

Meeting aggressive data delivery timelines in one of the first-ever CAR-T studies with pediatric and adolescent patients



A KEY QUESTION



How can a proactive approach help biotech sponsors handle complexity, prioritize site support and meet data review timelines?

KEYWORDS

CAR-T-Cell Therapy, Blood Cancer, Non-Hodgkin Lymphoma, Pediatric Clinical Trials, Biotech, Site Support, Data Quality

Introduction

A biotech sponsor selected Fortrea to conduct four studies within its CAR-T program. One of the studies focused on pediatric and adolescent subjects with relapsed/refractory B-precursor acute lymphoblastic leukemia (ALL) or relapsed/refractory B-cell non-Hodgkin lymphoma.

Learn how Fortrea actively supported data integrity efforts, addressed aggressive data analysis timelines and provided the primary analysis deliverables ahead of schedule to promote timely decision-making.



Recognizing challenges and implementing clarity

Study challenge	Fortrea solution
<p>Lack of data visibility</p> <p>With the sponsor managing the medical monitoring, statistics, safety and translational medicine, Fortrea found that its team had limited visibility into the sponsor's data review process while facing aggressive data cleaning timelines.</p>	<p>To enhance transparency and meet timelines, Fortrea created a dossier data deliverable dashboard. This dashboard included critical data, such as query detail, pending source data verification (SDV), SDV aging, adverse events, concomitant medications and transfusion data. This data was highlighted to review on a weekly basis and any outstanding SDV and open queries were shared with the sponsor.</p>
<p>Late queries and fragmented communication</p> <p>The sponsor faced internal communication challenges across its team as their medical scientist issued queries without informing the sponsor's clinical team. Many of these queries took place after the final query issued date.</p>	<p>Fortrea needed to respond with urgency to align resources and keep the study on track. The team first proactively forecasted monitoring visits and estimated "days on site" (DOS) to align the projected scheduled visits and perform sufficient data review. Additional DOS were then planned to support late queries or re-queries.</p>
<p>Site fatigue</p> <p>The volume and timing of queries posed a potential burden on site staff.</p>	<p>Fortrea prioritized site support, providing weekly or as needed reminders to the sites and highlighting the upcoming deadline. They offered ad hoc meetings with site staff to help with challenging queries and increased monitoring frequency as they reviewed data entry remotely.</p>

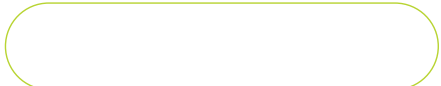
Focusing on lessons learned to promote data quality

To drive quality at every data point, Fortrea helped:

- **Increase monitoring efficiency:** Fortrea worked remotely with the site staff to address queries prior to the monitoring visits
- **Create site-specific data execution plans:** Fortrea found that challenging sites could be supported with the timely development of data execution plans
- **Address challenging data queries:** By involving principal investigators (PIs) in the support process, Fortrea could assist site staff with challenging data queries

Solutions provided:

- **Ahead of schedule delivery**
- **Proactive query management**
- **Real-time data visibility**



Recognizing how ownership drives outcomes

Biotech sponsors rely on dependable data across all phases of their study to enable consistency, meet critical timelines and reach key milestones. As a result of Fortrea's cohesive data standards and the dashboard with full visibility into progress, they involved the sponsor and sites in critical-path conversations, enhanced communication and increased data review efficiency.

Fortrea was proud to provide the sponsor with the primary analysis data deliverables two weeks ahead of schedule. They also successfully performed a database snapshot as planned—avoiding last-minute or delayed data issues and demonstrating the team's continued accountability in addressing challenges and delivering reliable results.



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