

STEP 1

ASSESS YOUR READINESS

OVERVIEW

The first step is to assess the readiness of your organization for the rigor and discipline of building a robust plan. This tool describes some key success factors including how it's critical that this is a CEO driven mandate with a deliverable to the board; that one senior leadership team member must be singularly accountable for the plan; and, most importantly, that the strategy connects directly to achieving your mission. Launching the strategy is not a one-off event – the organizational culture needs to be ready to embrace it in an ongoing and measurable way.

Without this preparedness – the process will likely fail due to lack of capacity, capability, or commitment.

Five Key Success Factors

1

Does your mission statement clearly specify the role your organization plays?

Readiness starts with having a clear mission statement that will determine what is in scope and out of scope for your strategy. To quote HBS Professor Michael Porter – “the essence of strategy is choosing what not to do.”

2

Has your organization determined where your core capabilities create differentiation and competitive advantage delivering the mission?

Has this identified the ‘how’ the mission will be progressed – i.e., do your core strengths and desired outcomes most relate to funding, convening, building – or a combination of all three?



THE FUNDER
Raising money to
find a cure



THE CONVENER
Creating alliances to
find a cure



THE DOER
Building processes
to find a cure



**THE END-TO-END
INTEGRATOR**
A combination of funding,
convening, and/or building

Five Key Success Factors continued

3

Have you identified a leader for the initiative who is 'wired' to be strategic?

Determining a strategic direction is very different from operational delivery and will require a leader that is not defined or limited by the world as it is. The right leader thinks strategically and is open to hearing a broad array of thoughts and ideas from the ecosystem.

Readiness to lead your strategic plan development requires combing the organization (or externally hiring) for the right profile leader, some properties include:

Willingness to put aside current constraints and push the envelope of the possible

Curiosity to embrace ideas from outside your organization's focus

Gravitas and energy to engage externally in exploring the landscape

Underlying pragmatism to connect up to mission and down to operational feasibility

Five Key Success Factors continued

4

Is the strategy unequivocally championed by senior leadership?

In developing a progressive strategy, the organization will be challenged to consider unfamiliar business models, roles, and partners. Preparing (sometimes reluctant) colleagues to embrace this journey will require the explicit support of a CEO mandate and board level sign off to be credible and command the attention of the whole organization.

Some key steps to prepare are:

Broadly communicate
CEO level mandate
to develop a strategic
plan

Set expectations and
schedule for status
final deliverable for
board approval

Ensure charter
includes the delivery
of near-, medium-, and
long-term wins

Require that the plan will
selectively embrace risk
to push the envelope

Develop periodic
communications cascade
to update colleague
on progress

Purposefully involve
medical, scientific,
marketing, development
on governance, etc.

Create incentives on the
process to develop the
strategy as well as to
deliver it

Five Key Success Factors continued

5

Are you prepared to invest to fill any readiness gaps?

The work of developing the strategic plan can take anywhere from 3 months to the better part of a year. If your organization is not replete with the capabilities, capacity, or process rigor to dedicate to the plan – you may need to consider hiring external consultants for specific, time-bound roles.

Some examples of where consultants can play an important role in catalyzing the process are:

Data sourcing, analysis, and framing of analytics i.e., landscaping

Creating interview guides, reference materials, and capturing insights from interviews

Overall project management from a dedicated program management office

These are expensive options not in the budget for every organization - but where appropriately applied can make the difference between success and failure.

STEP 2

DEVELOP THE LANDSCAPE

OVERVIEW

Once you're ready and prepared, the next step is to understand the current situation through developing a landscape. The purpose of the landscapes is not to simply describe the external environment – it is vital to also frame the findings in a way that identifies where you are on the map and where are the gaps and unmet needs.

This results in hypotheses for the white space that can be filled by the unique capabilities of your particular cure-seeking organization.

This part of the toolkit describes a structured approach to secondary research to capture the state of science, translation, data and advanced analytics, clinical development, funding, clinical care, and outcomes for the disease.

The approach includes a consideration of the analysis approach. It's often useful to plot your findings on a two by two (2x2) matrix with axes designed to discriminate clusters of ongoing activity and isolate white space hypotheses for where your capabilities fill critical gaps in the landscape.

Without a hypotheses on how to target white space – the key opinion leader interviews will lack the specificity required to elicit actionable guidance.

Three Key Success Factors

1

A comprehensive perspective on the cure ecosystem and its adjacencies

It is often surprising to realize how broad the landscape must be to capture the full ecosystem insinuated in developing a cure. The following section outlines the cure value chain and the constituencies to study to comprehensively landscape your disease.

The universe includes academic medical centers, biopharma companies, venture capital, diagnostics and biobanking, advanced analytics, other disease foundations, and community hospital and health systems.

*Three Key Success Factors continued***Academic Medical
Centers (AMCs)**

AMCs are hospitals with a tripartite mission of care, education and research. There are about 120 in the US, or about 5% of all US hospitals. Some pre-eminent examples include Mayo Clinic, Massachusetts General Hospital and UCSF Medical Center.

Cures almost invariably start with fundamental science in AMCs that explores the root cause of disease and experiment with interventions in the pathway to interrupt development of the disease.

It will be important to determine if the biology of your disease is understood and whether the science is supporting symptom treatment (management) or disease modification (cure).

**Biopharma
Companies**

The best science gets bridged into ideas for therapeutics (translational science) and then into clinical research where the safety and efficacy of experimental therapies are evaluated. This research is sponsored by both academic centers through grants and the biopharma industry through sponsored clinical trials.

It will be key to map out the status of therapies in the pipeline from pre-clinical translational science through first in human, proof of concept, large scale statistical efficacy, and finally, any approved therapies with their risks and benefits.

*Three Key Success Factors continued***Venture
Capital**

The innovative early stage clinical research pipeline is often concentrated in venture funded start-up companies and then tends to transition to the pharmaceutical industry before marketing and reimbursement approval.

Knowing where Venture is focused – and where the gaps are – may provide key ideas on the addressable white space.

**Diagnostics and
Biobanked Tissue**

Increasingly, therapies are becoming specific to particular genetic or other molecular markers. Many therapies today incorporate a companion diagnostic to identify patients that will benefit.

The activities of leading players in the biobanking of tissue and the development of esoteric assays and diagnostics can often provide clues into where the puck is headed for your disease (or analogues of your disease).

**Analytics: Artificial
Intelligence (AI) and
Machine Learning (ML)**

The advent of large scale, deeply characterized and longitudinal data has created the opportunity for AI and ML approaches to recognize unanticipated patterns and correlations between patient profiles, therapies and outcomes.

As you develop the landscape it will be important to understand if these technologies are fit for purpose in your disease, if they have been commissioned and deployed - and if not if why and if that opens a white space opportunity.

*Three Key Success Factors continued***The Not-For-Profit
Universe**

Given the grass-roots origins of many not-for-profit disease focused entities - it's possible (even likely) that your mission may overlap with existing organizations at either a national or international level.

The landscape of potentially similar organizations will help identify areas to avoid duplication or find complementarity.

**Community Hospital /
Health Systems**

Community hospitals provide the vast majority of care in the US and include innovators such as Intermountain Healthcare and Kaiser Permanente.

These clinics deliver standard of care diagnosis and treatment. Your white space may involve optimizing treatment pathways through improving decision support or reducing the variance in standard of care. Some areas to map out would be:

- How is a diagnosis made?
- What is the standard of care and variance?
- Are outcomes for approved therapies understood?
- Are there screening methods in place to diagnose patients sooner?

Three Key Success Factors continued

2

An analysis plan that specifies how and where to get secondary data

Much of the data you will need to populate the landscape is captured in publicly available sources. The analysis plan should include the following:

Some key steps to prepare are:

PubMed – scientific, translational and clinical research peer reviewed publications

Clinicaltrials.gov – every clinical trial reported by Federal mandate

Company websites and SEC filings – development programs and pipeline assets

UpToDate – details on how disease is approached in the clinic

NCCN – well established guidelines for treating specific cancers

Professional organizations (American Association of Cardiologists, ASCO, etc.)

Three Key Success Factors continued

3

Facility with analytical approaches used to identify and communicate white space

Identifying white space matched to your mission and capabilities requires an analytical framework to capture and visualize secondary data.

For each strategy this can be an extensive exercise in exploring multiple views of the data to inform your hypotheses. However, if you're just starting out don't let the perfect be the enemy of the good. Here are three illustrative examples of variables that when plotted against each other in a 2x2 matrix can potentially identify immediate questions (like who to partner with) to more technical opportunities (like gaps in the funding or bio-specimens).

Simply capturing who the leading AMCs and biopharma companies are in your space on one axis and plotting against your perception of how willing they are to work you is a great way to identify potential partners.

Mechanisms of action (from the science) plotted against biopharma pipelines (from the industry) may identify that new science such as a vaccine or immunotherapy is locked in AMC studies and not translated to industry. Your hypothesis may be that this due to a lack of venture capital.

Emerging platform diagnostics (such as circulating free DNA assays or genetic markers) plotted against use in adjacent disease states may indicate that your cure is not represented. A hypothesis may be that this is driven by a lack of tissue.

STEP 3

INTERVIEW THE KEY OPINION LEADERS

OVERVIEW

Your landscape has generated hypothesized strategic pillars to address unattended white space based on the current status of best practices – but probably not based on ‘next practices.’

The purpose of the Key Opinion Leader (KOL) interviews is to test the hypotheses with experts active in several key areas in the cure process including AMCs, Health Systems, Biopharma, Technology, and investment. This section describes how to elicit their feedback to confirm or negate your hypotheses – and also provide pivot points to extend your perspective on the opportunity space in unanticipated ways.

These experts can also become key advocates to enhance and advance your strategy. Many will not have realized the power of the emerging role of patient driven data organizations and may want to partner or fund initiatives supporting the strategy.

You have to get outside of the four walls of your organization and learn from other diseases and even other industries. Without this broad engagement of leaders, your perspectives may remain partial, parochial, or naïve and miss out on the next practices with potential new partners.

Four Key Success Factors

1

Identify the right people to speak with

The interview target list should include key leaders from the landscape including academic medical centers, biopharma companies, venture capital, diagnostics and biobanking, advanced analytics, other disease foundations and community health care providers.

The landscape white space analysis will have prioritized the segments most relevant to test your first ideas on the strategic pillars and identified the leaders in each. Naturally, each will have his or her own agenda when it comes to priorities and funding so the interviewer must listen with an ear for your patients.

Four Key Success Factors continued

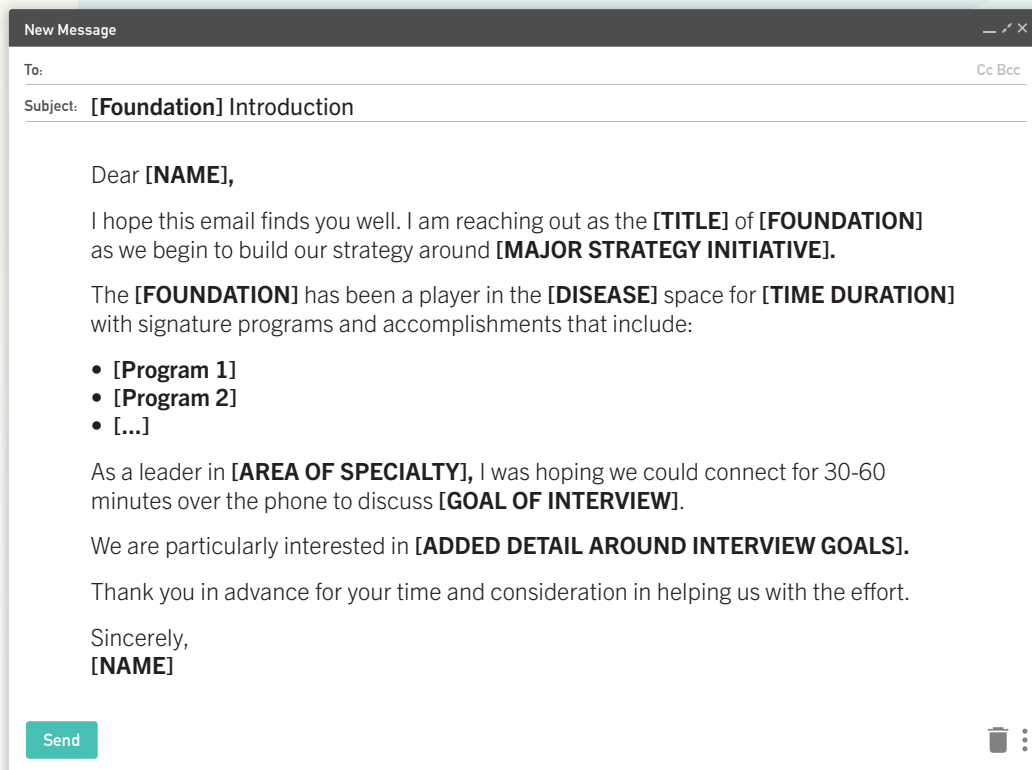
2

Present a compelling reason to get on their calendar

There has to be a compelling reason to secure time from experts as varied as say the Chief Scientific Officer at the VA to the CEO of an AI company. You may only get one shot, so the first step is getting your email opened. This will depend on how well established and known your organization (or whomever is drafting the email) is. For emerging organizations, you may need to secure a highly visible external champion and leverage their brand to open access.

The rationale and potential benefit to both parties has to be clear. Each outreach email must crisply communicate your goal in terms of validating/negating/elaborating on specific hypotheses on the addressable white space where your organization can help each other to accelerate cures. This is often a two-way street – so be prepared to answer how you can help them.

Interviews are normally 30-60 minutes long and a templated email is attached below.



Four Key Success Factors continued

3

Provide pre-read materials and create a customized interview guide

To maximize productivity, it's good practice to send a (no more than) 10 slide deck a couple of days in advance that describes your mission, the landscape findings on white space, and 3-5 specific questions on the presumptive pillars to open the conversation.

The interview guide should be specific to the interviewee, their company, and sector and may take up to 4 hours to prepare. The guide should solicit feedback on specific ideas raised in the landscape yet also elicit ideas and guidance based on original thoughts on future developments and what else is happening in the ecosystem.

4

Get the most from the interview – and use it to shape and update the pillars

For a 30-60 minute interview - you should only take 4-7 minutes providing context and describing your organization and your planning process. The rest of the time should be listening to answers to your questions.

It is important that the questions are not framed as being answered with closed 'yes/no' answers – they should be along the lines of '...our landscape analysis has identified this as an opportunity – what are we missing...?' Your last question should always include an ask to reconnect later to review the final plan – and inquire whom else they think you should speak with. An example interview guide from the Multiple Myeloma Research Foundation case study is downloadable under this section.

Finally - make time for a formal debrief on each interview and to continuously capture new learnings in updates that refine and elaborate the strategic pillars – and adapt the next interview guide.

STEP 4

WRITE THE STRATEGIC PLAN

OVERVIEW

The strategic plan is the definitive record of specific commitments the organization is making to its board, patients, donors, and partners. It needs to be both ambitious and be able to realize near-term wins. It also needs to be sufficiently clear and compelling to be sent externally to mobilize your stakeholders around your plan. Finally – it needs to be focused (for instance, 3 pillars works well) to be effective.

This section details the criteria and structure for a robust strategic plan document. Without a well structured and accessible document the plan will lack the specificity necessary to drive an operational plan and miss the evidence required to compel funding and organizational commitment.

Three Key Success Factors

1

A comprehensive and logical structure

The structure of the document should clearly explain how the strategic pillars (three pillars works well to ensure focus) explicitly connect your mission, goals, and objectives to delivery programs.

The (downloadable) Multiple Myeloma Research Foundation case example illustrates some key components of that structure. Note that in the MMRF parlance the ‘pillars’ are called ‘strategic initiatives’.

2

A 1-2 page executive summary

This is a vital component of any strategic plan. Each pillar must specifically address a particular critical white space in the ecosystem and be supported by a clear rationale of why your organization is uniquely positioned to address the gap.

From a process perspective the discipline of synthesizing the plan into summary form helps excise any extraneous thinking and highlights the core rationale.

From a communications perspective - the summary forms the base content for external communications and becomes an anchor for consistency across the organization including CEO messages, development, and marketing.

Three Key Success Factors continued

3

A clear ‘story’

The craft in writing the plan involves weaving the hypotheses that were shaped and revealed in the KOL interviews into clear, actionable, and measurable programs.

One approach to systemizing this art is to think through what are the three key ‘needles you can move’ – and for each – what are the three key ‘levers to deploy.’

For instance - in a hypothetical (but increasingly plausible) case where the research showed that the biopharma pipeline is stalled due to a scarcity of genomic profiling – then an example of an ambitious ‘needle to move’ would be to make sequencing routine.

In this pillar of ‘democratizing sequencing’ the programmatic levers might be to:

Create a precompetitive partnership to source funding

Develop a CLIA grade panel

Systemize data collection in a registry

Admittedly – this would be a massive undertaking – but the point is that sketching out three pillars each with three programs and rigorously following the logic of what specific actions would be and how they would be measured will quickly form the core of the story and create an executable, measurable plan.

STEP 5

WRITE THE OPERATING PLAN

OVERVIEW

The Operating Plan translates the strategic pillars into the specifics of timing, people, and dollars. Through defining concrete units of specific activity to reach particular milestones on a well-defined timeline, it will identify associated resource commitments and cash costs that determine what is feasible in programming and what is required from fund raising.

This section describes the requirements and structure of an operational plan and the criteria to ensure it's feasible and measurable against success metrics.

This is an iterative process starting from a simple outline that discretely links the 3-5 strategic pillars to specific programs and activities and quantitates the reality of what's doable with existing capacity, capability, and funding. Through this calibration process a realistic costed and timed operational plan will emerge.

Absent a robust operational plan, the strategies may flounder due to lack of accountability, resources, or tactical management to achieve milestones.

Three Key Success Factors

1

Granular timed and costed activities

Each pillar in the the operating plan has singular accountability - however the programmatic delivery requires collective responsibility across the organization's key functional leaders. In the operating plan, you need to put names/initials against each program.

Each of the implicated contributing activities (for instance fundraising dollars each quarter, grant making, data infrastructure, marketing, and communications) must be assessed for resource allocation, cash costs, timing, and reporting metrics.

One additional reason why the costing is important is that the source (industry, philanthropy, venture, etc.) forces consideration of innovative models for sustainability and mechanisms to secure seed funding before initiatives begin.

This is a template from the downloadable MMRF case example used to specify the tactical operating plan implementation and identify gaps in the organization that must be filled to successfully deliver each pillar in the strategic plan.

Three Key Success Factors continued

The key to the operating plan is that it addresses timing, cost, and people. This assessment helps understand if you have to stagger initiatives or go and raise more money.

What are the specific activities that must be accomplished?

Who is assigned to each work-stream?

What are the milestones and timing?

Where are organizational capacity or capability gaps?

What's the implication for partnering or hiring?

2

Explicit governance

The board should hold the organization accountable for the tactical delivery of the plan and the sufficiency of fundraising to match the budget. Pillar owners must circulate periodic updates (e.g., quarterly) on progress and should bring decisions required from the leadership team based on reported progress metrics to course correct and adapt the strategy as necessary.

Three Key Success Factors continued

3

Adoption by the culture - and adaption to change

The strategic and operational plans are living documents that should infuse direction, purpose, and meaning into all the organization's functions and activities. Reviews of the plan and operational delivery against it should become a regular part of the culture and feature in periodic communications to staff (all hands meetings) and donor presentations.

Additionally, achieving key milestones should be signaled in marketing and communications with blogs, press announcements, and podium pieces at key conferences.

As cures evolve over the period of a 3-5 year plan, it will be natural to adapt and evolve the pillars; however this must be done strategically with approval of the CEO, leadership team, and the board.

STEP 6

CONTINUOUSLY COMMUNICATE

OVERVIEW

The strategy and operational plans can only effect impact and provide traction for strategic pillars on the white space if they are understood and adopted by your key stakeholders of board, donors, partners, providers, and the patient community.

In order to remain engaged, each stakeholder group will require periodic and regular refreshes of the strategy and operational achievements against it.

This section describes how to formulate and execute an effective communications plan including desired outcomes, targets, messages, and channels.

Without good communications to your key stakeholders, you will not be able to align and support partners and investors to achieve your strategic goals.

Three Key Success Factors

1

Known desired outcomes for each stakeholder group

A proactive schedule of communications is fundamental to eliciting continued support from our stakeholders. The design process starts with identifying what outcomes are required from each group. For instance:

The board will need to know that initiatives are on-time, on budget, and appropriately resourced

Patients need hope from progress reports on both innovations in current care and how their participation is contributing to a future cure

AMC partners will want technical updates on status of databases, tissue banks, esoteric assays in development, etc.

Investors may need to hear about near-term wins to maintain confidence and preserve commitment

Three Key Success Factors continued

2

Stakeholder appropriate messages and channels

Clear, simple, impactful materials delivered through multichannel marketing of video, blog, social media platforms, podcasts, and traditional slide presentations will all be required to create a sticky strategy.

The downloadable case example of the Multiple Myeloma Research Foundation communications deck provides an example of the level of clarity required for board and donor communications.

3

Consensus meetings (as appropriate)

Your pillars may require a partnered approach with for instance biopharma companies and academic medical centers to close the gap in translational research between grants and clinical research programs.

Should this be the case, it will be necessary to periodically (i.e., yearly) convene stakeholders for a 1-2 days in order to drill down to consensus on priorities, roles, precompetitive funding, etc.