Phase III Immunotherapy Clinical Trial

Synteract Adapts to Evolving Needs

Highlights

- Synteract helped qualify, identify, enroll patients in complex Phase III trial.
- It helped build morale and coordinate communications.
- It was pivotal in accommodating sponsor needs and increasing scale as needed.

Introduction

A biotechnology company focused on developing personalized immunotherapy products came to Synteract to help it qualify, identify, and enroll patients in a complex Phase III blinded clinical trial for an innovative dendritic cell vaccine in aggressive solid tumors. Subjects were followed for progression free survival as the primary endpoint, and overall survival as secondary endpoint after discontinuation or completion of treatment.

Synteract was tasked with managing the project, performing safety management, data management, biostats analysis, and some regulatory work and has also helped to rescue the sponsor's European Clinical Trial.

Challenges

- With the drug being produced in parallel to selection and screening for each patient, numerous intricate, involved processes needed to be coordinated.
- Given the longer than average (three month) screening process and aggressive nature of the disease, screen failure was extremely high at 80%.
- Patients had to be screened just after being diagnosed and before having surgery. They were then required to have surgery, undergo chemo and radiation, prior to introduction of the product. Missing critical testing points could result in enrollment rejection.
- Multiple vendors needed to be coordinated for labs, imaging, immune monitoring, pathology, drug manufacturing throughout North America and Europe.
- Patients had to be followed throughout treatment for an extended period to show efficacy of the vaccine and rule out side effects.

Our Solutions

- **Synteract helped to coordinate, and maintain morale across, 90 sites in the U.S., Germany, UK, and Canada,** to continuously identify and expeditiously screen patients.
- Synteract instituted targeted roundtable discussions regularly bringing together CRAs, management team, and sponsors to brainstorm on challenges at sites.
- **Leave-behind cards were created to inform everyone involved as an integral part of the patient's care** (neurosurgeons, in addition to neuro-oncologists) about the study.
- Synteract expanded outreach beyond the study's investigators by asking for names of other physicians that might have patients who could be appropriate.
- "Dear Doctor" letters were created to inform physicians about the trial. Cards were given to the rest of the team; the study protocol was shrunk into a manageable list for quick reference, information about it was posted on the sponsor's website.
- As patients were enrolled, frequent rounds of recruitment questionnaires were implemented enabling Synteract to constantly assess potential issues and successes.
- To further assist CRAs with expectations for site management, and the complexity of what needed to occur, Synteract implemented tracking tools to help CRAs stay on track.

- Synteract developed study specific plans and data cleaning tools to track progress on site monitoring, query resolution, reconciliation to help ensure completeness and accuracy of data.
- With regular communication key, Synteract representatives were always available.

Program Success

- Though this initial clinical trial with the sponsor was projected to last less than two years, its scope expanded significantly—from a small study with a handful of sites to a much larger one, taking on Germany, the UK, changes in protocol, all of which often needed to be done quickly.
- **Synteract was pivotal in accommodating sponsor requests and refocusing resources/efforts as needed.** It helped to quickly increase sites and scale to new countries, and went above and beyond to transfer tumor kits to a site in need on tight deadline to ensure continued patient involvement.
- The client continues to be happy with Synteract's responsiveness and flexibility, which has enabled it to close the gap on missing potential subjects, increase the number of subjects in prescreening and screening, implement communication best practices, and set realistic projections in trial timelines with new information going forward.
- Synteract continues to follow patients in this ongoing Phase III trial.

About Synteract

With employees across 21 countries, Synteract is an innovative, full-service CRO supporting biopharma companies across all phases of drug development to help bring new medicines to market. Synteract has conducted 4,000 studies on six continents and in more than 60 countries, working with more than 26,000 investigative sites and 750,000 patients. It has contributed to more than 240 product approvals. Synteract offers a notable depth of therapeutic expertise in oncology, dermatology, and neuro degenerative indications, as well as rare and orphan, pediatric, and immunotherapy studies.

For more information on how we can support your clinical trial, please visit www.synteract.com/Therapeutic-Expertise/Oncology or ContactUs@synteract.com.

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