

Where Do You Think *You're* Going? Strategic Planning for Clinical Research Sites

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According to *Forbes* magazine, approximately 50% of small businesses fail by their fifth year. By year 10, only one in three businesses has survived. To make it to the decade mark, a business needs one or more strategic goals, a strategy to achieve them, and a strategic plan to implement that strategy. This article will focus on independent clinical research sites, such as Injury Care Research (led by Jill Heinz), but it is equally applicable to organizations of all types that are not content to just see what happens.

According to Michael Porter, an expert on business strategy at Harvard Business School, competitive strategy is about being different.¹ It means performing different activities than rivals are performing or performing similar activities in different ways. Even the simple sounding strategy of competing on price requires doing different things differently than competitors. For example, Walmart's strategy involves a lot more than stacking them high, pricing them low, and moving them fast.

At each step in the process below, consider how to gain competitive advantages by differentiating your site from other sites. Strategic planning can be an enormous diversion from actually conducting your business, so keep it simple and concise, including only the most important elements. You are predicting the future, so you will probably not get everything right. Think of it as an exercise in righting the ship and adjusting your course. Assume there will be deviations. Trust yourself to manage them until you update your strategic plan, perhaps in a year. At that time, you can assess where you went astray and sharpen your next strategic plan accordingly.

Your Vision and Mission Statements

Lewis Carroll, the author of *Alice in Wonderland*, wrote, "If you don't know where you are going, any road can take you there." The first step in deciding where you want to lead your business is creating your vision and mission statements. These statements go hand in hand and may be combined into one statement. They should be bold yet realistic, inspiring and good for at least a few years.

There are two types of vision statements. In the first type, you describe what the world will look like if you are successful. For example, the Alzheimer's Association has a simple, yet powerful vision statement: A world without Alzheimer's disease.

In the second type, you describe what your business will look like if you are successful. For example, the vision statement for your site might be: We will become the top enrolling site in the U.S. for half our studies in three therapeutic areas within five years.

Your business's mission statement specifies its *raison d'être*: its most important reason for existence. The challenges in writing an inspiring mission statement are being concise and meaningful (i.e., finding the balance between ambition and practicality). "Curing disease" sounds too ambitious. "Serving the greater Denver area with clinical research services" sounds practical but is not inspiring. "We provide safe, rapid, high-quality clinical research that makes a meaningful difference in the health of our communities" sounds about right.

Simon Sinek, in his recent book, *The Infinite Game*, says that an inspiring and enduring mission statement should include a “just cause” with the following qualities:²

- Affirmative
- Optimistic
- Inclusive
- Service-oriented
- Resilient
- Idealistic

An idealistic mission statement is inspiring. You should never be able to check a box and say you have accomplished the just cause. It should provide a constant direction, a North Star for your business. The mission statement, “We provide safe, rapid, high-quality clinical research that makes a meaningful difference in the health of our communities,” can never expire.

In combination, your vision and mission statements define you are, what you are about, and why anyone should care:

We provide safe, rapid, high-quality clinical research that makes a meaningful difference in the health of our communities. While doing so, we will become the top enrolling site in the U.S. for half our studies in three therapeutic areas within five years.

Your Strategic Goals

In combination, your mission and vision statements are your North Star. However, they provide only the most general guidance for leading a business. To steer your business in the direction of its mission and vision, you need one or more strategic goals.

A strategic goal is an overarching objective against which courses of action can be assessed and focused. Ideally, a business will have only one strategic goal. With any more than three strategic goals, your efforts will probably be diluted. If you have multiple strategic goals, there is a good chance that some of them serve a single, higher-level goal.

As the leader of a clinical research site, you might have two strategic goals, for example:

- Maintain current profit margins while growing the current business by 10% per year
- Enter a new therapeutic area and profitably generate \$500,000 of revenue within three years.

Once you have set your strategic goals, consider every decision you make with these goals in mind. While your business will likely engage in some nonstrategic activities, ruthlessly resist the impulse to stray. For example, if a study comes your way that is too far outside your therapeutic areas, it will likely be a distraction from achieving your strategic goals.

Your Strategic Plan

Once you have your strategic goals, you will need a well-defined strategy to achieve them. For example, if your goal is to expand your site into a new therapeutic area, your strategy may include the objectives (also known as sub-strategies, secondary strategies, strategic

elements or tactics) of securing the services of a new investigator, acquiring new equipment, and researching the pharmaceutical companies in that market.

Elucidate your strategy in a strategic plan that includes your top-level strategic goals, supporting objectives, timelines and other information that explains who, when, how, why and where your strategy is to be implemented.

With a strategic plan, you will have a much better understanding of your business and how to lead it:

- You will have defined the operational objectives to accomplish your strategic goals.
- You will be able to communicate to your team the importance of their contributions to the business, motivating performance by giving their work more meaning.
- You will know how to find new study sponsors and select new studies that support your goals.
- You will know how to increase the operational efficiency of your business by applying your limited resources to your goals.
- You will understand how fluctuations in your business fit into the larger picture so you can react accordingly.
- You will be prepared to act proactively by anticipating various scenarios and knowing how to avoid, mitigate or enhance their outcomes.

Your strategic plan will address the challenges your business faces. Before you try to cure a disease, it helps to diagnose the illness. Similarly, before you can overcome a business challenge, it helps to diagnose the challenge.

According to Richard Rumelt's book *Good Strategy, Bad Strategy*, a diagnosis defines or explains the nature of the challenge.³ A good diagnosis simplifies the complexity of reality by identifying the critical factors. At minimum, a diagnosis names or classifies the challenge, linking facts into patterns and suggesting that more attention be paid to some issues and less to others. Ask yourself, "What is really going on here?" A guiding principle is a generalizable approach to dealing with multiple obstacles identified by diagnosis so you can concentrate on a pivotal or decisive aspect of each challenge in a coherent manner. A strategic plan should consist of a set of coherent actions that are consistent with guiding principles.

Strategic planning is an exercise in setting priorities. Each objective competes for resources with other objectives. You have to husband your resources for only the highest priorities. It is your job to make the hard decisions and tell your team (and yourself) that the lower priorities did not make the cut.

Steve Jobs, co-founder and former CEO of Apple, would periodically take the top 100 people in the company to an off-site meeting.⁴ He would ask them where they thought the industry was going, how they should capitalize on it, etc. Jobs would write these ideas on whiteboards. The group would then slash the list down to the top 10 ideas on one whiteboard. Jobs would then unceremoniously cross off seven of the 10. The company would focus on the remaining three.

Strategic planning is also an exercise in coherence. Each objective should complement the others in a coherent whole. The puzzle pieces need to fit together: Missing, extra, defective or misplaced pieces are a problem.

Your Strategic Value Position

According to Michael Porter², there are three types of value positions:

- **You can serve the needs of many.** For example, your site could conduct clinical studies for any indication arising in a family practice.
- **You can serve many needs of a few customers.** For example, your site could conduct phase 1 to 4 drug, device and diagnostic studies in a single therapeutic indication, such as asthma.
- **You can serve many needs of many customers in a narrow market.** For example, your site could conduct all types of studies in a wide variety of therapeutic areas but only in a fully virtual manner.

In your strategic plan, choose one of these value positions. You can further focus your value position based on geographical location, language, facilities or another factor that gives your site a unique value position.

Fresh Thinking

Businesses that know they have problems have a big advantage: they know they have problems. Businesses that are “going along just fine” can become complacent and get caught by surprise when an unappreciated problem raises its ugly head.³ Just look at all the companies that have run off the tracks in the middle of building their glamorous new corporate headquarters.

Expand your thinking and focus on the essentials with the following exercises:

- **Find new perspectives.** For example, what can you learn from the hospitality industry about patient-centricity?
- **Create a sense of urgency.** For example, if you had to sell your site in one year, what would you do to prepare?
- **Imagine the unmanageable.** For example, if your site is out of business in five years, why would that be? If your site is on top of the world in five years, why would that be?
- **War game your site’s future.** For example, what would you do if a new, competing site opened up next door; what would they do?
- **Imagine a shock to your system.** For example, what would you do if 50% of your studies were cancelled tomorrow? What would you do if a new study gave you the opportunity to grow your business 50% this year?
- **Imagine a windfall.** For example, if you won a million-dollar lottery and had to spend the money on your site this year, how would you spend it?
- **Imagine a big assumption completely changes next year.** For example, what can you do to ensure survival if clinical research in your primary therapeutic area dries up?
- **Imagine you had to lead your site with five text messages a day.** What questions would you ask? What directions would you give?

Analytical Tools

You can use the following analytical tools when developing your strategic plan:

SWOT Analysis

When developing your strategic plan, it will help to know your business's major strengths, weaknesses, opportunities and threats (SWOTs). Use SWOT analysis to answer the following questions:

- **What are our major strengths and how can we leverage them?** For example, we have access to a large population of patients for certain indications, but we need to communicate with them in their language.
- **What are our major weaknesses and how can we correct or mitigate them?** For example, our computer systems are antiquated, but new technologies are available.
- **What are the major opportunities and how can we make the most of them?** For example, two smaller sites want to be acquired, but can we risk the added overhead?
- **What are the major threats and how can we protect ourselves from them?** For example, two of our investigators may retire soon; how can we replace them?

Gap Analysis

Gap analysis involves the following steps:

1. Describe the current state of certain aspects of your business.
2. Describe the desired future state of your business, say in one to five years.
3. Describe the gaps between the two states.
4. Develop strategies to close the gaps between current and future states.
5. Assess whether these strategies are realistic, unrealistic or unambitious.

Optionality Analysis

Optionality is a concept from the world of finance that looks beyond the expected return on an investment to the options an investment creates. For example, does buying 10% of a company give you the option to buy the company or partner with it on a new venture?

Optionality analysis involves the following steps:

- List the decisions your strategic plan explicitly or implicitly makes.
- Describe the expected benefits and risks of each decision.
- Describe the options each decision opens or closes, including in risk scenarios.
- Consider the net benefits of each decision in the context of the options it opens or closes.
- Adjust the decisions accordingly.

For example, if you decide to expand into a new therapeutic area, it probably closes the option of expanding into a different therapeutic area or buying that site across town. Are those options you are willing to sacrifice?

Feedback Analysis

Peter Drucker, the well-known management consultant, created what he called a feedback analysis model. Feedback analysis in the context of strategic planning involves the following steps:

1. Create your plan, including the expected outcome.
2. After the period of the plan, say a year, record the actual outcome.
3. Compare the expected outcome to the actual outcome.
4. Use the results to inform your expectations and process for the next plan.

It is highly unlikely that an ambitious but realistic strategic plan will see no positive or negative surprises from the business environment or the business itself. Rather than starting from scratch with each plan, use them as learning experiences.

Conclusion

Strategic planning can give your business direction, your leadership and team accountability, and your accomplishments meaning. However, it requires time and discipline to go through the process rigorously while thinking flexibly and making hard decisions.

In most years, developing a one-year strategic plan is relatively straightforward; there is only so much you can do in one year. A five-year strategic plan is another matter entirely. Five years gives you time to accomplish long-term goals, but so much can change in five years that strategic plans of that duration also have to emphasize creating options and maintaining flexibility.

The COVID-19 pandemic has brought to the fore the dark partner of planning: surprise. Surprise does not make your strategic plan obsolete; it gives you the agility to quickly mitigate any damage and seize any opportunities. Agile clinical research sites have quickly secured new COVID-19 studies and re-established other studies in the new-normal world of clinical research.

References

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