

Information Technology Strategic Roadmap:

Multiyear Planning of IT Investments for Commercial Launch

by **Scott Chizzo**

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**An IT Strategic
Roadmap can help
a biotech business
become a timely,
effective, scalable
and compliant
commercial
company.**

The launch of an emerging biotech company's first commercial product is a transforming event. A broad set of new capabilities must be established to manage the launch of the product as well as its position in the marketplace. One area that is often overlooked is that new and improved information systems are needed to manage additional data and metrics associated with operating a commercial company.

For most companies, the process of planning for an effective commercial IT infrastructure can be challenging. Typical issues that must be overcome are:

- Modest or minimal current IT infrastructure. Often at a precommercial stage, biotech companies have invested in just a basic level of IT capability and do not have a significant platform on which to build.
- Few, if any, enterprise business applications. The IT focus of an emerging biotech company is typically on scientific data/analysis and basic business infrastructure (such as network and e-mail). More complex business applications are usually not part of the technical portfolio.
- Limited IT support resources and skills. The IT team, if it exists at all, tends to be small and focused mainly on infrastructure. Often, IT staff members lack knowledge and experience in many business application areas.
- Unfamiliarity with validated applications. Because of the virtual nature of many of these companies, there is typically limited experience with 21 CFR Part 11-compliant applications.

As challenging as the IT environment in an emerging biotech company may be, the business environment is equally challenging. There is a high level of scientific and business uncertainty resulting in a natural tendency to avoid investing in a new IT environment prior to the results of clinical trials and FDA approval.

Yet, implementing enterprise IT applications requires long lead times to accompany most commercial launch preparations. How can emerging biotech companies reconcile the need to invest in future IT capabilities needed to become a commercial company with the understandable caution to preserve cash?

KEY PRINCIPLES

Creating an IT strategic roadmap provides a means for emerging biotech companies to look ahead and plan for the investments in applications, infrastructure, and resources that will be needed to operate as a commercial organization. By developing and executing according to a multiyear plan, business and technical

leaders can ensure that the IT environment is aligned with the company's direction and enables the development of business capabilities needed to succeed.

When developing a roadmap, organizations can use a set of basic principles to ensure an effective strategy:

The plan should be business driven, not technology driven.

Ultimately, the goal is to support the strategy and needs of the company. The roadmap development process should help prioritize and align the needs of the business and the commercial capabilities needed with the right IT environment and applications to support those goals.

Unified participation must exist, along with strong ownership by the business function leaders and performers. Key business areas of the company

With these basic principles, an emerging biotech company can develop and execute an IT Strategic Plan that ensures they will become a timely, effective, scalable, and compliant commercial product company.

STRUCTURED PROCESS

Although technical management can lead the process to develop the IT strategic roadmap, business executives must be significantly involved.

A structured process should include the following steps:

Determine and verify the key drivers and major milestones. An IT strategic planning process should begin by defining and verifying the key business strategies, issues, and drivers of the organization. Key points of consideration at this level include the following:

- What will the product and clinical pipeline look like 3-5 years ahead?

Workshops with the senior executive team can be used to confidentially explore these issues. The results of this step are typically a short, high-level list of key business drivers, a timeline of major milestones that must be considered, and some key requirements for future IT capabilities.

Perform a functional needs assessment. The next step is to assess the current and anticipated IT capabilities needed to support key functional areas of the company, in light of major milestones, including:

- research and development;
- clinical operations and regulatory affairs;
- product supply operations, including procurement, manufacturing, and quality;
- commercial operations, including marketing, and sales and distribution;
- business support, including finance, human resources, legal, and so forth; and
- external business partners, including contract research organizations, manufacturers, and distributors.

An effective way to perform functional needs assessments is to conduct workshops with the relevant participants and explore identification of current business processes, IT tools, systems and data currently used, future processes and desired capabilities, and priorities and time frames associated with those future capabilities.

The objective is to determine, at a reasonable level of depth, the desired level of automation and the IT capabilities needed to support the key business processes into the future.

Identify IT issues and opportunities. Every organization has IT issues it deals with, and in which it sees potential opportunities for implementing new capabilities. This step is designed to capture all known issues and any new ones revealed from the steps mentioned earlier as well as to catalog ideas for improvement. In this way, a

Although each biotech company has different needs, every company can explore the best possible solutions

must be involved and ultimately agree to the strategy and the plan. A roadmap developed solely by technical people is doomed to fail.

The roadmap must be a multiyear plan. When planning for commercial launch, it is critical to transcend the normal annual planning and budgeting process and take a multiyear view.

Begin planning two to three years before an expected commercial launch. Planning and implementing enterprise IT applications take time and can be implemented at less cost and with less risk if there is sufficient time allotted. An extended time frame also allows mitigation of the inevitable resource conflicts that exist in an emerging biotech company.

Integrate the implementation of the IT Strategy with ongoing commercial launch planning, budgeting, and decision-making processes. This process will help ensure that IT plans continue to move forward, remaining flexible, actionable, and updated as the current situation changes.

- What level of vertical integration is desired and in which areas of the business? For example, developing internal clinical trial management capabilities may be seen as a strategic priority while manufacturing is still outsourced.
- What prevailing business issues and challenges currently exist?
- What business changes might be contemplated in the future and what is the probability of those changes occurring?
- What other key business capabilities will be needed to execute on the company's business strategy?
- What is the timing of key business milestones (for example, FDA submission, IPO, expected FDA approval, and so forth) during the next three to five years?

plan can be developed to overcome the problems or threats that currently exist. The company can also leverage areas of strength, existing technology capabilities, or enhanced investments that provide the highest potential for leveraging IT capabilities to build and support a commercial enterprise.

Explore alternative IT strategies.

Although each biotech company has different needs and potential solutions, with a proper planning process, every company can explore the best possible solutions. Some approaches include the following:

- Examine adoption of industry proven solutions by companies of similar size and scale. By looking at successful models of companies a little further ahead in the commercialization lifecycle, a sense of confidence can be developed in potential solutions.
- Capitalize on emerging technology trends and solutions. A wide range of new IT solutions exist that can address fundamental business challenges at moderate cost. Workflow solutions, for example, can help streamline internal processes and enhance both productivity and compliance. Collaboration and portal technologies can be used to foster better teamwork and knowledge sharing.
- Look at outsourcing the lower-value components of IT. Although growth within the technical organization to support launch is inevitable, focus on transitioning IT into a strategic business partner by adding business analysts instead of help-desk support and computer operations staff. Those roles can scale more cost effectively through outsourcing as the hours of support are extended with national field staff.

A thorough investigation of alternative IT strategies can accelerate the adoption of technical solutions that enhance commercial readiness.

Construct, review and approve the IT strategic roadmap. Based on the steps above, an initial roadmap can be developed consisting of a two-to-four-year, time-phased set of business and

IT initiatives that help the organization prepare for product launch and sustain it as a commercial enterprise. The roadmap construction process should be iterative, with initial drafts developed, reviewed with key functional leaders, and ultimately with senior management.

Develop a framework for implementation.

To drive business value, the IT strategic roadmap must be actionable and managed. To do this, companies should integrate the roadmap into all the appropriate decision-making processes of the company, including:

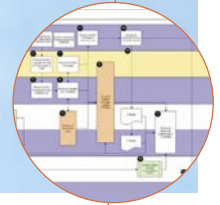
- annual business planning;
- commercial launch planning;
- budgeting cycles; and
- senior management meetings.

In addition, companies at this stage should establish a cross-functional IT steering committee designed to evaluate and prioritize investments and serve as the sponsors for implementation efforts. This committee should consist of IT leadership, the CFO, and other key business executives.

An IT strategic roadmap is a powerful tool for designing the future and guiding the investments that an emerging biotech company needs to become a commercial enterprise. By using a structured process and adopting a handful of key guiding principles, organizations can develop an IT action plan that balances the need to invest with the desire to use their resources cautiously. By integrating the IT strategic roadmap into existing and ongoing business decision frameworks, the plan can be implemented in ways that enhance the success and reduce the risk of commercial launch. ~

Scott Chizzo is the president and CEO of Maxiom Group. He may be contacted at schizzo@maxiomgroup.com, or for more information visit www.maxiomgroup.com.

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Client Life Cycle Stage	Key Challenges	Our Solutions
 <p>Emerging Companies Proceeding through clinical trials and beginning to think about and plan for commercialization</p>	<ul style="list-style-type: none"> • Lack of resources and business infrastructure • Significant financial constraints • Balancing investments with business uncertainty • Need to plan, design and build business infrastructure 	<ul style="list-style-type: none"> • Strategic Decision Support • Supply Chain Management • Commercial Launch • IT Strategic Roadmap • Software Package Selection • Quality & Compliance
 <p>Established Companies With one or more initial commercial products and a growing clinical process</p>	<ul style="list-style-type: none"> • Growing complexity of business • Changing product requirements • Incomplete or inefficient business processes • Not leveraging information systems to maximum extent • Protect product supply chain 	<ul style="list-style-type: none"> • Strategic Decision Support • Supply Chain Management • Business Process Design • IT Utilization/Value Assessment • Software Package Selection • Software Package Implementation • Project Management Office • Quality & Compliance • Brand Security
 <p>Mature Companies With multiple commercial products and a deep clinical pipeline</p>	<ul style="list-style-type: none"> • Optimize performance of overall (often global) supply chain • Implement specific systems • Increase integration with key supply chain partners • Implement advanced distribution strategies • Seek continuous process improvement • Protect product supply chain 	<ul style="list-style-type: none"> • Strategic Decision Support • Supply Chain Management • Operational Excellence • Software Package Selection • Software Package Implementation • System Integration • Project Management Office • Quality & Compliance • Brand Security

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- Building business strategies and supporting critical decisions
- Bringing new products to market faster and more effectively
- Establishing effective, scalable and compliant infrastructure
- Improving productivity and work environment
- Achieving better financial performance to fund new discoveries
- Continuously improving business and achieving operational excellence