WEP Clinical.

We are With Every Patient,
as we believe every patient should have access to treatment

CASE STUDY: USING EXPANDED ACCESS AS AN ALTERNATIVE TO AN OPEN LABEL EXTENSION (OLE) STUDY

About the Sponsor

The Sponsor is a global pharmaceutical company focused on developing next-generation drugs to treat multiple CNS disorders. With headquarters in Asia and offices throughout the world, the company is developing a diverse pipeline of therapies and is committed to providing access to patients globally.

The Challenge

Like many companies in the industry, the Sponsor chose to continue to provide access to phase 3 clinical trial patients through an Open Label Extension Study (OLE). The Sponsor's primary need was to provide access to patients, as it was not required to collect follow-up data after their phase 3 trial.

The Sponsor quickly realized that it lacked the internal resources to continue to run the OLE without affecting ongoing clinical trials. Due to the mounting cost and limited internal resources, the Sponsor decided to close the OLE and find a partner who could transition the OLE patients to a cost-effective alternative program. They came to WEP to explore the possibility of an Expanded Access Program (EAP).

At the time the OLE study was closed out:

- **The drug was being reviewed for approval by the FDA for the treatment of a debilitating neurological disorder.**
- **There were 500+ patients receiving treatment through the OLE.**
- **Patients were located in 14 different countries across 4 continents.**
- **Sponsor's primary requirement was to ensure seamless transition with no disruption to treatment.**

OLE versus EAP

The first thing WEP did with the Sponsor was explore the differences between an OLE and an EAP. The table below outlines these.

OLE		EAP
Meet FDA requirements for the collection of longe-term safety and efficacy data after a pivotal trial	Intended Purpose	Provide continued treatment access for patients after a pivotal trial has ended
A protocol is required and must have regulatory body (e.g. FDA) input and approval	Protocol Requirement	A protocol is only required if doing a cohort EAP or if collecting data. EAPs typically utilize treatment guidelines
Site payments are required as they would be in a typical clinical trial	Site Payments	Payments are not required. If data is to be collected, Sponsors may choose to cover cost of site admin time, but a a reduced amount versus a CT
Serious Adverse Events (SAE) and Adverse Event (AE) is required	Safety Reporting	SAE reporting is the only requirement in an EAP
Efficacy data may be required as advised by regulatory bodies	Efficacy Data Collection	Companies can collect data if they choose but this is not a requirement
Any data collected must be included in the CSR for NDA approval	Efficacy Data Reporting	Data collected is not required to be reported, but Sponsors can choose to, to support their clinical trial data

The Outcome

The Sponsor decided to partner with WEP to transition the patients to an EAP. The EAP provided many benefits to the Sponsor which included significant time and cost savings as well as reduced internal burden. The patients were transferred from the OLE to the EAP within 3 months, with no disruption to treatment. The program outcomes are highlighted below:

3

The EAP has been running for over 3 years

13,000

Over 13,000 units of drug have been shipped

508

508 patients have been enrolled into the EAP