



Can analytics enhance human resource management in pharma R&D?

Exploring strategies to optimize R&D clinical resources

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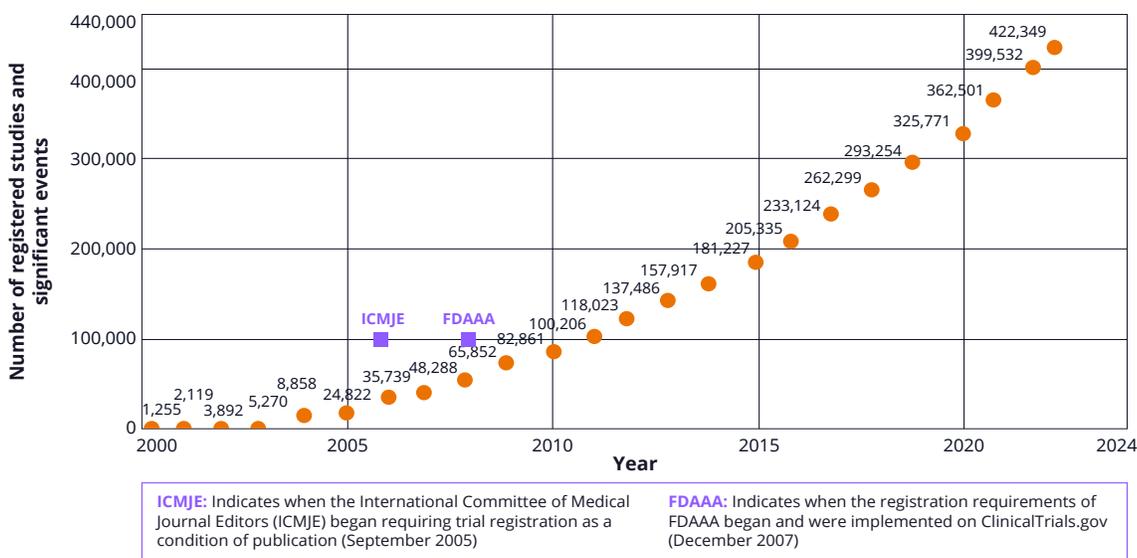
With pharmaceutical companies continuing to invest more resources in research and development (R&D), the need for skilled professionals who can run clinical trials is growing. However, there are a limited number of these professionals available, and an aging workforce may lead that number to shrink over the coming years. Resource management—in this case, ensuring the proper personnel are in place to run clinical trials—will continue to be critical for pharmaceutical companies as patients count on them to develop the next generation of life sciences breakthroughs.

Pharmaceutical companies can optimize resource management using data-driven analytics and several strategies, including assessing their resource management maturity, exploring how they can use forecasting algorithms to improve resource planning and developing a resource management center of excellence.

Some background: As the number of registered clinical trials has grown (Figure 1), so too has the need for R&D professionals who can oversee clinical trials—though these employees make up only a fraction of a pharmaceutical company’s staff (Figure 2).

FIGURE 1: The volume of clinical trials is growing

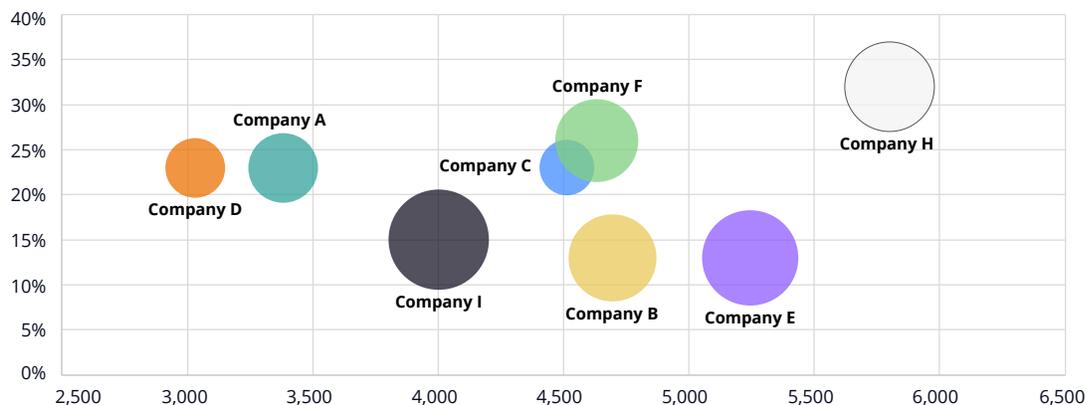
Number of registered studies over time and some significant events (as of July 21, 2022)



Source: ClinicalTrials.gov

FIGURE 2: Distribution of R&D employees versus active trials

Number of trials versus the percentage of a company's employees focused on R&D
(bubble size represents relative overall employee count)



Source for number of trials: Citeline (data as of April 2022)

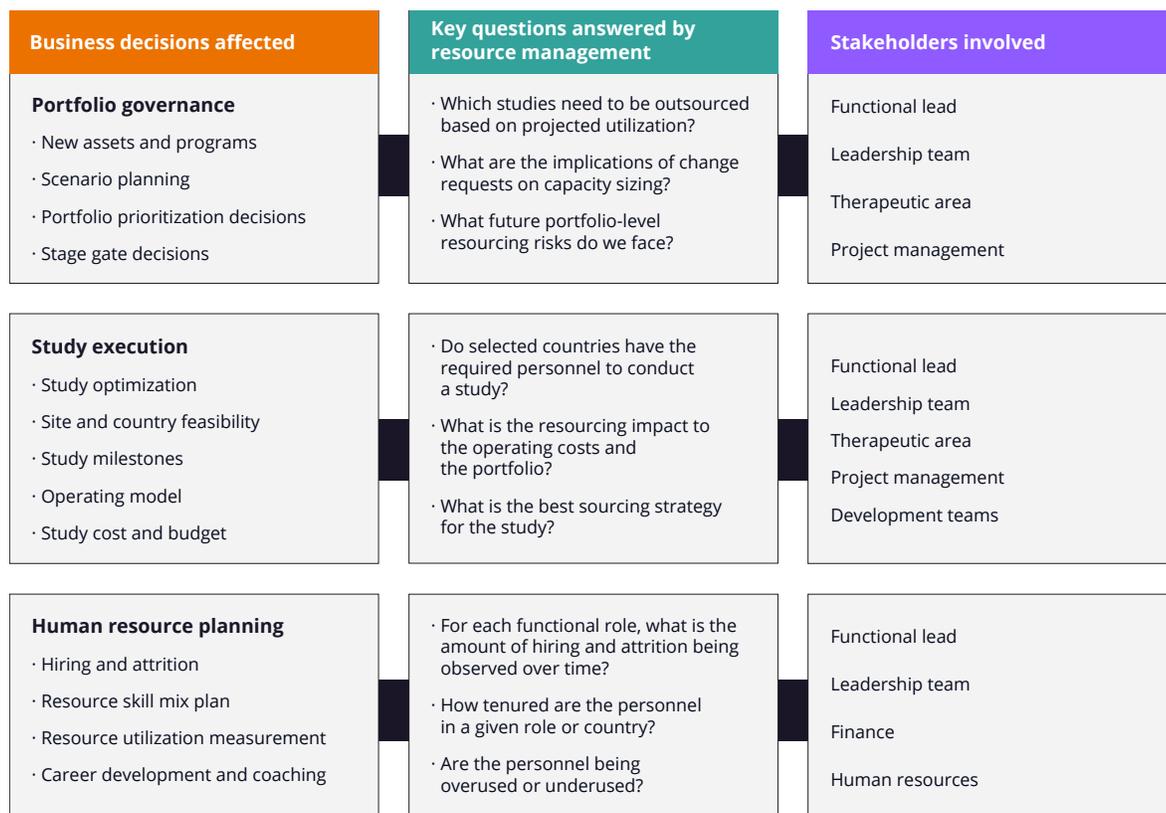
Source for number of employees: public research from sites like Forbes.com, Fortune.com, Statista.com and company sites

Not surprisingly, there is competition among pharmaceutical companies for the limited number of skilled professionals who can run clinical trials. These companies also navigate high attrition rates—sometimes in the 30% range—and long hiring cycles. It often takes three to six months to hire a qualified individual, but the process can take as long as 18 months, depending on location and the skills needed.

It appears both the pandemic and the “Great Resignation” have further exacerbated the situation. Many companies are aiming to accelerate trials that had been paused due to COVID-19 just as the availability of experienced professionals is dwindling. Some executives have expressed concerns that a significant percentage of the R&D workforce could retire in the coming years.

The cost of drug development is also rising, leading pharmaceutical and biotechnology companies to seek faster and less expensive solutions. With personnel costs accounting for a considerable proportion of their total budgets, many companies are exploring strategies to lower costs, including using analytics. Additional strategies companies are pursuing include internal sourcing; running trials in less expensive locations, such as Eastern Europe, Latin America and India; and using analytics to increase the effectiveness of resource management, which can impact several different areas within a company (Figure 3).

FIGURE 3: Key decisions and stakeholders affected by resource management



With these factors in mind, it’s imperative for R&D leaders at organizations of all sizes to evaluate their operations—especially the core capability of resource management. R&D leaders must be able to assess their organization’s workload, capacity and capabilities in a clear way to make key portfolio management decisions. Good resource management will help:

- Lower costs through appropriate sizing
- Allow for proactive recruiting strategies that align with predictive workload needs
- Empower an agile workforce that can flex to minimize gaps and shorten timelines
- Improve overall study and submission quality through decreased resource turnover
- Improve employee satisfaction and decrease burnout, which could lead to decreased turnover and overhead costs

Assessing your organization's resource management maturity

ZS has observed wide variations in resource management maturity at pharmaceutical companies. The maturity of resource management capabilities for any pharmaceutical company can be assessed through four key dimensions: process, analytics, system and people.

Process: An independent resource management function ensures objectivity in decision-making and fosters the development of advanced capabilities.

Analytics: Evidence-based benchmarking and sophisticated machine learning (ML)-based modeling leads to robust resource forecasting.

System: An integrated system enables seamless connections with upstream data sources and data quality assurance.

People: Clearly defined responsibilities and strong collaboration channels are crucial because resource management touches a wide variety of stakeholders within the firm.



FIGURE 4: The 4 dimensions for assessing maturity



The 6 key elements of a sophisticated resource optimization ecosystem

End-to-end resource optimization capabilities include several different elements that must be integrated seamlessly to ensure effective resource forecasting and management.

FIGURE 5: The elements of an optimized ecosystem



1. Role operating model alignment: A clear understanding of a role’s responsibilities and deliverables in the clinical trial’s life cycle is critical for forecasting. That’s why it’s necessary to establish a clear operating model between roles to ensure appropriate handoffs. When there are gray areas, we often see duplicative efforts or the overuse or underuse of resources. There are no established norms on the totality of responsibilities for a role across the pharmaceutical industry. Differences are driven by maturity and the size of the company, with startups providing more responsibilities within individual roles than their larger pharmaceutical counterparts. For example, who is responsible for ensuring the launch of the trial? The clinical trial associate or the clinical trial manager?

2. Data quality management capability: Several key data inputs are required for effective resource management and forecasting. The most critical one is the understanding of the portfolio of trials. Also important are country allocation, the probability of success of trials and historical time entry data for the various roles. In many cases, we have observed that available data is either incorrect, incomplete or unknown.

In one such case, we observed there were about 10 studies missing from the portfolio used for demand prediction. This led to a difference of approximately 50 full-time equivalents (FTEs) per quarter across the various development functions, such as clinical trial monitors, site managers and data managers. Similarly, when forecasting resources below the enterprise level, we observed that countries are not allocated appropriately for trials in the planning system, which results in incorrect predictions.

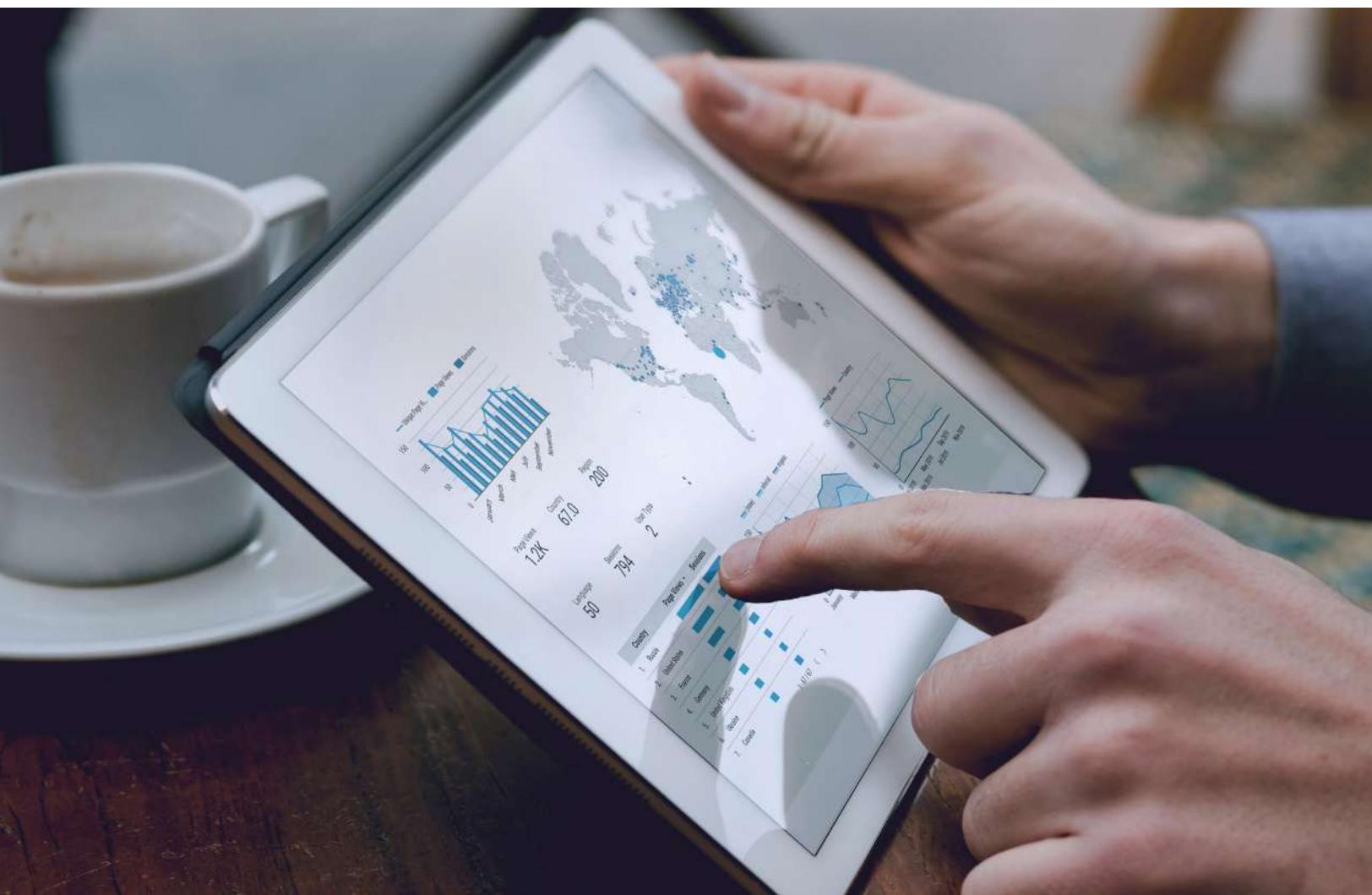
Predictive and accurate resource management is dependent on the ability to identify and rectify data discrepancies.

3. Resource forecasting algorithm: Having a predictive resource forecasting algorithm, which learns over time and provides output for different granularities (overall, function, asset, therapy area, country and protocol), is vital for demand prediction. Identifying the right drivers is a key step for developing strong resource forecast algorithms, but in many situations, the drivers are not selected correctly.

Drivers can vary depending on the role. For example, in a large pharmaceutical client, monitoring frequency was identified as a critical driver for the site monitor role. However, it was often not considered during FTE estimations. Similarly, the complexity of the protocol is not considered when estimating the resources required for the clinical development group. Using the right drivers leads to predictive, accurate algorithms, which help maintain desirable resource utilization levels.

4. Optimization through benchmarks: Once the initial FTE estimation is complete, we must benchmark it against internal and external data. Benchmarking can help surface inefficiencies in the current resourcing ecosystem. Pharmaceutical companies can partner with external agencies to develop a benchmarking database that can help make their internal processes more efficient. This area requires a concerted effort.

- 5. Closed-loop planning:** The R&D ecosystem is dynamic and continually evolving. Monitoring the reality on the ground and comparing the actual utilization of resources with predicted demand leads to continuous improvement. It is also important to develop a process for line managers, country leads and others to provide regular transparent feedback on the prediction algorithm. This will enable the algorithm to adapt over time, helping to improve its accuracy and power.
- 6. Real-time optimization and scenario planning:** Having the capability to view and prioritize resource allocation in real time provides obvious strategic value, which varies by persona. For managers who oversee allocation of staff, understanding utilization and open capacity is essential. For development and therapy area leads, it's important to understand the future personnel planning and hiring strategy. To start trials in a timely manner without delays, real-time views into the resource utilization, on-the-go optimization and scenario planning can help ensure trials are staffed in an optimal manner.



Enabling an appropriate resource management ecosystem

We recommend creating a resource management center of excellence that will not only help standardize resource forecasting and capacity management across the organization, but also remove bias and support capability development. All of this enables a pharmaceutical company to better prepare for the future.

For example, a large pharmaceutical company needed to quickly determine its FTE resource availability to ensure it had adequate resources for newly mandated studies. Country heads were required to assess their available capacity quickly and accurately. By using harmonized and standardized algorithms, each country head had a clear and objective way to quickly ascertain their available capacity. This gave the organization more confidence in the predicted output, and the cross-country comparison further solidified confidence in the overall output.

Another example: At a midsize pharmaceutical company, the clinical operations lead requested therapy area leads to provide FTE estimates for their respective clinical trials. One therapy area lead used a driver-based approach to estimate FTEs required at the country level, while another therapy area lead used contract research organization benchmarks to estimate the resources at a trial level. As a result, the clinical operations lead had no way of comparing and objectively assessing the FTEs requested by the two leads. In such cases, a center of excellence could have provided guidance to ensure that methodology, analytics and process were streamlined.

What is the impact of a sophisticated resource optimization ecosystem?

Having the right resource management capability offers several advantages for a pharmaceutical company. It not only enables pharmaceutical companies to understand and use their resources effectively, but also can help them meet business needs, contain costs and maintain a right-sized organization.

The current portfolio planning and resource allocation process can be tedious and time consuming. There are several negotiations and, in some cases, no objective way to assess the demands of the various functions, therapy areas and development teams. A resource management center of excellence can help standardize and govern the resource prediction process, help remove subjectivity and improve the overall process. It is similar to the trial design centers of excellence many companies employ to ensure proper trial design from a scientific and operational lens.

A resource management center of excellence affords other advantages:

- **Transparency and agility in resource allocation:** In one pharmaceutical company, generic resource forecasts were only completed twice a year during the budgeting cycle. These forecasts quickly became outdated because of a whole host of factors, including the company's evolving portfolio, shifting competitor landscapes, recruitment lags and more. These factors highlight the need for resource management to be continuous and dynamic so that it can handle change and continue to provide an overview of the situation at any point in time, all while enabling agile resource allocation. This is possible only if there is an objective and standardized way of looking at resource forecasts.
- **High-quality clinical trials:** Understanding resource needs in the short- and long-term will enable pharmaceutical companies to hire and contract resources with the right educational qualifications and training for execution of clinical trials. Today, due to lack of proper planning, companies face a number of challenges. They must determine if they should deprioritize some trials or engage with external agencies to obtain the resources necessary to avoid last-minute delays. They must also figure out how to meet deadlines without stretching their teams past their capacity, which can lead to staff burnout and increased attrition. Unfortunately, the available solutions to meet resource needs often are not optimal and can negatively impact on-site relationships, while putting study data at risk.
- **Cost management:** Acquiring staff resources at the last moment can be a costly affair for pharmaceutical companies. This can increase the trial's budget and eventually lead to increased costs for patients. Having confidence in your long-term resourcing needs is critical.
- **Resourcing mix:** Having a clear view of current resource utilization and future demand can help companies determine the optimal resourcing strategy, including when to use in-house resources and when to outsource.
- **Human resource development:** As companies replace retiring or departing personnel, understanding the current resourcing mix and future needs will help pharmaceutical companies plan better skill development and retention strategies.
- **More cures for patients:** The current resource estimation process involves a lot of subjectivity from managers, as we have discussed. This can result in inefficient resource allocation, underutilization of resources and decreased productivity, which all affect the budgeting process for clinical trials. Optimal resource allocation increases the chances of more clinical trials being executed, which enables the development of more life-changing drugs for patients.

Overcoming resource management challenges

There are three potential challenges companies may face as they establish their analytics-enhanced resource management capability.

Challenges	Resolutions
Lack of accurate or complete clinical portfolios is common. In many cases, data is dispersed and there is no single source of truth.	<ul style="list-style-type: none"> • Ensure data is being entered and maintained correctly in the planning systems through a top-down push • Provide appropriate training for the personnel tasked with managing the information • Install proper governance mechanisms for issues and escalations
Some countries, especially in the EU, limit the ability to capture actual hours, and some companies rely on manual time entry. This can result in a scarcity of accurate insights due to a lack of historical benchmarking.	<ul style="list-style-type: none"> • Improve accuracy using automated mechanisms, such as one that monitors time spent doing a certain activity • Provide clear communication about the advantages of capturing time accurately
Enabling behavioral change requires significant effort. Everyone may not be on board with having a standardized and consistent way of optimizing resources across the ecosystem. Many people will see this as a loss of control and could be resistant to change.	Build sponsorship across all levels. To achieve this, leaders should ensure personnel at every level understand the impact and benefits of transparency and ongoing communication. For example, individuals at the lowest level of the company should understand that clear communication enables equitable allocation of work. Managers benefit because they're empowered to ask for additional resources when needed. Having a persona-based change management approach is critical.

Resource management: The stakes are high

A resource management center of excellence can help improve operational efficiency, decrease trial costs and develop high-quality clinical trials. Establishing a center of excellence is an iterative process, as resource management is complex and depends on several upstream and downstream workstreams. The sooner companies can master this process, the better.

Establishing a center of excellence is a great first step for optimizing R&D resources, but pharmaceutical companies should also explore making their sourcing and hiring strategies more sustainable. Leaders must think about how they can objectively make clinical trial operating model decisions.

As pharmaceutical companies aim to build improved resource management ecosystems, the stakes are high. Patients are counting on pharmaceutical companies to deliver life-changing cures, and to do so, companies must have the proper teams in place.

About the authors



Aaron Mitchell is a principal in the San Francisco office and serves as ZS's global R&D excellence practice lead. In this role, he partners with clients to strengthen the value of their pipelines, optimize the execution of clinical trials, drive the effective use of real-world evidence and improve medical and scientific engagement.



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Kerri Mussari-Smith is a manager with ZS's R&D clinical development excellence group in the Princeton office. She has more than 30 years of pharmaceutical industry experience focused on clinical development and clinical operations across multiple therapeutic areas. Kerri has spent the last 15 years evaluating and building dynamic resource forecasting tools for large pharmaceutical companies. She partners with leading biopharma companies to solve problems and optimize operational efficiencies.



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Sarath Jagabattula is a manager in the Pune office with nine years of management consulting experience. He has supported bio-pharmaceutical clients across R&D portfolio governance and resource management, in addition to various commercialization issues for oncology and immunology drugs. Within R&D, he has partnered with clients to enable key decisions through portfolio and resource assessment, helping them rethink resource forecasting and optimization through data-driven analytics.



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