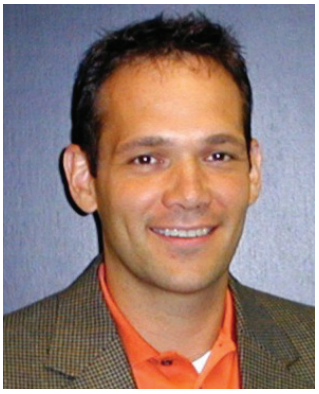

# A Roadmap to Success for Surgeon Inventors, Part 4: The Cost of Developing Your Idea

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This series of articles focuses on a different paradigm for bringing new ideas to market, one in which you as a surgeon inventor retain control over designs, aggressively pursue milestones on your own (such as issuance of a patent, testing of prototypes or obtaining a regulatory clearance) and build value before presenting them to industry for possible licensing or sale. Why would you consider this option? Why not just take your sketch straight to a big company? One of the best reasons to pursue development on your own is that the value of your idea can increase exponentially compared to the costs of development—*if* the process is managed properly.

We continue the series this time with a deeper look at how much the development process will cost. Last time, we introduced a new laser sintering technology that has potential to make prototypes quickly and in some cases more cost-effectively than traditional manufacturing methods. Today we take a broad look at the cost structure of a 'typical' project; that is, the process of taking your design idea all the way from concept through regulatory clearance. Along the way we will lay out a framework for budgeting and discuss why and how costs rise (and fall), and how to manage them.

As you might expect, there is no such thing as a typical project. I have been involved in projects with surgeon inventors in which half of one million dollars was spent on IP-related legal fees before a single design was prototyped. And I have been involved in others where the total project budget was less than $50,000. Every project has its own set of variables, which makes pinpoint estimates of timelines and budgets a challenge. However, most new product ideas of a given technical complexity, regulatory category (FDA Class I, II or III) and material will share similar characteristics. Said another way, many of the same types of expense items (i.e. testing, prototyping, design, etc.) will show up for every project of the same kind, and in general, these expenses will remain consistent.

**Example**

For sake of illustration, we will assume the following conditions for laying out a representative new product budget. Your own situation will probably differ in some respects, and you may decide not to take your project as far down the development path as we are suggesting. Our example project is a new orthopaedic implant that has unique features but incorporates standard implantable materials. It is a Class II 510(k) device with known predicates. It is not a comprehensive system (i.e. complete implant and instrument sets), but rather a single implant design that may spawn line extensions and ancillary instrumentation in the future. And although it is close enough to similar devices already on the market for purposes of being "substantially equivalent" to FDA, the unique features are patentable.

For the example just described, a budget estimation in the range of $75,000 to $250,000 to get the project to the point of presentation to a corporate partner is reasonable, depending on the extent of the IP legal work. The rest of the article explains how this budget is broken down, how the number may rise or fall and tips for keeping it under control.

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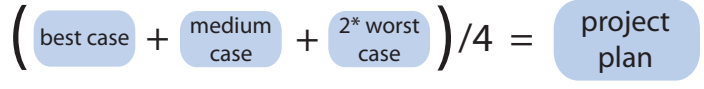
**Project Planning**

Breaking a project down into major expense categories for budgeting purposes is best done under the direction of an experienced project manager and in the context of a larger planning function. Taking a few days or weeks to establish a comprehensive plan and budget for the anticipated project at the beginning of the process will save weeks or even months down the road. The planning process includes the necessary but often difficult task of ensuring that all required steps throughout the project are included and given due time and investment. Ironically, people will sometimes bypass the planning step altogether and get right into the design process in order to save money and time. Neither savings is realized.

Also, recognize that your project will never proceed exactly as planned. There is no way to foresee all of the variables and risks from the beginning. In addition, many of the deliverables of any project are predicated on outside resources, and resources get backed up from time to time. One way to deal with these risks is to build a contingency budget into the plan. Often the contingency is based on a percentage of the overall project budget. I have seen this percentage vary from ten to 25 percent dependent upon the complexity of the project. Another way to deal with these risks is to determine a "realistic case," which can either be expressed in units of time (for the timeline) or money (for the budget). Exhibit 1 shows one example.

***Exhibit 1: Developing a Realistic Scenario***



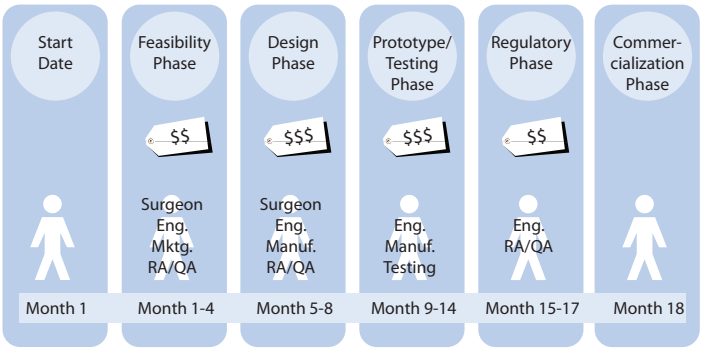

This particular formula implies that the worst case is weighted twice as heavily as either the medium or the best cases. Why? The idea is not to be overly pessimistic, of course, but merely to recognize that it will be next to impossible to have 100 percent of the tasks fall into place exactly on time during the course of the project.

**Cost Breakdown**

Overall project cost assessment and budget development can be accomplished in several ways. For example, major expenses may be broken down per phase of the project, as shown in Exhibit 2.

In this example, the project is divided into five phases, with the last one (commercialization) handled by a corporate partner and not the surgeon inventor or his direct team. Therefore, the bulk of the investment in time and money is spent in the middle phases. The exhibit shows how the costs for a project rise once design and prototyping begin and then fall towards the end as the regulatory submission is completed.

***Exhibit 2: Expense by product phase***




Feasibility studies, the first phase in the above diagram, have been explained in detail in a previous installment in this series. It is a good idea to budget $15,000 to $35,000 for this activity. The Design and Prototyping phases will consume the bulk of the project budget, usually between $50,000 and $150,000. This is a wide range and will be affected by three major factors: the number of design/prototype iterations, the amount of testing completed and extent of IP legal work undertaken. Finally, the Regulatory phase, which comprises testing for the 510(k) submission, FDA fees and regulatory consulting fees, will cost between $35,000 and $50,000. Bear in mind that these are very rough guidelines for illustration purposes, and that specific projects will vary. Also, these numbers assume that testing is straightforward and biomechanical in nature (as opposed to biocompatibility testing) and the IP legal work is limited to a patent landscape search and drafting of a provisional patent. If either of these assumptions are not true for your specific project, the costs may rise quickly.

Another way to look at project expenses is to group them into functional buckets, as shown in Exhibit 3. Next to each group of activities are rough numbers for the percent of the total project budget that the particular set of activities will most likely take.

***Exhibit 3: Estimated portion of budget allotted to activities***

| Activity | Percentage of Total Budget |
|---|---|
| **Design/Analysis/Drafting** | 25% |
| **Prototyping/Manufacturing** | 20% |
| **Testing** | 10% |
| **Regulatory** | 10% |
| **Quality/Documentation** | 5% |
| **IP Legal** | 15% |
| **Project Management Fees** | 15% |

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For our example, let's use $150,000 as a total project budget for ease of calculation. This is well within the range noted previously. Assuming this budget, you may expect to pay almost $40,000 for the design and drafting work, $30,000 for prototyping, and so on. Note that not all of these budget areas scale easily. For example, the cost of executing a patent landscape search and the cost of running a complete battery of testing will more or less remain constant despite the relative size of the project. In other words, some costs behave as fixed costs with step function changes rather than linearly related to the overall total.

**Managing Costs**

Given the variability between projects and multiple ways to execute a successful development effort, it makes sense to understand the 20 percent of factors that account for 80 percent of the budget. The following pointers will help to guide you as to where to focus your efforts in reducing unnecessary cost:

- **Start simple** – Don't try to do everything at once. It often helps to develop a simple, bare bones version of your idea first and see that through to completion before adding extra bells and whistles that are not required and could cause a project to stumble.

- **Be clear about your objectives and forthright with your expectations** – The team that helps you achieve success will need to know what you expect from a project and what you are trying to do in as much detail as possible.

- **Beware of "Scope Creep"** – Many projects fail to come in on time and under budget because things get added along the way. A laser focus on a well defined set of objectives will pay dividends in the end. Much like the first tip, you can add more details (or more parts, or more instruments, or more sizes...) later.

- **Challenge assumptions** – The more you challenge your assumptions (and those of your team), the better they will become. And a good set of assumptions will help eliminate wasted effort and money.

- **Document everything** – This is important for the team as well as for your chances of obtaining a patent later on.

- **Hire good people** – Assembling a solid team of experts alongside you is one of your best bets for success. They will be able to apply lessons learned from past experience to minimize your cost and time. Demand transparency from them and make sure that they are competitively bidding outside services.

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**Conclusion**

In my own experience, the first time a surgeon inventor undertakes the process of product development, he is usually surprised by the length of time and amount of investment required. The costs associated with product development are likely higher than most people realize; however, it is often money well spent. Just as a successful surgery requires meticulous preoperative planning, so does the development effort for commercializing an idea. With a budget framework in mind, you should be able to head into your next project with a solid understanding of the major activities and sensitivity to the key cost drivers. This will help you and your team to make good decisions along the way. These good project management decisions keep the development process running smoothly, and as we have seen several times during this series of articles, exponential value will be created.

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