WHY SYNTERACTHCR?

A full-service CRO, SynteractHCR has a proven track record of success in all phases of clinical development.

Shared Work – Shared Vision: This is a promised standard, the way we do business. It conveys our collaborative, customized approach to conducting trials tailored to your needs, which meet or exceed your expectations.

Case Study: CDISC Conversion in Oncology Clinical Trial

Often, early-development stage companies are working on pharmaceuticals and medical devices that have promising clinical intellectual property and commercial prospects. They may even have large pharma partners that help with financing and, eventually, submissions around the world. But in the beginning of trial phases they are often working with shoe-string budgets and simply trying to see if the innovative product will be efficacious.

The original data may be put into traditional table and listing format. In the early phase of development, providing the datasets in CDISC format is not typically done due to the added complexity and associated costs. But when these innovative companies realize that their product is headed for submission to the FDA, the team needs a way of integrating all their data. A case like this occurred in 2011, where the sponsor came back to SynteractHCR and asked for all of the initial datasets to be converted into CDISC format.

The sponsor had been working with SynteractHCR since 2007 on a phase 1, dose-escalating, Maximum Tolerated Dose (MTD) study for oncology. SynteractHCR was initially contracted for data management and biostatistics while the sponsor managed the clinical operations, medical, and regulatory components.

In 2011 the sponsor hit a milestone with its Phase III registrational trial and was now faced with the FDA requirements for submission of the New Drug Application (NDA) and including data from all of its other studies in a compatible format.

Challenges

CDISC requires a higher level of experience, takes more time, and needs an increased level of programming versus the traditional way of analyzing data in tabular format, i.e. tables, listings, and figures (TLF). In Phase I studies where the drug may or may not work, sponsors often don't want the expense, so they are not done in CDISC.

In order to integrate the data from one study into a larger dataset from other studies, all data needed to be in the same format. CDISC is an acceptable format for such submissions to the FDA and other countries' regulatory bodies so it is becoming the industry standard. The sponsor asked if SynteractHCR could convert the original datasets (TLFs) into SDTM CDISC formatted datasets.

Getting the datasets converted is a challenge in itself – requiring substantial hours, and multiple back and forth interaction with the client. Ensuring the SDTM datasets are compatible with broader datasets is critical. Once the initial SDTM programming was completed, additional data cuts could be made and new data could be provided to the sponsor at subsequent time-points. Initially, SynteractHCR was asked to convert and deliver just the SDTM datasets. But it became clear that in order for the sponsor to meet its obligations to the FDA, there was a need for continued deliveries of the SDTM datasets at time points correlating with their ongoing submission to the agency in the US and abroad. SynteractHCR was able to provide additional deliveries of the data within specified time frames.

In addition to the SDTM domains, SynteractHCR provided defined documents in both XML and PDF format, as well as the validation reports to support the quality of this output.

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Our Solutions and Successful Results:

SynteractHCR established regular communications, and our experienced, cross-functional project team knew the questions to ask to clearly define the objectives, in order to provide the highest quality product. This gave confidence to the sponsor that SynteractHCR could manage such a complicated task. Sponsor management continued to ask SynteractHCR for additional services such as bookmarked PDF casebooks for all 140 patients. It was important that SynteractHCR meet tight timelines, based on the scheduling of when the sponsor needed to submit to the FDA; critical milestones had to coincide with various events required during the submission and post submission process.

This conversion and project management required a tremendous coordinated effort by SynteractHCR's data management and biostats departments, in particular. The project required a level of detail that was intense. Going back to early stage studies to be able to integrate them into a larger group of data that occurred in later phase studies took extra attention to detail and expertise. The team worked closely with the sponsor to support the continuing development process.

Quickly, the sponsor's oncology drug was on its way to approval, and SynteractHCR was proud to be a part of this milestone event with a longstanding client. Being able to convert the datasets and deliver on time made for a mutually successful opportunity for both parties.

Now that the data has been successfully used in the sponsor's US submission to the FDA as well as in EMEA submissions, the drug is now marketed internationally.

Most important, the client is happy. The sponsor has continued to work with SynteractHCR several times since, including coming back to us for more data set conversions on this study and for more studies, including a rescue from another CRO.

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