WEP

With Every Patient.

CASE STUDY:
Using Expanded Access as a Strategic Alternative for Post-Trial Access Versus a Traditional Open Label Extension Study

Executive Summary

Following the completion of a pivotal Phase 3 clinical trial, a global pharmaceutical company required a pathway to continue treatment access for patients with a debilitating neurological disorder. The Sponsor had originally decided to provide continued treatment through an Open Label Extension (OLE) study through their incumbent CRO. However, over time, the OLE proved to be burdensome and costly to the Sponsor, which forced them to look for other alternatives.

While the Sponsor's product was under final review by the FDA, more than 500 patients were receiving continued treatment through the OLE across 14 countries and 4 continents. Although the Sponsor remained committed to treatment continuity, there were no further requirements from regulatory agencies to collect additional long-term follow-up data after the pivotal study. As a result, the OLE model created an increasingly complex and resource-intensive structure for what was primarily an access objective.

WEP Clinical worked with the Sponsor to evaluate an adaptable Post-Trial Access model, which led us to choose Expanded Access as a more practical alternative. The goal was clear: transition patients from the OLE into a compliant Expanded Access Program (EAP) while maintaining uninterrupted treatment access across multiple countries. **Within three months, WEP Clinical supported the transition of patients from the OLE to an EAP with no disruption to treatment!**

The Challenge

Open Label Extension studies are often used after a clinical trial to provide continued access to an investigational therapy while collecting additional long-term safety, efficacy, or tolerability data. However, in this particular case, the Sponsor's primary objective was treatment continuity.

The OLE became difficult to sustain because it required the Sponsor to maintain clinical trial infrastructure across a large, geographically dispersed patient population. More than 500 patients were receiving treatment in 14 countries, creating significant coordination requirements across sites, treating physicians, supply chains, regulatory pathways, and internal Sponsor teams.

The Sponsor also needed to preserve resources for ongoing clinical trials and development activities. Continuing the OLE in its existing form would have required substantial internal oversight and ongoing site management, despite the fact that the Sponsor had not been required by the FDA to collect additional follow-up data after the Phase 3 study.

The Sponsor needed an alternative model that would:

- Maintain continued access for patients already receiving treatment, without avoidable delays or disruption
- Reduce the internal operational and site burden associated with the OLE
- Provide a regulatory compliant structure outside the traditional clinical trial setting
- Support a coordinated transition across multiple countries

Why Expanded Access Was the Right Fit

EAPs provide a pathway for eligible patients to access investigational medicines outside of a clinical trial when no satisfactory alternative treatment options are available.

For this Sponsor, Expanded Access offered a practical alternative because the purpose of the program was access, not continued clinical data collection.

Unlike an OLE, which is generally structured as a clinical trial and may require more extensive protocol-driven procedures, an EAP can often be designed around treatment access and safety oversight, with additional data collection included only when appropriate for the program, the country, and the Sponsor's objectives.

This distinction was critical. The Sponsor did not want to withdraw treatment from patients who had completed the Phase 3 trial, but it also needed to move away from a model that placed significant strain on internal resources and costs to their company. An EAP provided a way to maintain patient access while reducing costs and overall involvement from the Sponsor.

WEP Clinical's Approach

WEP Clinical worked with the Sponsor to develop a transition strategy focused on continuity, compliance, and operational efficiency. The approach centered on moving patients from the OLE into an Expanded Access framework without interrupting treatment.

1. Program Assessment and Transition Planning

WEP Clinical first supported the Sponsor in assessing whether an EAP was appropriate for the patient population, the treatment objective, and the countries involved. This included reviewing the differences between an OLE and EAP model, identifying key operational considerations, and defining a transition plan that could be implemented within the Sponsor's required timelines.

2. Country-by-Country Access Strategy

Since patients were located across 14 countries, the transition required careful coordination of country-specific access pathways. WEP Clinical helped structure the program around the local requirements, recognizing that Expanded Access regulations, documentation, approval processes, and timelines vary by country.

3. Physician and Site Coordination

A successful transition depended on clear communication with treating physicians and sites. WEP Clinical supported the operational steps required to move patients from the OLE study into the EAP, helping to reduce administrative burden while maintaining appropriate oversight.

4. Drug Supply and Logistics Continuity

Treatment continuity was the Sponsor's primary requirement. WEP Clinical took over supply chain management for the EAP and coordinated the program's logistics to support ongoing drug supply across multiple countries. This precise supply chain planning ensured patients continued to receive treatment without disruption during the transition.

5. Ongoing Program Management

After the transition, WEP Clinical continued to manage the EAP, providing operational oversight, warehousing and distribution, program documentation management, and ongoing site support. This allowed the Sponsor to maintain its commitment to patients while reducing the internal burden and costs associated with the previous OLE.

The Outcome

Since launch, the program has delivered measurable impact: For the Sponsor, the EAP provided a way to maintain continuity of care while redirecting internal resources toward ongoing clinical development activities. For patients and physicians, it enabled continued treatment access through a more appropriate Post-Trial Access model.

Key Takeaways for Sponsors

1. When The Objective Is Access Or Continued Treatment, An OLE May Not Always Be The Most Practical Model

OLE studies can be valuable when additional structured clinical data are required. However, when the primary goal is continued treatment access, an EAP may provide a more appropriate and sustainable alternative.

2. Early Transition Planning Is Essential

Moving patients from an OLE to an EAP requires careful planning, particularly when patients are spread across multiple countries. Regulatory requirements, physician engagement, supply continuity, and program documentation all need to be coordinated early.

Alternatively, having discussions with WEP Clinical early in protocol development can provide a clear path for Post-Trial Access.

3. Global Access Programs Require Local Flexibility

Expanded Access requirements differ by country. A successful program needs a global strategy that can be adapted to local regulations, timelines, documentation expectations, and treatment pathways, while also recognizing potential risks.

4. Continuity Should Remain The Central Measure Of Success

For patients already receiving treatment after a clinical trial, any transition must be designed around avoiding interruption. In this case, the program's success was defined not only by operational efficiency, but by the ability to maintain uninterrupted treatment access for more than 500 patients.

TO LEARN MORE OR DISCUSS YOUR POST-TRIAL ACCESS PLANS, REACH OUT TO US

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