

POST-TRIAL ACCESS PROGRAM • HEMATOLOGY

Supporting a Biotechnology Company with a Global Post-Trial Access Program

How WEP Clinical helped a biotechnology Sponsor deliver a complex global Post-Trial Access Program across multiple countries — keeping eligible patients on treatment after a Phase 3 rare disease trial.

PROGRAM SNAPSHOT

Therapeutic Area

Rare
Hematology

Program Type

Post-Trial Access
Program (PTA)

Pediatric

Yes

Country in Scope

6 globally

BACKGROUND

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

The Sponsor needed a structured and compliant way to continue treatment for eligible patients after the clinical trial ended. This required more than a single global access route. Each country had different expectations, regulatory pathways, institutional requirements, documentation needs, and supply considerations.

WEP approached the program as a country-by-country exercise in problem-solving, helping the Sponsor identify the right pathway in each market while maintaining continuity of care for patients.

THE CHALLENGE

PTA can be complex because there is no single global pathway that works across every country. For this program, the Sponsor needed to support continued treatment for a rare disease patient population, including pediatric patients, while navigating different local frameworks after the Phase 3 trial ended.

The challenge was not only regulatory. The Sponsor also needed to manage site expectations, physician preferences, institutional requirements, supply continuity, patient communication, pharmacovigilance obligations, and country-specific timelines.

The key challenge was clear: create a compliant, country-specific PTA model that allowed eligible patients to continue treatment without unnecessary disruption.

WEP CLINICAL'S SOLUTION

WEP worked with the Sponsor to design and manage a PTA Program that reflected the realities of each country in scope.

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.

This allowed the Sponsor to avoid a one-size-fits-all approach and instead create a practical PTA model tailored to local requirements.

COUNTRY-SPECIFIC PTA DELIVERY

1

Israel

PTA required: Yes

Pathway: No single mandatory PTA pathway. Sponsors generally select an appropriate operational route with input from the site and IEC.

In Israel, WEP recommended the treatment access route because it was simpler and involved less stringent requirements. However, the treating physician preferred to apply through a clinical trial route, specifically an Investigator Initiated Study. This significantly increased the documentation burden, moving beyond import and distribution paperwork to include clinical trial materials.

To keep patient access on track, WEP rapidly adapted to the physician's preferred pathway and assembled a new dossier in just four days. WEP also leveraged an experienced in-country agent who understood local requirements and could support the site with local paperwork and regulatory submissions in the local language.

WEP Impact: WEP helped the Sponsor pivot quickly to a more complex pathway while keeping the patient access timeline moving.

2

Poland

PTA required: No

Pathway: Treatment continuation is handled case by case and may be provided through open-label extensions, compassionate use programs, or by switching to a licensed alternative.

During the Phase 3 trial, Polish patients had traveled to a site in Germany to receive treatment. When the trial ended, German authorities would not permit PTA for those patients because they were not German residents.

The Sponsor needed WEP to find a way to continue treatment for the Polish patients through a local pathway.

WEP helped support the setup of a new site in Poland and coordinated the steps required to bring it online and keep it operational. WEP also advised on the Polish regulatory pathway and practical requirements so the Sponsor's internal teams and country affiliates could align quickly. WEP also supported clear communication with Polish patients so they understood the change in treatment location and what it meant for their continued access.

WEP Impact: WEP helped create a local continuation route after cross-border treatment access was no longer possible.

3

Hong Kong

PTA required: No

Pathway: PTA is highly institution dependent. Some hospitals may require direct import only, while others prefer a compassionate use or clinical trial pathway.

In Hong Kong, WEP followed the compassionate use route selected by the institution. The physician chose this pathway to keep the process streamlined and reduce the burden and paperwork required.

Where possible, WEP used the hospital's own forms, including compassionate use request forms, consent forms, and pharmacy logs, instead of requiring the physician to use WEP templates.

WEP pre-assembled the hospital packet, completed non-clinical fields, attached the Investigator letter, SmPC or IB, stability information, and supply plan, so the physician only needed to complete the remaining clinical fields and sign.

WEP also managed Drug Office notifications and import-license work as Importer of Record, aligned safety and privacy using the hospital's SAE template, and timed shipments around patient refill needs to reduce unnecessary import-license requirements.

WEP Impact: WEP reduced site burden by adapting to the institution's preferred process while managing the access, documentation, safety, privacy, and import requirements.

4

Czech Republic

PTA required: No

Pathway: Treatment continuation may be provided through an open-label extension or through a Specific Therapeutic Program.

In Czech Republic, WEP coordinated with the Sponsor's Czech affiliate to apply to SÚKL and the Ministry of Health for a cohort Specific Therapeutic Program. This pathway carried strict conditions and documentation requirements.

To keep timelines realistic, WEP provided targeted quality and regulatory input that helped the local office select the correct STP pathway, structure the dossier, and secure the required import approvals. In parallel, WEP aligned import and export controls, pharmacy accountability, an in-country consignee, and depot-to-site flows that met STP requirements. This enabled approved cohort access with ongoing import compliance, supporting future resupply without treatment interruption.

WEP Impact: WEP helped establish a compliant STP pathway that supported continued treatment and future resupply planning.

THE OUTCOME

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, multicounty PTA into an efficient and compliant service that maintains continuity of care and reduces operational risk for Sponsors.

To date, the program has supported:

60+ Patients

9 sites

6 countries/markets

WHY THIS MATTERS

PTA is one of the most important transition points in clinical development. Sponsors may need to continue treatment for patients after a trial ends, but the pathway for doing so can vary significantly by country.

Without early planning, PTA can create delays, site confusion, supply disruption, regulatory misalignment, and unnecessary pressure on Sponsor teams.

This case demonstrates how WEP Clinical can help Sponsors manage PTA through local pathway assessment, regulatory coordination, site and physician engagement, supply planning, and practical country-by-country execution.

NEED TO PLAN OR DELIVER A GLOBAL POST-TRIAL ACCESS PROGRAM?

Let WEP help build a country-specific PTA plan that keeps patient access moving

WEP Clinical supports Sponsors with PTA strategy, country pathway assessment, regulatory coordination, site and physician engagement, supply planning, pharmacovigilance continuity, and operational delivery across complex global programs.



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