

EXPANDED ACCESS PROGRAM • RARE DISEASE

Helping a Sponsor Rescue an Existing EAP From Another Vendor

How WEP Clinical helped a rare disease Sponsor rescue and transition an existing multi-country EAP from another vendor – stabilizing operations across 22 countries while maintaining uninterrupted patient access.

PROGRAM SNAPSHOT

Therapeutic Area

Rare disease /
autoimmune

Program Type

Expanded Access
Program (EAP)

Advanced Therapy

Yes

Country in Scope

22 globally

ABOUT THE SPONSOR

The Sponsor is a global biopharmaceutical company headquartered in the United States, focused on researching, developing, and commercializing medicines for patients with orphan, autoimmune, and severe inflammatory diseases.

The Sponsor had established an Expanded Access Program (EAP) to provide treatment access to eligible patients outside the United States who were unable to enroll in a clinical trial for one of the company's rare disease therapies.

THE CHALLENGE

The Sponsor's existing EAP had become increasingly difficult to manage under the incumbent vendor.

Participating sites were not receiving the level of communication, operational attention, and day-to-day guidance needed to run the program effectively. This created confusion for Healthcare Providers, inefficiencies across the program, and frustration for both the Sponsor and participating sites.

As a result, the Sponsor's internal team had to spend more time overseeing the program, resolving operational questions, and managing issues that should have been handled by their access program partner.

At the same time, the Sponsor was focused on key business-critical priorities, including commercial launch planning and ongoing ex-US clinical trial activity. The team needed the EAP to be stabilized quickly, without disrupting access for patients already receiving treatment.

The key challenge was clear: transition an existing multi-country EAP from another vendor while maintaining continuity of patient access.

WEP CLINICAL'S SOLUTION

WEP Clinical was selected to take over full management of the EAP and transition the program into a more structured and responsive operating model. A dedicated WEP Project Manager was assigned to lead the transition, coordinate internal and external stakeholders, and act as the central point of contact for the Sponsor.

WEP worked closely with the Sponsor to review the existing program, identify the root causes of operational challenges, and develop a bespoke transition plan focused on continuity, clarity, and control.

WEP'S APPROACH

1

Assessing the Existing Program

WEP began with a detailed review of the current EAP model to identify operational gaps, stakeholder pain points, and areas of potential risk. This included assessing site communication, logistics, regulatory requirements, documentation, roles and responsibilities, and urgent actions needed to maintain treatment access during the transition. This review allowed WEP to build a practical transition plan that addressed immediate risks while creating a stronger foundation for long-term program delivery.

2

Establishing Governance and Clear Ownership

WEP developed a detailed transition and implementation plan for the new WEP-managed program. The plan defined responsibilities, key milestones, documentation requirements, training needs, communication cadence, escalation pathways, reporting expectations, and KPIs.

This gave the Sponsor greater visibility and confidence, while reducing the level of day-to-day involvement required from their internal team.

3

Re-Engaging Sites and Physicians

A key priority was rebuilding confidence with treating physicians and participating sites. The program includes **59 sites to date**. These sites had varying levels of experience with Expanded Access, so WEP tailored communication and guidance based on each site's needs. WEP helped sites understand the transition process, the new WEP-led program model, documentation requirements, shipment processes, and escalation routes. This gave Healthcare Providers a clearer, more reliable point of contact and helped reduce confusion across the program.

4

Protecting Product Supply and Shipment Continuity

Maintaining uninterrupted product supply was critical because patients were already receiving treatment through the EAP.

WEP managed product receipt, storage, inventory oversight, distribution, and customs clearance across the program footprint. The logistics model included warehousing and distribution routes across the US, UK, Ireland, and 3PL network. To date, the WEP-managed program has supported 415 completed shipments. This helped ensure the vendor transition did not compromise ongoing access for patients or create avoidable disruption for participating sites.

5

Managing Multi-Country Delivery

The EAP had a broad international footprint, with **22 countries, including Austria, Bulgaria, Colombia, Czechia, Estonia, Hungary, South Korea, Mexico, New Zealand, Peru, Poland, Russia, Serbia, South Africa, Thailand, Australia, Hong Kong, Taiwan, Moldova, Spain, Germany, and Israel**. WEP coordinated country-specific requirements across regulatory, logistics, site, and patient access activities. This enabled the Sponsor to manage a complex international EAP through a single experienced partner.

6

Recovering a Delayed French Early Access Pathway

A French Early Access component had experienced delays under the previous vendor due to limited local expertise and missed submission timelines. WEP's Market Access and Project Management teams stepped in to manage the pathway, including Exploitant services, dossier preparation, submissions, Real World Data (RWD) collection requirements, ANSM and HAS interactions, and ongoing stakeholder coordination. This helped bring a delayed access pathway back under structured, expert-led management.

7

Integrating Pharmacovigilance

Because the Sponsor required pharmacovigilance support, WEP's dedicated PV team was integrated into the program model. This ensured safety reporting processes were aligned with the requirements of the EAP.

THE OUTCOME

WEP successfully transitioned the EAP from the incumbent vendor into a WEP-managed program, creating a more stable and responsive access model. By taking ownership of project management, site communications, logistics, French Early Access activities, pharmacovigilance coordination, and Sponsor reporting, WEP helped stabilize the program and reduce the operational burden on the Sponsor's internal team. Most importantly, patients continued to receive access through a clearer, more responsive program model, while the Sponsor was able to refocus attention on commercial launch and ongoing ex-US clinical trial priorities.

WHY THIS MATTERS

EAPs can become operationally complex very quickly, particularly when multiple countries, active patients, site relationships, product shipments, regulatory requirements, and safety obligations are involved. When a program is underperforming, the risk is not just administrative inefficiency. It can create disruption to patient care, loss of site confidence, increased Sponsor workload, and delays in critical access pathways. This case demonstrates how WEP Clinical can step into an existing access program, restore structure, strengthen day-to-day delivery, and maintain continuity for patients during a sensitive vendor transition.

NEED TO TRANSITION OR RESCUE AN EXISTING ACCESS PROGRAM?

Let WEP help you rescue and stabilize your existing access program while protecting continuity for patients.

WEP Clinical supports Sponsors with the strategy, project management, logistics, regulatory coordination, pharmacovigilance, and site support needed to stabilize complex EAPs and maintain continuity for patients.



RWD@WEPCLINICAL.COM



WWW.WEPCLINICAL.COM