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ERP Planning for Pre-Commercial Biotech Companies

The biotechnology industry is entering a new era. For decades, emerging biotech companies have typically partnered with, or been acquired by, larger pharmaceutical organizations to manage commercialization. Today, that path remains common, yet scientific advances and a growing network of external partners now give more emerging biotech companies the option to bring therapies to market independently. With that opportunity comes a more complex operating model.

As organizations near launch, they need an operational foundation that can support growth. For many growing biotech companies, the first signs of this transition appear gradually. As spreadsheets and point solutions accumulate, teams spend more time reconciling data while visibility across the business declines. This is often when leaders begin asking a more important question: *When is the right time to invest in an enterprise platform like SAP?*

There's no single company size or clinical milestone that determines when an enterprise platform becomes appropriate. The right entry point depends on the commercialization strategy, the operating model, and the level of regulatory rigor the company must support. It also depends on where the organization expects to be in the years ahead.

Contrary to common perception, implementing SAP is no longer an all-or-nothing decision reserved for global pharmaceutical manufacturers. Modern cloud-based solutions like SAP Cloud ERP allow pre-commercial biotech organizations to begin with priority capabilities, such as finance and reporting, then expand as the business grows.

Drawing on industry experience and proven SAP best practices, this guide explains how pre-commercial biotech companies can build a scalable operational foundation without adding unnecessary complexity.

Part 1: The New Reality of Pre-Commercial Biotech

Many organizations think of commercialization as the point when a product receives regulatory approval and enters the market, but in reality, it begins much earlier. Decisions made during clinical development, from selecting partners to building core business processes, shape how prepared the organization will be for launch. That means the ERP decision may need to occur before the need for ERP feels obvious. Technology and process choices made during clinical development can become costly and disruptive to unwind once launch is near.

As companies approach pivotal trials, manufacturing networks expand and compliance requirements increase. Lean teams must manage these demands while continuing to advance the science, which often leads organizations to delay investments in operational infrastructure. That may be appropriate early on, but eventually, the business begins to outgrow its existing platforms and point solutions.

Growth Creates Operational Complexity

It's important to note that complexity, not just company size, should trigger the conversation about the need for an ERP system. As biotech companies mature, operational complexity often grows faster than headcount. A relatively small organization coordinating outsourced manufacturing, multiple external partners, inventory ownership, and a near-term launch may need a stronger enterprise foundation sooner than a larger company with a simpler operating model.

Funding, clinical progress, new partners, and commercialization planning can each introduce new processes, data requirements, and control needs. Teams begin reconciling information across multiple systems and manually consolidating inventory data. Leadership may also struggle to develop a consistent view of business performance. These issues often develop gradually, making them easy to overlook until they begin to limit the organization.

Organizations frequently discover that the systems that supported a 30-person clinical-stage company are no longer sufficient for a 150-person organization preparing for launch.

Operational Readiness is a Competitive Advantage

Commercial readiness depends on more than manufacturing capacity or regulatory approval. Organizations also need repeatable processes and reliable information across core business functions, and decision-makers must be able to access that information when they need it.

Building this operational foundation early creates value that extends well beyond launch. Companies with standardized processes and integrated data are often better positioned to respond to investor due diligence,

support strategic partnerships, integrate acquisitions, and expand into new markets. This readiness also preserves strategic optionality. Disciplined controls and trusted information add value whether a company launches independently, licenses a product, pursues a partnership, or is acquired.

The Role of Enterprise Technology

Modern ERP solutions connect functions that have traditionally operated independently. They provide consistent data across finance and manufacturing. Supply chain and procurement teams can work from the same foundation, as can quality and commercial operations.

Rather than replacing every existing application, cloud ERP platforms can integrate specialized systems and provide a shared foundation for core business processes. This capability is particularly important for life sciences organizations, where regulatory compliance and complex supply chains require reliable information across the business.

The more strategic question is not whether an emerging biotech company will eventually need an enterprise platform. It's, ***"At what point does an enterprise platform create more value than continuing to extend point solutions?"***




Part 2: When Is the Right Time for SAP?

For pre-commercial biotech leaders, ERP readiness is best evaluated through a combination of business triggers rather than a single milestone. Implement too early, and the organization may take on capabilities it's not prepared to use. Wait too long, and teams may be forced to redesign fragmented processes while simultaneously preparing for commercial manufacturing or launch.

The right timing depends on whether existing tools can support the operating model the company is building toward.

Every biotech company begins with a focus on advancing the science. Early-stage biotech companies prioritize speed and flexibility. Lean teams often rely on spreadsheets or specialized software, but the number of processes and data sources increases as the organization grows.

Teams may adopt separate systems for finance and clinical operations, while manufacturing or supply chain data remains with external partners. Each solution addresses an immediate need, but the resulting processes become harder to manage as commercialization approaches.

Building a Scalable SAP Journey

Finance is a common starting point because growing organizations often need stronger controls and reporting, but it's not a prescribed entry point. For another company, procurement, inventory visibility, supply chain coordination, or quality-related processes may present the more immediate risk.

The SAP journey should begin where business value and operational risk are greatest, then expand as commercialization priorities evolve.

Stage	Organizational Priorities	Common Challenges	Recommended SAP Capabilities
Clinical Development	▪ Advance Clinical Programs ▪ Manage Funding ▪ Establish Financial Controls	▪ Spreadsheets ▪ Manual Reporting ▪ Disconnected Finance Processes	▪ SAP S/4HANA ▪ General Ledger ▪ Accounts Payable/Receivable ▪ Project Accounting ▪ Financial Reporting ▪ AI-Enabled Financial Insights & Anomaly Detection
Pivotal Trial & Commercial Planning	▪ Prepare For Commercialization ▪ Strengthen Governance ▪ Improve Forecasting	▪ Growing Headcount ▪ Multiple Vendors ▪ Increasing Compliance Requirements	▪ Procurement/Ariba ▪ Spend Management ▪ Budgeting & Planning ▪ BDC ▪ Basic Inventory Management ▪ AI-Assisted Forecasting & Scenario Planning
Manufacturing Scale-Up	▪ Coordinate CMOs ▪ Manage Inventory ▪ Improve Supply Chain Visibility	▪ Multiple Manufacturing Partners ▪ Inventory Tracking ▪ Planning Complexity	▪ Materials Management ▪ Supply Chain Planning ▪ Warehouse & Inventory Management ▪ Quality Management ▪ AI-Enabled Demand Sensing & Exception Management
Commercial Launch	▪ Execute Launch ▪ Manage Orders ▪ Ensure Regulatory Compliance ▪ Support Commercial Operations	▪ Gross-To-Net ▪ Fulfillment ▪ Demand Planning ▪ Financial Close ▪ Commercial Reporting	▪ Order Management ▪ Manufacturing ▪ Advanced Available-To-Promise, ▪ Batch Traceability ▪ Revenue Management ▪ Embedded Analytics ▪ AI-Powered Demand Forecasting ▪ Intelligent Order Promising
Growth & Expansion	▪ Optimize Operations, ▪ Expand Globally, ▪ Improve Decision-Making, ▪ Support Acquisitions	▪ Process Standardization ▪ Automation ▪ Executive Visibility ▪ Scalability	▪ Business AI (Including Joule) ▪ BAIP ▪ Automation ▪ Predictive Analytics ▪ Integrated Planning ▪ Advanced Reporting

Figure 1. A Scalable SAP Journey for Pre-Commercial Biotech

Figure 1 illustrates one possible path for introducing SAP capabilities across the commercialization journey. It's intentionally illustrative rather than prescriptive; the sequence should reflect each company's priorities, risks, commercialization model, and readiness.

Recognizing the Tipping Point

ERP readiness usually becomes clear through a pattern of signals rather than one event. It may be time to begin the SAP conversation when:

- The commercialization strategy is becoming more defined
- Dependence on external manufacturing and supply partners is increasing
- Ownership of inventory is becoming more complex
- The company expects significant organizational or geographic expansion in the next 18 to 36 months
- Inventory or supply visibility increasingly lives outside the organization
- Regulatory, audit, or validation expectations are increasing
- Leadership can't readily get a trusted view of the business or lacks confidence in enterprise data

No single trigger means a company needs SAP. The combination of these factors, and where the business expects to be over the next several years, should determine when an enterprise platform evaluation begins.

Choosing the Right Decision Horizon

As commercialization approaches, technology choices should be evaluated against the operating model the company expects to support in the future. A lighter-weight solution may be entirely appropriate when it's selected intentionally as a bridge. The risk arises when a short-term choice becomes an unplanned constraint as finance, supply chain, manufacturing, quality, and commercial processes become more interconnected.

The more useful question is whether the selected platform can support the company's expected complexity and growth horizon without forcing repeated technology resets. That framing allows leaders to weigh near-term cost and speed against future integration, validation, scalability, and change management implications.

Rethinking SAP

SAP was once viewed as too large or complex for an emerging biotech company. Cloud ERP has changed that perception by allowing organizations to adopt enterprise capabilities incrementally rather than through a large-scale implementation. Companies can begin with business functions that provide immediate value and then expand the platform as operational requirements evolve.

This modular approach, supported by Business AI Platform (BAIP), allows organizations to extend and integrate capabilities without unnecessary customization. This helps preserve flexibility as business needs change. Rather than replacing every specialized application, SAP becomes the operational backbone that connects business functions and data across the enterprise.

Part 3: A Smarter Approach to SAP Implementation

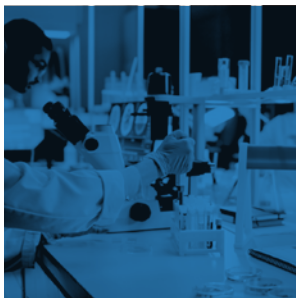
By the time a pre-commercial biotech company decides it's ready for SAP, another question quickly follows: How do we implement SAP without disrupting the business we've worked so hard to build?

Rather than asking which SAP modules to implement, leadership teams should first ask:

- *What business challenges are we trying to solve?*
- *Which processes create the greatest operational risk today?*
- *What capabilities will we need over the next 18 to 36 months?*
- *How can we establish a foundation that supports future growth?*
- *How do we expect to commercialize, and what operating model will that strategy require?*

Answering these questions creates a business roadmap that technology can support—not the other way around.



Avoid the "Big Bang" Mentality

ERP implementations were once viewed as multi-year projects that replaced many systems at once. SAP can support a phased approach that limits organizational change and gives users time to build confidence before additional capabilities are introduced.

Phase	Initial Focus	How Value Expands
1	Finance, Reporting, Project Accounting	Establish Control and Trusted Reporting
2	Procurement, Inventory, Planning	Improve Coordination and Visibility
3	Manufacturing, Supply Chain, Quality	Support Scale-Up and Partner Operations
4	Commercial Operations, Order Management, Revenue Management	Support Launch and Commercial Execution
5	Optimization, Business AI, Automation, Advanced Analytics	Enable Continuous Improvement as Data Maturity Grows

Figure 2. Sample Phased SAP Implementation Roadmap
Figure 2 illustrates how organizations can implement SAP in stages. Each phase builds upon the previous one, creating a scalable foundation without requiring a large-scale transformation all at once.

Standardize Before You Customize

A scalable cloud ERP strategy depends on a clean core mindset: adopt standard and industry-aligned processes where they meet the business needs, and reserve extensions or customization for areas that create meaningful differentiation.

For life sciences leaders, this requires deciding where standardization reduces risk and complexity, and where the operating model truly requires something different. Those choices shape the platform's long-term flexibility and agility.

Part 4: Why SAP Is Different for Life Sciences

Pre-commercial biotech companies need an enterprise platform that can support today's lean operating model without limiting tomorrow's complexity. SAP brings life sciences process depth and scalable enterprise capabilities. Its ecosystem can support growing sophistication across finance, supply chain, manufacturing, quality, commercial operations, data, and AI.

For an emerging biotech company, the value is the ability to establish a foundation early and expand it as the business model evolves.

Designed for Complexity

Preparing for launch requires coordination across scientific and business functions while maintaining compliance with evolving regulations. Life sciences organizations often depend on contract manufacturers (CMOs) and contract development and manufacturing organizations (CDMOs), along with third-party logistics providers (3PLs) and specialized suppliers. Without integrated systems, data moving across this network can require manual reconciliation and increase operational risk.

SAP provides a shared operational foundation that connects core business functions while integrating with specialized clinical and manufacturing applications.

Supporting Compliance

As pre-commercial companies grow, they must demonstrate that critical processes are controlled and traceable. SAP supports this need through standardized workflows and audit trails. Role-based security can provide additional control, while configurable workflows can help maintain operational integrity.

For companies operating in GxP-regulated environments, SAP provides cloud capabilities and supporting documentation that can contribute to qualification and validation activities. However, each company remains responsible for validating its own processes and environment. Validation implications should therefore be considered early when making ERP architecture or implementation decisions, rather than treated as a downstream deployment task.

Building Resilient Supply Chains

Emerging biotech companies often depend on globally distributed supplier networks and specialized manufacturing partners. Temperature-controlled logistics and regulated distribution channels add further complexity. Even small disruptions can have significant implications, which makes coordination across the supply chain essential.

SAP can improve planning and visibility across the supply chain while supporting coordination with external partners. Integration with the broader SAP ecosystem can further strengthen collaboration, helping organizations respond more effectively to change while improving transparency across the supply chain.

Part 5: Expanding Value Over Time

SAP's value starts with establishing stronger control, connected processes, and more reliable information. It expands as the organization is ready to use greater levels of automation, analytics, and AI. As a pre-commercial biotech becomes a commercial organization, the same enterprise foundation can support continuous improvement and more intelligent ways of working.

Implementation creates consistent processes and a reliable source of enterprise data. With greater confidence in reporting, leadership can spend less time validating information and more time deciding what to do next. The conversation shifts from ***"What happened?"*** to ***"What should we do next?"***

Turning Data into Action

Growing biotech companies generate substantial operational data. That information has traditionally been distributed across separate systems and reviewed in static reports.

SAP can consolidate operational data into dashboards that give leaders a clearer view of business performance. Instead of spending days preparing reports, teams can monitor key metrics and identify trends as they develop. This visibility can support more informed decisions and help organizations respond earlier to emerging issues.

SAP Business AI

SAP has embedded AI capabilities throughout its cloud portfolio. These tools can automate repetitive work and support decision-making without requiring users to have advanced data skills. SAP Business AI and Joule, SAP's AI copilot, are designed to work within existing business processes.

Users can interact with enterprise data through natural language rather than searching through multiple reports. They can also generate summaries or complete routine tasks more efficiently. These capabilities are intended to support human judgment. For lean biotech teams, time saved on routine work can be redirected to work that requires greater expertise.

The enterprise foundation created today also establishes the trusted processes and business context that AI increasingly needs tomorrow.

A Platform That Evolves with the Business

Selecting the right enterprise foundation early can reduce the need for repeated technology resets as the business changes. With SAP, organizations can expand capabilities on the same platform as new therapies, markets, manufacturing models, acquisitions, or commercial requirements emerge.

Whether SAP should become that foundation now – and which capabilities should come first – still depends on the individual company's commercialization path, operating model, current systems, and growth horizon.

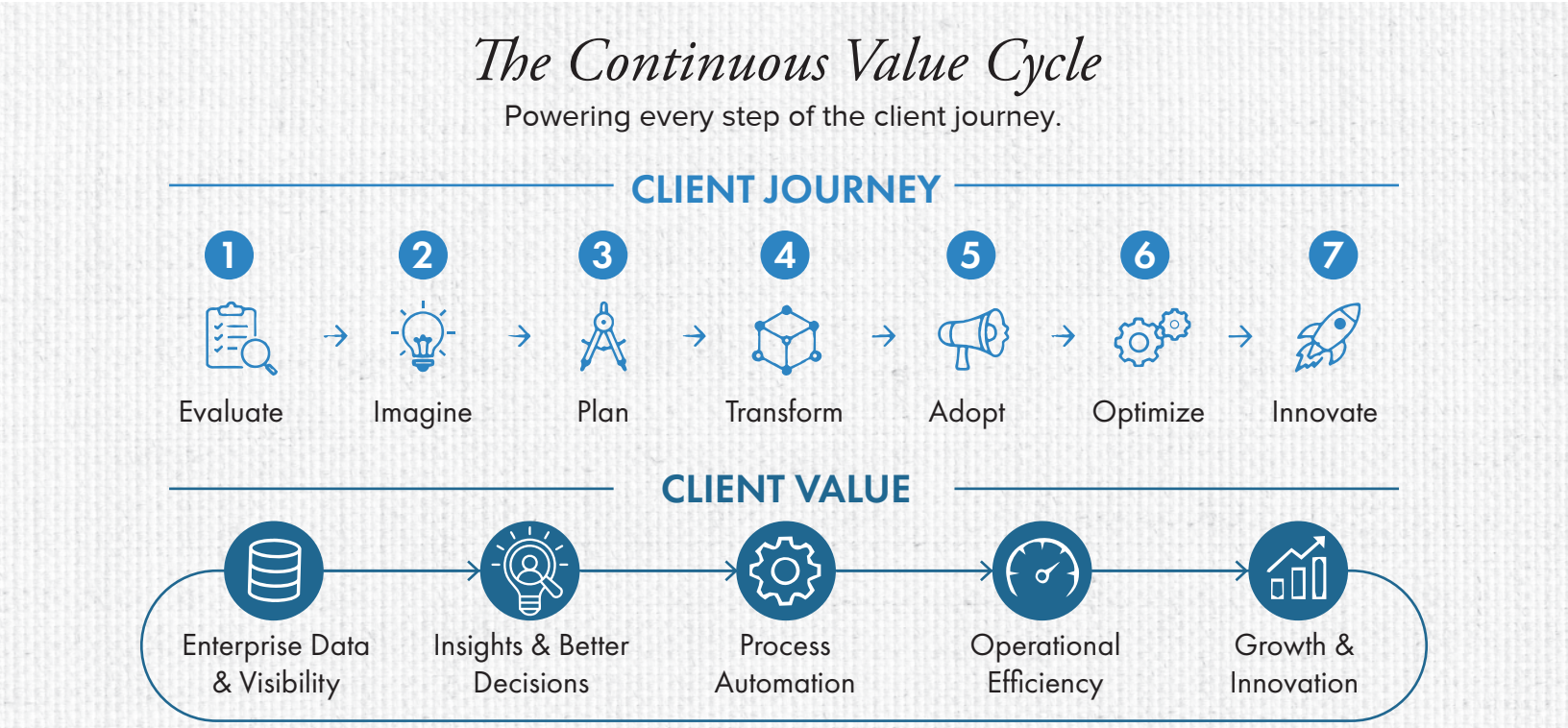


Figure 4. The Continuous Value Cycle

Preparing for What's Next

Commercialization is the result of decisions made throughout a company's growth, and enterprise technology is one of those decisions. The goal isn't to implement SAP at a predetermined milestone, but to recognize when the value of a scalable, connected foundation begins to outweigh the cost and risk of extending point solutions.

No two biotech companies follow the same path to commercialization. Identifying the right SAP entry point requires considering commercialization strategy alongside the operating model. It also requires considering validation implications, current systems, and future capabilities. That assessment helps leaders determine whether SAP fits the destination and when introducing it creates the greatest business value with the least disruption.

At Clarkston, we've helped life sciences organizations align technology decisions with their commercialization plans. Early planning can help companies scale operations while maintaining focus on bringing therapies to patients.

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