NEOANTIGEN CANCER VACCINE CASE STUDY

San Francisco Bay Area biotech advances Phase I-II cancer immunotherapy trial with Fortrea

A San Francisco Bay Area biotech company approached Fortrea to manage a Phase I-II clinical trial evaluating a personalized, neoantigen-based vaccine. The immunotherapy was tested in patients with non-small cell lung cancer, colorectal cancer and gastroesophageal cancer.

Through rigorous site selection, training and logistics, as well as close communication, Fortrea recruited and enrolled patients who met extensive inclusion/exclusion criteria. More importantly, the contract research organization (CRO) successfully managed time-sensitive sample collection, manufacturing and dosing requirements, leading to successful regulatory submission.

Challenge: execute to perfection

The study drug, an autologous vaccine, was manufactured from patient tumor and blood samples and administered by injection. The complex nature of the trial and the study drug—not to mention the critical nature of the patients' disease—necessitated superior performance and efficiency on all accounts. Top priorities included:

- Activate an elite roster of high-performing sites with specific expertise in personalized oncology vaccine trials
- Conduct rigorous sample management training for site staff
- Develop and manage a tightly controlled logistics process to ensure fragile samples made it from the site, through manufacturing and back to the patient without issue

STUDY FACTS

Patients screened:
190

Patients recruited:
30

Patients enrolled:
29

Sites activated:
12

Countries:
2 (USA and Australia)

Fortrea

Solution: white-glove care

Fortrea implemented a white-glove approach across site selection, logistics and overall communication and project management. Its carefully considered strategy included the following:

- **Select site selection:** Fortrea reached out specifically to sites with proven expertise in precision oncology. Fortrea then used its Xcellerate® clinical trial optimization tool to cross-reference identified sites with recruitment performance. This selection method allowed Fortrea to initiate 12 right-fit sites
- **Superior sample management:** Patients agreed to a tumor biopsy and blood samples at the start of the trial; samples were later sequenced and ultimately developed into the study vaccine. Fortrea conducted extensive sample management training so site staff could expertly manage pharmacokinetic and pharmacodynamic (PK/PD) tests. They also developed a detailed tracking mechanism for samples collected and used in the study
- **Strict logistics:** The fragility of the samples and the study drug left no room for delay in the supply chain. Fortrea developed a risk management strategy, established detailed status trackers and developed a strict logistics process to support manufacturing timing. As part of that process, they implemented a collaborative document that both the CRO and sponsor could review and update in real time
- **Always-on access:** Fortrea's startup team, project managers and other team members remained accessible and available through the duration of the study. The clinical trial liaison and in-house clinical research associate (CRA) met regularly with investigators and study coordinators to answer questions. Study coordinators could also set up one-to-one calls with CRAs to discuss patient, collection timing and sample shipment issues. Between meetings and calls, site staff could email the Fortrea team via a study-specific email address. Regardless of communication method, the CRO set a goal to respond to site questions within two hours during the workday. This high level of communication built trust and ensured a smooth, efficient process

Result: novel immunotherapy advances to Phase II-III

A high-touch approach and rigorous planning were keys to the study's success. Complex precision oncology studies can easily fall apart due to communication breakdown or sub-par project management. Here, Fortrea's startup, clinical and project management teams collaborated openly and often with the sponsor and sites to move the trial forward without redundant or delayed effort.

Accomplishments that show exceptional is possible:

- Fortrea's targeted approach to site selection and patient recruitment led to enrollment within the boundaries of baseline targets; meeting recruitment and enrollment goals gave the team confidence to set—and hit—future milestones
- Because of its decades of clinical research experience and deep expertise in oncology, including precision medicine, immuno-oncology and solid tumors, Fortrea's medical and operations teams knew what it would take to execute this trial; its experts leveraged their insight-driven expertise to develop detailed training, logistics and risk management strategies
- Fortrea worked side by side with sites and the sponsor for the duration, successfully leading the study to regulatory submission; after reporting positive results from the Phase I-II trial, the sponsor advanced its immunotherapy to a randomized Phase II-III trial

In the last five years

We've been honored to serve as a CRO partner of choice for our biotech and pharmaceutical customers as we've advanced their oncology drug development and supported:

1,350+	34,000+	265,000+
Studies	Sites	Participants

Exceptional is possible when you have the right partner.

Looking to go beyond cookie-cutter solutions that don't address your deepest concerns?

Meet with us

LEARN MORE at fortrea.com

Fortrea