CRO to CRO transition of two global oncology trials

Successful tripartite engagement for a key partner

Background

This case study highlights the successful transition of two global oncology trials between CROs, showcasing the power of a collaborative, tripartite approach. Study A addressed advanced or metastatic solid tumors and relapsed/refractory hematologic malignancies, and Study B focused on relapsed/refractory CD20-positive B-cell Non-Hodgkin Lymphoma. Both were Phase I/II trials conducted across North America, Europe, and Asia-Pacific regions. Study A involved 202 patients and included an open-label, dose-escalation and expansion design structured as a basket trial with six cohorts of a monotherapy compound. Study B enrolled 145 patients and had a similar structure, with the investigational compound used in combination with an approved therapy.

Objective

The primary objective of this transition initiative was to ensure a smooth transfer of trial responsibilities from one CRO to another, without disrupting trial timelines or compromising data quality. Managing two complex, global studies required tight coordination between the sponsor, the outgoing CRO, and the incoming CRO. Key goals included preserving site and patient engagement, maintaining regulatory and operational momentum, and integrating new vendors and systems as needed.

I'm proud of the success of these two transitions, driven by our team's experience and proven process. Clear communication, close collaboration, and consistent site engagement ensured a smooth handoff and strong working relationships throughout the study.

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Strategy

To achieve this, the team implemented a series of strategic actions. Roles and responsibilities were clearly defined from the start, and regular communication touchpoints were established across all three organizations. As new information emerged, plans were continuously reviewed and updated. A shared terminology and set of goals helped ensure alignment, while tri-party meetings allowed for joint decision-making and proactive resolution of potential issues. Functional team leads were designated, including the assignment of a dedicated Transition Study Process Lead, to keep activities on track. Timelines were carefully managed, and critical startup activities were clearly assigned and prioritized. Sponsor outreach to study sites helped ease concerns and provide support during the transition. A Site Assignment Letter was issued to provide clarity on the handoff, and the incoming CRO was flexible in accommodating sponsor-specific processes. New vendors were introduced where needed, with appropriate training provided. A robust plan was in place to manage the electronic Trial Master File and any documentation gaps identified during the transition were addressed once the handover was complete.

Results

The results demonstrated the effectiveness of this collaborative approach. Early planning, enhanced communication, and aligned team efforts were critical to a smooth and successful transition. The transition had minimal impact on ongoing study timelines, and clinical sites remained engaged and informed. Clear responsibilities and adherence to shared timelines reduced confusion and facilitated momentum. Ultimately, the project proved that with the right preparation and cross-functional coordination, complex transition studies can be executed without compromising the integrity or continuity of a clinical trial.

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