Veeva

REPORT

Navigating 2025: Key Clinical Operations Strategies for Emerging Biotechs

The Evolving Clinical Operations Landscape in Emerging Biotechs

As the life sciences industry continues to evolve, emerging biotechs face unprecedented challenges and opportunities with changing regulatory guidance, rapid shifts in investment strategies, and new technologies. The need to quickly establish proof of concept in lead candidates, coupled with the pressure to deliver high-quality clinical trials, is greater than ever. To succeed in modern clinical development, clinical leaders must optimize their teams and have a better understanding of trial health at all stages.

Veeva hosted a series of roundtables with clinical operations leaders from emerging biotechs to facilitate open dialogue and identify best practices. By engaging directly with experienced leaders, we aim to collectively drive improvements in trial management and shorten timelines without compromising quality.

In this report, we will examine key observations from 2024 and highlight suggested clinical strategies for 2025. We want to empower clinical operations leaders to effectively navigate the changing landscape and amplify their voices to accelerate innovation that drives trial efficiencies.

2024 IN REVIEW

3 Key Takeaways

01.

Flexibility Without Sacrificing Control Is Necessary for Success

Clinical trials have undergone significant transformation in recent years. Growth in biotech pipelines, combined with the trend for biotechs to retain assets for longer, highlights the criticality of a strong partnership between sponsors, CROs, and development partners.[1] The expertise, scale, and specialized capabilities offered by outsourcing providers remain crucial for executing complex clinical trials effectively.

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>
> **McKinsey,** *CROs and biotech: Fine-tuning the partnership*

While outsourcing remains essential, biotechs are increasingly shifting to complete ownership of their trial data. This trend appears to be driven by a need for greater control and transparency in the data collection and management process, allowing clinical leaders to identify trial risks sooner and adjust faster.

02.

Standardization Is Crucial To Enable Data-Driven Decisions

The industry is inundated with data, yet extracting meaningful insights remains a significant challenge. Even with data lakes, cleaning and standardizing data takes time, hindering timely analysis and proactive decision-making.

Additionally, senior leadership's diverse reporting needs can often burden lean teams, diverting resources from core study activities. Varying stakeholder perspectives complicate data interpretation, leading to miscommunication and potentially incorrect decisions.

To address these challenges, sponsors should standardize core datasets across all stakeholders to facilitate data access, foster informed dialogue, and empower informed decision-making. While implementing new technologies may feel daunting, it's a necessary step to streamline trial operations.

[1]"CROs and biotech companies: Fine-tuning the partnership," McKinsey, June 2022.

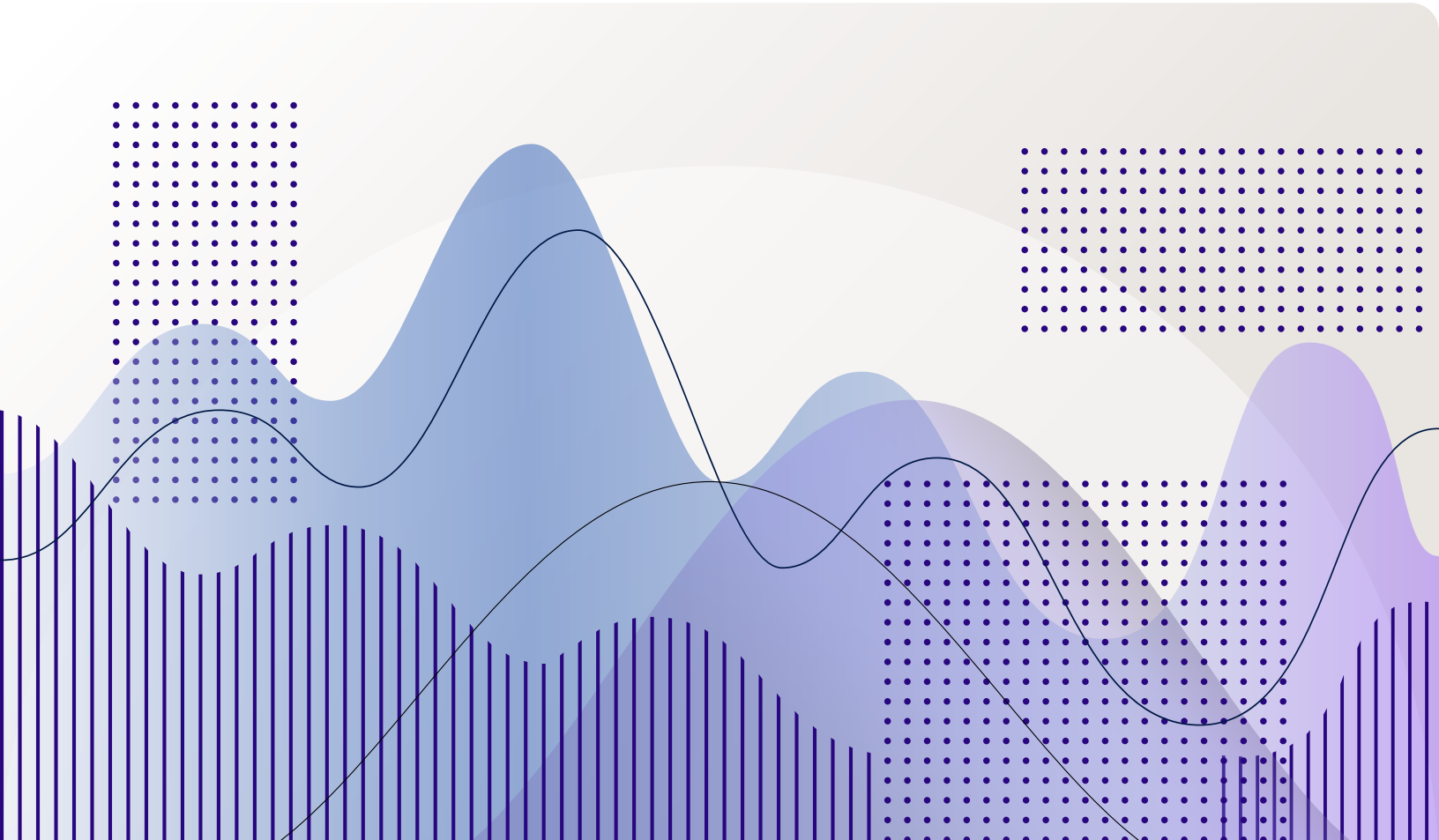
03.

Process Optimization and a Culture of Change Are Drivers of Operational Excellence

Sponsors increasingly recognize there are significant inefficiencies and redundancies in how teams meet, document, communicate, and collaborate throughout a trial. For example, weekly project meetings often feature a handful of stakeholders sharing updates and addressing escalations, while entire project teams attend as passive participants "just in case." Meanwhile, opportunities for daily process optimization are frequently overshadowed by pressing trial milestones, such as site activation and patient enrollment.

Study teams and sites report that these inefficiencies, coupled with inconsistent processes, hinder their ability to maintain critical oversight, execute site relationship strategies, and foster meaningful collaboration within integrated study teams. The result is a ripple effect on trial quality, speed, and overall effectiveness.

In response to these challenges, sponsors are leveraging internal resources or contracting external experts to establish change champions. These champions play a pivotal role in driving more efficient and standardized ways of working, as well as integrating processes and technology.



LOOKING AHEAD

2025 Suggested Strategies

01.

Beyond the Contract: Stronger Sponsor-CRO Partnerships

A well-defined governance structure is essential to foster successful partnerships between sponsors and CROs. By establishing clear expectations and responsibilities upfront, both parties can create a transformative culture of stronger study team engagement and site relationships.

Strategies to Improve Sponsor-CRO Collaboration

1. **Create a more detailed, role-based responsibilities matrix within the Transfer Of Regulatory Operations (TORO).** Clearly define each study team member's roles and responsibilities, as early as during the RFP process, to avoid misunderstandings and ensure that everyone knows their expected contributions.
2. **Develop goals and project plans for mutual success.** Clearly articulate the desired outcomes so both the sponsor and CRO can work towards the same objectives. Then, create a comprehensive project plan that outlines key milestones, timelines, and deliverables. This will help ensure that both parties are on the same page and can identify potential areas of disagreement early on. Reaffirm these expectations during the study kickoff meeting across the integrated study team and continually ensure that CROs have ongoing visibility to how sponsors will assess performance.
3. **Take an intentional, strategic approach to KPIs.** They should be risk-based, easily measurable, and aligned with the sponsor's goals—not just generic industry metrics. Establish KPIs by study, functional area, and therapeutic area, and ensure everyone has access to the same source data and metrics. Some sponsors and CROs add KPIs and source data access to their contractual agreements to avoid miscommunication later in the engagement.
4. **Establish communication channels.** Implement regular communication channels, such as weekly status updates or monthly review meetings, to facilitate open and transparent communication. Regular governance meetings provide a great forum for the integrated study team to present results and actions, communicate the results of deep dives, and share feedback that can shape future processes.
5. **Embed a culture of continuous improvement.** Set a schedule to monitor and review metrics, from start-up to closeout. If a metric doesn't meet a pre-defined threshold, perform a root cause analysis, institute mitigation plans, and follow up to ensure successful resolution. If a sponsor works with multiple vendors, analyze and compare vendor performance to identify bottlenecks and issues across partners.

Assessing Infrastructure and Capabilities for Scalability

To ensure the integrated study team has the necessary resources, processes, and technologies, trial stakeholders should consider the following factors:

1. **Right expertise:** Do you have a team of experienced professionals and subject matter experts with a proven track record of success in similar trials?
2. **Adequate resources:** Do you have the necessary resources and facilities in the right geographical regions to support the scale and complexity of the trial?
3. **Clinical systems:** Do you have robust systems to ensure data integrity and compliance with regulatory requirements? Can you easily access your trial's source data for real-time visibility? Can your integrated study team collaborate on data and documents as a single source of truth to improve inspection readiness?
4. **Scalability planning:** Do you have a plan for scaling up operations to accommodate your trial's growth?

Champion your strategic plan early and factor in these considerations to avoid burdensome operational changes during programs. How you run early phase trials may differ from later-stage trials. Clearly communicate expectations and needs upfront, and establish a strong governance structure involving vendors, functional areas, and leadership to create effective models to run current and future studies.

02.

Transactional to Transformational Study Oversight

The industry is shifting away from manual, transactional oversight. Efficient digital solutions are replacing traditional methods like reviewing source data, maintaining multiple spreadsheets, and adding comments to shared trackers.

By consolidating data into a single platform, clinical teams gain a comprehensive view of their studies. This enables them to easily identify and address potential issues early, leading to faster and more effective trials.

The TMF (trial master file) is a prime example of this transformation. Teams now have a real-time snapshot of TMF completeness and health, rather than waiting until the end of the study to find problems.

Building on the success of the TMF community's initiatives to create standards, the industry is now looking to apply similar principles to study oversight. By standardizing roles, metrics, and processes, we can streamline oversight activities based on baselines across therapeutic areas.

03.

A Community-Driven Approach to Meaningful Metrics

While industry groups and consortiums offer some standardized metrics and KPIs, sponsors often need more tailored solutions to address their needs.

Challenges with metrics and KPIs are not unique to emerging pharmas. Sponsors of all sizes grapple with the complexity of clinical trials and the need to interpret and measure their performance effectively. Different organizations' motivations and goals can influence their approach to risk assessment and decision-making.

It's also important to distinguish between simple metrics such as the number of safety events submitted outside the required window, and more complex ones like identifying enrollment delays across multiple CROs. Metrics are not definitive indicators of success or failure but serve as signals of potential issues.

The 2024 roundtable discussions revealed a desire for a collaborative, community-driven approach to developing standard ways of working. While no concrete standards were established, the need for a common framework is evident and is a top priority for 2025.

By fostering collaboration, the industry can develop standardized ways of working and create foundational metrics that will benefit all organizations.

Conclusion

The future is bright for biotechs as technology advancements create new possibilities and opportunities for how clinical teams can operate. As investments continue to increase to power R&D innovation[2], we encourage sponsors to prioritize strategic partnerships, invest in infrastructure that can support trials at scale, and monitor key metrics to thrive in 2025 and beyond. Veeva is committed to fostering a community to tackle these challenges together and drive advancements industry-wide.

Connect with an industry expert for a deep-dive assessment of your organization's tools and processes and how to position your company for success in 2025.

[2] "Biotech industry overcomes slump, adapts to new normal," BioSpace, August 2024.

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