many people or businesses are using competitor's equivalent products or services?
- What are the customer characteristics; including their frequency of switching products and brand loyalty?

For more details, please refer to Section 3.7.

4.2.7 Competitive Analysis

The Competitive Analysis section outlines your competitive position in the market. Competitive Analysis is the process of identifying and examining companies in your market area or sector of industry which are identified as established providers of products or services competing with your business for a share of the same market.

Competitive Analysis is an intensive examination of your major competitors' strengths, offerings and vulnerabilities. This examination forms a basis to compare your concept or product in the market area that is currently dominated by established competitors; and it helps you identify weaknesses and strengths in your business. The Competitive Analysis portion of your Business Plan should efficiently answer these questions:

- Who are the competitors? If there are no competitors, explain why.
- How is your concept, product or service better; including all differentiating factors? Explain why customers would prefer your product.
- How will competitors react to your entry into the Market? Explain how you will respond to their reaction.

Important: Be sure to acknowledge your business' weaknesses as well as its strengths in your Business Plan; this will demonstrate objectivity and realism.

For more details, please refer to Section 3.7.3.

4.2.8 Marketing Strategies

The Marketing Strategies section outlines your Strategic Marketing Plan. According to "Marketing Management" by Philip Kotler and Kevin Lane Keller, the Strategic Marketing Plan lays out "target markets and the value proposition that will be offered, based on analysis of the best market opportunities." A value proposition "that will be offered" encompasses the total benefit your concept, product or service promises to deliver to the Target Market.

For more details, please refer to Section 3.7.

4.2.9 Patents & Trademarks

The Patents & Trademarks section explains how your business protects its intellectual property from competitors, and how this protection will enable the commercialization of your concept, product or service. Consider answering following questions in the Patents & Trademarks portion of your Business Plan:

- What patents and trademarks protect your intellectual property?
- To whom do they belong?
- When do they expire?
- How can they be used to impede potential competitors?
- Do patents exist that could prevent or inhibit you from successfully entering the Market? If so, do you know who holds them, when they expire or if you could license them?

For more details, please refer to Section 3.6.

4.2.10 Property & Facilities

The Property & Facilities section outlines details regarding the facility which houses the business. Describe the type of space required and the costs. The costs include the lease and lease hold improvements. In addition, outline the terms and condition of any leases with the length and terms. Be sure to include any pertinent information regarding the property.

For more details, please refer to the Appendix: Resources for Investigators.

4.2.11 Research & Development (R&D)

The R&D section outlines strategies for introducing new products and services; describes techniques for conducting research; and discusses plans for product development. For example, if you offer consulting services based on a government agency's activities, part of your R&D strategy might be to review all of the agency's publications; make personal contacts within the agency; and attend all of the agency's public functions. The knowledge gained from this strategic activity would enable you to be prepared to offer services that meet new regulations and requirements.

For more details, please refer to the Appendix: Resources for Investigators.

4.2.12 Government Regulations

The Government Regulations section explains the government regulations which are pertinent to the business. The business must comply with these are regulations in a cost-effective manner. Questions that you, as the business owner, should consider:

- Industry: What are the Government Regulations for this industry? Remember, it is best to error on the side of caution.
- Licensing: What are the Federal, State, County and City Licensing Regulations?
- Zoning: Can you operate your business where you want?
- Environment: Are there Environmental Protection Agency (EPA) standards you must comply with regarding pollution, toxins, proper waste disposal for your product or byproducts?

For more details, please refer to the Appendix: Resources for Investigators.

4.2.13 Insurance & Taxes

The Insurance & Taxes section addresses the product and personal liability. State whether or not all taxes are paid and are current. In addition, state the status of other taxes paid by the company, such as example payroll, Social Security and corporate taxes. Questions you should address:

- Is there a Key employee insurance to support a buy-sell agreement or succession plan?
- Are all taxes current?
- Do you need special insurance?
- How will you protect your assets?
- Are their additional taxes on your product? Are there sin taxes?

For more details, please refer to the Appendix: Resources for Investigators.

4.2.14 Organization & Management

The Organization & Management section provides a detailed depiction of the organizational structure of the company. The organizational structure is the framework of the company's management structure by hierarchal structure and authority lines. This section offers details about the ownership of your company, profiles of your management team, and the qualifications of your board of directors. Be sure to provide a detailed description of each division or department, and its function.

For more details, please refer to the Appendix: Resources for Investigators.

4.2.15 Risk Factors

It is important for a business owner to identify potential risk factors associated with the business, and to be as transparent as a possible with the person reading their Business Plan; i.e., a potential investor. Disclosing risk builds credibility with investors and provides protection against some liabilities. There are common risk factors that should be included in most Business Plan such as:

- Recurring revenue
- Operating profitability and history
- Economic uncertainty
- Accuracy and details of financial records
- Effects of related party transactions
- Need for dilution and additional funding risk
- Lack of liquidity and public market
- Voting position
- Need to retain key employees
- Adverse changes, cost changes, management effectiveness, improvement cost changes
- Effects of contracts and transactions
- Sale and purchase agreements
- Notes and loans
- Effect of affiliates and related party transactions
- Common management
- Speculative nature of the investment

For more details, please refer to the Appendix: Resources for Investigators.

4.2.16 Financial Plan

The Financial Plan section is the heart of any Business Plan. It summarizes the company's financial history (if applicable), and provides financial projections with the assumptions they are based on. It also includes projected capital requirements, and how the capital will be used and repaid. Your potential investor or lender wants to know when your business is going to make money. The financial section of a Business Plan is also the most essential component of the plan; especially if you are seeking to win over investors or obtain a bank loan. Even if you do not require financing, financial projections are essential because it is a prudent business practice to compile a financial forecast when planning for the future success and growth of any business.

Continued on next page

4.2.16 Financial Plan (continued)

Prior to beginning the financial plan and narrative, you must create a set of projected financial statements that reflect the goals and information you've provided in the previous sections of your Business Plan; these financial statements are also known as projections. Financial projections should include estimates of how much money the business hopes to borrow or obtain through grants, and the interest repayments on those loans. It is imperative that the financials follow the Generally Accepted Accounting Principles (GAAP). These principles are established by the Financial Accounting Standards Board (FASB); the private-sector organization responsible for setting financial accounting and reporting standards in the United States. If financial reporting is a new concept to you, have an accountant review and/or prepare your financial statements and projections. Potential investors and lenders are usually more comfortable investing in a company whose owners have shown a good understanding of the financial aspects of the business. Financial projections typically span three (3) to five (5) years of operating requirements.

The financial projections you should make:

A break-even analysis: Here you will use income and expense estimates to determine whether, in theory at least, your business will bring in enough money to meet its costs.

A profit-and-loss (income statement) forecast: Next, you will refine the sales and expense estimates that you used for your break-even analysis into a formal, month-by-month projection of your business' profit for the first year of operations.

A cash flow projection: Even if your profit-and-loss forecast indicates your business will have higher revenues than expenses -- in other words, that it will be profitable -- those numbers will not guarantee sufficient cash will be on hand from month-to-month to pay your rent or buy additional inventory. A cash-flow projection shows how much money you will have -- or how much you will be short -- each month. This projection lets you know if you will need a credit line or other arrangement to cover periodic shortfalls.

A start-up cost estimate: This is simply the total of all expenses you will incur before your business opens. If you need to pay off these costs during the first year or two of business, they should be included in your month-to-month cash-flow projection.

The key is to be as thorough as possible, regardless of the audience, when preparing your business' projections. Bad accounting practices will most likely lead to business failure. So, take your time. Be sure to include thoughtful and fully documented assumptions. Do not be afraid to hire an expert.

Continued on next page

4.2.16 Financial Plan (continued)

Again, no matter who your audience is, be as thorough as possible when calculating your break-even analysis and profit-and-loss forecast. The last thing you want is to experience the very real misery of starting a business that never had a chance to make a solid profit.

Important questions to consider when preparing projections:

- How many steps of financing are needed?
- For what period is the finance required?
- What type (common stock or debt with warrants) is offered?
- Will the capital you seek be used for product design and development, capital equipment, marketing? Or, will it be used as general working capital?
- Will you be ready to exit the business venture through an Initial Public Offering (IPO), sale or other mechanism in the next five (5) to eight (8) years?
- Do you prefer to find an investor who is charging an interest rate like banks do?
- Do you want to earn money through an exit? Or, is your main objective to continue with the entrepreneurship of company ownership?
- What rate of return can your investor expect?

For more details, please refer to the Appendix: Resources for Investigators.

4.3 Identify Stakeholders: Who are "Stakeholders"?

In the context of this document, the "stakeholders" are the individuals involved in one or more areas of the commercialization process. The importance of each stakeholder's role will vary, as does the type of interaction the investigator has with them. For example, a stakeholder may be a colleague who assists the investigator with the concept development or the commercialization process.

4.3.1 Importance of Stakeholders

As an investigator, your mission and goals must be delivered upon to be successful. A key measure of success is determined through the stakeholders. To successfully meet the stakeholder's requirements, you must first understand their roles and expectations. The stakeholder's significance and power depends on the type of concept and its development phase. These factors must be understood to manage development and achieve positive results. Stakeholders impact value creation for a business – meeting expectations of stakeholders means you are creating value for them. Stakeholders can create a competitive advantage through the relationship you build with them. Finally, the majority of studies show that the number of relationships built with stakeholders correlate to financial performance.

4.3.2 Stakeholder Roles

Rank the importance of the stakeholders using the Stakeholder Identification table below. This exercise ranks each stakeholder type according to their level of importance. Note: this table is only an example, but this exercise can be related to any industry.

Table 4-1: Stakeholder Identification

Stakeholder Type	Ranking	Specific Stakeholders per Stakeholder Type
Customers	1	▪ Doctors ▪ Patients ▪ End Users ▪ Hospitals
Employees	2	▪ Colleagues ▪ Employees within the organization (if business started; i.e., Sales, Marketing and Finance departments etc.)
Shareholder, investors, owners	3	▪ Investors ▪ Funding sources (Government or Non-Government)
Regulators	4	▪ Patent Office
Business partners	6	▪ Academic Institutions - TTO ▪ Employees ▪ Lawyers
Government	7	Government (Applicable Organizations; i.e., the FDA)
Suppliers	8	Suppliers

For each of these stakeholders, the next step is to identify their role using the RACI Matrix Definition table below.

Table 4-2: RACI Matrix Definition

RACI	Description
R = Responsible	Stakeholder(s) who performs an activity, who is (are) responsible for action/implementation. There can be multiple stakeholders who are assigned a 'R'
A = Accountable	The stakeholder who has to make sure it's done. Only one "A" can be assigned to an activity/decision
C = Consulted	Stakeholder(s) who should be consulted for necessary information.
I = Informed	Stakeholder(s) that should be informed after a decision or action is taken or informed of decision results.

Continued on next page

4.3.2 Stakeholder Roles (continued)

Assign a RACI value to each stakeholder type in order to confirm their accountability and role. This exercise will help you understand and document the stakeholder's expectations and their level of influence; which will, in turn, determine their importance in the decision-making process. Also, be sure to continuously review and update this table during the commercialization process.

The Stakeholder Responsibility table below identifies each stakeholder, their RACI status and a description of their involvement during the commercialization process. The Expectation and Level of Influence columns should be populated with your specific expectations and the stakeholder's level of influence; this information will vary according to the unique requirements of your concept's commercialization process. Note that you, the investigator, are not included in this table; this is due to the fact that you are an 'A,' Accountable, for the development of the concept, and you are involved in all phases of its commercialization process.

Table 4-3: Stakeholder Responsibility

Stakeholder	RACI	Definition /Involvement within the Project/Per Phases	Expectation	Level of Influence
Colleagues	R	▪ Involved in the initial stages of the commercialization process ▪ Assist with the concept research, design, development and/or testing as instructed by the investigator		
Academic Institution's TTO	R	▪ Receives the application for the concept ▪ Reviews and approves/rejects the concept for next steps ▪ If the concept is approved, applies for the Patent and works through the commercialization process for the investigator		
USPTO	R	▪ Provides protection of the idea through approval of the Patent Application		
Investor	R	▪ Receives and evaluates the Business Plan in order to provide funding for the concept		
Employees	R	▪ Work on all aspects of developing the concept (and business, if applicable) once the Patent Application is approved		

Continued on next page

4.3.2 Stakeholder Roles (continued)

Table 4-3: Stakeholder Responsibility (continued)

Stakeholder	RACI	Definition /Involvement within the Project/Per Phases	Expectation	Level of Influence
Government (Applicable Organizations)	C	▪ Notes regulations that the investigator must follow to develop their concept ▪ May require reviews and approvals of the concept ▪ If the investigator/business does not comply, may have to take legal action		
Patient (Drugs) or End User (Process and Device)	I	▪ Potentially involved during the investigator's market research ▪ Is informed of the concept during "launch" of the concept		
Doctors	C	▪ May be consulted in terms of clinical trials ▪ May also be end users of the concept		
Lawyer	C	▪ Involved with the Patent ▪ Involved , if required, during the creation of the business entity ▪ Involved if issues arise with the Government or if there are user complaints		
Suppliers	R	▪ Supply materials		

4.3.3 Stakeholder Involvement

Once stakeholders are identified, it is critical to ensure they are correctly engaged in the process. This engagement allows for their support for the concept and encourages them to follow through on their activities. Be sure to develop a communications plan to share with the stakeholders; this plan should set expectations for the communication type, frequency and content required to effectively move the commercialization process forward. For example, employees within a company could expect initial communication to occur via a meeting request to receive updates about the concept's development. On a monthly basis, regular communication regarding changes in the communication plan would be helpful. Another example is that investors need regular status updates regarding financial documents; the communications plan will set their expectations. The Stakeholder Communication Plan Template below provides a sample of how to organize the communications plan.

Continued on next page

4.3.3 Stakeholder Involvement (continued)

Table 4-4: Stakeholder Communication Plan Template

Stakeholder	Type/Media	Frequency	Content
Investor (s)			
Employees (e.g. Sales, Marketing, Finance, etc.)			
Government (Applicable Organizations)			
Patient (Drugs) or End User (Process and Device)			
Doctors			

4.3.4 Stakeholder Management

After the communication plan is identified and implemented, you as the investigator, and possibly the business owner, must monitor the effectiveness of stakeholder management; this may occur through feedback received via the communications methods identified in your communications plan (as referenced above). For example, as a result of status meetings or associated documentation, stakeholders may express concern about your current strategy, disagree on issues, or recommend new courses of action. You will have to integrate their feedback and manage their expectations. In addition, the stakeholders, their roles and/or their level of influence may change at any time during the commercialization process. Depending on the change, your Stakeholder tables may have to be reevaluated and adjusted accordingly.

5.0 Financial & Accounting

5.1 Understanding Financial Statements

Starting a business requires, at the very least, a basic understanding of accounting and financial statements. Any entrepreneur who does not understand the importance and meaning behind each financial document and line item on their statements is headed down a path that could lead to failure. It is critical that you understand and address the reason and need for each financial document that is applicable to your business. There are many resources available to gain a basic sense of finance and accounting, including books, classes and workshops and seminars. In addition, there are many online resources.

The following financial statements have the most value, although there are additional statements that may be important:

- Balance sheets
- Income statements (Sometimes referred to as profit and loss)
- Cash flow statements

5.1.1 Balance Sheet

A balance sheet is a financial report that provides a snapshot of a business's position at a given point in time, including its assets (economic resources), its liabilities (debts or obligations), and its total or net worth (assets less liabilities).

On the balance sheet, assets go on the left side while liabilities and shareholder's equity appears on the right. After adding everything, the numbers on the left and right should be the same, thus balanced using the following formula:

Assets = Liabilities + Shareholders' Equity

Its value comes in showing how much the company owes and who owes the company. It can be used to do trend analysis by comparing how a company changed over the years at a particular point. For example, a balance sheet can show what assets helped a company generate cash and how it paid for those assets whether it was through loan or other funding.

5.1.2 Income Statements

An income statement shows how much your company has earned and its costs and expenses for earning its revenue. It is a report that shows how much revenue a company earned over a specific time period, typically within a 12 month time frame. The literal “bottom line” of the statement usually shows the company’s net earnings or losses. This tells you how much the company earned or lost over the time frame or period. The simplest equation to describe income is:

Net Income = Revenue - Expenses

Revenue refers to inflows from the delivery or manufacture of a product or from the rendering of a service. Expenses are outflows incurred to produce revenue.

5.1.3 Cash Flow Statements

A cash flow statement is a financial report that describes a company’s sources of cash and how that cash was spent over a specified time period.

Cash statements focus on the cash that goes in and out of the business. A cash flow statement organizes the cash activities into three categories: operating, investing and financing activities. It uses data from the balance sheet and income statement, but in a different way. Unlike income statements, cash flow statements do not consider incoming and outgoing cash the company has not recorded; this is because earnings and cash are not the same thing.

The example below illustrates the important difference between earnings and cash:

> You sell oilfield parts for $1 million with the agreement you will receive the full amount within one year. This deal appears in your income statement as $1 million in earnings. However, your bank account has not yet received the $1 million. Therefore, the cash flow statement will not reflect this deal. Because you do not have the cash from the sale, you cannot rack up $1 million in expenses. As a result, the income statement could show profit and the company could still go bankrupt by spending the $1 million before it is available. Accounting tricks cannot fake cash flow.

5.2 Sources of Funding

There are two basic types of funding: equity and debt. Equity funding requires the sale of partial ownership of the company. In exchange for money, investors ask for a share of business profits. Debt funding is simply borrowing the money needed to finance business operations and growth. This is normally in the form of a loan or line of credit tied to a particular interest rate and other applicable terms and conditions. There are also grant opportunities available to well qualified candidates offered by the 26 federal grant-making agencies which can be found online at www.Grants.gov. The specific criteria and conditions differ depending on the grant type and program served.

Types of equity funding:

- Personal funds (bootstrap finances) can be obtained from savings, credit cards, retirement accounts, and property equity
- Friends and family can lend money for a stake in the company
- Angel investors and venture capitalists
- Investment banking firms and Initial Public Offering (IPO)
- Government-backed Small Business Investment Corporations (SBICs)

Types of debt funding:

- Loans, including Small Business Administration (SBA) loans
- Home Equity Lines
- Credit Cards
- Bonds

Please refer to the Table 5-1 and Figure 5-1 on the following pages.

Continued on next page

5.2 Sources of Funding (continued)

Table 5-1: Equity and Funding

	Equity Funding	Debt Funding
Advantages	• Provides capital on a permanent basis with no requirement of repayment of principle or interest • Increases the company's net worth, hence improving the financial stability of the company and its ability for other debt financing • Can result in outside expertise being available for management or Board of Directors responsibilities	• Debt financing allows you to have control of your own destiny regarding your business. You do not have investors or partners to answer to and you can make all the decisions. You own all the profit you make. • If you finance your business using debt, the interest you repay on your loan is tax-deductible. This means that it shields part of your business income from taxes and lowers your tax liability every year. Your interest is usually based on the prime interest rate • The lender(s) from whom you borrow money do not share in your profits. All you have to do is make your loan payments in a timely manner • You can apply for a Small Business Administration loan that has more favorable terms for small businesses than traditional commercial bank loans.
Disadvantages	• Carries a higher cost of capital; therefore, more expensive • Dilutes ownership control of the business • Profits must be shared • Equity capital is permanent financing and is often difficult to obtain • Potential for conflict between company founder and investors • Controlling interest often becomes a critical issue with the founder • Can require more detailed and timely reports	• A large loan payment at a time when its critical to invest every penny into the startup costs of your business • If you default on making any loan payments or if you are late making any loan or credit card payments you stand the risk of ruining your credit rating. This could lead to difficulty borrowing in the future for personal or business reasons. • If you borrowed from a friend or family member and you do not make your loan payments on time, you could strain those relationships. • Banks often require business owners to pledge personal as well as business assets as collateral, such as a home. Default could lead to the loss of whatever collateral used to secure the loan. This could be your primary home or life savings. If your business goes under, you could lose your personal assets. • Any time you use debt financing, you are running the risk of bankruptcy. The more debt financing you use, the higher the risk of bankruptcy.

Continued on next page

5.2 Sources of Funding (continued)

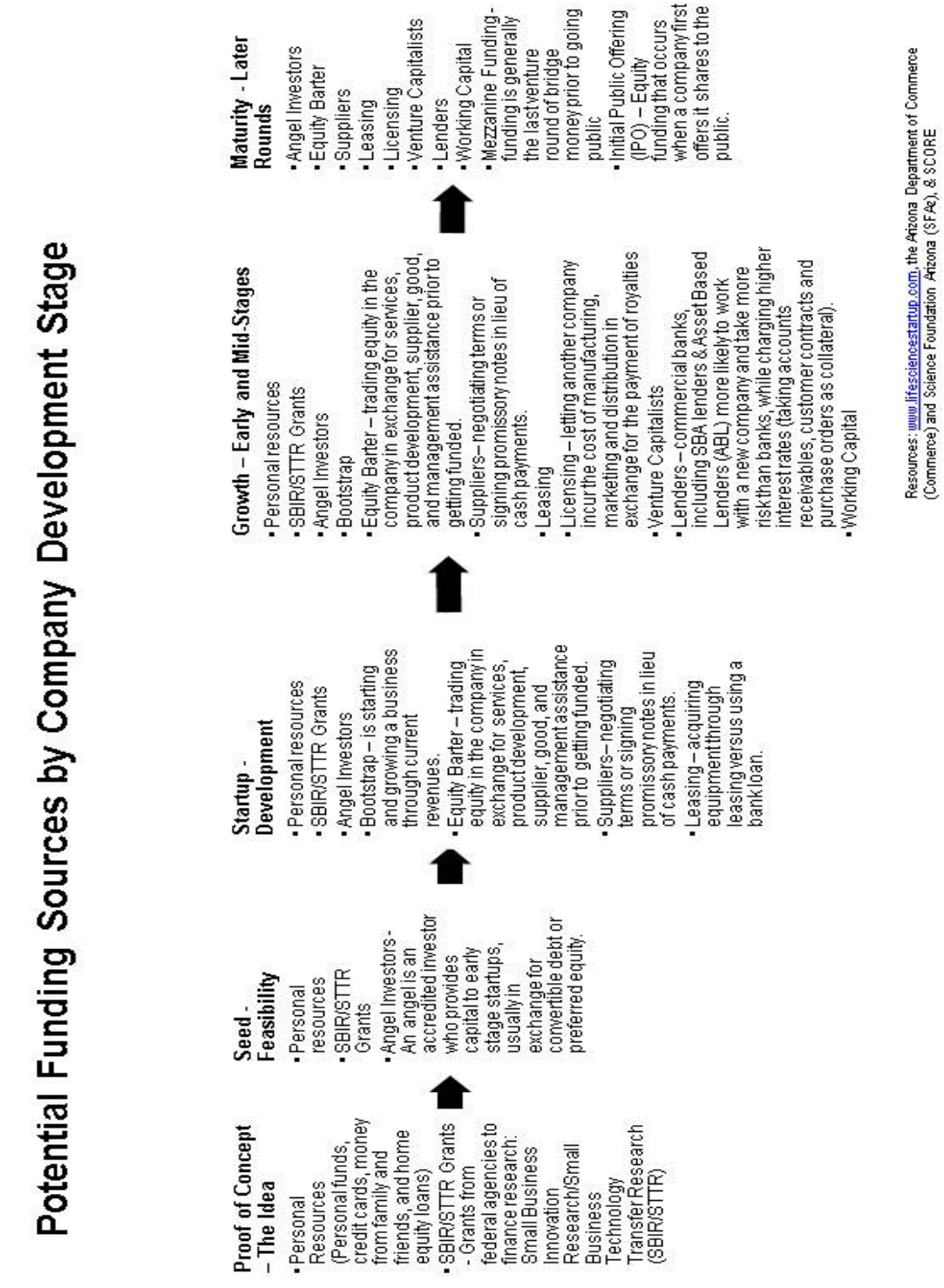


Figure 5-1: Potential Funding by Company Development Stage

5.2.1 Grants

There are grant possible grant opportunities available at the beginning and growth stages. Grants are attractive because you are not taking on debt nor are you redistributing the equity of the business. The Small Business Innovation Development Act of 1982 requires that federal agencies with R&D budgets in excess of $100 million set aside a percentage of their extramural research budget to fund innovative research in small businesses. Grants are available from a variety of agencies including state governments, local governments, and foundations. However, the largest amount of money to support biomedical research is available through federal programs, primarily the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs, associated with the National Institutes of Health and the Department of Defense. NIH has one of the largest SBIR/STTR programs focusing on biotechnology and biomedical product.

SBIR:

The SBIR program was designed to encourage domestic small businesses to engage in Federal Research/Research and Development (R/R&D) that has the potential for commercialization. Through a competitive awards-based program, SBIR enables small businesses to explore their technological potential and provides the incentive to profit from its commercialization. The program is implemented in two phases. Federal agencies with extramural research and development budgets over $100 million are mandated to allocate 2.6% (FY2012) of its annual budget to support SBIR programs. Currently, eleven Federal agencies participate in the SBIR program: the Departments of Health and Human Services (DHHS), Agriculture (USDA), Commerce (DOC), Defense (DOD), Education (ED), Energy (DOE), Homeland Security (DHS), and Transportation (DOT); the Environmental Protection Agency (EPA), the National Aeronautics and Space Administration (NASA), and the National Science Foundation (NSF). In addition, some agencies such as NIH and The National Institute of Standards and Technology (NIST), offer SBIR Technology Transfer (SBIR-TT) grants. At NIH these grants help advance commercially-viable innovative technologies from the NIH Intramural Program to the marketplace.

Continued on next page

5.2.1 Grants (continued)

STTR: The STTR program provides funding opportunities in the federal innovation research and development (R&D) arena. Central to the program is expansion of the public/private sector partnership to include the joint venture opportunities for small businesses and nonprofit research institutions. The unique feature of the STTR program is the requirement for the small business to formally collaborate with a research institution in Phase I and Phase II. STTR's most important role is to bridge the gap between performance of basic science and commercialization of resulting innovations.

The STTR program was implemented to stimulate a partnership of ideas and technologies between innovative small business concerns (SBCs) and non-profit research institutions through federally funded research or research and development (R/R&D). The STTR program assists the small business and research communities by commercializing innovative technologies. Federal agencies with extramural R&D budgets over $1 billion annually are required to administer STTR programs for awards to small companies that conduct collaborative research with non-profit research institutions. The amount of funding for fiscal year 2013 is 0.35% of the total annual budget. The STTR program is administered by DOD, DOE, HHS/NIH, NASA and NSF. In fiscal year 2011, NIH made over $73 million in STTR awards.

Phases of SBIR and STTR: SBIR and STTR programs are structured in three phases. The objective of Phase I is to establish the technical/scientific merit and feasibility of the proposed R/R&D efforts. The objective of Phase II is to continue the research or R&D efforts initiated in Phase I. An objective of the SBIR/STTR program is to increase private sector commercialization of innovations derived from Federal R/R&D (supported by federal grants). The objective of Phase III, where appropriate, is for the SBC to pursue with non-SBIR/STTR funds (either Federal or non-Federal) the commercialization objectives resulting from the results of the R/R&D funded in Phases I and II. In some Federal agencies, Phase III may involve follow-on, non-SBIR/STTR funded R&D, or production contracts for products or processes intended for use by the U.S. Government.

Support normally may not exceed the following:

SBIR Phase I: $150,000 total costs for 6 months

STTR Phase I: $150,000 total costs for 12 months

SBIR Phase II: $1,000,000 total costs for 2 years

STTR Phase II: $1,000,000 total costs for 2 years

(Costs are based on total costs, which include direct costs, F&A costs, and negotiated fee.)

Continued on next page

5.2.1 Grants (continued)

Funding Criteria: Under the terms of SBIR, the Primary Investigator (PI) must have his/her primary employment (more than fifty percent) with the SBC at the time of award and for the duration of the project. In the STTR program, the PI(s) may be employed either with the SBC or the single, "partnering" non-profit research institution with a formal commitment (minimum of ten percent effort to the project) to the applicant SBC. Such an effort does not necessarily involve a salary or other form of remuneration. At least forty percent of the work in STTR Phase I and Phase II must be performed by the SBC. The single, "partnering" research institution must perform thirty percent or more of the work. In general, the basis for determining the percentage of work to be performed by each of the involved parties will be the total of direct and F&A/indirect costs attributable to each party. However, it may vary to some extent if it is described and justified in "Consortium/Contractual Arrangements".

Other pertinent information: Based on NIH regulations, a Phase I awardee is eligible to submit a Phase II application either before or after expiration of the Phase I budget period, unless the awardee elects to submit a Phase I and Phase II application concurrently under the Fast-Track procedure, in which case they are reviewed as one application. In addition, to maintain eligibility for Phase II application, a Phase I awardee should submit the required application within the first six due dates following the expiration of the Phase I budget period.

State Technology Initiative: Most states have technology initiative programs to promote innovations. States have incubators to lease spaces to start-ups at very cheap rent to conduct R & D. They also provide some funding or tax breaks to start-ups get off the ground. Maryland's technology initiative is known as Maryland Technology Development Corporation (Maryland-TEDCO). The Incubator Development Fund program under TEDCO provides funding for capital expenditures in the development of new and the renovation of existing technology incubators in the state. Several new facilities were supported by this fund and they include the ETC@Johns Hopkins Eastern, the Silver Spring Innovation Center, and the Rockville Innovation Center, etc. Furthermore, TEDCO's annual business assistance funding has enabled the existing technology incubators to enhance their service such as outside business consultants, entrepreneurial training, and in depth strategy planning.

TEDCO administers the Feasibility Study Grant program. It provides funding to a government, government-related or university-related organization to engage an outside consultant to conduct a feasibility study to determine whether or not to start or expand an incubator.

For more details, please refer to the Appendix: Resources for Investigators.

5.2.2 Angel Investors

An angel investor, unlike a venture capitalist who gathers other individuals' money, invests their own funds to provide capital for a business start-up. Research has shown a large number of investors to have worked in large technology firms, such as Google and Microsoft. Funds received from angel investors can assist in financing critical key activities in the early stages of business development, such as securing intellectual property, hiring appropriate team members and completing regulatory requirements.

5.2.3 Venture Capital

Venture Capital (VC) is an equity funding source that addresses the funding needs of entrepreneurial companies that for reasons of size, assets, and stage of development cannot seek capital from more traditional sources, such as public markets and banks. Cash is received in exchange for equity ownership.

Role of VCs: Typically, investments at the early stages of a company's development, involve a significant amount of risk. Capital resources are limited. VC financing differs from traditional financing options. Traditionally VC focuses on young, high growth companies, accepting the higher risks in return for a potentially higher return. The investment is seen as a long term investment. Venture capitalists are actively involved, monitoring its portfolio of companies via board participation, strategic marketing, governance, and capital structure.

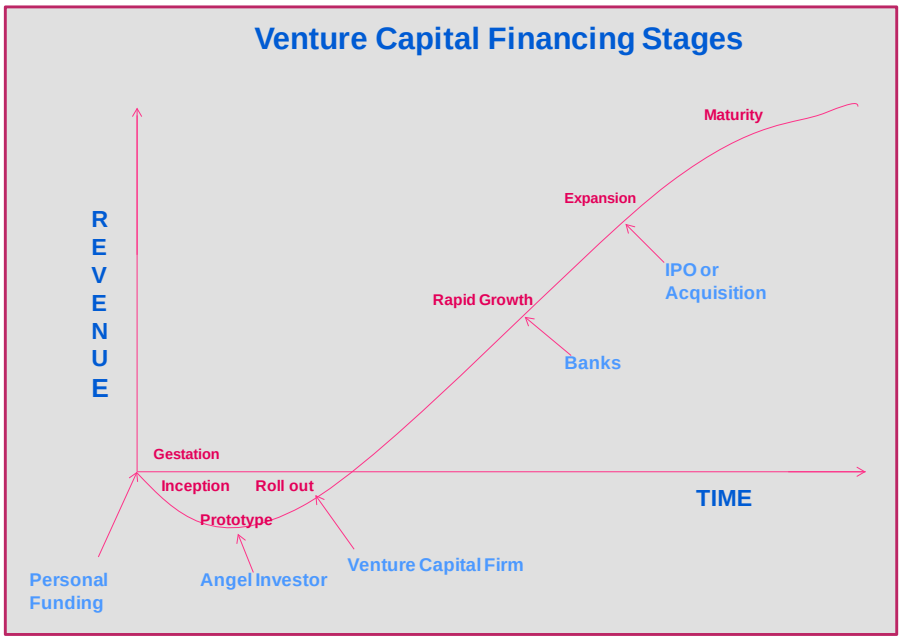


Figure 5-2: Venture Capital Financing Stages

Continued on next page

5.2.3 Venture Capital (continued)

Venture Capitalists usually sit on board of directors of their investments and actively participate in the company's operations and personnel management. This commitment often includes providing strategic counsel regarding development and production, making connections to aid sales and marketing efforts, and assisting in hiring key management. VC's also guides the company through multiple rounds of financing. At each growth milestone, the company must meet or achieve certain predetermined performance levels to receive new funding. If the company fails to meet these goals, the VCs' responsibility to their investors may require them to walk away.

VC funding is typically extended to a company for 5-7 years. Usually the objective is to grow the company to a point where it can go public or be acquired by a larger firm at a price that far exceeds the amount of capital invested. This is termed the "exit" strategy. One-third of the companies that receive venture capital funds fail. However, the successful investments can bring a return that far exceeds its initial investment. Three characteristics: patience, hands-on guidance, and the willingness to take on risk make venture capital a unique funding source.

VC funding to start-ups can be at different stages and at different levels as described below:

Early Stage Financing: $25,000- $250,000

- Seed Capital: Primarily used for product development and market research.
- Startup Capital: At this stage the company has complete business plan and initial marketing begins. At this stage no commercial sales have occurred.

Expansion Financing: $500,000 - $5,000,000

- First Stage: Funds are used for manufacturing and cost of goods expenses.
- Second Stage: Funds are for working capital for growing receivables, inventories, and payables. At this stage the company starts generating revenue, but may not yet be profitable.

Third Stage (Also known as "Mezzanine Financing):

- A company may need Funds for a major expansion, new products and may reach near break-even stage.

Fourth Stage (Known as "Bridge Financing"):

- A company expected to go public in the next six months may need Bridge Financing "bridging" the gap in cash flow prior to the Initial Public Offering (IPO) or the equity restructure of the firm. This typically short term financing.

Continued on next page

5.2.3 Venture Capital (continued)

The role of venture capitalist to the US economy is profound. In general, the average venture-backed company employs nearly 100 workers within five years and creates almost twice as many jobs as their non-venture supported competitors. Your institution's Tech Transfer Office (TTO) can be an excellent resource, connecting your company with a venture capital firm. Your TTO can find the venture capital firm that's best suited for your concept and business structure. It is important for the investigators to present a well-crafted business plan to the Venture capital office within your institution's TTO. They can provide assistance, developing a business strategy for presenting to the venture capital firms. In addition to your local tech transfer office, the Internet is a good resource for locating venture capital firms within your area.

For more details, please refer to the Appendix: Resources for Investigators.

5.2.4 Personal Resources

Financing a new business venture is not easy. In some cases, it can seem almost impossible. The key is to be creative and think outside established norms. Many new businesses are funded through personal resources, such as personal savings, credit cards and home equity loans. Traditional lending sources, such banks, typically require good credit, a source of repayment and collateral:

- Personal Savings
- 401(K) or another retirement fund account
- Credit Cards
- Home Equity Loan
- Bank Loans and Credit Lines, including SBA loans
- Friends and Family

Friends and Family: Friends and family members are great resources to obtain initial start-up funding for new businesses. In some cases, friends and family could be easier to deal with in terms of understanding and believing in your concept. In addition, there are fewer legal expenses and issues linked to this option. However, it is extremely important to always stay professional and maintain communication throughout the process. To preserve your relationships, be sure everyone clearly understands their financial role within the company and the return they can expect to receive for their contribution.

Continued on next page

5.2.4 Personal Resources (continued)

Bank loans: Small business loans can be taken out as another option to gain additional capital funds. For many new business ventures, it is not an easy task to obtain a commercial loan. In many cases, a strong business plan, excellent credit, collateral, and a source of repayment are required. Banks also require a personal guarantee. In addition to local banking institutions, there are a variety of state programs which you can utilize. Additional information on the available resources can be found at your local Small Business Development Centers (SBDCs). Personal loan options include, but are not limited to, a Home Equity Line Of Credit (HELOC) and personal unsecured loans.

401(K) or another retirement fund account: Funding your start-up business with funds from your IRA and 401(k) is an option some new entrepreneurs take. However, it is not a simple task. There are significant legal steps. The funds within your retirement account are rolled over into a corporate retirement account that permits you to invest in your business. This type of funding is best handled by an expert such as a financial planner or third-party retirement-plan administrator. If this is not handled properly and you are under age 59.5, you will be subject to paying taxes and early-withdrawal penalties on the money you use. Advisers tend to charge several thousand dollars to set up a plan like this and charge large annual fees. This can be a risky and unwise strategy for funding a new business venture since many start-ups fail. You risk losing your entire retirement.

Credit Cards: The use of credit cards as a source of funding your business is one of the most common and popular means of funding used by entrepreneurs. Business credit cards normally require signing a personal guarantee. As a result, this credit card debt is tied to you personally. So, should business slow down or the project does not move as quickly as hoped, you could fall behind on the payments. This would negatively affect your personal credit rating and your ability to borrow in the future.

5.3 Managing Cash Flow

Cash is king and many start-ups fail before they ever take off due to poor cash management. Cash is an element of working capital and the most liquid of current assets. Good cash management is essential to business growth and development. Cash Management is the collection, concentration and disbursement of cash. Cash flow refers to the flow or stream of cash, its inflows and outflows. An organization should manage the company's cash balances in a way that the company maintains a level of liquidity that allows a company to certain level of agility. A company should be able to invest in fixed assets and inventory without the risk of becoming insolvent. The inability to manage could lead to cash flow problems. Cash flow issues leads to the inability to handle unexpected expenses. When a company, no matter the developmental stage, lacks cash it becomes difficult to borrow funds. Employee retention could also be affected if the lack of cash prohibits the company from making payroll.

For more details, please refer to the Appendix: Resources for Investigators.

6.0 Licensing

6.1 Licensing Overview

Licensing is a very important part of the technology transfer process. It is a contractual agreement that gives permission to use patents, materials, or assets to bring a product and or concept to market. In exchange, the research institution receives financial benefits.

Upon the successful completion of a feasibility study, the TTO usually solicits potential partners for the invention, seeking partners for the licensing of the technology. The payments generated by the technology agreements come in the form of an up-front lump sum or as a royalty or a combination of both.

The technology transfer strategies of a non-profit research institution are often classified into six categories:

1) Contracting R&D to industrial partners
2) Working with industrial consortia
3) Licensing to industry
4) Influencing key decision makers
5) Working with broker organizations
6) Generating end-user demand

6.2 Initial Payment

Technology agreements frequently involve the transfer of valuable know-how; and he licensor usually requires an initial lump-sum payment when the licensee is executed.

This payment depends on the value of information obtained at the early stages of the agreement. It precludes receiving no payment should problems develop with implementing the license. Similarly, the licensee should also avoid accepting a lump sum payment provision that could amount to a write-off if the agreement is not continued later.

An up-front payment is usually found in agreements including know-how. It is also very common for patent licenses without know-how to include an upfront payment. It encourages a licensee to pursue the technology diligently to develop a marketable product. In addition to lump sum, the licensor usually requires minimum royalty payments. However, if the licensee has a good negotiating position, it may pursue deletion of up-front payment and only offer minimum royalties.

The amount of up-front payments depends on several factors:

- An assessment of the value of the technology
- Whether the license is exclusive or non-exclusive and whether it allows sublicensing or not
- Whether advance payment of royalties is included
- The rate of running royalties to be paid
- The amount of minimum royalties
- The length of the period for which royalties are payable

6.3 Royalties

Often licenses require payment of royalties based on a percentage of the net sales of the licensed product. Advance payments are made initially or over a period of time; they are applied against running royalties. More often, royalties are collected at set periods (three months, six months or yearly) based on the net sales for the period immediately preceding.

Exclusive licenses commonly contain a yearly minimum royalty provision representing the yearly guaranteed earnings for the licensor. Such provisions are not uncommon in nonexclusive agreements. The negotiating parties generally set the minimum based on a conservative estimate of projected net sales over the life of the agreement. The drawback of this kind of agreement is that a minimum royalty provision could represent a relatively heavy financial burden if there are of delays in start-up of production. The licensee should negotiate for minimum payment at the initial commercialization period and increase gradually (for five or so years) up to an agreed upon amount that generally remains in effect for the life of the agreement.

By setting minimum royalty payment the licensor attempts to ensure vigorous effort on the part of the licensee to commercialize the technology. Agreements may provide for termination of the license if the minimums are not being met or, less stringently, to convert the license from exclusive to non-exclusive status. For this reason, the licensee must do its utmost to have fair, realistic minimums set during the agreement.

Defining absolutes rules on setting minimum royalties is difficult because so many factors are involved. A reasonable procedure is for the licensor and licensee to try to develop theoretical sales projections, or to use market projections based on the project feasibility study and then to reduce those projections by 20-40% to arrive at a fair, conservative amount to be used in the agreement.

6.4 Separate Payments for Patents and Know-how

Some license agreements separate patent and know-how royalty payments (refer to Section 6.11 for definition details). Reasons for the separation include:

- Patent royalties are subject to risk given the possibility it could be declared invalid
- Patent royalties can remain in effect only for the life of the patent, but know-how royalties may continue well after the licensed patents expire, which should benefit licensor
- The subject matter of the license with respect to patents is limited to the scope of the claims, whereas the subject matter can be defined more broadly under the scope of the know-how

Given these reasons, the licensor may try to obtain higher royalties for the transfer of know-how than can be obtained from patent rights. However, the licensee should act with caution during the negotiations to protect their interests.

6.5 Tangible Items

The agreement should also specify how the licensor will bill and collect for any machinery sold to the licensee, and for such items as operating manuals, blueprints, drawings, manufacturing, specifications, test equipment or devices supplied by licensor to licensee. Charges may apply for quantities that exceed the agreement.

6.6 Acquisition of Machinery

When a licensor sells proprietary machinery to a licensee, the terms for such a transaction should be included in separate paragraph of the agreement, in a schedule attached to the agreement or in a separate sales agreement. Sometimes, a licensee is also permitted to buy machinery from a third party based on the licensed patents and/or know-how.

6.7 Technical Services

In addition to the above payments, it is possible the licensor may also charge separate fees for technical services it provides to the licensee in connection with the license. These services may include (a) training programs for licensees personnel, (b) specific technical services performed in the licensor`s works and facilities, and (c) technical experts supplied by the licensor to the licensee's plant.

6.8 Payment Method and Currency

This is not a concern for host countries where checks or bank transfers are easily arranged. However, if the licensor and licensee are based in different countries, the type of currency, exchange control, governmental taxes and other factors have to be considered. The agreement must provide details for how payments are to be handled.

6.9 Interest on Overdue Payments

If the licensee fails to make a payment when it is due, then they are bound by the license agreement to make interest payments at a specified rate and in the agreed-on currency. In domestic agreements, a rate of 3-5% above a recognized banking rate in that country is customary. In cases of international agreements, the parties negotiate to select the international bank to be used for the base rate, which is subject to the applicable government rules in the licensee's country.

6.10 Licensee Records

It is appropriate for the licensee to provide a statement that is certified by the licensee's designated officer or an independent certified public accountant whom is acceptable to both parties. The statement should contain royalty calculations in sufficient detail to avoid any problems in future between licensor and licensee.

Additional provisions requiring the licensee to maintain records verifying all payments made and due to the licensor are usually included in the statement. These records should be open to inspection by the licensor or to a third party accounting firm acceptable to both parties on reasonable notice. In case an audit is necessary, the agreement should provide for the handling of the cost.

In most cases, the licensor will want to avoid the use of an accounting firm for conducting audits, as their fees can be high. However, depending on the relationship between the licensor and licensee, the licensee may prefer to have any inspection of its records be done by a third party.

6.11 Term of the License Agreement

Patent license: If the licensor has a patent, then the term of the license agreement is usually from the effective date of the license until the expiration of the licensed patents; or, as long as the licensed patents remain in effect. However, if there are no existing patents, but only patent applications, it is common practice that the license terminates after an agreed-on period, unless a patent or patent is issue during that period. The licensee should negotiate for this provision in such cases.

Know-how license: In case of know-how licenses (with or without patents), the know-how royalty period is established by negotiation. Some developing countries limit the term by law but in many countries, there is no time boundary. At the end of a know-how license term, the licensee may be renewed with revised conditions.

When negotiating the license agreement, parties should consider local laws, their plans for the licensed technology, and their bargaining options to get the most beneficial deal possible.

7.0 Risk Management

7.1 What are Risk and the Risk Management Process?

Risk is the uncertainty in a project. The uncertainty may relate to securing the necessary funding, the quality of the invention produced (running it through the necessary level of testing), and the time the concept may take to arrive at the market. Risk management is performed to manage ambiguity through continuous risk identification, mitigation and monitoring. The figure below provides an example of the risk management process. . This figure illustrates the key concepts: Identify, Analyze and Prioritize, Develop Response Plans and Continuous Risk Management. While you should be performing risk management for your concept, be sure to consult with the necessary stakeholders during each stage of the commercialization process.

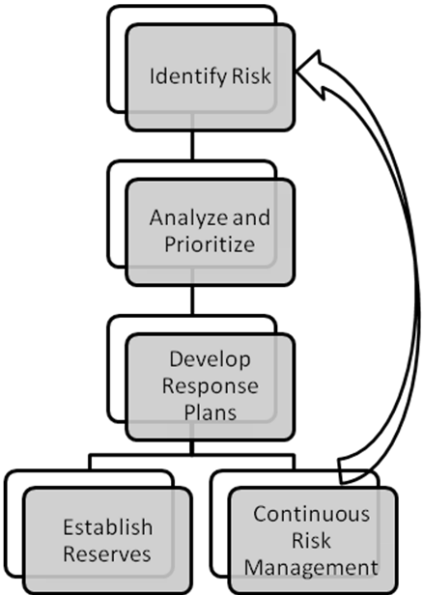


Figure 7-1: Risk Management Process

7.1.1 Risk Identification

Risks should first be identified at the beginning of a project, and during the first phase of developing the concept. These risks may originally be documented as assumptions because if assumptions turn out to be false, they can become risks. It is important to remember to document risks that could apply to all phases within the commercialization process. While these are initial thoughts, risks should be considered and documented during the beginning of each stage of the process because risk management itself is a continuous process. Once additional risks are identified, all risks should be reviewed holistically and reprioritized, if necessary; this allows for the significant risks to be handled as a priority.

7.1.2 Risk Evaluation, Documentation & Management

Once risks have been identified and documented, you must identify the probability the risk will occur and the impact it would have. The probability of risk occurrence or likelihood is defined in the table below. Once risks have been identified and documented, calculate the probability that the risk will occur.

Table 7-1: Risk Probability of Occurrence Levels

Likelihood/Probability of Occurrence Level	Likelihood/Probability of Occurrence Definition
High	The risk is highly motivated and sufficiently capable, and controls to prevent the vulnerability from being exercised are ineffective. Note: "Controls" reference a way to prevent the risk from occurring and are more pertinent for the technology industry.
Medium	The risk is motivated and capable, but controls are in place that may impede successful exercise of the vulnerability.
Low	The risk lacks motivation or capability, or controls are in place to prevent, or at least significantly impede, the vulnerability from being exercised.

Next, document the consequence of the risk occurring, and the impact this occurrence would have on the corporation (whether it be high, medium or low). This risk categorization may be subjective, depending on the concept or corporation/business. Those risks with a high probability and impact should have the highest priorities. As a result, these should be evaluated first and foremost in terms of devising the mitigation strategy to either eliminate or decrease the impact of the risk.

Continued on next page

7.1.2 Risk Evaluation, Documentation & Management (continued)

Finally, develop a mitigation strategy for each risk. A mitigation strategy is an action plan that minimizes or removes the impact of the risk. For example, if securing funding is a risk, a mitigation strategy would identify possible sources of funding arranged in a list from the most preferable to the least. The Risk Management template below provides an example of how you could document risks using the following columns:

- ID: a sequential number to keep track of the risk
- Category: The type of risk, such as Operational, Testing or Funding
- Description: Narrative of the identified risk
- Probability of Occurrence: High, Medium or Low (use the definitions above)
- Impact Level: High Medium or Low (as defined by you, the investigator)
- Score: Calculated value derived from the probability of occurrence and impact level
- Priority: High, Medium or Low per figure above
- Mitigation Strategy: Description of actions to take
- Owner: Individual to follow up on the mitigation strategy
- Status: Open, In Progress or Closed

In addition, include and define columns for the Date Opened, Due Date, Date Closed, Identified By and Comments.

Table 7-2: Risk Management Template

ID	Category	Description	Probability of Occurrence	Impact Level	Score	Priority	Mitigation Strategy	Owner	Status

7.1.2.1 Risk Management at NIH

The NIH has a formal and extensive Risk Management (RM) Program. Guides that refer to Risk Management should follow conventions used in NIH's RM Program.

8.0 Drugs, Devices & Processes

8.1 FDA Approval Process for Drugs, Devices & Processes

When utilizing a new drug or device in research, the FDA must approve this for pre-approval/pre-licensing to use in human subjects prior to occurring. It is highly recommended to hire a skilled regulatory specialist or staff with experience in the same disease category whom can assist with executing this submission process, as well as guide you throughout the clinical trial stages. This testing phase will take years to complete and substantial amounts of money to carry out. For a start-up biotech company, this is a crucial time to carefully focus and plan the development of the invention, as this phase could make or break the business.

The following sections will outline the requirements for both new drug and device submissions to the FDA, as well as information on the medical device approval process.

8.1.1 Investigational New Drug (IND)

There are 3 different IND types:

Investigator IND: An Investigator IND is submitted by a physician who both initiates and conducts an investigation, and under whose immediate direction the investigational drug is administered or dispensed. A physician might submit a research IND to propose studying an unapproved drug, or an approved product for a new indication or in a new patient population. This will be the more common type of IND type submission involving new drugs.

Emergency IND: An Emergency Use IND allows the FDA to authorize use of an experimental drug in an emergency situation that does not allow time for submission of an IND in accordance with 21CFR , Sec. 312.23 or Sec. 312.34. It is also used for patients who do not meet the criteria of an existing study protocol, or if an approved study protocol does not exist.

Treatment IND: A Treatment IND is submitted for experimental drugs showing promise in clinical testing for serious or immediately life-threatening conditions while the final clinical work is conducted and the FDA review takes place.

8.1.2 Original Investigational New Drug (IND) Submission Packet

As the investigator, you and/or your team will need to work together to compile all the necessary documents to supply to the FDA to request approval. We have compiled a list of all the items needed to be sent below in the table below.

Table 8-1: Overview of items to be submitted for an initial application to use an IND

Submission Items	Description
Cover Letter	Summary of items in submission packet
Form 1571	IND application
Table of Contents	Navigational overview of submission packet
Environmental Assessment	
Clinical Supply Labels	
General Investigational Plan	Study rationale, type of trial, indications, enrollment
Investigators Brochure	Pharmaceutical properties and formulation
Introductory Statement	Drug name/description, protocol objectives
CMC Introduction	Chemistry, Manufacturing and Controls information
Nonclinical Summary	
Previous Human Experience - Clinical Summary	
Additional Information	
Chemistry Manufacturing and Control	
Pharmacology/Toxicology Information	Evaluation of toxicities, study reports
Nonclinical Reports	
Clinical Protocol and Consent	Protocol and consents that involves IND
Form 1572	Statement of Investigator
Investigator CV & Medical License	Principal Investigator's CV and license
Previous Human Experience - Clinical Reports	
Form 3674	Certification of Compliance
Form 3454	Financial Interests and Arrangements of Clinical Investigators

For more details, please refer to the Appendix: Resources for Investigators.

8.1.3 Investigational Device Exemption (IDE)

A sponsor of a significant risk device study must submit a complete IDE application to FDA. There are no preprinted forms for an IDE application; however, an IDE application must include certain required information. The sponsor must demonstrate in the application that there is reason to believe that the risks to human subjects from the proposed investigation are outweighed by the anticipated benefits to subjects and the importance of the knowledge to be gained, that the investigation is scientifically sound, and that there is reason to believe that the device as proposed for use will be effective.

For more details, please refer to the Appendix: Resources for Investigators.

8.1.4 Medical Device Development and Approval Process

Medical Device Development and Approval is a multi-step process as shown in the figure. The first step is the concept and design process which may take 3-12 months. Next step is the Preclinical Development process which may include bench testing, biocompatibility and other laboratory testing, and animal studies. It usually takes between 12-24 months. Now, if the device falls under certain class I/II devices (defined by FDA) it does not require 510(K) pre-market notification from FDA. Examples of such devices are pathological, microbiological or general hospital or personal use devices. However, if the device has substantial health risk, but the device is substantially equivalent to a predicate device (previously marketed device), it is subject to 3 months premarket notification. Finally, if the device has substantial health risk and is not substantially equivalent to a previously marketed device premarket approval (PMA) must be obtained from FDA. Manufacturer obtains Investigational Device Exemption (IDE) from FDA to conduct clinical testing of the device in order to obtain safety data that has to be submitted during PMA application. IDE process is described in detail in the following section.

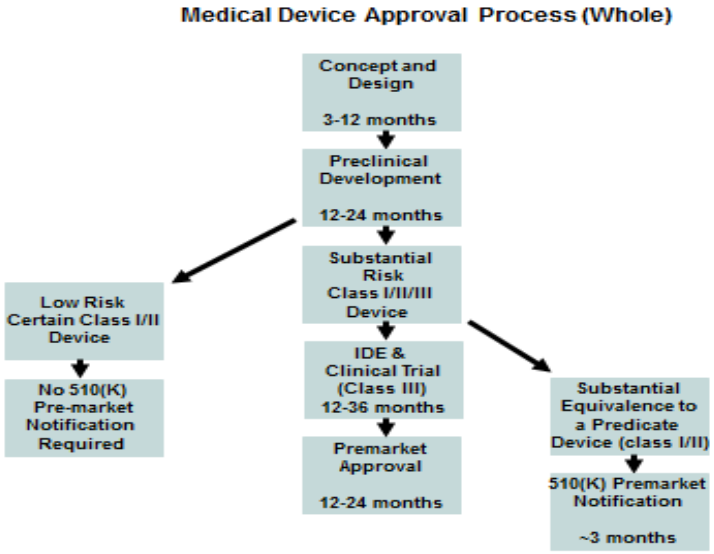


Figure 8-1: Medical Device Approval Process (Whole)

9.0 Appendix: Resources for Investigators

9.1 Discovery & Research

Identify the Idea

J. Fred Pritchard*, M. J.-R. (JULY 2003 VOLUME 2). MAKING BETTER DRUGS:DECISION GATES IN NON-CLINICAL. *www.nature.com/reviews/drugdisc* , 542.

Product Development Institute Inc. (n.d.). Retrieved from Stage-Gate® - Your Roadmap for New Product Development : http://www.prod-dev.com/stage-gate.php

Protect IP & Start Business Planning

Agreement, S. o. (Vienna, 1996). *1000Ventures.com*. Retrieved from Manual on Technology Transfer Negotiation, General Studies Series, United Nations Industrial Development Organization: http://www.1000ventures.com/technology_transfer/tt_contract_checklist_byunido.html

Georgia Tech. (n.d.). Retrieved from Energy@Georgia Tech: http://www.energy.gatech.edu/technology-transfer/

Johns Hopkins University Technology Transfer Office. (n.d.). Retrieved from http://www.techtransfer.jhu.edu/

National Institute of Health Office of Technology Transfer. (n.d.). Retrieved from http://www.ott.nih.gov/Technologies/AbsSearchBox.aspx

The United States Patent and Trademark Office. (n.d.). Retrieved from uspto.gov: http://www.uspto.gov/

Perform Market Research

Peter Kolchinsky, P. (2001). *The Entrepreneur's Guide to a Biotech Startup.* Retrieved from Evelexa BioResources : http://www.evelexa.com/resources/EGBS4_Kolchinsky.pdf

Philip Kotler, K. L. (2009). *Marketing Management.* Upper Saddle River: Pearson Education, Inc.

9.2 Design & Development

Develop the Business Plan

Allied Focus, LLC . (2009). *Business Plan Cover Page - Professional but Not an Art Project*. Retrieved from GreatBusinessPlans.Com : http://www.greatbusinessplans.com/business-plan-template/your-cover-page

BusinessTown.com LLC. . (2003). *Business Planning - Creating Plans*. Retrieved from BusinessTown.com: http://www.businesstown.com/planning/creating.asp

Elia & Partners, LLC . (2003). *Business Plan Secrets Revealed*. Retrieved from Business Plan Secrets Revealed: http://www.business-plan-secrets-revealed.com/business-plan-cover-page.html

Peter Kolchinsky, P. (2001). *The Entrepreneur's Guide to a Biotech Startup.* Retrieved from Evelexa BioResources : http://www.evelexa.com/resources/EGBS4_Kolchinsky.pdf

Identify Stakeholders

Bourne, D. L. (2009). *Stakeholder Relationship Management : A Maturity Model for Organisational.*

Sybille Sachs, E. R. (2011). *Stakeholders Matter: A New Paradigm for Strategy in Society.*

The Stakeholder Circle. (04/01/2012). Retrieved from Manage the Right Stakeholder: http://www.stakeholder-management.com/shopcontent.asp?type=methodology-description

9.3 Financial & Accounting

Understanding Financial Statements

America's Small Business Development Center Network is the most comprehensive small business assistance network in the United States and its territories. The mission of the network is to help new entrepreneurs realize their dream of business ownership, and assist existing businesses to remain competitive in the complex marketplace of an ever-changing global economy. Locate your local center at http://asbdc-us.org/.

Burton III, V. L. (November 12, 2010). *Encyclopedia of Small Business.* Gale Group.

Peavler, R. (2012). *Cash Management is Important for Your Small Business.* Retrieved from http://bizfinance.about.com: http://bizfinance.about.com/od/cashmanagement/a/cash_mngt_2.htm?p=1.

Peavler, R. (2012). *How to Bootstrap Your Startup or New Business.* Retrieved from About.com Guide: http://bizfinance.about.com/od/cashmanagement/a/cash_mngt_2.htm?p=1

Scientific, W. (2010). Lead with Cash: Cash Flow for Corporate Renewal. Singapore: World Scientific

SCORE is a nonprofit association dedicated to helping small businesses get off the ground, grow and achieve their goals through education and mentorship. It is supported by the U.S. Small Business Administration (SBA), with a network of 13,000+ volunteers, delivering services at no charge or at very low cost. Locate your local SCORE office at http://www.score.org.

U.S. Small Business Administration. (2011). *Understanding the Basics*. Retrieved April 20, 2011, from http://www.sba.gov: http://www.sba.gov/category/navigation-structure/starting-managing-business/starting-business/preparing-your-finances/understanding-basics

Grants

Department of Health and Human Services. (2012). Retrieved from National Institutes of Health (NIH): http://grants.nih.gov/grants/guide/pa-files/PA-12-089.html

SBIR/STTR (Small Business Innovation Research/ Small Business Technology Transfer. (n.d.). Retrieved from An Official Website of the United States Government: http://www.sbir.gov/about/about-sbir

TEDCO. (n.d.). Retrieved from Maryland Technology Development Corporation: http://www.marylandtedco.org/

Continued on next page

9.3 Financial & Accounting (continued)

Venture Capital

AmeriFinancial. (n.d.). Retrieved from http://www.amerifinancial.com/entrepreneurs.htm

GoBIG network. (n.d.). Retrieved from http://www.gobignetwork.com/

Mid-Atlantic Venture Assocaition. (n.d.). Retrieved from http://www.mava.org/

National Association of Seed and Venture Funds. (n.d.). Retrieved from http://www.nasvf.org/

National Venture Capital Association. (n.d.). Retrieved from http://www.nvca.org/index.php?option=com_content&view=article&id=133&Itemid=164

Price Water House Cooper. (n.d.). Retrieved from Money Tree Report: https://www.pwcmoneytree.com/MTPublic/ns/index.jsp

Regional Capital Organizations. (n.d.). Retrieved from Nationtal Venture Capital Association: http://www.nvca.org/index.php?option=com_content&view=article&id=106&Itemid=592#regional

TEDCO. (n.d.). Retrieved from Maryland Technology Development Corporation: http://www.marylandtedco.org/

Websites that match entrepreneurs and small business owners with investors: The investigators or the University TTO can post funding requests on these websites (listed below). These requests are then visible to thousands of potential venture capitalists. A match in criteria is followed by an email introducing the parties to a possible combined venture.

- www.gobignetwork.com (Go Big Network): This website offers small business owners and startups to request funding from a select 4,000-plus investors. On the other hand, investigators can also search for investors by funding portfolios.
- www.genesisexchange.com (Genesis Exchange): This website finds medical and biotech investors for companies. It has more than 1,000 listed investors and has secured more than $400 million in term sheets for its clients. The company's search database provides full investor profiles and a chance to showcase the business.

Examples of Venture Capitalists that specialize in early-stage startups: AmeriFinancial is a VC that invests in startup companies with a primary focus on early-stage tech, medical and consumer companies. It has invested in more than 50 companies with equity capital of up to $10 million. Another VC known as ARCH Venture Partners has invested in more than 120 life science companies and manages a portfolio nearing $1.5 billion.

Continued on next page

9.3 Financial & Accounting (continued)

Managing Cash Flow

Use the SBA Locate Loans and Grants Search Tool to help you identify what government financing programs may be available to help you start or expand your business: http://www.sba.gov/content/search-business-loans-grants-and-financing.

Burton III, V. L. (November 12, 2010). Encyclopedia of Small Business. Gale Group.

Peavler, R. (2012). Cash Management is Important for Your Small Business. Retrieved from http://bizfinance.about.com: http://bizfinance.about.com/od/cashmanagement/a/cash_mngt_2.htm?p=1

Peavler, R. (2012). How to Bootstrap Your Startup or New Business. Retrieved from About.com Guide: http://bizfinance.about.com/od/cashmanagement/a/cash_mngt_2.htm?p=

9.4 Licensing

See Protect IP and Start Business Planning under Discovery & Research

9.5 Risk Management

National Institute of Standard Technology. (Special Publication 800-30). Retrieved from Risk Management Guide for Information Technology Systems: http://csrc.nist.gov/publications/nistpubs/800-30/sp800-30.pdf

Wheelen, T. L. (October 2011). *Strategic Management and Business Policy.* Prentice Hall.

9.6 Drugs, Devices & Processes

U.S. Food and Drug Administration. (n.d.). Retrieved from http://www.fda.gov/

10.0 Bibliography

Agreement, S. o. (Vienna, 1996). *1000Ventures.com*. Retrieved from Manual on Technology Transfer Negotiation, General Studies Series, United Nations Industrial Development Organization: http://www.1000ventures.com/technology_transfer/tt_contract_checklist_byunido.html

Alexander, D., McMerty, B., Frey, K., & Waddell, A. (2012). *Life Science Trends 2012.* Morrisville, NC: Carlyle & Conlan.

Allied Focus, LLC . (2009). *Business Plan Cover Page - Professional but Not an Art Project*. Retrieved from GreatBusinessPlans.Com : http://www.greatbusinessplans.com/business-plan-template/your-cover-page

AmeriFinancial. (n.d.). Retrieved from http://www.amerifinancial.com/entrepreneurs.htm

Bourne, D. L. (2009). *Stakeholder Relationship Management : A Maturity Model for Organisational.*

Burton III, V. L. (November 12, 2010). *Encyclopedia of Small Business.* Gale Group.

BusinessTown.com LLC. . (2003). *Business Planning - Creating Plans*. Retrieved from BusinessTown.com: http://www.businesstown.com/planning/creating.asp

Deloitte. (2012). *Industry Insight: Accounting Update for the Life Sciences Industry.* Deloitte.

Department of Health and Human Services. (2012). Retrieved from National Institutes of Health (NIH): http://grants.nih.gov/grants/guide/pa-files/PA-12-089.html

Elia & Partners, LLC . (2003). *Business Plan Secrets Revealed*. Retrieved from Business Plan Secrets Revealed: http://www.business-plan-secrets-revealed.com/business-plan-cover-page.html

Ernst & Young. (2011). *Beyond Borders Global Biotechnology Report 2011 .* Retrieved April 2012, from Ernst & Young: http://www.ey.com/GL/en/Industries/Life-Sciences/Beyond-borders--global-biotechnology-report-2011

Ewing Marion Kauffman Foundation. (2011). *Research and Policy at the Kaufman Foundation*. Retrieved from http://www.kauffman.org: http://www.kauffman.org/Section.aspx?id=Research_And_Policy

Financing Options for a Small Business: Finding the Right Funding. (n.d.). Retrieved April 6, 2012, from startupnation: http://www.startupnation.com/business-articles/890/1/AT_FindingFundingThatsRight.asp

Continued on next page

10.0 Bibliography (continued)

Gapenski, L. (2009). *Fundamentals of Healthcare Finance.* Chicago: Health Administration Press.

Georgia Tech. (n.d.). Retrieved from Energy@Georgia Tech: http://www.energy.gatech.edu/technology-transfer/

Ghosh, S. (2012). *Startup Failure Rates (Very Sobering)*. Retrieved April 2012, from http://www.newventurelab.com: http://www.newventurelab.com/resources/blog.php?id=261

GoBIG network. (n.d.). Retrieved from http://www.gobignetwork.com/

IBM Global Services. (2011). *IBM GLobal business services: Life Sciences Executive Summary.* Somers, NY: IBM Corporation.

J. Fred Pritchard*, M. J.-R. (JULY 2003 VOLUME 2). MAKING BETTER DRUGS:DECISION GATES IN NON-CLINICAL. *www.nature.com/reviews/drugdisc* , 542.

Johns Hopkins University Technology Transfer Office. (n.d.). Retrieved from http://www.techtransfer.jhu.edu/

KOLCHINSKY, P. (2001). *The Entrepreneur's Guide to a Biotech Startup, 4th Edition.* Retrieved from http://www.evelexa.com/: www.evelexa.com/resources/EGBS4_Kolchinsky.pdf

McKinsey & Company. (2010). *Invention Reinvented:McKinsey Perspectives on Pharmaceutical R&D Report.* New York: McKinsey & Company.

Mergent. (2011). *North America Pharmaceuticals Sectors.* New York: http://webreports.mergent.com.

Mid-Atlantic Venture Assocaition. (n.d.). Retrieved from http://www.mava.org/

National Association of Seed and Venture Funds. (n.d.). Retrieved from http://www.nasvf.org/

National Institute of Health Office of Technology Transfer. (n.d.). Retrieved from http://www.ott.nih.gov/Technologies/AbsSearchBox.aspx

National Institute of Standard Technology. (Special Publication 800-30). Retrieved from Risk Management Guide for Information Technology Systems: http://csrc.nist.gov/publications/nistpubs/800-30/sp800-30.pdf

Continued on next page

10.0 Bibliography (continued)

National Venture Capital Association. (n.d.). Retrieved from http://www.nvca.org/index.php?option=com_content&view=article&id=133&Itemid=164

Nobel, C. (2011). Why Companies Fail--and How Their Founders Can Bounce Back. *HARVARD BUSINESS SCHOOL. WORKING KNOWLEDGE. HBSWK.HBS.EDU*, 1-2.

Peavler, R. (2012). *Cash Management is Important for Your Small Business.* Retrieved from http://bizfinance.about.com: http://bizfinance.about.com/od/cashmanagement/a/cash_mngt_2.htm?p=1

Peavler, R. (2012). *How to Bootstrap Your Startup or New Business.* Retrieved from About.com Guide: http://bizfinance.about.com/od/cashmanagement/a/cash_mngt_2.htm?p=1

Peter Kolchinsky, P. (2001). *The Entrepreneur's Guide to a Biotech Startup.* Retrieved from Evelexa BioResources : http://www.evelexa.com/resources/EGBS4_Kolchinsky.pdf

Philip Kotler, K. L. (2009). *Marketing Management.* Upper Saddle River: Pearson Education, Inc.

Price Water House Cooper. (n.d.). Retrieved from Money Tree Report: https://www.pwcmoneytree.com/MTPublic/ns/index.jsp

Product Development Institute Inc. (n.d.). Retrieved from Stage-Gate® - Your Roadmap for New Product Development : http://www.prod-dev.com/stage-gate.php

Regional Capital Organizations. (n.d.). Retrieved from Nationtal Venture Capital Association: http://www.nvca.org/index.php?option=com_content&view=article&id=106&Itemid=592#regional

SBIR/STTR (Small Business Innovation Research/ Small Business Technology Transfer. (n.d.). Retrieved from An Official Website of the United States Government: http://www.sbir.gov/about/about-sbir

Scientific, W. (2010). *Lead with Cash: Cash Flow for Corporate Renewal.* Singapore: World Scientific.

Standard and Poors. (2012). *Industry Surveys: Biotechnology.* New York: S&P Capital IQ Industry Surveys.

Continued on next page

10.0 Bibliography (continued)

State of Maryland. (2011). *Life Sciences Maryland: Jobs Analysis & Economic Impact Report June 2011.* Baltimoe: Maryland Biotechnology Center.

Sybille Sachs, E. R. (2011). *Stakeholders Matter: A New Paradigm for Strategy in Society.*

TEDCO. (n.d.). Retrieved from Maryland Technology Development Corporation: http://www.marylandtedco.org/

The Stakeholder Circle. (04/01/2012). Retrieved from Manage the Right Stakeholder: http://www.stakeholder-management.com/shopcontent.asp?type=methodology-descrip

The United States Patent and Trademark Office. (n.d.). Retrieved from uspto.gov: http://www.uspto.gov/

U.S. Food and Drug Administration. (n.d.). Retrieved from http://www.fda.gov/

U.S. Small Business Administration. (2011). *Understanding the Basics*. Retrieved April 20, 2011, from http://www.sba.gov: http://www.sba.gov/category/navigation-structure/starting-managing-business/starting-business/preparing-your-finances/understanding-basics

University of Georgia's Selig Center for Economic. (2011). *Georgia Life Sciences Industry Analysis 2011.* Atlanta: Kochut, Beata; Humphreys, Jeffrey. Selig Center for Economic Growth.

University of Tennessee Research. (2011). *Startup Business Failure Rate By Industry.* University of Tennessee Research.

Vascellaro, J. (2012, February 2). *'Angel' Invesetors Exist Outside Tech Elite, Too*. Retrieved April 7, 2012, from Wall Street Journal: http://marylandbiocenter.org/businessdevelopment/Pages/accesstocapital.aspx

Wheelen, T. L. (October 2011). *Strategic Management and Business Policy.* Prentice Hall.