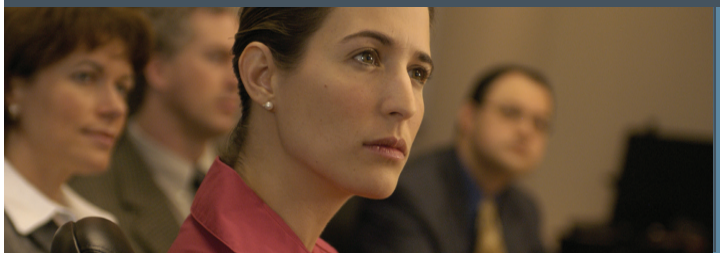
BUSINESS VALUE GUIDE
VERSION 2

COGNOS PERFORMANCE BLUEPRINTS

CLINICAL TRIAL FORECASTING



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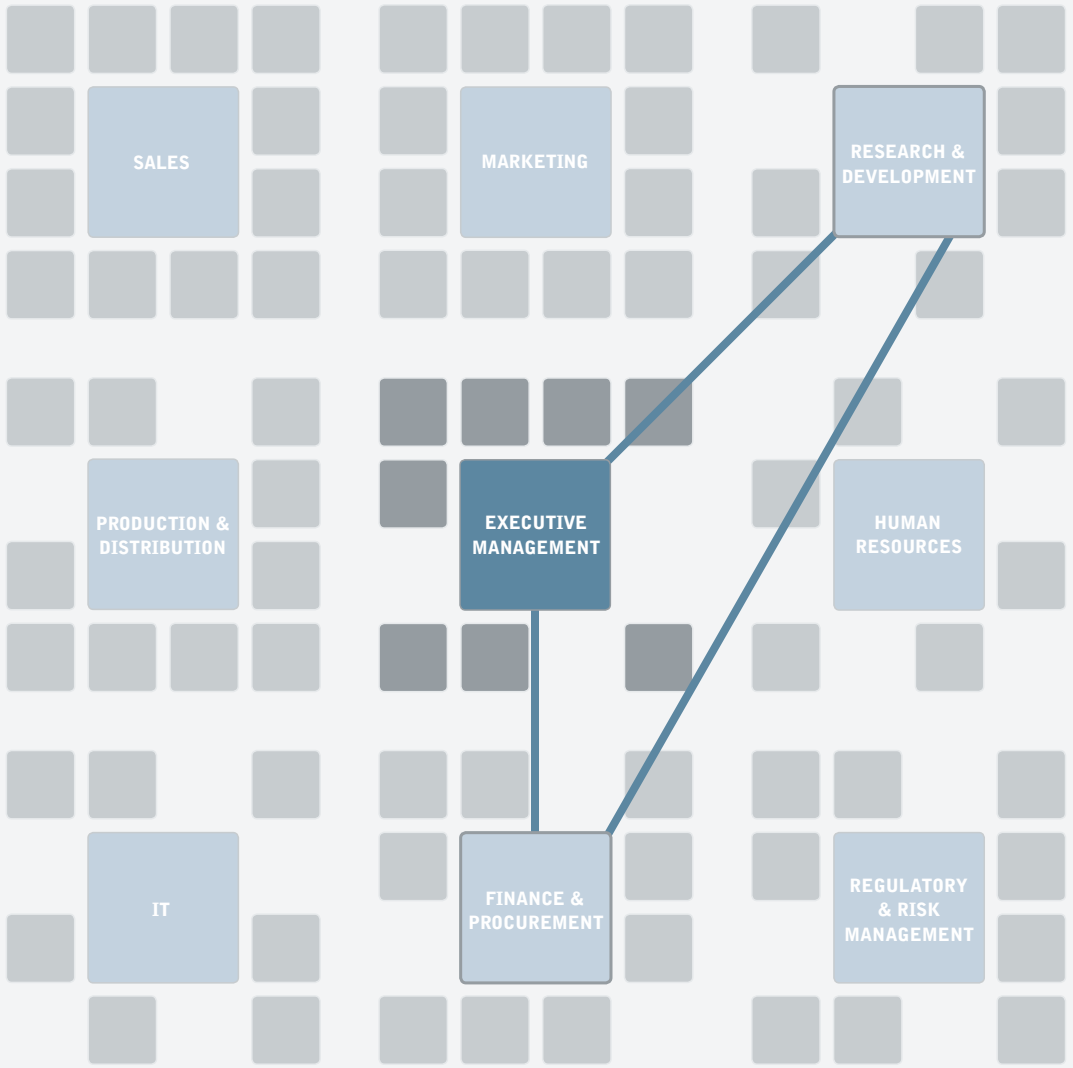
Clinical Trial Forecasting helps companies better anticipate resource and expenditure needs to meet FDA filing requirements.

The importance of managing the clinical trial process cannot be understated. Pharmaceutical companies spend more than $400 million—some 37 percent of their total research and development budgets (according to *Cutting Edge Information*). While costs of trials are increasing, so is their complexity, as the process expands beyond Finance to include both internal and external clinical development functions.

Clearly, a more proactive approach is required to better match process realities with expenditure management. The *Clinical Trials Forecasting Blueprint* is designed to facilitate more effective expense management by mapping expenses to activities, rather than using time-based accrual. Through a review of fixed and variable cost-driven enrollments, clinical trial expenses can be modeled to simplify bottom-up forecasting, increase plan accuracy and timeliness, and enhance resource allocation decision-making.

Clinical trial forecasting requires:

- Collaborative decision support for all stakeholders in the clinical trials process.
- A standardized corporate rationale for clinical trials planning.
- A consolidated view of clinical trials across the organization.
- Resource transfer to under-performing clinical trials to insure completion.
- Input from thousands of field-level reps.
- Senior-executive visibility into the overall clinical trials spend.

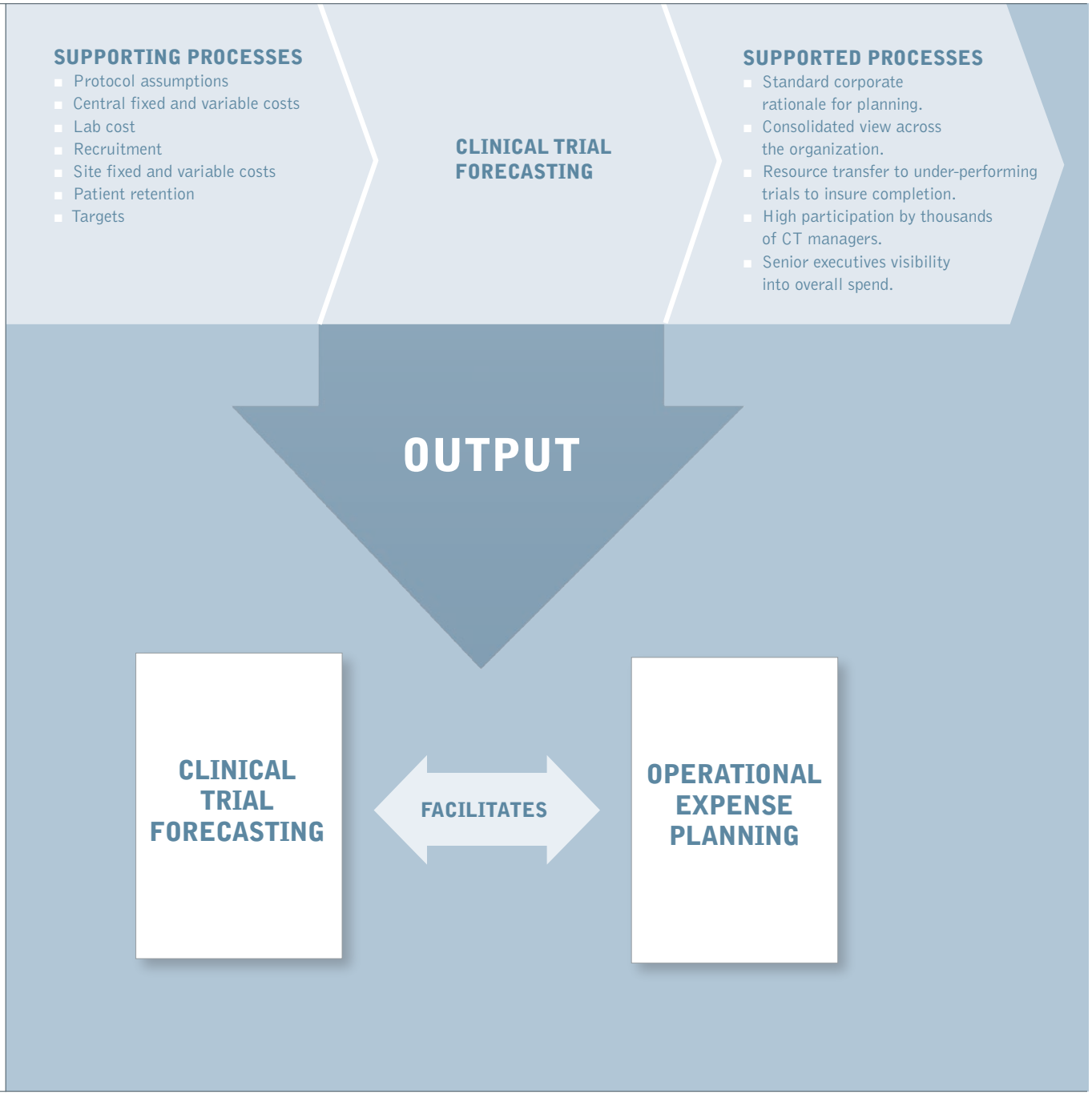


The key output of Clinical Trial Forecasting is an expense plan that allocates resources supporting a company's FDA filing.

Clinical Trial Forecasting requires the setting of protocol assumptions, tracking of central fixed and variable costs, lab costs, recruitment, site fixed and variable costs, while taking into account patient retention and protocol targets or goals. Such factors are all inputs to the clinical trial process.

Clinical trial forecasting provides a standard rationale for trial planning and a consolidated view across all protocols which enables resource transfer where necessary, high participation by clinical trial managers, and executive visibility to overall spending.

Ultimately, the forecasting process provides a pharmaceutical company an accurate prediction of clinical trial operating expenses.



Protocol definition begins the process. Based on assumptions and fixed costs, enrollment drivers can be established to predict variables such as per-patient costs that include investigator and lab fees. Driver-based forecasting improves accuracy.

As noted, clinical trials represent the largest direct-spend component in most BioPharma company R&D budgets. Large, global Phase 3 clinical trials often cost more than $20 million to execute.

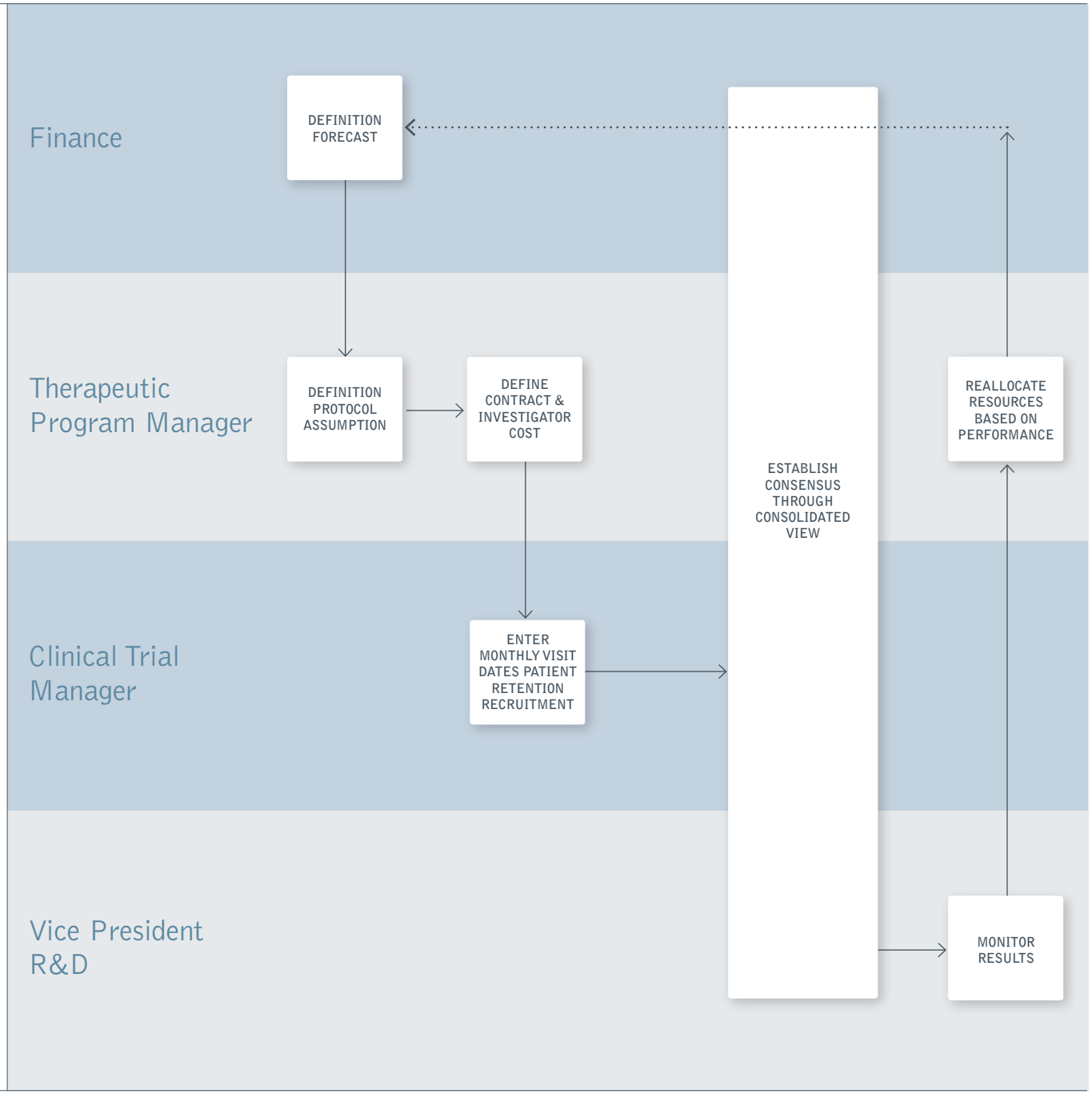
It is important to clearly understand and rapidly model project cost drivers, and be able to consolidate them by portfolio for "what-if" analyses and scenario planning.

It is also important to understand the performance characteristics of particular site- or country options. By modeling performance data using this process, it becomes easier to analyze the data and use it to make more effective resource allocation decisions.

A typical workflow supporting Clinical Trial Forecasting.

In many companies, the clinical trial process is managed by four primary stakeholders:

- *Finance* defines the trial forecasting process.
- The *therapeutic program manager* defines protocol assumptions and fixed/variable costs, which can include contract and investigator costs. It is important to note that even within the same protocol or study, these costs can vary by site location.
- Once defined, the *clinical trial manager* enters on a monthly basis the costs associated by protocol enrollees. This process is repeated across all protocols for the month.
- One data is collected, finance consolidates this information to be reviewed by the *R&D executive team* to monitor trials results.

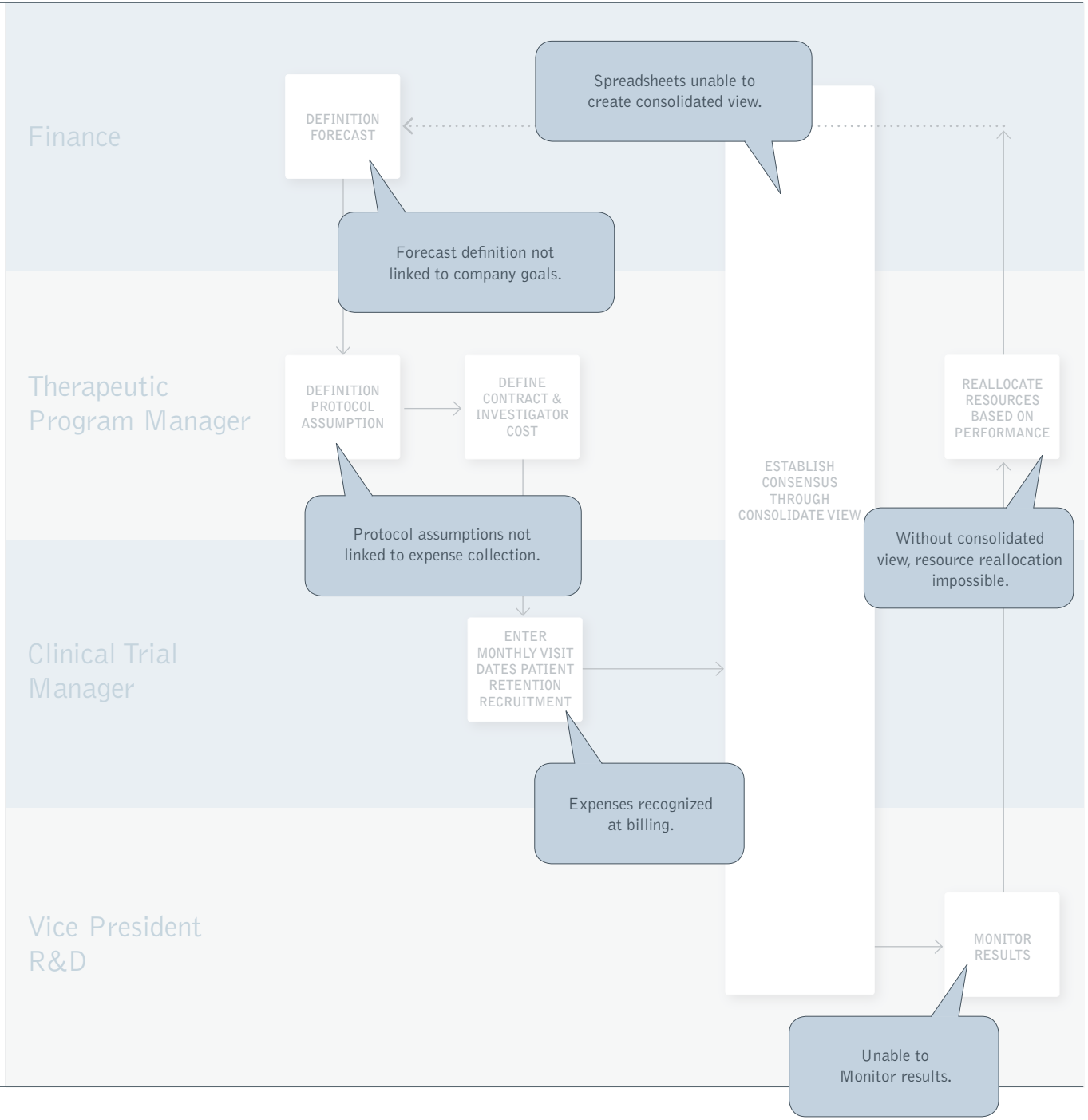


Most companies manage the process using spreadsheets, which leads to error and difficulty in arriving at a consolidated Clinical Trial Forecast plan with sufficient detail to improve forecast accuracy.

This already-complex process is further complicated by the use of spreadsheets that—although flexible—lack the consistent business rules needed to communicate process intricacies.

Typically, forecast goals are not linked to protocol assumptions. Expenses have to be recorded when billed, as apposed to being derived through enrollment figures.

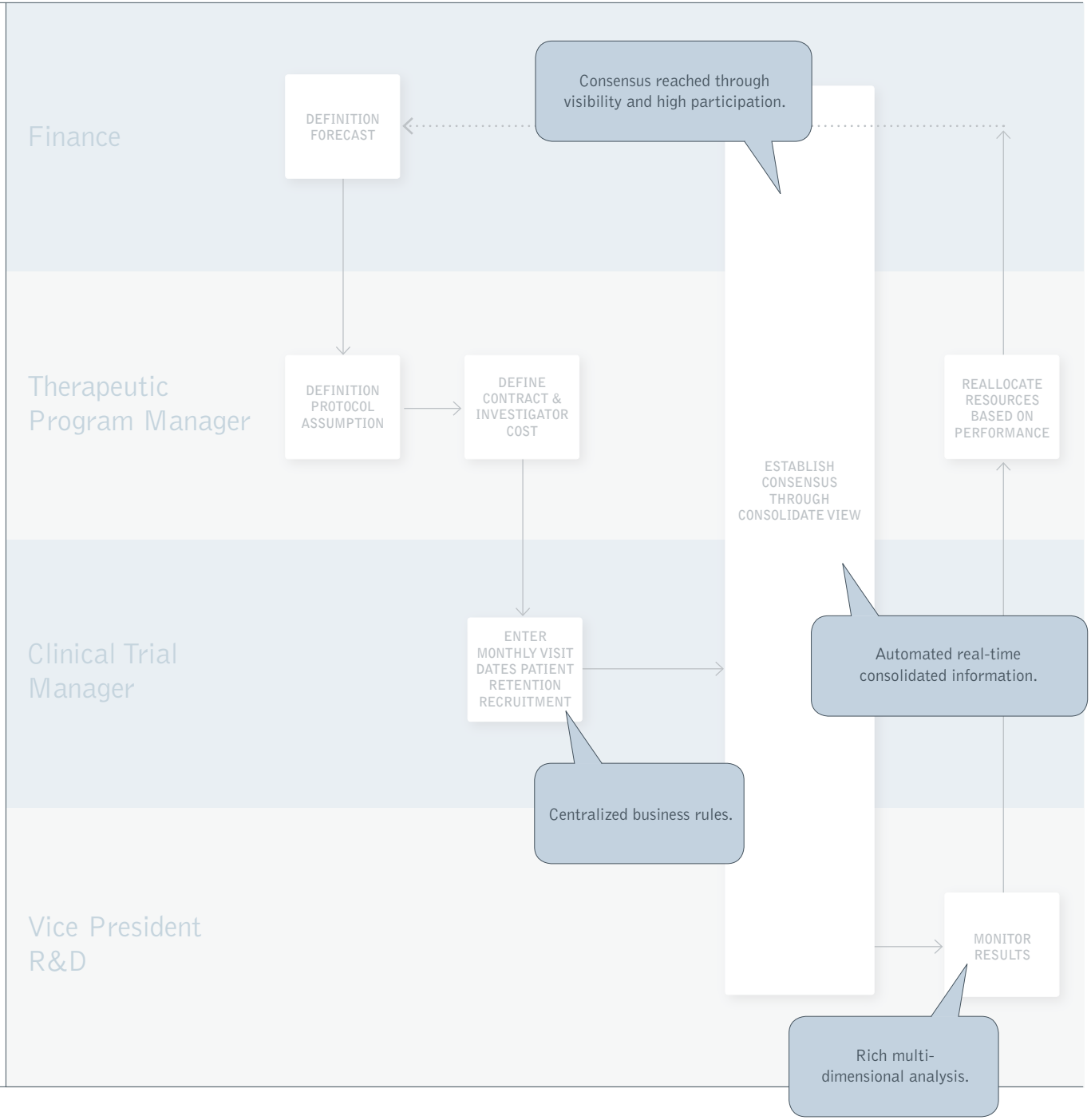
And most importantly, due to the sheer volume of spreadsheets typically generated, a consolidated view across all protocols is difficult. Effective performance monitoring and resource reallocation becomes nearly impossible.



High-performance companies replace manual spreadsheets with robust multi-dimensional modeling and integrated workflows that limit error, improve control, enhance visibility, and boost accountability.

The clinical trial process requires an approach that combines central business rules management with driver-based planning in a collaborative decision-support environment that allows all the right people to participate.

Through such an approach, expenses can be better anticipated and results can be consolidated instantly to better facilitate monitoring. The consolidated view also allows for better analysis an potentially resource allocation to improve overall protocol performance.



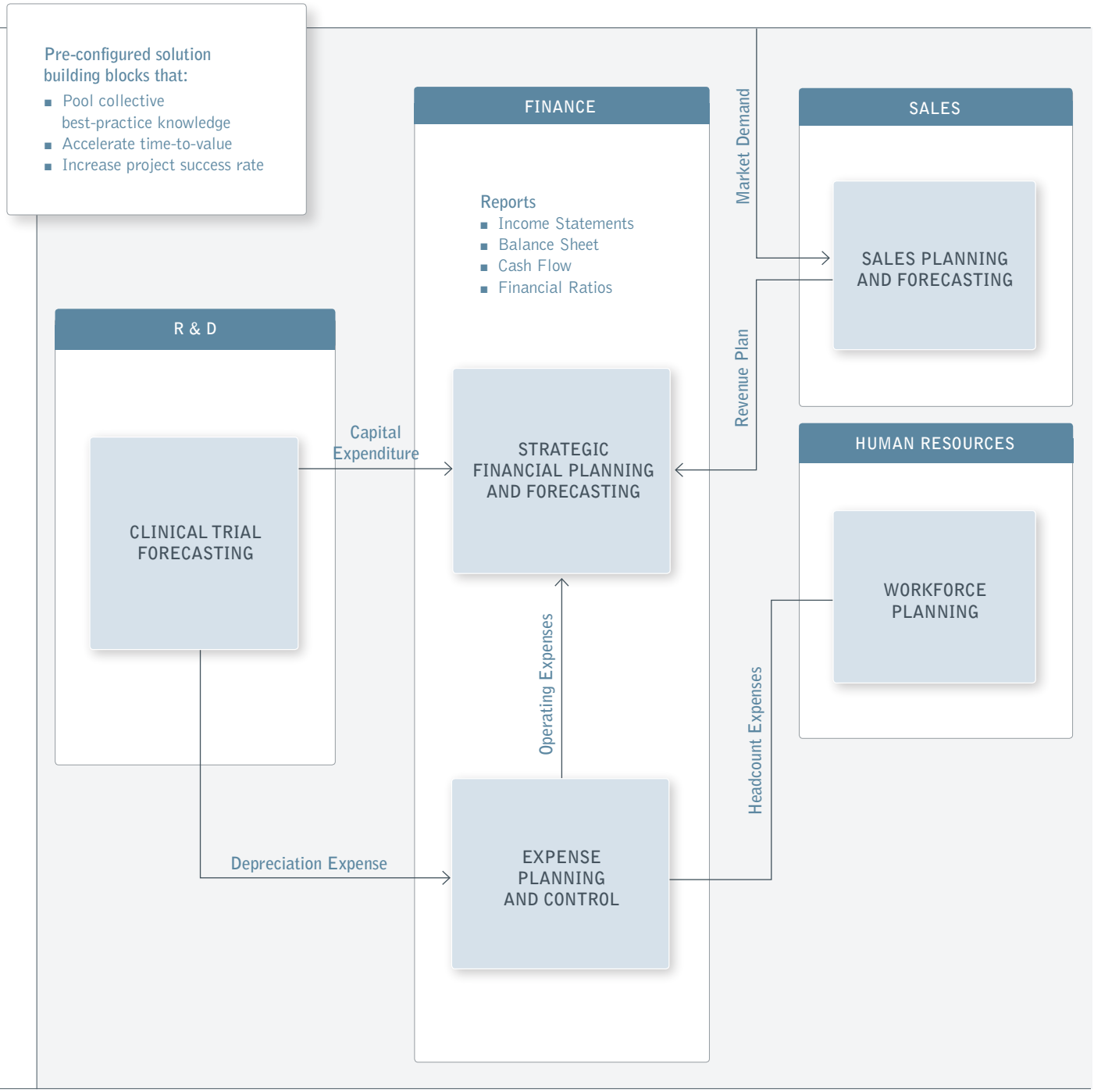
The Cognos Clinical Trial Forecasting Blueprint enables an integrated process that aligns clinical trials with corporate objectives.

Cognos Performance Blueprints offer the visibility and control you need to change direction and meet goals with confidence. Performance management enabled with Cognos Blueprints offer the ability to adapt, to identify trends, and to proactively address change—both internal and external—more quickly and accurately than traditional accounting and reporting tools can.

Developed for a wide variety of functional areas and industries, Performance Blueprints are pre-defined data, process, and policy models based on proven best practices in enterprise planning and financial management and control. The Blueprints can jump-start deployments in key functional areas like strategic financial planning and forecasting, workforce planning, and management and financial reporting, as well as industry-specific processes such as retail store operations planning or bank branch performance forecasting.

In the hands of Cognos Implementation Services consultants, Cognos certified implementation partners or experienced customers, Blueprints enable implementations to reduce project implementation schedules and improve project success rates.

The Clinical Trial Forecasting Blueprint enables finance and research & development to focus resources on the protocols that are missing key dates in their FDA filing process. The Blueprint resolves the business challenges of limited insight into enrollment indicators that can affect the progress of the study. And it provides the structure for R&D to ensure that the protocols are aligned with corporate targets.

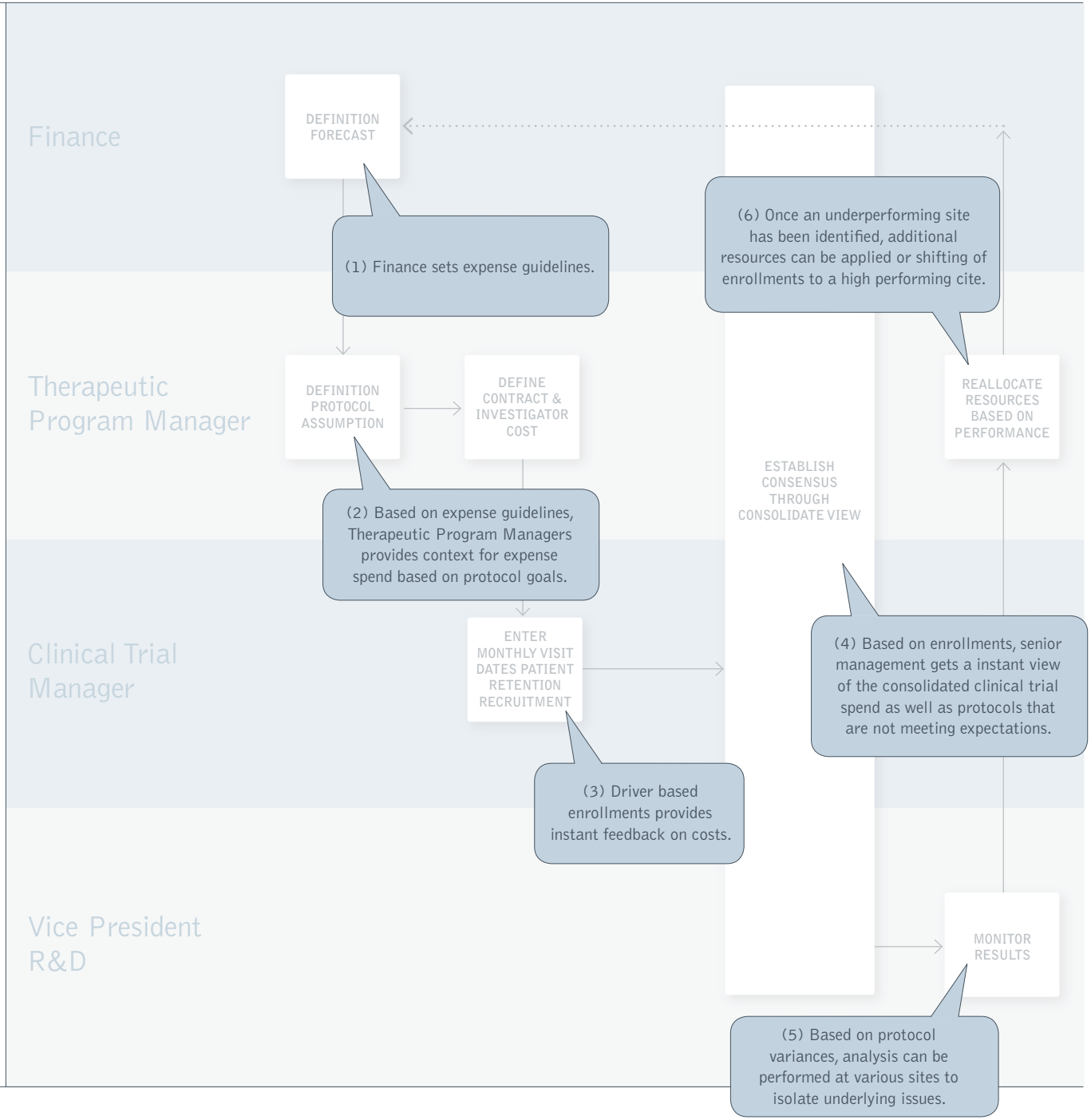


Best-practice workflow enabled by Cognos Performance Blueprints quickly captures expense requirements at the point closest to the study—the Clinical Trial Manager—and provides the detail needed to improve forecast accuracy.

Consider a company that launches a new a new oncology protocol. As part of the launch, finance sets expense guidelines based on the therapeutic area. During the forecasting period, all 20-plus clinical trial reps across multiple cites are entered. The process is repeated across hundreds of protocols across the company.

Based on enrollments, senior management gets an instant view of the consolidated clinical trial spend, as well as protocols that are not meeting expectations. A variance analysis on the performance of the protocol and contributing cites provides unprecedented visibility. Such visibility allows additional resources to be applied or enrollments to be shifted to a high-performing site.

Using the Cognos Clinical Trial Forecasting Blueprint, forecast accuracy has been running at 95 percent. The solution readily captures expense requirements at the point closest to the study—the Clinical Trial Manager—and provides the detail needed to improve forecast accuracy.



Clinical Trial Forecast Blueprint Benefits

COGNOS PLANNING DELIVERS KEY BENEFITS TO THE CLINICAL TRIAL PROCESS:

- Optimized resource allocation.
- Increased visibility into enrollment and accompanying expense tracking of clinical trials.
- Simplified gathering and validation of clinical trial enrollment.
- Flexible model development that adapts to your business process.
- High-participation work flow and Web-based deployment for data collection and consolidation.
- Real-time workflow to evaluate the status of your planning process.
- Real-time consolidation for an instance global view of your sample distribution.
- Real-time calculations in the browser for immediate insight into CT performance.
- Single operational system can be used across multiple products and sales forces.
- Scalable architecture with proven deployments to thousands of users.

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The Cognos Innovation Center for Performance Management is dedicated to the understanding, adoption, and implementation of next-generation planning and performance management practices. It is a consortium of industry leaders, practitioners, thought leaders, forward-looking executives, and technology experts experienced in, and committed to, the advancement and successful application of technology-enabled performance management best practices. The Innovation Center seeks to assist organizations in optimizing the alignment of their plans, processes, and resources with corporate goals and strategies.