CASE STUDY

WCG IRB+ Expedites Phase I CRISPR-Edited CAR-T Cell Therapy Trial

CHALLENGE

A Top 5 CRO faced a critical challenge in managing an expedited Phase I hematology trial for a novel CRISPR-edited allogeneic CAR-T cell therapy. The trial, spanning only four sites, demanded a rapid and efficient IRB review process to meet aggressive enrollment timelines, while maintaining the high-quality standards essential for early-phase, cohort gated, dose escalation, dose expansion hematology research.



SOLUTION

The CRO implemented WCG's IRB+ service. This service provided a dedicated team of 17 operational experts who offered →

White-Glove Service: The IRB+ team took ownership of the IRB submission process, ensuring all documents were complete and accurate for the three participating sites.

Accelerated Processing: Because the dedicated IRB+ experts are all functionally cross-trained, document processing timelines were significantly reduced and potential error introduction was mitigated, without sacrificing the integrity of the Board review.

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RESULTS

Exceptional Turnaround Time: By leveraging IRB+, the CRO achieved remarkable results. For full board review, IRB+ secured an average turnaround time of just 3.0 days, exceeding industry standards for Phase I trials. For expedited reviews, the IRB+ team achieved an even faster turnaround time of only 1.6 days. This expedited process ensured the trial remained on track and allowed for the most efficient patient enrollment.

Improved Efficiency: The dedicated IRB+ team minimized the burden on the CRO's internal staff, allowing them to focus on critical trial management tasks specific to the complex CAR-T therapy.

Enhanced Communication: The IRB+ team fostered clear communication between the CRO, investigators at all three sites, and the IRB throughout the review process, addressing any questions or concerns promptly.

TURNAROUND TIME	DAYS
FULL BOARD	3.0
EXPEDITED	1.6
NEW STANDARD PI	0.0
NEW CUSTOMIZED PI	1.3

BENEFITS OF IRB+ FOR EARLY PHASE STUDIES

This case study demonstrates the significant value of IRB+ for CROs managing early phase studies, particularly those involving complex or novel therapies like CAR-T. IRB+ accelerates the IRB review process without sacrificing the quality of review, resulting in faster trial initiation, reduced administrative burden for the CRO, and exceptional turnaround times. This allows the CRO to focus on scientific excellence and patient recruitment, ultimately accelerating advancements in life-saving treatments. IRB+ is specifically geared towards supporting early phase hematology/oncology trial structures that can experience sizable changes through trial amendments, dose modification, toxicity management guidelines, and Informed consent revisions to ensure cohort advancement or expansion can proceed efficiently.