

EXPANDED ACCESS PROGRAM • NEUROLOGY

Rapidly Scaling an Expanded Access Program to Fulfill Unmet Clinical Need for Patients with Life-Threatening Seizures

How WEP Clinical helped a rare disease Sponsor scale an Existing EAP and transition a new pediatric patient population onto treatment within one month — without a single missed dose.

PROGRAM SNAPSHOT

Therapeutic Area

Rare Neurology

Program Type

Expanded Access Program (EAP)

Pediatric

Yes

Country in Scope

United States & Australia

BACKGROUND

A rare disease Sponsor partnered with WEP Clinical to manage an Expanded Access Program (EAP) for patients with life-threatening seizures. During the program lifecycle, the Sponsor asked WEP to scale the access program to help support a new, additional patient population. These patients had been receiving a different investigational therapy through another EAP, but that program was closing. Without a new access route, the rare disease patients were at risk of losing much-needed treatment.

Because there were no other treatment options available, the Sponsor wanted to help meet this urgent unmet clinical need and ensure eligible patients could continue receiving therapy.

THE CHALLENGE

The new sites needed to be activated and ready to treat patients within one month. This timeline was critical because the disease caused life-threatening seizures, and any treatment gap could have serious consequences for patients.

Under WEP's standard EAP enrollment process, patients are usually screened at the site using a Patient Eligibility Form. WEP's regulatory and medical teams then review the form, confirm approval, and return it to the Project Manager so product shipment can be organized.

For this situation, WEP's Project Manager quickly identified that the standard staged process would not work. The timeline was too urgent, and the program was being scaled during the year-end holiday period, when courier capacity and shipping timelines can be more difficult to predict.

The key challenge was clear: rapidly scale the EAP and transition patients into the new program without interrupting access to treatment.

WEP CLINICAL'S SOLUTION

WEP adapted its standard operating approach to meet the urgency of the patient need while maintaining quality and compliance.

The team worked cross-functionally across Project Management, Regulatory, Medical, Warehouse, Logistics, Quality, and leadership teams to modify the enrollment and shipment process. Rather than waiting for each step to happen sequentially, WEP redesigned the process so that critical activities could run in parallel.

WEP'S RAPID SCALE-UP APPROACH



Rapid Mobilization

WEP's Project Management team immediately brought together the internal stakeholders needed to make quick decisions. Because WEP operates with an agile structure, the team was able to work efficiently across functions and gain timely input from leadership and quality teams. This helped accelerate decision-making while keeping the program aligned with internal standards.

WEP Impact: The program could move quickly without waiting for a slow, sequential internal review process.



Process Customization Without Compromising Compliance

WEP's Project Managers worked with Regulatory and Warehouse teams to adapt the usual enrollment workflow. The team decoupled product shipment from final Patient Eligibility Form approval, allowing shipment preparation and patient eligibility review to move forward in parallel. This was supported by a risk-mitigation plan to maintain compliance and quality oversight.

WEP Impact: WEP created a faster pathway while still protecting regulatory, medical, and quality requirements.



Process Customization Without Compromising Compliance

WEP kept the Sponsor and sites closely informed throughout the scale-up. The team worked directly with sites to understand expected patient numbers, confirm timing needs, and ensure suitable supply levels for each site. This helped reduce uncertainty and allowed the program team to anticipate demand before treatment visits took place.

WEP Impact: Sites and the Sponsor had clear visibility during a time-sensitive transition, helping support rapid issue resolution.



Logistics Planning During a High-Risk Shipping Period

Because the scale-up took place during the year-end holiday period, logistics planning was especially important.

WEP pre-booked holiday courier capacity with logistics partners and implemented real-time temperature and location tracking to help protect drug integrity during transit.

WEP Impact: WEP helped manage urgent shipment requirements at a time when logistics timelines were less predictable.

THE OUTCOME

WEP successfully helped the Sponsor scale the EAP and transition patients into the new program without interrupting treatment. Under the modified enrollment process, patients were able to visit the site for screening, quickly confirm eligibility, and receive treatment immediately. This reduced the process from around one week to one day. Most importantly, every patient was able to transition seamlessly to the new program and continue receiving therapy without missing a scheduled dose.

WHY THIS MATTERS

In urgent Expanded Access scenarios, process flexibility can directly affect patient continuity. Standard EAP workflows are important for quality and compliance, but some situations require a controlled, risk-based adaptation to prevent treatment gaps. This is especially important for patients with life-threatening conditions, where delays can have serious consequences.

This case demonstrates how WEP Clinical can respond quickly, adapt processes responsibly, and keep patient continuity at the center of access program delivery.

WHY WEP CLINICAL

Flexible Processes

SOPs designed to allow rapid customization without compromising quality.

Collaborative Culture

Project Management, Regulatory, Logistics, Warehouse, Quality, and leadership teams working together to accelerate decisions.

With Every Patient Mindset

Every decision was guided by the goal of maintaining uninterrupted access for patients with urgent clinical need.

NEED TO RAPIDLY SCALE AN EXPANDED ACCESS PROGRAM?

Let's the WEP team help build a scale-up plan that protects patient continuity.

WEP Clinical supports Sponsors with the project management, regulatory coordination, site communication, logistics planning, warehousing, and operational flexibility needed to scale urgent EAPs while maintaining patient continuity.



EAP@WEPCLINICAL.COM



WWW.WEPCLINICAL.COM