



COMPLEX GLOBAL ALLIANCE SUCCESSFULLY EXECUTES CLINICAL TRIALS

A pharmaceutical company formed an alliance with a global CRO to plan and execute multiple phase 1/phase II clinical trials for biosimilars to support development in both emerging and regulated markets. The company embraced a “fully outsourced model” and looked to the global CRO to support both the strategic and operational aspects of the clinical development programs. Besides the two major players in this partnership, there were also multiple vendors and consultants engaged either through the CRO or the sponsoring pharmaceutical company who contributed to various aspects of clinical development. It became clear within the first year of the working relationship that the framework to successfully execute projects in this multi-partnership model was not well defined, leading to significant delays and concerns around budget overruns and quality.

Further complicating this partnership was the geographical distribution of team leaders and members across the globe, prohibiting face-to-face interaction. The partnership lacked disciplined project management and an effective governance system, which often led to miscommunication and eroding trust amongst team members. Finally, since this was somewhat uncharted territory for both organizations, business processes to support this alliance partnership had to be developed and optimized to introduce efficiency in the system and for long-term sustainability.

SOLUTION:

The pharmaceutical company engaged Integrated Project Management Company (IPM) to support the clinical department, leading cross-functional project teams across the alliance and establishing best practices.

CRITICAL ELEMENTS OF SUCCESS ►

IPM introduced disciplined project management methodologies and optimized key business processes to successfully plan and execute clinical trials under the multi-partnership model.

Risk Mitigation

IPM conducted a risk-management workshop to help team members identify project risks and develop risk mitigation strategies, which were documented and monitored throughout the project lifecycle.

Communication

IPM set up best practices for project team meetings, created dashboards for progress reporting and streamlined communication channels.

Structure

IPM set up a governance structure and integrated project teams that represented both organizations at the strategic and functional levels respectively, and was engaged in developing a management procedure manual that described the working model in detail. Additionally, a defined structure and process for issue escalation was instituted to enable the project teams.

IPM conducted a gap analysis to identify areas for process improvements and streamlined business processes for contracts management and budget reporting.

Accountability

IPM delineated roles and responsibilities and defined the end to end process and workflow for the clinical trial so that team members understood their deliverables and could stay focused on milestones. IPM worked with the teams to find efficiencies where possible, allowing them to compress the schedule.

IPM’s effective project and alliance management approach strengthened the pharmaceutical company and CRO relationship, building trust and increasing communication. IPM ensured all of the partners adhered to the schedule and budget while focusing on quality. Together the alliance completed one of its clinical trials and regulatory submissions for two other molecules in multiple countries. The methodologies and best practices set up by IPM has helped position the partnership for future success.

RESULTS