

EXPANDED ACCESS PROGRAM • ONCOLOGY

Helping a Sponsor Collect Data in an Expanded Access Program to Support Clinical Trial Data

How WEP Clinical helped a radiopharmaceutical oncology Sponsor design a compliant, site-friendly Real World Data collection model within an Expanded Access Program – without compromising the program's primary purpose of patient access.

PROGRAM SNAPSHOT

Therapeutic Area

Rare Oncology

Program Type

Expanded Access Program (EAP)

Advanced Therapy

Yes

Country in Scope

United States

ABOUT THE SPONSOR

The Sponsor is a radiopharmaceutical-focused oncology company headquartered in Massachusetts, with offices across North America and Europe. The Sponsor partnered with WEP Clinical to set up and manage an Expanded Access Program (EAP) for one of its lead rare product candidates. The program was designed to provide treatment access to eligible patients in the United States who were unable to enroll in active clinical trials and unable to access marketed alternatives.

THE CHALLENGE

The Sponsor wanted to collect Real World Data (RWD) within its EAP to help supplement its clinical trial data and support future regulatory, reimbursement, and indication-expansion discussions. However, the Sponsor had limited experience collecting data outside the structure of a clinical trial.

The team initially approached the EAP data collection plan in a similar way to a trial, with a broad list of eCRFs and data points they wanted sites to complete. This created an important challenge.

In an EAP, the primary objective is to provide treatment access, not to generate clinical evidence. Any data collection must, therefore, be purposeful, compliant, and practical for sites primarily focused on patient care. The Sponsor needed an access partner that could help answer three critical questions:

01

What data is appropriate to collect in an EAP setting?

02

How can the data support the Sponsor's wider evidence strategy?

03

How can the Sponsor collect meaningful RWD without creating unnecessary burden for sites?

The key challenge was clear: build a compliant and manageable data collection model within an EAP while protecting the primary goal of patient access.

WEP CLINICAL'S SOLUTION

WEP Clinical worked with the Sponsor to design and operationalize a data collection plan that balanced evidence-generation goals with the realities of Expanded Access delivery. Rather than replicating the clinical trial data model, WEP helped the Sponsor focus on the data points most relevant to the intended end use, while keeping the process manageable for participating sites. The result was a more focused, practical, and site-friendly data collection program.

WEP'S APPROACH

1

Aligning the Data Strategy with the EAP Setting

WEP began by helping the Sponsor understand the difference between data collection in a clinical trial and data collection in an EAP. The team reviewed the Sponsor's evidence goals and considered which clinical trial endpoints could reasonably be supported by RWD collected in the EAP. This helped shift the program away from broad data capture and toward a more targeted approach focused on the data most likely to be useful, complete, and appropriate for the EAP setting.

2

Reducing Site Burden

The Sponsor initially proposed a data collection model that included 26 eCRFs. WEP reviewed the proposed data requirements and worked with the Sponsor to identify which forms were most important for the intended use of the data.

This reduced the data collection model from 26 eCRFs to 13 eCRFs, creating a more manageable approach for sites while preserving the most relevant evidence-generating elements.

This was one of the most important improvements in the EAP. By simplifying the data model, WEP helped reduce the risk of incomplete data, inconsistent site participation, and unnecessary administrative burden.

3

Building a Compliant Data Collection Platform

WEP's Data Management team managed the build of the data collection program within a 21 CFR Part 11-compliant EDC system. The database was built in approximately five weeks and configured around the final set of 13 eCRFs specific to the Sponsor's data collection needs. WEP then supported rollout across participating EAP sites, helping site staff understand the system, the documentation expectations, and the importance of consistent data entry.

4

Supporting Site Activation and Oversight

The program included 7 sites, all of which have been activated to date. WEP provided cross-functional support across Clinical Monitoring, Data Management, Project Management, Regulatory, Site Payments, and Medical Affairs. This helped ensure the program was not treated as a standalone data project, but as an integrated access program with the right operational infrastructure around it.

5

Managing the Operational EAP Infrastructure

Alongside the data collection work, WEP supported the broader EAP infrastructure needed to provide treatment access to patients. To date, the program has supported:

50+ Patients

7 sites

200+ shipments

This demonstrates that WEP was able to support both sides of the EAP: patient access delivery and structured data collection.

6

Advising on Site Payments

Because the Sponsor was asking sites to complete meaningful data collection activities as part of the EAP, WEP advised the importance of a site payment model. This helped recognize the additional effort required from sites and encouraged consistent participation in the data collection process. This was an important practical step in helping the Sponsor protect data completeness and site engagement.

THE OUTCOME

WEP helped the Sponsor move from a broad, trial-style data collection concept to a focused, compliant EAP data model — one that captured meaningful evidence without slowing down patient access.

The streamlined model held up in practice: all 7 sites remained active and data collection ran alongside patient care without disrupting enrollment or shipment timelines.

By combining EAP expertise with data management, site support, monitoring, regulatory coordination, and logistics under one program, WEP gave the Sponsor a single point of accountability for both sides of the EAP: getting treatment to patients, and building an evidence base that can support the Sponsor's future regulatory, reimbursement, and indication-expansion conversations. Most importantly, the Sponsor achieved this without compromising the EAP's primary purpose — providing treatment access to eligible patients.

WHY THIS MATTERS

RWD can add significant value to an EAP, but only when the data collection model is designed strategically. Too complex, and sites struggle to complete it consistently. Too broad, and the data becomes difficult to interpret. Too burdensome, and it distracts from the program's core purpose: patient access. The stakes are higher still in a rare oncology, advanced therapy setting like this one, where sites are often managing complex handling and administration requirements on top of a small, geographically dispersed patient population — leaving even less room for data collection to add friction. This case demonstrates how WEP Clinical helps Sponsors design data collection plans that are evidence-led, compliant, and workable for the sites and patients an EAP is built to serve.

NEED TO COLLECT RWD WITHIN AN EXPANDED ACCESS PROGRAM?

Let WEP help you design a data collection model built for real-world EAP delivery.

WEP Clinical supports Sponsors with the strategy, data management, EDC build, site engagement, monitoring, regulatory coordination, logistics, and operational delivery needed to collect meaningful RWD within an EAP. Contact us to learn more:



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