CASE STUDY

Guiding a biotech's development of an immunotherapy cancer treatment with 'out-of-the-box' thinking

A U.S.-based biotech company was developing a unique, intratumoral immunotherapy treatment preparing for a Phase I study. They had mostly performed their work in-house along with niche providers. They now wanted to work with a CRO that could help support every aspect of their studies and ensure continuity in their program—from early development to commercialization.

This case study shares how Fortrea served as more than a partner to provide both operational and scientific guidance that helped reshape the sponsor's protocol, co-develop their strategies and optimize their clinical approach.

Understanding the challenge

As the late-stage biotech was expanding their pipeline, the scope of their studies expanded to several indications. Instead of managing multiple vendors, they realized that they required the support of a larger CRO to handle all aspects of their study's needs.

Their novel immunotherapy cancer treatment included the use of a physical transfection method to increase the efficiency of the response rate in patients' tumors. To support their program's success, they needed a CRO that could provide a holistic evaluation of their protocol design and implement an end-to-end strategy.

Evaluating the patient and provider experience

The Fortrea team approached the proposed study from several angles. First, they reached out to experienced study sites to better understand the use of a physical transfection method with an immunotherapy treatment and learn about its potential impact on patient recruitment for the study. The sites reported that the method did not cause discomfort for the patients, and they didn't believe this factor would affect the trial's recruitment rates.

From the provider's perspective, the Fortrea team also recognized that the combination of a physical transfection method with an intratumoral therapy was not a standard technique at most study

HOW FORTREA SERVED AS MORE THAN A PARTNER

- Demonstrated clear understanding of a biotech's needs
- Evaluated the patient perspective of a novel treatment
- Leveraged data to generate aggressive patient enrollment projections
- Proposed a train-the-trainer model for the unique treatment procedure
- Evaluated the protocol and suggested key changes to meet regulatory requirements
- Provided a full suite of solutions that anticipated potential pain points and set the sponsor up for success

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sites. They proposed developing a “train-the-trainer” model at regional hubs where trained investigators would share their knowledge with other sites in the area so that every investigator would be certified in the technique.

Generating expected recruitment rates

After understanding the patient impact and provider’s unique role in the treatment delivery, the Fortrea team created estimated timelines and recruitment rates for the proposed studies. To generate the expected recruitment rates, they used Fortrea central lab data as well as internal historical data. They also solicited feedback from country heads, sites and medical monitors and leveraged established relationships with academic institutions and private hospitals to create a model for the sponsor. In the bid defense meeting, the sponsor was impressed with Fortrea’s data-driven recruitment rates, which were more aggressive than the other two bids received.

Providing scientific strategy across the development continuum

The Fortrea team’s medical director also evaluated the sponsor’s protocol to identify any risks. Recognizing a potential gap, the Fortrea team recommended that the sponsor modify their Phase I cohort design to ensure it would capture sufficient safety data and withstand any scrutiny from regulators and ethics committees. They also looked beyond the immediate need for running the trial and obtaining regulatory approval to determine if the treatment, once marketed, would be reimbursed by payers.

Earning the trust of the sponsor

Throughout the bid defense process, Fortrea demonstrated their shared commitment to enable success in the studies and created a holistic vision of the treatment’s progression beyond the Phase I trial. Fortrea also examined the proposal from the operational and scientific perspectives and provided “out-of-the-box” solutions to optimize the sponsor’s end-to-end drug development journey.

As a result of the meticulous evaluation of the protocol and proposed strategic guidance, the Fortrea team earned the trust of the sponsor. The sponsor updated their protocol based on the recommendations and asked Fortrea to become their CRO provider. The partnership continues to strengthen as the teams work to deliver a treatment that will be able to improve the health and lives of patients once it reaches the market.

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