WEP

With Every Patient.

CASE STUDY:

SUPPORTING A BIOTECHNOLOGY COMPANY WITH A GLOBAL POST-TRIAL ACCESS PROGRAM

Background

WEP partnered with a biotechnology company (Sponsor) to help set up and deliver a global Post-Trial Access (PTA) Program to ensure continuity of care for patients completing a Phase 3 rare disease clinical trial.

WEP possesses a deep understanding of how PTA is regulated and operationalized in different countries around the world. Therefore, we approached this program as a country-by-country exercise in problem-solving. For all countries in scope, we:

- **Mapped the regulatory routes available (e.g., compassionate use, clinical-trial pathways, or direct import)**
- **Confirmed institutional expectations**
- **Ensured supply chain readiness and pharmacovigilance continuity**
- **Aligned PTA timelines with regulatory & market entry milestones**
- **Supported stakeholder engagement and Sponsor reputation management**

Below are four country-specific examples to illustrate how WEP's PTA approach translates into action, showcasing how our team adapts to differing rules, documentation standards, and institutional preferences to deliver timely & compliant access to patients.

Israel

Is PTA required? Yes

Pathway: There is no one single PTA pathway that Sponsors must utilize. Sponsors generally select an appropriate operational route to use with input from the site/IEC.

In this case: WEP recommended the physician in Israel utilize the treatment access route, as it is much simpler with less stringent requirements. However, the physician opted to apply via the clinical-trial route – an Investigator Initiated Study (IIS). This significantly increased the documentation burden, extending beyond import and distribution paperwork, to include clinical-trial materials.

To keep patient access on track, we rapidly pivoted and assembled a new dossier tailored to that pathway, turning it around in just four days. To help with this process we leveraged our network utilizing our experienced in-country agent who is well-versed in local country requirements and spoke the local language. This network provider supported the site with completion of local paperwork and regulatory submissions on our behalf. Their local expertise proved invaluable in navigating a particularly complex environment in a quick manner.

Poland

Is PTA required? No

Pathway: There is no one single PTA pathway that Sponsors must utilize. Treatment continuation is handled on a case-by-case basis and is usually provided through open-label extensions, compassionate use programs, or by switching to a licensed alternative.

In this case: During the Phase 3 clinical trial, Polish patients traveled to received treatment at a site in Germany. When the trial ended, German authorities would not permit PTA for these patients because they were not German residents. The Sponsor wanted WEP to find a way to continue supplying the drug to these Polish patients, so we decided to set up a naïve site in Poland and provide continued therapy under the local access pathway. Once the Sponsor identified the Polish site, WEP coordinated the end-to-end set-up and ongoing interactions needed to bring it online and keep it operational.

We advised on the Polish regulatory pathway and practical steps so the Sponsor's internal teams and country affiliates could align quickly and execute efficiently. We also worked with the Sponsor to ensure clear and consistent communication with the Polish patients, to ensure they were aware of the change in their treatment location.

Hong Kong

Is PTA required? No

Pathway: There is no one single PTA pathway that Sponsors must utilize. Hong Kong's approach to PTA is highly institution dependent. When providing PTA, some hospitals require only a direct import to the site with no ethics committee approval, while others prefer to proceed under either a compassionate use or clinical trial pathway.

In this case: WEP followed the compassionate use route selected by the institution. The physician chose this route as they wanted to make the process as streamlined as possible and limit the burden and paperwork required. To help with this, where possible, our team made use of the hospital's own forms (compassionate-use request, consent forms, pharmacy logs, etc.), rather than requesting the physician use WEP's standard templates. We pre-assembled the hospital packet, completing non-clinical fields and attaching the Investigator letter, SmPC/IB, stability, and supply plan, so that all the physician was required to do was fill in the remaining open fields and sign. We managed all Drug Office notifications and import-license work as Importer of Record and aligned safety and privacy using the hospital's SAE template. We also made sure to time shipments for patient refills which reduce overall license requirements to import the drug for PTA use.

Czech Republic

Is PTA required? No

Pathway: There is no one single PTA pathway that Sponsors must utilize. Treatment continuation can be provided through an open-label extension or by utilizing an access pathway called a Specific Therapeutic Program (STP).

In this case: WEP coordinated with the Sponsor's Czech affiliate to apply to SÚKL/Ministry of Health for a cohort Specific Therapeutic Program (STP), which carries strict conditions and documentation. To keep timelines realistic, we contributed targeted QA/regulatory intelligence that enabled the local office to select the correct STP pathway, structure the dossier, and secure the necessary import approvals. In parallel, we aligned import/export controls and pharmacy accountability, onboarded an in-country consignee, and established depot-to-site flows that met STP requirements. This allowed WEP to provide approved cohort access with ongoing import compliance which covers future resupply with no treatment interruption.

Summary

Across these jurisdictions, **the common thread is flexibility guided by local reality.** Whether pivoting to an alternative pathway at a moment's notice or establishing a new treatment site to meet residency constraints, WEP Clinical aligned quickly with the Sponsor, regulators, and institutions to keep patients on therapy without interruption.

The lessons are consistent: select the route that fits the local framework, plan operational details early & clearly, and stay close to site-level preferences and adjust as necessary. Following this approach allows WEP to consistently turn a complex, multi-country PTA into an efficient and compliant service that maintains continuity of care and reduces operational risk for Sponsors.