

CASE STUDY: RAPIDLY SCALING AN EXPANDED ACCESS PROGRAM TO FULFILL UNMET CLINICAL NEED FOR PATIENTS WITH LIFE-THREATENING SEIZURES

Background

A rare disease Sponsor, who partnered with WEP for an Expanded Access Program (EAP), requested that our team find a way to scale its program to extend access to a new patient population. These patients, who had been receiving a different investigational therapy through another EAP, were about to lose access, due to program closure. There were no other treatment options available, so the Sponsor wanted to help fulfill this unmet clinical need.

Challenges

- The new sites needed to be activated and ready to treat patients with drug within 1 month, to ensure patients did not experience a lapse in treatment:

This was critical, as the seizures caused by the disease are life-threatening.

- WEP's regulatory and medical process for patient enrollment in an EAP is a staged one. In most cases, patients are screened at the site using our patient eligibility form (PEF). WEP's regulatory and medical team then review the PEF to confirm approval. Once the patient is approved, the PEF is returned to the WEP Project Manager (PM) to organize product shipment to site.

WEP's PM immediately identified that this process would not work, from timing standpoint, based on the urgent need to continue uninterrupted treatment for these patients.

- This all took place over the year-end holiday period.

This is a time when shipping timelines can be particularly unpredictable.

Our Solution

Rapid mobilization:

As an agile organization with a flat structure, our PM team was able to work efficiently and cross-functionally to modify our standard regulatory and medical process, allowing timely input and approvals from leadership and quality teams.

Process customization:

The PMs then worked with our regulatory and warehouse teams to decouple drug shipment from PEF approval, so that activities could run in parallel. This was supported by a risk-mitigation plan that maintained full compliance.

Proactive communication:

We kept the sites and Sponsor informed on progress, ensuring alignment and rapid issue resolution. We collaborated closely with sites to understand expected patient numbers and ensure suitable supply levels for each site.

Logistics foresight:

We pre-booked holiday courier capacity with our logistics partners. We also implemented real-time temperature and location tracking, to ensure drug integrity during transit.

Outcome

Under the modified EAP enrollment process, patients were able to visit the site for screening, quickly confirm eligibility, and receive treatment immediately, reducing the process from ~1 week to 1 day. This allowed every patient to transition seamlessly to the new program and continue receiving therapy, without missing a single scheduled dose. The Sponsor greatly appreciated our ability to flex and modify our processes to help meet their patients' needs.

Why WEP

Flexible Processes:

SOPs designed for rapid customization without compromising quality.

Collaborative Culture:

Project management, regulatory, logistics, and quality teams work closely and efficiently, with regular input from leadership, accelerating decisions. WEP is a TEAM-FIRST organization.

With Every Patient Mindset:

Success is measured by uninterrupted access to therapy for every patient – every decision flows from that goal.