WEP

With Every Patient.

CASE STUDY: HELPING A SPONSOR COLLECT DATA IN AN EXPANDED ACCESS PROGRAM TO SUPPORT CLINICAL TRIAL DATA

Background

Headquartered in Massachusetts, US, and with offices across North America and Europe, the Sponsor is a radiopharmaceutical-focused company committed to developing and commercializing novel oncology products.

The Sponsor partnered with WEP to set up and manage an Expanded Access Program (EAP) for one of it's lead product candidates. This EAP was set up to provide treatment access for patients who are unable to enrol into active clinical trials and unable to access marketed medicines in the US.

The Challenge

The Sponsor wanted to collect Real World Data (RWD) in its Expanded Access Program (EAP) to submit to the FDA in support of its clinical trial data for approval, reimbursement, and expanded indication decisions.

However, the Sponsor did not have experience collecting data in a setting outside of the clinical trial. The Sponsor team wanted to find an EAP partner that could help design and manage an effective and compliant data collection plan, that could potentially support the Sponsor's clinical trial endpoints.

Below we have outline how we supported this Sponsor.

Sharing Expertise and Best Practices

Because the Sponsor wanted to collect data to support its clinical trial findings, the Sponsor team assumed that the data collected in the EAP should be similar to what is collected in the clinical trial.

This is not an uncommon assumption. At the outset of every EAP, the WEP Data team takes the time to ensure the Sponsor is aware of the differences between data collection in an EAP and data collection in a clinical trial. Because the primary goal of an EAP is to provide treatment to patients, not generate evidence, the amount and type of data that can be collected is different.

Examples of data that can/should be collected in an EAP include dosing information, disease progression, patient and physician impression of change, impression of severity, long term survival information, pain scales, other efficacy data, safety data, etc. Examples of data collection methods in an EAP include questionnaires, patient diaries, quality of life assessments, standard rating scales, etc.

Our team took the time to understand what clinical trial endpoints the Sponsor wanted to collect data in the EAP to support. We were then able to suggest the **type of data** that would best provide evidence on those endpoints and advise the team on **how we could collect this data** in a way that was appropriate within the context of an EAP.

Keeping the Site in Mind

Because data collection is not required in an EAP, it was important to create a data collection plan that is manageable and does not overburden the site. The Sponsor initially came to us with a long list of CRFs it wanted the sites to complete. Our experienced team stressed the importance of keeping data collection simple, quick, and consistent to ensure the RWD collected is complete and accurate throughout the duration of the program.

Utilizing WEP's expertise and experience, the Sponsor was able to narrow down their data collection from 26 eCRFs to the 13 eCRFs that were the most important for the intended end use.

Additionally, WEP advised on a payment plan for the sites. Companies can choose not to pay sites if they prefer. However, due to the amount of data the Sponsor was requesting sites to collect, we recommended site payments to ensure compliance.

Building the Data Collection Program

WEP's preferred EDC system for EAPs is a cost-effective, 21 CFR Part 11 compliant, intuitive web-based platform that makes data collection compliant and efficient. It has the robustness of commonly used clinical trial EDCs (such as InForm and Rave, etc) but at a reduced build cost, hosting and setup time.

Our Dara Management team managed the complete build of the Sponsors data collection program within this system. Database build time was approximately 5 weeks and consisted of 13 eCRF's specific to the data collection needs of the sponsor. We then oversaw the rollout of this system across all EAP sites and provided support and guidance for site staff to ensure compliance.

Work with WEP for your Data Collection

WEP recommends that all Sponsors consider collecting RWD in their EAPs. If you do not wish to submit RWD to regulator bodies, there are other uses for the data, including:

- Increasing understanding of a drug and its value-effectiveness in existing and new patient populations
- Informing future clinical study efforts by evaluating whether new outcomes are significant and warrant additional clinical trials
- Increasing awareness among key stakeholders and KOLs who could be future advocates for and prescribers of your drug

If you would like to chat with our team about how we how we can support your data collection program, please contact us at:

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