

Ensuring Effective and Compliant Vendor Oversight in an Era of Increased Outsourcing



Industry Challenge

Biopharmaceutical companies today are increasingly leveraging outsourced solutions to help reduce fixed costs and expand access to new talent and capabilities. These companies face two key challenges, however: how to balance the benefits of outsourcing with the need to maintain control of their development programs *and* how to readily demonstrate the proper level of oversight to both internal stakeholders and external regulators. The expectations from regulators are clear; vendors are considered an extension of the sponsor and sponsors are ultimately accountable. Developing a framework that provides the proper controls over activities, while giving vendors the freedom to do what they do best, is easier said than done. Our solution targets specific pain points to help companies develop a robust capability that provides **transparency**, increases **efficiency**, builds **trust** across stakeholders and helps ensure **compliance**.

The TriRadial Solution

Transparency, both internal and external, is paramount to an effective vendor oversight capability. Achieving the right level of transparency and control requires a line of sight to emerging risks and monitoring the actions needed to mitigate those risks to levels that are acceptable to all key stakeholders. TriRadial has identified three key components needed for effective vendor management and oversight: a clearly defined **governance model**, robust **risk identification and management processes**, and a set of **metrics, tools and templates** to proactively monitor key activities,

The need to demonstrate full awareness and control of key vendor activities and outputs is becoming more critical as outsourcing continues to increase

performance levels and potential risk areas. Combined, these three elements improve efficiency, create a more transparent and trust-based environment for both sponsors and vendors, and provide a consistent ability to demonstrate proper oversight to regulators.

Governance Model:

The primary and most visible component of an effective oversight capability is the cross-functional governance model. Building the right cross-functional team, guided by an approved charter and empowered to drive actions, is a key success driver to ensure ongoing oversight and management of outsourced processes and outputs. Companies need to establish and maintain these governance teams to help ensure key risks are mitigated and their strategic goals remain achievable. Developing an overarching governance model, versus optimizing interactions with each vendor, takes concerted effort to develop but standardized processes, interfaces, and roles can dramatically improve efficiency and speed, especially when bringing on new vendors.

Establishing the proper overlap between sponsor and vendor responsibilities is often the biggest challenge; many emerging companies grapple with how to shift internal skills from *doing* to *active oversight* for outsourced functions. Companies need evidence to demonstrate this active oversight to regulators and governance structures, properly constructed, can help demonstrate that control.

Risk Identification and Management Processes:

A risk-based approach to identifying key vendors and areas of known risk, is essential to establishing and maintaining a robust state of control. TriRadial has experience facilitating both the identification of critical-path processes and the risks inherent to each process. With risks identified, the governance team can monitor actions required to mitigate each risk. Over time, some risks no longer factor onto the critical path, while others emerge. Having a well-functioning vendor oversight team allays internal stakeholder concern and rightly demonstrates to regulators that outsourced processes are properly identified and rigorously managed.

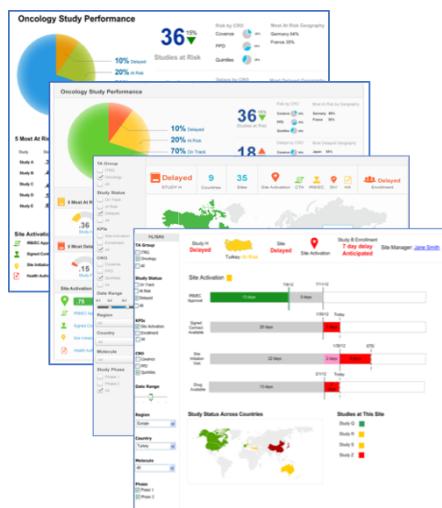
Metrics, Tools and Templates

Key enablers to accelerate the establishment and exercise of this control include templated charters, pre-configured dashboards, escalation pathways and defined thresholds for action. TriRadial comes equipped with examples and experience to accelerate the creation of the essential tools needed to rapidly move the company to the appropriate state of control.

Up-front Strategic Planning (optional):

For companies that want to ensure their overall sourcing strategy is appropriate for their stage of evolution and risk tolerance, we offer up-front advisory services to assess, diagnose and establish a vision and strategy for how best to outsource key components of the drug development process. One of the most helpful exercises during this phase is the

Core/Non-Core Analysis, where organizations determine what capabilities to build internally versus outsource based on various factors, such as strategic differentiators, business impact and the vendor landscape. Function-specific strategies highlight what each group needs for growth, as well as key dependencies and interfaces across functions. Implementation plans and roadmaps outline the steps necessary to enable the future-state.



The Results

Internally, stakeholders at all levels are able to quickly identify risks, understand underlying issues and ensure appropriate mitigations are in place to effectively manage all key activities. When management asks how prepared the organization is to meet critical objectives, the governance structure and oversight framework provide confidence that the organization is well-prepared to deal with potential issues and can effectively manage all aspects of the process, regardless of whether activities are performed in-house or by a vendor. Externally, regulators see a structured and rigorous process to identify, manage and track risks to closure over time. They can readily see the lifecycle of risk management being executed and a comprehensive process for vendor oversight and management.

Contact Us:

Phone: 1-866-TRI-RADL (874-7235)

On the web: www.triradial.com

Email: info@TriRadial.com

