Oncology Phase III Rescue Trial in India for a Global Biopharmaceutical Company

When tasked with rescuing a Phase III oncology trial in India, TAKE Solutions delivered on-time, quality outcomes for the Sponsor by:

- Ensuring regulatory compliance right from CRO transfer to study completion
- Quickly on-boarding resources with the required expertise for the study
- Orchestrating the study and site transfer in a structured manner
- Recruiting and engaging patients using innovative techniques
- Keeping all key stakeholders (from sponsor to patient) actively involved in the study

This resulted in:

- Completing the regulatory transfer within 15 days (as compared to the standard 45)
- Screening the first patient within the first 26 days of being awarded the trial
- Ensuring >90% patient retention till the study end point

Introduction

Given the complexity of clinical trials, despite best laid plans, certain trials can go off-track and this results in a severe business impact on the sponsor. At such a time, it takes a seasoned, reliable, and reputed team to take over and complete the trial. A rescue trial ensures successful completion of the clinical trial, thus minimizing the business impact.

Business Need

TAKE Solutions was awarded the rescue of a Phase III oncology trial to ensure a successful completion. The trial was previously under a global CRO and faced significant regulatory risk in India. Hence, the sponsor turned to TAKE Solutions to initiate the study in India, speed up recruitment and align India with global study timelines.

TAKE Solutions' Approach

Ensuring Regulatory Compliance: Given the criticality of the regulatory risk, TAKE Solutions prioritized a regulatory-level CRO transfer based on a thorough checklist. This was paired with close follow-ups with the Regulatory Authorities through our senior regulatory experts. Thus, we expedited the CRO Transfer and ensured that it was compliant with regulatory requirements.

Making Required Resources Available: Given the expertise required to ensure the success of the study, we immediately on-boarded a team with the requisite oncology experience. This quick on-boarding was made possible by the award-winning recruitment systems setup by the HR team at TAKE Solutions.

Complete within
first 26 days
from the time of being awarded the trial

- Regulatory approval of change in CRO
- Setup of Systems and Processes
- Initiation and On-Boarding of Sites
- First Patient First Visit

Client Feedback

On completion of an EMA inspection

"We can finish EMA inspection well thanks to your full support. I really appreciate your effort and cooperation!!"

– Country Clinical Ops Manager

On completion of the DB Lock

"Indian sites that TAKE Solutions team handled always showed high data performance and TAKE Solutions PM paid attention not only to operation issues, but also to DM issues"

– Global Clinical Data Manager

Smooth and Efficient Study & Site Transfer: We prepared a detailed CRO transfer checklist at the study and site levels to ensure a complete and efficient transfer.

Commitment to Timely Delivery: We extended our operations beyond regular working hours to ensure timely completion of set-up activities.

Strategic Patient Recruitment: Leveraging our database, prior experience and rapport with sites and investigators in India, about 300 potential patients were identified by sites to randomize 100+ patients into the study. In collaboration with the Sponsor, robust recruitment strategies were implemented including an awareness program to increase the pace and intensity of patient recruitment.

Good Patient Retention: Our systems ensured on-time tracking on patient follow-up visits. This enabled proactive risk mitigation and effective issue management leading to better patient retention with >90% of patients completing the surgery, which was required for assessing the primary end point of the study.

Effective Stakeholder Engagement: By involving the Sponsor through frequent visits and meetings, engaging with a network of patients and setting up proactive systems to monitor and mitigate risks, the TAKE Solutions team ensured that all stakeholders, including Global CRO, central labs, IMP depot and logistics, and the IWRS vendor were engaged till the successful completion of the trial.

Results

TAKE Solutions ensured that we completed all key milestones on-time with a high quality outcome. This is a result of our focus on delivering outcomes while ensuring compliance.

- Completed the regulatory transfer in compliance with regulatory requirements in <2 weeks, as compared to the standard 45 working days required
- Screened 1st patient within 26 days of being awarded the study
- Ensured >90% patient retention due to stakeholder engagement systems
- Completed key milestones of the study in accordance to global study timelines
- High quality data ensured through robust site training and monitoring, proactive risk mitigation and execution strategies
- No major or critical observations during audit or inspections

About TAKE Solutions

TAKE Solutions delivers domain-intensive services in Life Sciences. In the fast-growing Life Sciences space, TAKE offers clients a unique combination of full-service Clinical, Regulatory and Safety services backed by unique technology expertise. Our range of services span from clinical trials to regulatory submissions to post-marketing safety, all backed by insights derived through proprietary industry networks forums. With a team of leading Life Sciences experts, best-in-class systems and processes, and bespoke, industry-specific technology and analytics, TAKE delivers successful outcomes for clients. Our global roster of clients includes large and small innovator biopharmaceutical companies as well as generics manufacturers. With operations spread across North America, Europe, Asia, and South America, TAKE is a Public Company, listed in India on the Bombay Stock Exchange and the National Stock Exchange. Led by a team of industry stalwarts and domain experts, TAKE has been growing steadily with FY18 revenues touching INR 15,872 Mn, (USD 246 Mn).

TAKE®
Enabling Business Efficiencies

For more information

Americas +1 609 720 1002 **Europe** +49 69 668 0300 **APAC** +91 44 4590 9000

contact@takesolutions.com www.takesolutions.com /company/take-solutions