Solution Brief

Enterprise planning in clinical performance management

Technology and best practices to drive performance

Highlights

- ***Optimizes critical investments in R&D, pharmaceutical by gaining dynamic, real-time insight into all aspects of the clinical development process***
- ***Replaces the often fragmented enterprise planning process with continuous, collaborative planning***
- ***Facilitates creation of plans that maximize operational effectiveness, better anticipate resource requirements and expenses***
- ***Allows planning to be realigned as conditions change***
- ***Leverages new technologies and best practices in planning, budgeting, and forecasting for more accurate plans, timely forecasts, and effective decision-making***
- ***Helps save time, reduce errors, improve collaboration enterprise-wide for true competitive advantage***
- ***Helps to meet regulatory requirements by better anticipating resources and expenditures***

Introduction

Pharmaceutical companies are under intense pressure to deliver new drugs in record time and as efficiently as possible. Yet the reality is that drug research and development is expensive, lengthy, and increasingly regulated. To optimize critical investments in R&D, pharmaceutical companies need dynamic, real-time insight into all aspects of the clinical development process. And gaining that insight depends on having complete visibility into clinical information across the extended organization.

The enterprise planning process–planning, budgeting, forecasting and reporting–replaces what is typically a fragmented process with continuous, collaborative planning. The organization defines goals and turns them into discrete plans and budgets for the entire clinical team. Plans can be created to maximize operational effectiveness and better anticipate resource requirements and expenses. And they can be realigned as conditions change.

Yet, despite its importance to financial well-being, enterprise planning is often back-burnered because it is seen as burdensome and time-consuming. And therein lies an opportunity for the forward-thinking organization. Leading pharmaceutical companies are seizing the opportunity to improve business processes by leveraging new technologies and employing best practices in planning, budgeting, and forecasting. They are rewarded with more accurate plans, timely forecasts, and effective decision-making. Overall, they save time, reduce errors, improve collaboration enterprise-wide and foster a disciplined financial management culture that delivers true competitive advantage.

An improved forecasting and planning process can help these companies better anticipate resources and expenditures to meet regulatory requirements such as U.S. Food and Drug Administration (FDA) filings–so they may file sooner and experience fewer surprises. A consolidated view also allows stakeholders to quickly

determine how the organization is doing against established milestones, identify and isolate problems, and take the appropriate steps to address the issues. The insights gained from this analysis allow them to gain efficiencies, streamline operations, and reduce the costs of bringing new products to market.

In addition, improved enterprise planning can help companies:

- Analyze and report on clinical performance data to identify best practices and improve resource allocation.
- Monitor key performance indicators (KPIs) to identify problems quickly.
- Consolidate data from multiple sources to identify trends, anomalies, or opportunities.
- Forecast predictable and consistent future results.
- Leverage investments in clinical trial management systems (CTMS) and disparate data sources.

With the benefit of timely, reliable, and flexible plans, decision makers can quickly identify, analyze, and forecast the impact of changes as they occur. They can strengthen the link between strategic objectives and operational and financial plans, while fostering communication and collaboration among managers and clinical teams.

This guide will help you take the first steps toward improved enterprise budgeting, planning, and forecasting. It outlines a systematic approach that combines best practices and leading-edge technology with planning activities in your organization. By taking this approach, your organization can significantly improve its financial and operational performance.

Planning challenges

In life sciences organizations, corporate decision makers typically voice similar objections with regard to planning, budgeting, and forecasting:

- Processes are tedious and time-consuming.
- Changes are difficult to implement.
- Data integrity is questionable.
- Explanation of variances is difficult.

For managers outside finance, planning can be perceived as little more than a periodic invasion of their time with minimal benefit. Managers can feel besieged by demands for information and improved projections, while still being expected to deliver results.

"Regular planning and gap analysis reviews anchor the drug development process with business priorities and help 'identify failure early.' In practical terms, if a sponsor can identify a product as a risk in Phase 1, it can save tens of millions of dollars by 'killing' the product before it enters Phase 3."

~ from The Performance Manager for Life Sciences, by Roland Mosimann et al, 2008, an IBM business book

Origins of planning challenges

Despite substantial investments in clinical trial management systems (CTMS), enterprise resource planning (ERP), electronic data capture (EDC) and other enterprise systems, most pharmaceutical companies still rely on manual planning processes using spreadsheets–an approach that's cheap in software terms, but costly in the long term because spreadsheets are cumbersome, error-prone and ineffective in managing large amounts of data. Among the challenges of spreadsheets:

- Business rules (formulas) are mixed with data and prone to corruption.
- Files must be sent back and forth, creating version control issues.
- Presenting or analyzing data from different perspectives is difficult.
- It's difficult to follow or duplicate the logic of the spreadsheet's creator.
- Data aggregation is difficult and time-consuming.
- Complex calculations are not supported, and multidimensional reporting and analysis are impossible

Supporting best practices

Planning software should support best practices to enhance timeliness, information reliability, and participation by key people across the enterprise.

Align strategic and operating plans

In an industry that invests over $10 billion a year on clinical trials in the U.S. alone, the ongoing alignment of strategic and operating plans is vital. Finance must clearly communicate corporate strategic plans to those who run the day-to-day business. Finance can help translate strategic goals into financial targets and then into specific departmental plans and related revenue and expense drivers, such as patient enrollment. By translating strategic goals into operational plans, and by tracking and measuring performance against plan, pharmaceutical companies are better able to meet or exceed objectives and achieve these benefits:

- Receive daily, weekly or monthly updating of clinical development costs.
- Forecast the revenues and net income contribution of each entity in the R&D pipeline.
- Make go/no go decisions early on so funding and resources can be diverted from unpromising candidate compounds to successful ones.

Start at the top—and at the bottom

An important ingredient in successful budgeting and forecasting is the ability to align top-down financial targets with bottom-up plans. Some companies establish top-down targets and then turn the annual budgeting process over to finance, along with a mandate to meet those numbers. Other companies require detailed bottom-up planning, and then plug the total company numbers in at the top, so that the plan meets strategic targets. Neither of these approaches reflects a commitment to planning excellence.

Instead, pharmaceutical organizations should provide initial guidance from senior management's top-down perspective on strategic goals, objectives, and expectations. Then, department managers and clinical trial operations managers can build a plan from the bottom-up, indicating how they intend to meet established goals. The process requires frequent iterations for these approaches to meet and be reconciled.

> *"When you ask people to contribute a target number or set an acceptable threshold for a goal or measure, you have shared ownership of the outcome and helped link the person back to the financial results."*
>
> *~ from The Performance Manager for Life Sciences, by Roland Mosimann et al, 2008, an IBM business book*

The result is a plan that is supported by:

- Clinical trial operations managers in the field, because they help create it and will be rewarded for meeting it.
- Senior management, because operational goals are aligned with strategic goals.
- Finance managers, because they add value to a productive, collaborative effort, rather than demanding participation in a mere exercise.

The benefit is a comprehensive view–schedules, budgets, goals met and goals unmet. With this insight, clinical teams and company executives can make decisions that not only solve immediate problems, but improve clinical trial performance over time.

Drive collaboration between functions
Not only should strategic and operating plans be aligned, but plans between regions and functional areas should also be coordinated. Best practices include direct involvement by all business stakeholders along with a collaborative approach to budgeting and forecasting.

In addition to understanding strategic goals, managers also need to know what other functions are involved in planning. For example, in terms of compliance requirements such as the FDA's CFR 21, having timely access to all clinical data is essential. With an integrated platform, all managers work from a single source of risk and financial information that is consistent and auditable.

Such collaborative planning can be accomplished through an iterative process that lets managers forecast and share alternative scenarios. Finance also plays a key role in facilitating the coordination of plans across the company, which helps ensure that operational tactics are aligned with financial targets throughout the organization.

Adapt to changing business conditions
In a research-driven environment, life science companies need the ability to adjust plans, metrics, and resource allocations in response to market and internal variability. In this case, dynamic re-forecasting is required:

- Frequent re-forecasting. Forecasting may be needed monthly or even biweekly, especially in fast-moving, quickly growing businesses with multiple market pressures. Continuous reforecasting helps managers answer critical questions such as, "What did we expect?" "How are we doing against our plan?" and, even more importantly, "How should we adapt our plans going forward?"
- Rolling forecasts. A company running rolling forecasts is always looking forward to the immediate or near-term future. For them, business does not end on December 31st and restart on January 1st. The forecast timeframe should extend out two to eight quarters, depending on business volatility.

Planning should be an ongoing process with frequent opportunities for managers to view the company's latest internal and external performance data. They should be able to alter plans based on new information coming from sources such as other managers, monthly actuals, and top-down target revisions. Finance should be able to quickly consolidate plan data from all areas of the company, and to disseminate new information in real time. This process will facilitate more informed decision-making in the face of market or competitive pressures, emerging regulations, or organizational changes.

"Companies can cut costs and investments to meet short-term profit objectives, but at what point does this affect long-term financial health? This is a particularly difficult balancing act in the life sciences, where substantial investments are being spent upfront before a long-term return can be substantiated. A well informed executive team is able to understand the drivers, opportunities, and threats when balancing short- and long-term financial performance."

~ from The Performance Manager for Life Sciences, by Roland Mosimann et al, 2008, an IBM business book

Model business drivers

A first-rate budget or forecast is based on a model with formulas that are tied to fundamental business drivers. Simply importing and manipulating past actuals does not reflect underlying operational causes and financial effects. Building driver-based models into plans ensures appropriate consistency across functions and promotes planning coordination between functions.

For example, future clinical trial forecasts can be tied to current patient enrollment and location costs. Finance can provide managers with a useful model that includes information about past actuals and current rates, as well as formulas driven by assumptions. This does not violate the best practice that requires clinical trial managers to be responsible for creating their own budgets. Instead, it saves them time by providing a solid, fact-based baseline–a starting point that contains important information about their organizations' relationships to other functions. Managers can then make adjustments to this baseline based on the latest business conditions. This approach also ensures collaboration across functions.

Manage content that is material

A focus on material content in budgeting frees managers from unnecessary detail, enabling them to produce better plans. While supporting detail can provide an audit trail and insight into managers' thinking, more detail does not necessarily make a better plan. Managing material content requires attention to whatever has real and significant impact on expenses, revenues, capital, or cash flow. Content management helps an organization:

- Avoid false precision. A complex model might not have any more precision than a simpler model. More detail and intricate calculations can lure managers into the trap of thinking their plan is therefore more accurate.
- Monitor volatile – not stable – accounts. Efforts are best spent on fluid expenses such as trial enrollment.
- Aggregate accounts. The budget does not need to reflect the same level of detail as in the general ledger.

Even if the GL has 15 different travel accounts, managers can often plan in one.

Timeliness and reliability

Many companies have an inefficient and inflexible planning process, at the center of which is the annual budget. Time-consuming consolidation processes practically guarantee that plan data is out-of-date and irrelevant before it is even published– and plans based on stale data and assumptions are of no value. World-class organizations shorten their planning cycles by implementing the best practices described here. They also leverage technology so that they can manage budget consolidation and aggregations in real time.

Technology can especially help improve timeliness and reliability in the area of plan consolidations. Real-time plan consolidation eliminates the necessity to process results manually, and enables a smoother, more consistent, more accurate planning process. Variance reports delivered within two to four days from the period close allow managers to immediately evaluate their performance against plan, and then effectively adjust their businesses.

At an operational level, this type of planning will be less costly and will produce more accurate results than the processes followed by most companies today. At a strategic level, a company's ability to create timely and reliable financial plans will allow it to provide more credible guidance to stakeholders, and to make faster, better-informed business decisions.

Best-practice templates

The use of pre-built, best-practice templates or planning models can help organizations reduce implementation risk and accelerate time to business value. They are being developed by

software vendors for a wide range of functional areas and industries. With templates, companies can establish dynamic connections that keep strategic objectives, operational plans, people, and initiatives in sync as business conditions change. Executives can quickly see the impact of changes in operational plans on corporate financials. Clinical trial operations and project managers can quickly adjust resource allocations to support corporate objectives. And corporate guidelines and policies are more consistently communicated and applied throughout the business.

IBM Cognos® Performance Blueprints give finance more time for analysis and rolling forecasts. Blueprints are pre-configured planning, reporting and policy templates based upon IBM Cognos 8 Planning and IBM Cognos 8 Business Intelligence, downloadable from the Web for IBM Cognos software customers. Instead of re-keying or copying data from one spreadsheet to the next, users can simply click from one integrated plan to the next to see allocations, actuals, variances, and other key performance data. What emerges is a dynamic business that adapts quickly to trends, competitive challenges, and changing markets.

IBM Cognos Blueprints for the pharmaceutical and life sciences sector include:

- Integrated Brand Management: Helps brand and therapeutic area managers ensure successful product launches and maximize brand value. Developed in partnership with Palladium.
- Clinical Trial Enrollment Forecasting: Provides insight into patient enrollment indicators that can affect the progress of costly clinical trials.
- Clinical Trial Forecasting: Helps forecast clinical trial resource requirements and accompanying expenses to comply with FDA requirements.
- Sales Quota Allocation: Significantly reduces the time, overhead, complexity and cost of managing sales quota allocations.
- Sample Optimization: Enables executives to develop and implement sample allocation plans in line with corporate revenue objectives.

For more information on IBM Cognos Performance Blueprints, visit the IBM Cognos Innovation Center for Performance Management: www.ibm.com/cognos/innovationcenter

Technology that supports best practices

Leading pharmaceutical organizations recognize that spreadsheet-based planning impedes budgeting and forecasting best practices. Instead, they have moved to purpose-built applications with lean infrastructure requirements, which enable them to accurately plan and re-plan quickly, using the same or fewer resources than before.

Streamlining the planning process demands technology that can support a faster, more flexible and adaptive approach. By using an on-demand, dedicated planning, budgeting, and forecasting application that is delivered over the Web, organizations can readily implement best practices.

Leading companies formulate top-level requirements for evaluating and selecting world-class planning, budgeting and forecasting software. Solutions must be:

- **Integrated.** Strategic, operational, and financial planning resides in one system. Managers do not need to maintain shadow or duplicate planning systems.

- Collaborative. Web-based, distributed planning enables broad participation. The ability to use a secure Web connection allows everyone to access budget information wherever there is Internet connectivity.
- Adaptive. Simplified version control and the ability to frequently reforecast allow companies to respond to business changes with "what if" scenarios as often as necessary.
- Timely. Information is always current, because users contribute directly to a central planning database. Since consolidations and rollups are done automatically, deadlines are more easily met.
- Efficient. Finance and other managers spend less time managing data and more time managing the business.
- Relevant. Customized views for managers increase adoption and ownership. Formula capabilities enable modeling of all relevant business drivers.
- Accurate. Plans contain fewer errors, since broken links, improper rollups and missing components have been eliminated.
- Owned by finance. Finance must be responsible for planning process development, deployment, reporting, and analysis. This calls into focus product flexibility and ease-of-use, both in modeling and day-today activities.

Selecting the right planning software

Evaluating a vendor's product features and support is a complex task. It requires assessment of software functionality, its value to the planning process and its ability to support planning best practices. There are also intangibles like vendor support, user community, and commitment to customer success once the sale is complete.

The key is not just to evaluate product features, but also how features are implemented and by whom. It is important to test a planning solution that will be relied upon by a large number of stakeholders and play a critical role in organizational performance. Therefore, it is highly recommended that a workshop approach be used to evaluate not only solution features, but also the way a plan is constructed, distributed, and reported on. A business process should be defined (such as trial enrollment, headcount, or expense) as context for the evaluation of product features and intangibles such as ease of development, roles, references, and customer support.

The following matrix supports the evaluation process by relating best practices and features, as well as helping to prioritize features, and assessing how well they relate to vendor offerings.

The requisite experience

Clinical research organizations worldwide already choose IBM Cognos solutions, including 25 of the top 30 pharmaceutical firms. Small and midsize organizations also choose IBM Cognos software to provide flexible deployments that fit their needs and budgets, and can grow with their business. Large or small, these organizations recognize our innovative capabilities, vision, ability to deliver and technology leadership in the field of performance management.

For more information about IBM Cognos Planning in pharmaceuticals and life sciences, please visit www.cognos.com, which provides articles and resources that describe key factors to consider when evaluating enterprise planning solutions. Through case studies and demos, it also makes the case for choosing IBM Cognos performance management solutions.

Planning software selection matrix

Feature Category	Importance/ Weight (1 "least important" to 5 "most important)	Vendor 1(Weight * Score)	Vendor 2 (Weight * Score)	Vendor 3 (Weight * Score)
Align strategy & operational plans				
Module Application Development				
Application Linking (Planning- specific application modules can be developed one-at-a-time, then linked to model the entire company. Aligns operational planning with financial planning to improve decision-making.)				
Model business drivers				
Driver-based calculations				
Dimension separate from models				
Multi-cube development environment				
Driver-based calculations				
Finance-based functions				
Time intelligence functions				
Ease of development by finance				
Manage content				
Real-time workflow				
E-mail alerts				
Input validation				
Role based security				
Real-time calculations				
Web client				
Microsoft® Excel® client				
Offline capabilities				
Annotations support				
Supports timely & reliable planning				
Real-time plan consolidation				
Automated data loads between transactional systems				
Certified connector to ERP				
Standard reporting				
Multi dimensions analysis				
Dashboard and scorecarding				
Best Practices Templates (pre-built models)				
Allocation planning				
Capital expenditure planning				
Expense planning				
Initiative planning				

Continues

Feature Category	Importance/ Weight (1 "least important" to 5 "most important)	Vendor 1(Weight * Score)	Vendor 2 (Weight * Score)	Vendor 3 (Weight * Score)
Risk analysis				
Integrated income statement,				
balance sheet, and cash flow				
Sales forecasting				
Strategic planning				
Workforce planning				
Company Profile				
Quality of references				
Revenue				
Number of employees				
Number of customers				
Number of industry references				
Independent industry analyst ratings				
Implementation and Support				
Implementation methodology				
Training options				
Support hours				
User communities				
Customer forums				
Online knowledge base				
Partner network support				
Vendor consulting				
Quality of documentation				
IT Infrastructure Support				
Database support				
LDAP support				
Single sign-on				
Portal support				
Open API				
MDX support				
HTTPS support				
Total Score				

About IBM Cognos BI and Performance Management

IBM Cognos business intelligence (BI) and performance management solutions deliver world-leading enterprise planning, consolidation and BI software, support and services to help companies plan, understand and manage financial and operational performance. IBM Cognos solutions bring together technology, analytical applications, best practices, and a broad network of partners to give customers an open, adaptive and complete performance solution. Over 23,000 customers in more than 135 countries around the world choose IBM Cognos solutions.

For further information or to reach a representative: www.ibm.com/cognos

Request a call

To request a call or to ask a question, go to www.ibm.com/cognos/contactus. An IBM Cognos representative will respond to your enquiry within two business days.

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