Case study

Clinical trial transition studies

An innovative approach to transition studies

Swift transition for a key Phase IIIb pediatric trial

Background

When clinical trials face operational challenges, swift and strategic intervention is critical to maintaining progress and ensuring patient care. In this case study, we explore an innovative transition study approach for a Phase IIIb pediatric IV infusion treatment targeting Duchenne's muscular dystrophy. With 20+ vendors supporting the study and a 3-month transition period, the PPD™ clinical research business of Thermo Fisher Scientific was tasked with seamlessly managing the transfer while upholding data integrity, regulatory compliance and most importantly, pediatric patients' safety on the ongoing clinical trial. The transition aimed to stabilize operations, maintain submission timelines, successfully migrate key clinical systems, and enable continued advancement of the therapy with minimal operational risk.

Challenges

Transitioning a complex, late-stage pediatric study within a tight three-month timeline introduced several operational and regulatory hurdles. The team had to manage critical deliverables while coordinating multiple vendors, patient care, and ongoing submissions without interruption.

Key challenges included

- Conducting an expedited kick-off meeting (KOM) to align teams and priorities.
- Managing reliance on legacy CRO regulatory and ethics submissions during the transition.
- Releasing investigational medicinal product (IMP) dossiers mid-transition.
- Assuming clinical responsibilities earlier than planned due to study delays.
- Allocating high resource levels to support both legacy and new site operations.
- Coordinating the transition of more than 20 vendors.
- Migrating the electronic trial master file (eTMF) without disrupting study activities.

With deep experience of transitioning studies and a well-established framework, we were able to successfully transition from previous CRO within 3 months and helped advance this critical study toward life-changing therapies for children with Duchenne's muscular dystrophy

Strategy

A proactive, phased approach was implemented to stabilize operations and ensure a seamless transition. Early prioritization of critical activities, strong project management, and collaborative communication between teams helped maintain pediatric patients' safety and regulatory compliance by minimizing disruption to ongoing study activities.

- Held staggered kick-off meetings to address immediate operational needs and align cross-functional teams.
- Developed a country-specific regulatory and ethics committee submission plan to navigate regulatory complexities during the transition.
- Front-loaded staffing within the first six months to manage increased operational demands.
- Assigned a dedicated transition study process lead to oversee transition activities and vendor management.
- Implemented robust communication and escalation plans to ensure rapid decision-making and issue resolution.
- Seamlessly migrated the eTMF to a new platform to support uninterrupted study management.

Results

Through a proactive and collaborative approach, the team successfully achieved the client's request for a three-month study transition. The migration of the eTMF platform was completed without disruption, and all CRO submissions were completed on or ahead of schedule relative to the fully executed contract. By maintaining strong regulatory compliance, protecting patient safety, and ensuring minimal disruption, the team helped advance this critical study toward life-changing therapies for children with Duchenne's muscular dystrophy. Transitioning a study is not easy work, but we have proven through this case study and others that a proactive, collaborative approach enabled a successful transition strategy, ensuring minimal disruption and continued advancement toward life-changing therapies.

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