Case Study

617-302-9845
sales@clinicalresearch.io
www.clinicalresearch.io

Taking Research In-House with CRIO: SciTech's Multi-Center Phase 1 Study

OVERVIEW

SciTech Development, LLC is an early-stage clinical pharmaceutical company with a promising therapeutic and drug delivery platform developed to treat non-Hodgkin lymphoma (NHL) and other primary cancers. SciTech was able to forego using a third party CRO to manage its first-in-human Phase 1 study, saving considerable costs and enabling rapid review of data. SciTech leveraged the fact that the lead research site in the study is already a CRIO site client, entering data into CRIO eSource contemporaneously.

CHALLENGE

Launching a trial in a funding-constrained environment

Fenretinide is a promising cancer treatment that may also offer the benefit of strengthening the body's natural immune system to resist cancer. Fenretinide's limited solubility required a suitable drug delivery platform to overcome this bioavailability limitation. Oral fenretinide dosages were unable to overcome this limitation; and, intravenous methods utilized a triglyceride-rich emulsion to enhance the drug's bioavailability which resulted in grade 3 and 4 hypertriglyceridemia.

SciTech developed a patented formulation (ST-001) that enables the safe, rapid, intravenous delivery of high-dose fenretinide, without triglycerides. In 2023, after raising an initial seed round, SciTech Development launched its first clinical trial, a Phase 1 study to test the maximum tolerated dose for the treatment of refractory/relapsed non-Hodgkin lymphoma. The study duration is 2 years, targeting almost 50 patients, across multiple U.S. centers.

As a small company, SciTech needed to manage its funding carefully, and had a difficult time finding a full-service CRO that could manage the trial at a price point commensurate with the relatively low risk and complexity of the initial study. Every CRO scoped the study using a traditional EDC and on-site monitoring approach.

The clinical team learned about CRIO's integrated eSource-EDC solution from their lead research site, a prominent academic dermatology department that is a CRIO eSource client. When they reviewed the CRIO system, the team quickly realized that with this more streamlined approach, they could manage the study in-house, avoiding significant overhead costs.

SOLUTION

CRIO Reviewer

CRIO's eSource is a user-friendly application that lets sites capture data directly on electronic templates, with built-in edit checks, and upload, annotate and sign any study files as PDFs within CRIO.

For the study, SciTech is requiring all its centers, which are academic medical centers, to utilize CRIO. Some centers are using CRIO's direct data capture solution, transcribing data directly into CRIO as the source of truth for the trial, then updating their institution's EMR, while others are using their EMR as the source of truth, then subsequently updating CRIO and uploading the associated EMR documentation.

Either way, SciTech's team can utilize Reviewer's user-friendly interface to review the data, issue queries, lock visits or subjects, and extract data at any time, all while performing all Source Data Review and/or Source Data Verification remotely. The Reviewer platform extends this flexibility to both data and the associated PDFs, thus creating a centralized command center for all site collected data. This flexible approach lets the team avoid significant onsite monitoring costs while giving them rapid access to screening and enrollment data.

"The system is very easy to use," said SciTech's Clinical Study Director managing the project. "It was extremely intuitive, and the fact our lead research site was already using the system made the onboarding even easier."

The non-CRIO sites had no problem accepting use of the CRIO system. While they would use their institution's EMR as their main source of data collection, these sites appreciated the system's easy-to-use interface and downloadable source templates, which served as flowsheets for their teams, thus shortening startup time. The CRIO deployment and study build was extremely efficient - the turnaround time on build was about 6 weeks.

OUTCOMES

By managing the study themselves, SciTech saved their investors several hundred thousand dollars including personnel and overhead costs, travel costs and third party safety/medical monitoring tools and services. This savings is critical to extending the company's financial runway. Furthermore, rapid access to data, combined with the system's versatile reporting tool, will enable the clinical team to access study insights earlier and therefore have more flexibility adapting their clinical trial strategy.