ALTASCIENCES

CASE STUDY

Streamlining Clinical Trial Start-up for Accelerated Drug Development

INTRODUCTION

This case study examines the successful implementation of strategies and collaborative efforts employed in a Phase I study to achieve an expedited start-up. The study focuses on the partnership between the study team and the sponsor, emphasizing effective communication, strategic planning, and delegation of responsibilities. The case study showcases how these factors contributed to accelerating start-up timelines and the sponsor's overall drug development program.

BACKGROUND

The sponsor came to Altasciences with an immediate need to conduct their required Phase I, multiple ascending dose (MAD) study for a regulatory filing. To meet their goals, it was essential that Altasciences shorten the start-up time (time from award to first dose) from a standard of 12 weeks to less than four weeks. Tasks to be completed during this extremely shortened timeframe included: contract execution, regulatory document preparation, and Institutional Review Board (IRB) approval; preparation of documents and supply procurement for clinical, pharmacy, and laboratory procedures; site initiation and training; subject recruitment and screening; and clinical database/eSource release.

IMPLEMENTATION

✓ INTERNAL TEAM ALIGNMENT

Immediately upon award, Altasciences' dedicated project manager (PM) communicated the importance of a swift start-up and ensured alignment among all internal team members and their respective management.

✓ CLIENT ALIGNMENT

Upon introduction, Altasciences' PM and the sponsor created an open dialogue, and aligned expectations against feasibility. The sponsor committed to prompt responses to email communications and active participation in meetings. Both the PM and the sponsor proactively engaged in phone conversations (instead of email) to resolve issues. This close collaboration created a dynamic and agile working relationship.

✓ OPTIMIZED PROJECT MANAGEMENT

The study benefited from a dual project management structure with the primary PM located on the East Coast and a secondary/support PM based on the West Coast. The secondary PM's primary responsibility was to manage Altasciences' clinical trial site (located in Los Angeles). This geographical distribution effectively extended the availability of project management support to the sponsor, offering nearly 12 hours of support each day.

✓ DIRECT COMMUNICATION BETWEEN TEAM LEADS AND SPONSOR

Direct communication between the sponsor and functional leads expedited decision-making and issue resolution. The PMs and the project coordinator (PC) were always copied on emails and informed about conversations, while not becoming bottlenecks by requiring that all communication be channeled through them.

✓ EFFECTIVE MEETINGS STRATEGY

The primary PM implemented a well-structured meeting strategy that included three key meetings per week:

1. **Internal Meeting:** The project team intended this for internal discussions, allowing team members to collaboratively address issues and challenges, thus reducing the need for lengthy email exchanges.

2. **Full Team Meeting:** The meeting agendas, designed for all stakeholders, including the client, were specific and focused on specialized points for each functional group to address. This approach promoted active participation and removed vague agenda items.

3. **Altasciences PM-Client PM Meeting:** The primary PM and the sponsor PM held this meeting at the end of each week, intending it for one-on-one communication. It provided a forum to review the previous week and look ahead to the coming week, with the goal of confirming deliverables and reviewing risks to any critical-path items.

✓ FOCUSED TIMELINE MANAGEMENT

The primary PM strategically guided the team by splitting the timelines and focusing on **start-up through first subject first visit (FSFV)** to achieve the sponsor's KPI of " first dose."

This sharp focus on the early phase of the study allowed the team to meticulously review tasks and identify areas where time could be saved. Collaboration among cross-functional teams allowed start-up tasks to be completed in parallel. Regulatory document preparation and IRB approval occurred while teams generated study documents, acquired supplies, and built the database/eSource. Upon receipt of IRB approval the team was ready to move forward with recruitment and screening of participants to meet the sponsor's critical target.

Once the sponsor's KPI was achieved, the team's attention shifted to the remainder of the timeline, ensuring continued efficiency throughout the study's duration.

CONCLUSION

The strategies outlined above resulted in a start-up timeframe of **3.5 weeks from study award to first subject first dose.** Strong, effective project management combined with a committed internal team and a collaborative sponsor, resulted in significant decreases to industry-standard start-up timelines. This case serves as a valuable reference for organizations seeking to streamline their clinical trial operations and achieve accelerated results.

Contact us today to get your program started with Altasciences.

ABOUT ALTASCIENCES

Altasciences is an integrated drug development solution company offering pharmaceutical and biotechnology companies a proven, flexible approach to preclinical and clinical pharmacology studies, including formulation, manufacturing, and analytical services. For over 25 years, Altasciences has been partnering with sponsors to help support educated, faster, and more complete early drug development decisions. Altasciences' integrated, full-service solutions include preclinical safety testing, clinical pharmacology and proof of concept, bioanalysis, program management, medical writing, biostatistics, and data management, all customizable to specific sponsor requirements. Altasciences helps sponsors get better drugs to the people who need them, faster.