

Worksheet: Business Plan

This worksheet is meant to help you organize and complete a business plan that may help you to obtain outside funding for your idea. The analysis that you have completed in each of the preceding sections will be critical in completing this plan.

Make sure to look at the example materials in this section of the CD for a sample business plan.

Before completing your business plan, take a moment to assess the type of funding that is appropriate for your concept. If necessary, review Leslie Bottorff's slides on potential funding sources. When writing your business plan, keep this target audience in mind, and tailor your plan to their interests and strengths.

A simple business plan summary is as follows; your business plan may differ from this format depending upon the specifics of the opportunity you are pursuing. In total, a well-formed business plan should contain between 15 and 20 pages.

- 1. Executive Summary**
 - a. One to three pages summarizing the key points of your business plan**
 - b. Include clinical need, market, solution, and unique contribution**
- 2. Clinical Background**
 - a. Describe the disease or clinical area**
 - b. Describe shortcomings of current solutions**
- 3. Product Details**
 - a. Describe your solution and how it addresses the need**
 - b. Describe the technical challenges that remain before your product is proven**
 - c. Summarize your patents and their status (pending, issued, licensed)**
 - d. Describe other solutions and demonstrate the uniqueness of your product**
- 4. Market Analysis**
 - a. Describe the customer base for your product, including the annual number of people affected**
 - b. State a fair price for your product, taking into account potential reimbursement, the cost of similar devices, and the value to the customer and to the healthcare system**

- c. Indicate whether reimbursement currently exists, and strategies for obtaining sufficient reimbursement for your product**
 - d. Indicate the total addressable market size, in dollars**
 - e. Describe the market growth history and potential**
 - f. Clearly state all assumptions used in arriving at these figures**
- 5. Regulatory Strategy**
 - a. Indicate the FDA requirements that will likely be imposed upon your device**
 - b. Provide a timeline for regulatory approval, taking into account all necessary trials**
- 6. Business Strategy**
 - a. Summarize the relevant experience of each founder**
 - b. Indicate key hires that will be necessary to bring the product to market**
 - c. Summarize any marketing strategies, distribution plans, or support requirements that would be unusual for your company**
 - d. Indicate facilities, equipment, and other fixed assets that will be required**
- 7. Financial Model**
 - a. Can be left blank for now; will be completed in the final section of this course**
- 8. Summary**
 - a. Analysis of risks**
 - b. Summary of compelling opportunities**