

Transforming clinical finance

How to evaluate purpose-built software that is revolutionizing biotech and pharma finance



Executive summary

Clinical finance and accounting in pharma is at a pivotal crossroads. As biotech and pharmaceutical companies accelerate growth and deal with regulatory and administrative challenges, the pressure to evolve from manual, outdated processes have never been greater. Today's transformative financial software solutions empower organizations to streamline complex regulatory requirements, enhance operational efficiency, and unlock real-time insights that drive strategic change. Gone are the days of cumbersome spreadsheets and reactive decision-making—modern software platforms offer agile, innovative tools designed to future-proof financial operations and propel enterprise-wide transformation.

This paper synthesizes leading practices and proven evaluation frameworks from industry thought leaders, offering a clear roadmap for selecting technology that drives both operational efficiency and long-term competitive advantage. By embracing innovative financial systems aligned with strategic goals, companies can build a resilient, future-proof financial foundation—enabling them to thrive amid uncertainty and remain at the forefront of industry evolution.

Introduction

In today's rapidly evolving biotech and pharmaceutical landscape, robust clinical finance and accounting practices are more than just back-office functions - they are strategic drivers for innovation and competitive advantage. This paper is designed to guide decision-makers through the holistic journey of selecting and implementing clinical finance software, confirming that every phase - from initial assessment to post-deployment optimization - is aligned with both operational needs and long-term strategic goals.

Before implementation, organizations should take a hard look at their unique financial and operational requirements. Smaller biotech firms often need cost-effective, scalable solutions that can be deployed quickly with minimal IT burden, while larger biopharma enterprises require enterprise-grade systems that manage complex regulatory demands, multi-currency transactions, and extensive data integration. This paper outlines key pre-implementation considerations such as defining core requirements, evaluating existing processes, and setting strategic objectives, so that decision-makers select technology that aligns with the organization's current landscape and future ambitions.

During and after implementation, the focus shifts to execution and continuous improvement. Success in this phase hinges on agile project management, effective change management, and ongoing performance monitoring. By following leading practices for seamless integration, fostering robust stakeholder collaboration, and refining processes iteratively, organizations can transform their clinical finance operations into a dynamic, insight-driven engine for innovation. This paper provides a structured, step-by-step guide to help companies navigate these critical phases, enabling a smooth transition and sustained competitive advantage in an increasingly complex environment.



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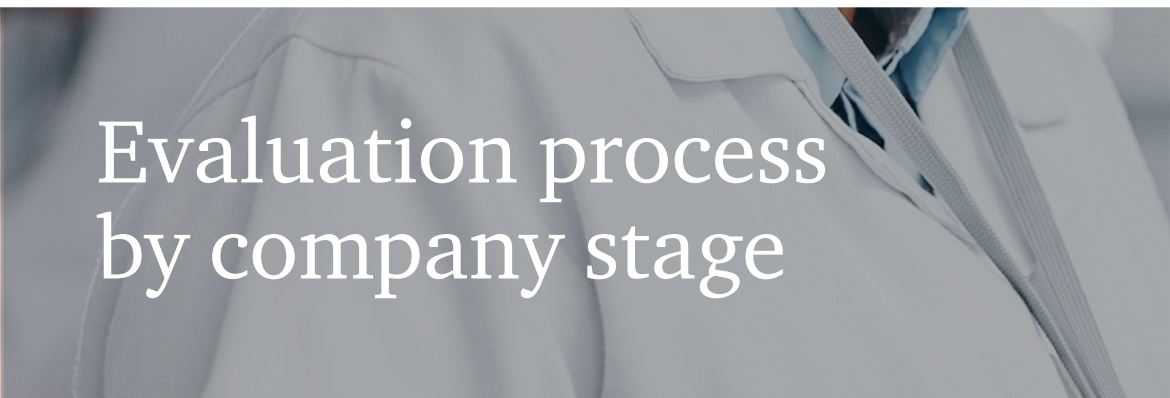
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Evaluation process for emerging biotech companies

Emerging biotech companies often reach a point where traditional spreadsheets and manual processes no longer suffice to meet the increasing complexity of clinical trials and financial management. As organizations scale, inefficiencies inherent in manual systems become apparent - whether through heightened audit risks, operational bottlenecks, or challenges in maintaining reporting accuracy and managing vendor billing. This evolution is particularly pronounced in scenarios such as Phase 1b/2 oncology trials, where the complexity of protocols and the critical nature of financial oversight underscore the urgent need for more advanced, automated solutions.

In these circumstances, the decision to adopt advanced software should be seen as a strategic pivot rather than a mere operational upgrade. Companies should proactively assess when their current processes are strained by increasing trial complexity, evolving compliance requirements, and escalating financial risks. When triggers like complex trial phases, potential inaccuracies in reporting, and vendor billing discrepancies arise, it becomes essential to consider software solutions that deliver real-time insights, robust risk mitigation, and scalable performance.

This paper encourages emerging biotech firms to evaluate the cost-benefit balance of transitioning from reactive fixes to a forward-thinking financial framework. By critically assessing these triggers and aligning technology investments with both immediate operational needs and long-term strategic ambitions, organizations can establish a resilient foundation that supports sustainable growth and positions them at the forefront of industry innovation.

Understanding tech-enabled services vs. SaaS

Tech-enabled services have long been positioned as a blend of software and high-touch support, offering dedicated account management, tailored integrations, and hands-on assistance. However, these solutions often rely on manual processes behind the scenes, meaning that while users interact with a software interface, much of the underlying work—such as data processing, analysis and reporting—is performed by human teams. This approach can introduce variability in speed, scalability, and consistency.

In contrast, true SaaS solutions are architected for automation and operational efficiency. Built on multi-tenant, cloud-native infrastructure, they allow for real-time data access, seamless integrations, and rapid iteration without reliance on manual intervention. Many modern SaaS providers also offer robust customer support and service packages, confirming companies receive professional guidance without compromising the scalability and agility inherent to the SaaS model.

For emerging biotech companies, the key consideration is not just the level of service provided, but the delivery model behind it. While tech-enabled services may offer a more customized experience, they can also introduce dependencies on human-driven processes and financial reporting errors. Organizations should evaluate whether a given solution aligns with their needs for automation, speed, and long-term flexibility, in addition to the level of support required.



Checklist: Evaluation process for smaller biotech companies



1. Define core needs

- Identify essential features such as budgeting, expense tracking, accruals, journal entries, forecasting and compliance requirements.
- Identify integration capabilities with existing tools and systems.



2. Determine the preferred service model

- **Staff augmentation:** For teams that need additional resources and would prefer to augment their team with service providers.
- **Self-serve:** For teams that want the full control of their process and platform with moderate support.
- **Hybrid:** Ability to flex between staff augmentation and self-serve model depending on business and resource needs.



3. Determine preferred software deployment model

- **SaaS:** For teams seeking an agile, scalable, cloud-native platform with real-time reporting and automated processes.
- **Tech-enabled services:** For teams that require a hands-on, customized approach with extensive vendor support, accepting potential reporting inconsistencies due to manual workflows.



4. Assess user experience

- Prioritize ease of use and intuitive interfaces to reduce training requirements.
- Evaluate vendor-provided support and training materials.
- For staff augmentation service models, assess the competency and capability of service teams.
 - Evaluate from reference calls how compliant, accurate and timely the reporting is.
 - Determine if the staff are onshore or offshore.
 - Assess the business and review process of staff augmentation team for proper input into software and review of reporting output. This is critical if complete and accurate reporting for compliance is a requirement.



5. Request demos and trials

- Engage directly with vendors to test software capabilities with real-world scenarios.
- Verify that key workflows align with the company's operational needs.



6. Evaluate total cost of ownership

- Look beyond initial pricing and assess long-term costs, including support and updates.
- Compare subscription pricing and service model pricing.

Late-stage biotech and large pharma evaluation process

When is it time to explore biotech and pharma-specific finance software?

Multiple factors can drive this decision. Organizations may need to explore upgraded solutions to accommodate scale and growth, address regulatory pressures, resolve operational bottlenecks, or overcome the limitations of legacy systems. At times, leadership or the Board may even launch company-wide digital transformation or financial optimization initiatives to secure real-time insights into trial performance, financial management, and risk mitigation strategies.

For some, piloting a new solution may be the best initial step. A targeted pilot can assess the software's value on a specific challenge - such as automating expense and accrual estimation for financial close or enabling R&D finance teams to run dynamic financial scenarios - before committing to a broader rollout. This focused approach helps build a solid business case and increases the likelihood that the selected solution delivers measurable benefits.

The playbook for evaluating options

Selecting clinical finance software that unifies R&D, clinical operations, finance, and accounting demands strategic alignment across the organization. Given the system's profound impact on program and portfolio financial management, compliance, and reporting, it is imperative that an internal team representing these key functions jointly establishes evaluation criteria prior to engaging with potential vendors. Moreover, it is up to the organization to determine who will own this initiative and define the primary user group - whether that be R&D finance or another critical stakeholder - confirming the solution meets the needs of its most frequent users.

A successful evaluation initiative requires a disciplined, cross-functional approach led by an executive sponsor and a dedicated project champion. Each stakeholder should conduct a thorough analysis of their department's objectives, challenges, and essential feature requirements. For instance, clinical teams may emphasize rigorous budgeting and vendor management, while R&D finance teams prioritize advanced forecasting and scenario planning. Meanwhile, accounting departments should seek solutions that enable automated expense accruals and journal entries to support SOX compliance, and IT should verify robust integration capabilities with existing systems and adherence to SOC/GxP standards.

After gathering these insights, the evaluation team should consolidate them into a holistic feature request list and define clear success metrics, such as expected ROI, operational efficiency gains, and enhanced compliance. Establishing these parameters at the outset allows for a more objective comparison of vendors, enabling the selected solution to deliver quantifiable benefits both in the immediate term and in the future.



Checklist: Multi-stakeholder evaluation process for larger biopharma

- **1. Appoint an executive sponsor and project champion**
 - The executive sponsor provides high-level oversight and alignment with organizational goals.
 - The project champion facilitates collaboration, allowing all stakeholders to contribute meaningfully.

- **2. Assemble the evaluation team**
 - Include finance leadership, accounting leadership, clinical business and operational teams, and IT administrators.

- **3. Define departmental requirements**
 - **Clinical / R&D operations teams:** Budgeting, vendor and resource management.
 - **FP&A / R&D finance teams:** Forecasting, scenario planning, long or mid-range planning.
 - **Accounting teams:** Accrual automation, financial close process, audit requirements.
 - **IT / informatics / technology teams:** Integrations, security and regulatory compliance.

- **4. Consolidate requirements into a feature list**
 - Develop a thorough list of must-have features based on cross-team input.
 - Identify compliance and reporting needs for regulatory alignment.

- **5. Define success metrics**
 - Establish key performance indicators (KPIs) such as expected ROI, operational efficiency gains, and compliance improvements.

- **6. Define evaluation metrics**
 - Establish a set of metrics for evaluation based on your success criteria to compare solutions.
 - Gain input and buy in from each department on evaluation metrics.

- **7. Compare vendor solutions**
 - Evaluate how each vendor meets consolidated feature requirements.
 - Conduct scenario-based demos to test real-world applications.
 - Consider integrating “day in the life” exercises and running a Proof of Concept (POC) or a limited pilot for a smooth transition, encourage buy-in, and test the proposed changes in a real-world context. These strategies provide immersive and tangible experiences, helping stakeholders visualize and experience the new processes and technology in action.

- **8. Assess long-term fit**
 - Assess vendor scalability and product roadmap to align with future business needs.
 - System integrates with existing workflows and enhances collaboration.
 - Business viability of vendor.



1. Operational performance

Effective software should enhance collaboration, improve financial planning, and support compliance.

- **Cross-department collaboration:** Unified platforms with real-time data sharing.
- **Custom reporting:** On-demand reporting is essential for transparency and informed decision-making.
- **Data-driven insights:** Built-in analytics for financial forecasting and resource allocation.

2. SOX compliance and risk mitigation

Compliance and audit readiness is critical.

- **Audit trails and compliance dashboards:** Real-time tracking of financial activities.
- **Internal controls and risk management:** Automated alerts for anomalies.
- **Continuous compliance monitoring:** Automated updates to regulatory frameworks.

3. Budgeting and forecasting

- **Forecasting, scenario planning, and cost tracking:** Run various scenarios with comparisons.
- **Real-time budgeting and change order management:** Dynamic budgeting with ability to measure, track and manage changes during the lifecycle of the contracts and trial.
- **Program and portfolio planning:** Model various scenarios and measure program and portfolio impact across internal resource planning, partner collaborations and external vendors.

4. ROI and cost efficiency

A cost-effective solution should provide predictable pricing and scale with business needs.

- **Cost predictability:** SaaS-based pricing with a 3-5 year cost horizon.
- **Scalability and flexibility:** The solution should be scalable and adaptable to organizational growth.
- **Security and compliance:** Enterprise-grade encryption and authentication.

5. Integration and data integrity

Seamless integration for efficient financial operations.

- **System integration:** Compatibility with existing IT infrastructure such as ERP, financial planning systems, and CTMS platforms is essential for real-time data synchronization and accuracy.
- **Automated data mapping:** Real-time data synchronization for accuracy.





Software deployment
options and flexibility



To make an informed decision about clinical finance software, it's important to understand the different software deployment models. These models impact how the software is accessed, deployed, modified, and managed. The three main software deployment models are on-premise, private cloud (single-tenant), and multi-tenant cloud.

- **On-premise:** Software is hosted and maintained on a company's premises by its IT department. The customer owns a perpetual license and is responsible for maintaining, evolving, and updating the software and hardware. The cost and effort increase over time.
- **Private (or single-tenant) cloud:** Each customer has their own software instance, but the vendor hosts the supporting infrastructure in their data center or on a cloud infrastructure. The vendor handles security, application access, operations, and maintenance. However, each software instance is siloed, leading to potential inefficiencies and risks similar to on-premise.
- **Multi-tenant cloud:** Multiple customers use a single version of the software on a shared infrastructure managed by the vendor. Customer data is securely segregated through virtual partitioning. Each customer uses the same software version, but configurations and customizations are unique. Multi-tenant cloud solutions have become a preferred delivery method because maintaining one version of the code allows vendors to innovate faster and provide more value to customers. This model facilitates a crowdsourced approach to quality, as defects are identified and fixed for all customers. Multi-tenant cloud environments also benefit from economies of scale for security investments, as every investment benefits every customer automatically.

The flexibility of the software is also an important consideration. Software should be agile enough to keep pace with business and market demands. When evaluating software, it's important to know if the solution is a purpose-built software application or a software application built on an application platform.

An application platform provides capabilities and infrastructure to build one or more applications, either packaged by the vendor or custom-built by customers or service partners.

When considering clinical finance software, evaluate vendors on their ability to support team leads in driving change management and re-imagining the future state. Assess the level of support provided for successful change management and the type of governance established between organizations to create alignment on success criteria.

Consider these questions to determine if the software is truly flexible:

- Is it flexible to meet the needs of different users or applicable business units?
- Is the flexibility enabled via configuration, custom code, or a combination of both?
- How easy is it to change, modify, or enhance the software?
- Can the software application be extended?





Evaluating vendors and selection frameworks

Selecting the right clinical finance software requires a structured and objective evaluation process, as enterprise tech buyers often become overwhelmed by extensive vendor documentation and sales materials. For a holistic and unbiased selection process, teams should focus on aligning vendor capabilities with organizational needs and compliance requirements.

Key vendor selection criteria

1. Business requirements

- Define the organization’s financial and operational needs.
- Align requirements with compliance, integration, and scalability needs.
- Document expected ROI and measurable success metrics.

2. Software features

- Assess if the system includes essential capabilities such as budgeting, forecasting, financial close, and audit trails.
- Evaluate automation, AI-driven insights, and workflow customization.
- Confirm data security and compliance with SOX and other regulatory standards.

3. Total cost of ownership (TCO) and ROI

- Assess both upfront and long-term costs, including implementation, licensing, and support.
- Estimate the time frame for realizing ROI through automation and efficiency gains.

4. System integration

- Assess compatibility with existing ERP, FP&A, CTMS, EDC, IRT, RTSM, and compliance systems.
- Assess available connectors for real-time data synchronization and interoperability.

5. Support and training

- Evaluate vendor-provided support, training, and documentation.
- Assess implementation assistance and long-term technical support options.
- Evaluate vendor’s ability to support team leads in driving change management and re-imagining future state.

6. Implementation and deployment

- Understand the deployment timeline and required internal resources.
- Determine whether phased implementation or full-scale rollout is preferable.
- Assess vendor experience in the life sciences sector.

7. Vendor industry expertise

- Given this is new technology, review the founding and leadership team’s background, to understand experience (i.e., strong track record with similar-sized biotech or pharma companies).
- Review case studies and customer references to assess success in similar deployments.

8. Technology and innovation

- Evaluate whether tech-enabled services align with your team’s needs or if an enterprise-grade architecture is more appropriate.
- Collaborate with IT to decide whether an on-premise, single-tenant, or multi-tenant platform best meets your requirements.
- Recognize that cloud technologies, artificial intelligence (AI), and machine learning can improve business processes, deliver deeper predictive analysis and insights, and offer a more personalized experience.
- Evaluate whether the technology is designed around appropriate compliance standards and incorporates the guardrails necessary for maintaining accounting integrity in reporting and processes.

9. Product roadmap and scalability

- Review vendor plans for future enhancements and product support.
- Confirm that the software will scale alongside business growth and evolving compliance needs.

10. Customization and flexibility

- Determine the level of customization available for workflows, dashboards, and reports.
- Assess the ability to adapt to future business needs without extensive reconfiguration.

By following this structured approach, biotech and pharma companies can more confidently navigate vendor selection, helping adopt solutions that align with operational, regulatory, and financial needs while driving efficiency and compliance in clinical finance automation.



Assessing clinical finance vendors: Key questions

After the evaluation team has compiled a shortlist of potential clinical finance software solutions, it's time to conduct a deeper assessment. The following key questions will help differentiate vendors and confirm the selection aligns with business needs and objectives.

1. Business requirements

- Does the software specifically support clinical finance and accounting in biotech and pharma?
- Does the software meet all outlined business requirements and compliance needs?
 - What percentage of the business requirements can be met with off the shelf capabilities?
 - What requirements need additional support and customization?
- How does the platform process real-time synchronization across multiple systems to maintain consistent and accurate financial records?

2. Software features, architecture and security

- Is the user interface intuitive and consistent across all modules?
- Can new features/modules be added as the business grows?
- Does the software include advanced reporting and business intelligence tools?
- What visualization and dashboard tools does the platform provide to deliver real-time insights and allow decision-makers to monitor key metrics instantly?
- How does the platform leverage cloud-based infrastructure to deliver high availability and low-latency processing for real-time data updates?
- How do you verify data is protected both in transit and at rest within your platform?
- How do you handle user authentication and access control?

3. Total cost of ownership (TCO) and ROI

- How does the pricing structure compare between vendors? Is the pricing model driven by user, enterprise, number of modules, therapeutic area, programs, clinical trials?
- How does the total cost structure scale with the organization's needs?
- What is the estimated timeline to achieve ROI? How do different vendors/alternatives compare in terms of the level of efficiency gained?
- Does one alternative have a higher ROI based on capabilities?
- How does the vendor handle major upgrades in the future? How do vendors compare on the innovation front?
- What are the various levels of service support, and comparatively the associated cost of services?

4. System integration

- How is existing data migrated into the system?
- Does the software provide middleware or APIs for integration with existing systems?
- Does it integrate with ERP, FP&A, CTMS, and compliance platforms?
- How does the platform deliver real-time synchronization across multiple systems?

5. Support and training

- What level of support is provided during implementation?
- What is the level of support provided to drive a successful change management?
- What ongoing support packages are available? What are the response times?
- What training options are provided (on-site, virtual, third-party)?
- What is the vendor's experience with establishing a formal governance structure to drive project alignment, success, and effective decision-making on an ongoing basis? Ask for concrete examples of governance frameworks the vendor has implemented in similar projects.
- What type of governance will be established between both organizations to create alignment on success criteria?

6. Implementation and deployment

- What is the expected timeline for implementation?
- Who are the vendor's implementation partners, and what knowledge do they offer?
- Are testing tools and user acceptance testing included before go-live?
- Will a sandbox environment be provided to secure proper testing prior to deployment?

7. Vendor industry knowledge

- How well does the vendor understand the unique financial and regulatory challenges of life sciences?
- How long has the vendor been in business?
- Where did the founders, core development and executive leadership team come from?
- Can the vendor provide references from other biotech or pharma organizations?

8. Technology and innovation

- How does the software scale as the business grows?
- Does the system leverage AI and machine learning for automation and predictive analytics?
- What recent innovations have been implemented in the platform, and how have they improved functionality, efficiency, or user experience?
- How does the vendor stay ahead of technological trends?
- What is the process for gathering customer feedback and incorporating it into the development of innovative features or improvements?
- What is the approach to continuous improvement, and how do they make sure that the platform evolves to meet the changing needs of the market?
- How do they balance innovation with maintaining the reliability and security of their platform?

By addressing these key questions, finance teams can conduct a thorough evaluation and select a vendor that aligns with their operational, regulatory, and strategic objectives.

9. Product roadmap and scalability

- What new features are planned, and what is the expected release schedule?
- Are software updates released on a defined schedule? Is there an additional cost for upgrades?
- How does the platform handle high volumes of real-time data, and what scalability measures are in place to accommodate increasing data flow or transaction load?

10. Customization and flexibility

- Can the software be customized to fit specific clinical finance workflows?
- Does the vendor provide APIs and development tools for further customization?



Conclusion

In conclusion, this paper delivers objective, professional guidance on evaluating and selecting clinical finance software - a process that is not merely beneficial but critical for the innovation and continuity of the pharmaceutical and biotech industry. By outlining a clear, structured roadmap—from identifying operational triggers and defining departmental requirements to establishing cross-functional ownership and measurable success metrics—this guide equips decision-makers to replace outdated, manual processes with agile, integrated solutions. Such a transition delivers robust ROI, streamlined compliance, and sustained competitive advantage, positioning organizations to navigate evolving regulatory and technological landscapes and secure long-term industry leadership.



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