

Resource Management for Clinical Operations

Unlocking the Value



Resource Management for Clinical Operations

In order to remain competitive today, and in an uncertain future, Life-science organizations must prioritize the establishment of a central resource management capability to use their resources efficiently by applying a consistent and strategic cross-functional deployment.

Current Trends: Resource Management Implications

Rapid advances in the life-sciences industry are improving patient outcomes, but are also increasing trial cost, complexity, and duration. These trends have increased pricing pressure from governments and payers, and brought new scrutiny to operating costs. Both of these factors have motivated research and development (R&D) leaders at organizations of all sizes to evaluate their operations, especially the core capability of resource management (RM).

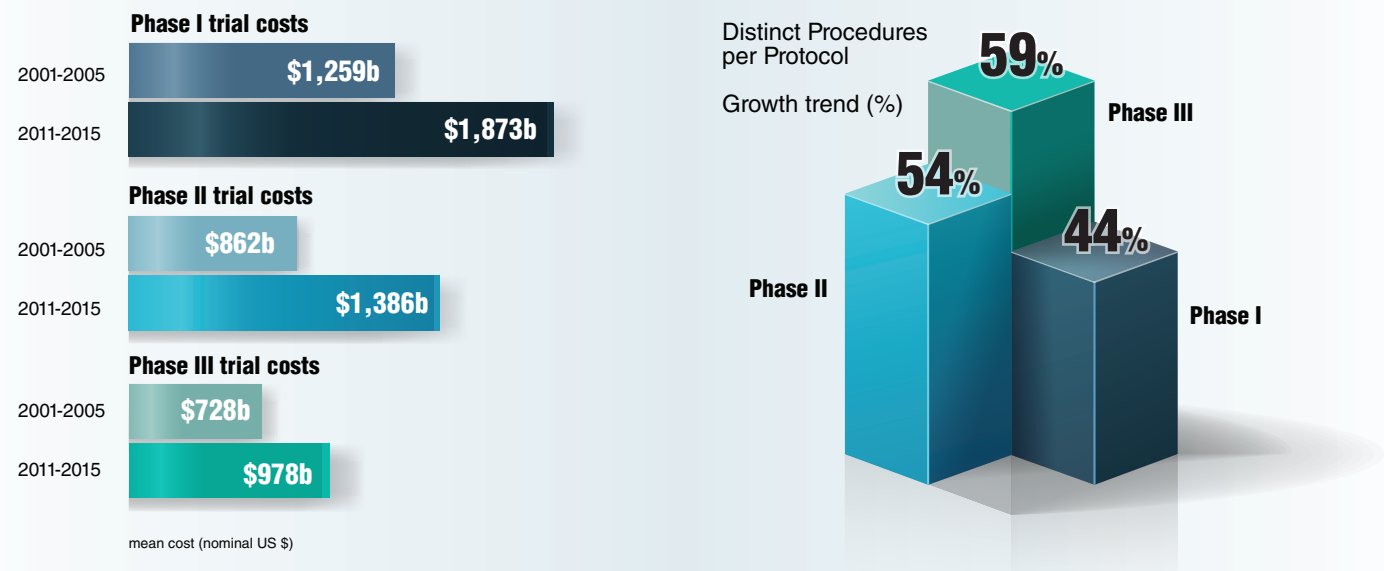
R&D leaders must be able to separate myth from fact when assessing their organization’s workload, capacity, and capabilities. The value of effective RM is straightforward: It enables organizational leaders to identify and address issues proactively in the dynamic landscape of resource supply and workload demand. Robust RM allows managers to ensure they have the right number and types of resources with sufficient bandwidth to support R&D operations. Good RM means being able to get the right people to the right place at the right time.

Dramatic changes have occurred in the past decade with respect to trial execution. Ken Getz of the Tufts Center for the Study of Drug Development examined trends in clinical trial design and execution from 2001-2015, with a focus on elements of study design associated with “executorial feasibility” (e.g., number of procedures performed, planned number of visits) and the associated work effort. Getz’s research uncovered significant growth in a troubling combination of measures: trial complexity, cost, and execution time.

The number of procedures called for in protocols has risen as much as 70%, and costs have soared between 34% and 67% **from 2001 to 2015** across trials in phases I, II, and III, increasing cycle times and instances of protocol amendments which add complexity. These factors take a toll on R&D staff as they struggle to adapt to rapidly shifting demands. In turn, this leads to longer study durations and delayed regulatory submissions.

Trends in the complexity and costs of clinical trials

Figure 1



In this type of environment, an understanding of total capacity and effective resource deployment are essential, as organizations are forced to do more with fixed resources.

Common Issues

Three forces that contribute to clinical R&D organizations' frustration with existing practices are **inefficient processes, inadequate infrastructure and tools**, and limited ability to **identify and address underlying reasons** for such inefficiency.

- **Inefficient Processes** – Resourcing practices are decentralized with redundant tracking efforts across functions. Resourcing information comes from many sources and requires significant effort to consolidate, interpret, and analyze
- **Inadequate Tools & Infrastructure** – Resourcing tools do not support proactive management due to functional limitations, or poorly defined operating infrastructure. As a result, tools do not enhance organizational visibility and are difficult to manage day-to-day
- **Limited Visibility and Value** – Tools/reports do not give leadership insight into resource demand and capacity. They also inhibit managers from translating information or considering broader strategic goals when making resourcing decisions. As a result, resourcing decisions may fall out of alignment with upcoming workload demand and organizational priorities

Due to the commonality of these root causes, issues manifest themselves in similar ways across clients. Typical issues include decentralized RM practices comprising a variety of function-specific tools, data sources, and calculation methodologies. In these situations, the reliability of forecasts and value of insights are limited due to inconsistency in analytic approaches and quality of data.

These inconsistencies represent just some of the challenges in consolidating disparate source data into a single, standardized view of resources across functions. Another scenario we frequently encounter is an established central resourcing process supported by internally developed resourcing tools. In this case, the goal of reporting to client leaders is well-intentioned, but the output falls short of driving value.

Growing Pains | Developing Resource Management Maturity

Simple reporting tools, although expedient, tend to offer inconsistent utility and limited actionable insights. Because these solutions are frequently labor intensive, the effort-versus-value equation is oftentimes out of balance.

Scenarios like these are all too familiar, and often follow a common evolutionary trajectory:

The early stages of developing a robust RM capability can feel like stepping into the plot of a Western movie—a new frontier fraught with challenges and lacking the structure and order afforded by government and laws. Significant effort is required to tame the “wild west” of disparate data, inconsistent practices, and limited visibility. In our experience building and improving our clients RM capabilities we have observed a common pattern in the development of mature RM practices.

Common Scenarios

Stage I | Decentralized RM – The decentralized RM model is marked by inconsistent processes with respect to data collection, synthesis, and reporting. Functional groups are left to develop their own approaches for assessment and analysis. Responsibilities are disaggregated across functions, requiring redundant resources to analyze and generate reports for each functional area.

This stage presents numerous challenges for senior leaders, as inconsistencies in the assumptions, analytical rigor, and data quality may prevent accurate cross-functional comparisons. In many cases quality checks of the information take a back seat to competing priorities, leaving errors unaddressed and improvement opportunities unrealized.

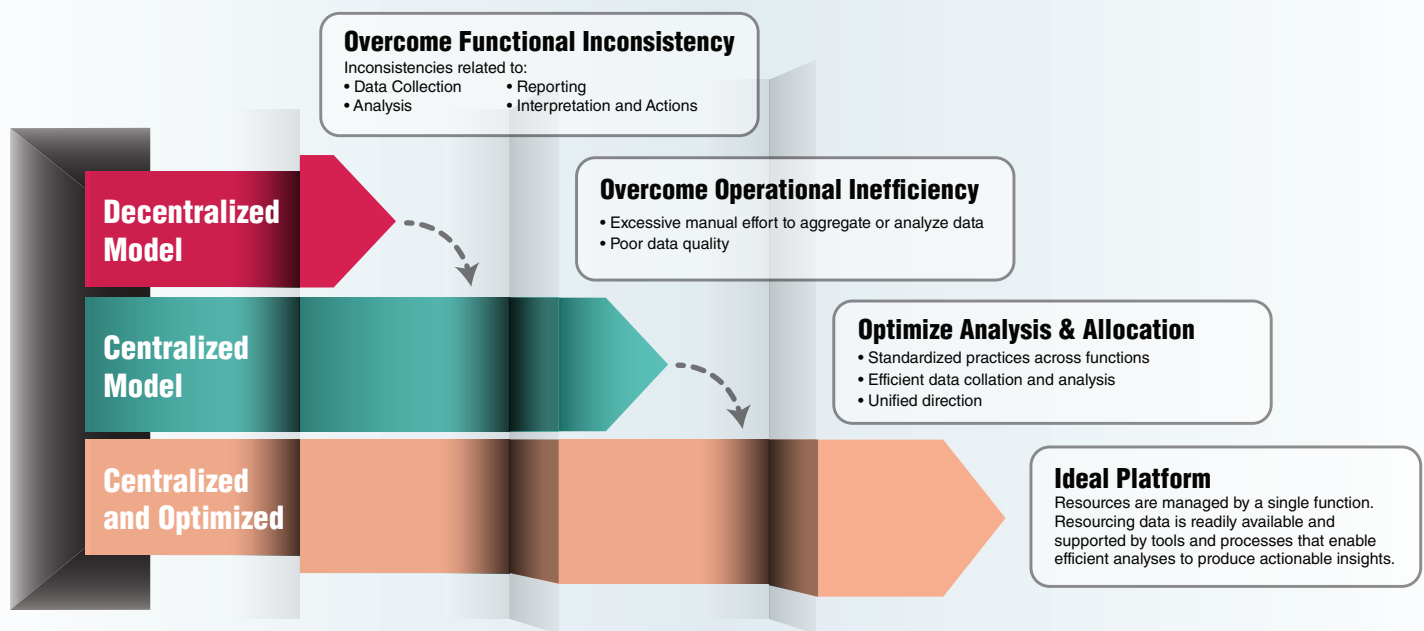
Stage II | Centralized (but Not Optimized) RM - At this stage the RM capability members are responsible for collecting, analyzing, and monitoring resourcing data across constituent functional groups, and providing insights to leadership through a standard assessment approach. This stage is marked by significant manual maintenance. The RM capability offers limited value due to poor data quality, limited data availability, excessive manual effort to aggregate or analyze data, and minimal insight provided by reporting (if reports are generated at all).

Stage III | Centralized and Optimized RM – This is the ideal organizational model. The company has mature practices and infrastructure to support operational efficiency in collecting, analyzing, and monitoring resourcing data across constituent functional groups. A regular reporting cadence has been established to provide insights to leadership through a standard assessment approach. Feedback loops are incorporated to solicit input from stakeholders and evaluate the accuracy of forecast algorithms.

Acquis helps clients at any stage of RM maturity navigate the challenges they face; our understanding of each client’s unique goals and priorities allows us to develop tailored solutions that deliver immediate value.

Resource Management Evolution

Figure 2: Organizations looking to establish a more mature RM capability often encounter unique challenges at each stage of development.



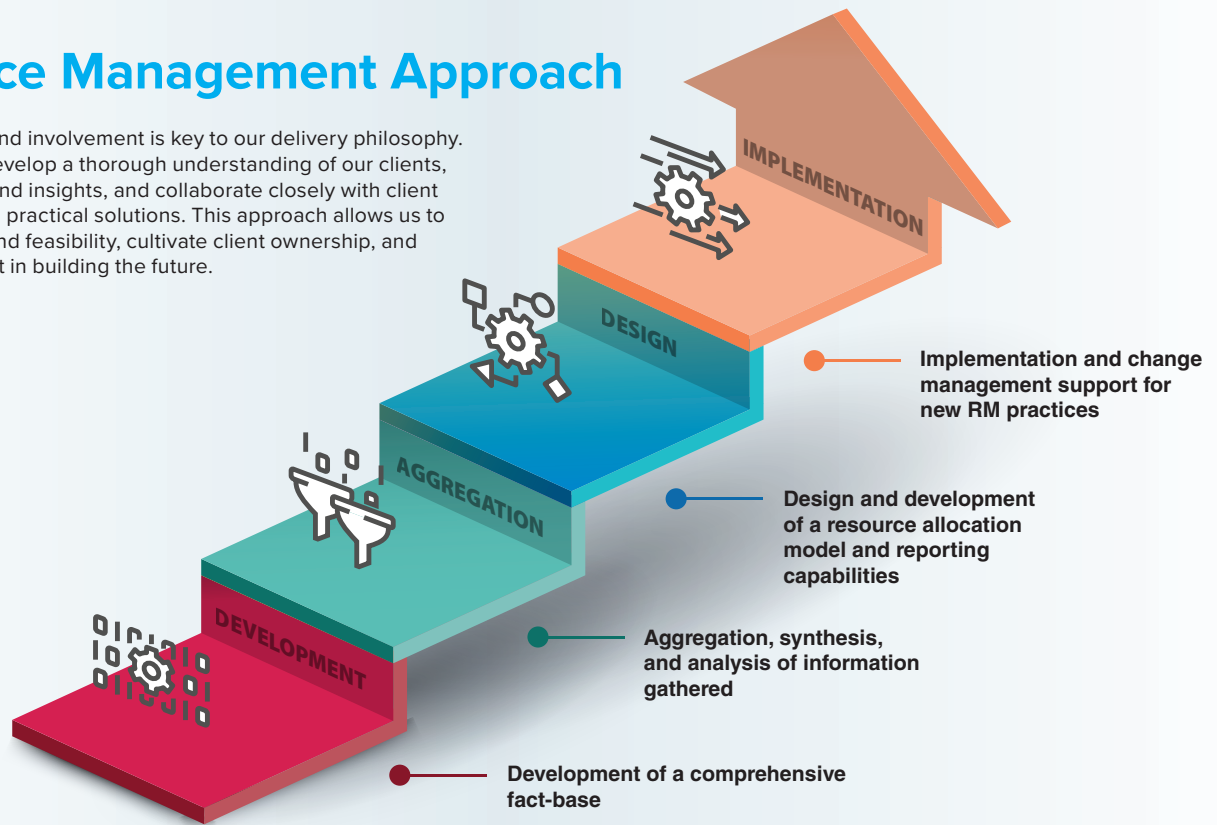
Engaging Acquis | Our Approach

Our core belief is that sustainable RM includes three critical components: operating and governance infrastructure; a tool driven by function-specific algorithms to track resource levels and forecasting demand; and a regular review process to assess the strategy and adjust as necessary.

End-to-end involvement is key to our delivery philosophy. By engaging clients closely from the outset, our consultants develop a thorough understanding at all levels: from the corporate goals, customs, and culture that drive decisions organization-wide, to the processes, procedures, and local nuances of functions within R&D.

Resource Management Approach

Figure 3: End-to-end involvement is key to our delivery philosophy. Our consultants develop a thorough understanding of our clients, frame key issues and insights, and collaborate closely with client leaders to develop practical solutions. This approach allows us to validate findings and feasibility, cultivate client ownership, and foster engagement in building the future.



To develop a solution tailored to the unique needs and challenges of each client organization, Acquis leads several key activities, including:

Development of a comprehensive fact base: Our efforts include fact-finding activities such as documentation review, interviews and surveys with key stakeholders across functions, and more. These activities provide both an understanding of current RM practices, as well as insights into user requirements, unmet needs, and priorities.

Acquis works to gather insights from all levels of an organization to understand issues beyond the data. This approach enables us to quickly deliver actionable insights that speak to how, and address why the ongoing management of resources differs from a leader's vision of ideal.

Aggregation, synthesis, and analysis of information gathered: Our activities focus on analyzing and contextualizing data to understand how resources are deployed and the impact of factors such as clinical trial size or number of patients. Acquis maintains a deep knowledge of industry best-practices and prevailing trends to support the development of a robust resource-allocation capability that measures performance against benchmarks.

We work with client leaders to define the “core” responsibilities of different roles, and conduct a thorough evaluation of their ideal state against the real world. This approach enables rapid identification of areas that unduly burden resources and reduce capacity.

Design and development of a resource-allocation model and reporting capabilities: Acquis frames key issues and insights from data collection and analysis efforts, and collaborates closely with client leaders during the design phase to develop practical solutions.

Our collaborative approach allows us to validate findings, assumptions, and feasibility, as well as to cultivate client ownership and foster engagement in building the future state. Our work at this stage drives development of key deliverables, such as:

Role / Task Optimization

Figure 4: Effective Resource Management allows client organizations to better identify key tasks and activities that drive strategic priorities, determine the best resources available for the task, and align them appropriately.



- **Customized algorithms:** We create algorithms tailored by function and role using data gathered during interviews and from surveys
- **Tailored reports:** Our team leverages a variety of analytics platforms including Excel and Tableau to create fit-for-purpose reports and custom dashboards for functional managers and senior executives

Implementation and change management support for new RM practices: The task of standing up an effective RM capability extends beyond design and development. Acquis helps clients successfully deploy solutions, taking them from PowerPoint into daily practice, ensuring immediate and lasting benefits to the organization.

Our hands-on engagement style gives our colleagues a deeper understanding of our clients, and helps establish trust and rapport across stakeholder groups. Our teams seamlessly integrate with client organizations and draw on their project and change management expertise to support successful implementation.

Outcomes

Our RM approach allows us to deliver meaningful benefits to clients across three key areas:

- **Process & Technology**
 - Standardized practices for resourcing across functions
 - Shared tools and processes to ensure consistent RM
 - Increased use of technology to enhance efficiency
- **Metrics and Reporting**
 - Optimized utilization of resource capacity
 - Improved monitoring to ensure resources are utilized efficiently, for high-priority/high-value activities, and to forecast future needs
 - Dynamic balancing of bandwidth/utilization levels to align available resources with areas of need
- **Continuous Improvement**
 - Direct feedback loops from employees via managers to RM capability leads to make adjustments as needed
 - Defined review cycles to support the continuous improvement of algorithms, tools, and processes

Improvement in these areas allows organizations to match the right people or roles to the right tasks to maximize efficiency.

In our experience, removal of nonessential tasks increased resource capacity by between 5% and 20% depending on the role. This increase translates directly to cost savings for the organization because existing resources can support a growing organizational pipeline. By identifying the most important activities and assigning those activities to the appropriate roles and resources that can execute them most efficiently, an organization can realize the true value of resource management.

Conclusions & Considerations

The concepts discussed in this paper can be applied to organizations of any size to assess and develop a customized RM solution. Life-science organizations that establish a centralized RM capability can use their resources efficiently thanks to consistent and strategic cross-functional deployment. Acquis believes RM should be an investment priority for clinical operations to remain competitive today, and to emerge successful in the future. ■

About Acquis

Acquis is a consulting firm specializing in Strategy and Implementation. We help ambitious organizations solve business challenges that enable sustainable growth and healthy efficiency. We do this by not just designing strategies but also putting them to work.

We draw on a broad toolkit of capabilities and consider the surrounding context of every problem in order to deliver solutions that properly align with client goals. Our team works directly with clients to understand their business needs, and provide tailored, practical solutions that turn strategic vision into reality.

Contact Us:



Kerby Houff
Partner
khouff@acquisconsulting.com



Ann Koehler
Senior Associate
akoehler@acquisconsulting.com



Gabe Flores
Senior Associate
gflores@acquisconsulting.com



Acquis Consulting Group
299 Broadway, 12th Floor
New York, NY 10007
t: +1 212 609 2700

acquisconsulting.com

Boston

120 St James Ave
Boston, MA 02116

London

1 Fore Street Avenue,
Suite 4067
London, EC2Y 9DT

Parsippany

9 Campus Drive
Floor 1
Parsippany, NJ 07054

San Francisco

2181 Greenwich Street
San Francisco, CA 94123

Frankfurt

Neue Rothofstraße 13-19
60313 Frankfurt am Main,
Germany