

GLOBAL EXPANDED ACCESS PROGRAM • ONCOLOGY

Helping a Sponsor Provide Access to a Promising Investigational Drug Outside of a Clinical Trial

How WEP Clinical helped a global biotech Sponsor turn unsolicited physician demand into a structured, compliant Expanded Access Program spanning 35 countries and 5 continents.

PROGRAM SNAPSHOT

Therapeutic Area

Rare Oncology

Program Type

Expanded Access Program (EAP)

Program Duration

5+ Years

Country in Scope

Global program with 35 countries

ABOUT THE SPONSOR

The Sponsor is a global biotech company headquartered in the United States and focused on designing and developing precision therapies for cancer, rare diseases, and immunotherapy.

At the time of the program, the Sponsor had a diverse portfolio that included newly FDA- and EMA-approved products, as well as promising investigational therapies in development.

THE CHALLENGE

The Sponsor began receiving unsolicited requests for one of its investigational oncology products from physicians whose patients were unable to enroll in the active clinical trial. The product was being developed to treat several rare gastrointestinal tumors, was in Phase 2 clinical trials, and addressed a disease area with limited treatment options.

As demand increased, the Sponsor needed a way to manage and review requests without disrupting focus on the ongoing clinical trial. The Sponsor also had limited internal resources and limited experience managing access to medicines on an unlicensed basis.

They needed a flexible partner with global Expanded Access expertise who could quickly build a compliant route for patients who met predefined inclusion criteria.

The key challenge was clear: create a global Expanded Access Program (EAP) that could respond to growing patient demand while allowing the Sponsor to remain focused on clinical development.

WEP CLINICAL'S SOLUTION

WEP Clinical partnered with the Sponsor to set up and manage a global EAP for the investigational oncology product. The program allowed eligible patients to access the drug outside of the clinical trial, contingent on meeting predefined inclusion criteria.

We assigned a dedicated Lead Project Manager and supporting project management team to develop a deep understanding of the program requirements, nuances, and overall goals. We then created a strategic project plan that covered the core elements needed to deliver the program globally.

Below, we outline the details of some of the key components of the program delivery model for this EAP.

WEP'S PROGRAM DELIVERY MODEL



Confirmed Program Scope

WEP worked with the Sponsor to agree on the countries in scope, define inclusion criteria, and develop the EAP policy. This helped create a clear framework for reviewing requests and determining which patients could be considered for access through the program.

WEP Impact: The Sponsor had a structured access pathway for reviewing unsolicited requests without pulling focus away from the clinical trial.



Set Up Physician Request Management

WEP created program-specific contact details, documentation, templates, and process flows to manage physician and patient requests consistently. This gave physicians a defined route for submitting requests and helped WEP track inquiries, documentation, eligibility, and next steps in a controlled way.

WEP Impact: The program moved from ad hoc request handling to a more organized and scalable intake process.



Managed Regulatory Requirements

WEP developed the regulatory plan for the program and handled interactions with local regulatory bodies. This was essential as the program operated across multiple countries, each with different access pathways, documentation requirements, and local expectations.

WEP Impact: The Sponsor was able to manage global access requests through a coordinated regulatory approach rather than handling country requirements individually.



Managed Product Supply, Warehousing, and Delivery

WEP managed warehousing and transportation of the drug to physician sites, including customs clearance. This operational infrastructure was critical because the EAP needed to support patients across a wide international footprint while maintaining supply continuity and timely delivery to treating physicians.

WEP Impact: Patients and sites could be supported through a global distribution model that handled practical supply and customs requirements.



Supported Physicians, Sites, and Patients

WEP maintained open communication channels with physicians and sites to ensure patient needs were continuously met throughout the program. This was particularly important as the program grew across countries and continents, with different local stakeholders, time zones, and operational expectations.

WEP Impact: Physicians and sites had a consistent point of contact, helping reduce uncertainty and support continuity throughout the patient access pathway.

THE OUTCOME

WEP helped the Sponsor turn unsolicited patient demand into a structured, global Expanded Access Program. The program has delivered significant global reach:

5+ yrs

Ongoing Program
Delivery

700+

Patients Treated

8,000+

Units of Drug
Shipped

35

Countries in
Scope

WEP has continued to work closely with the Sponsor's internal team to ensure the program continues to meet patient needs around the world. The relationship also expanded beyond this initial EAP, with WEP supporting additional EAPs and helping the company transition certain countries to commercial supply as the treatment gained European approval. Most importantly, the Sponsor was able to provide access to hundreds of eligible patients globally while maintaining focus on clinical development and later commercial transition planning.

WHY THIS MATTERS

Patients who are unable to participate in a clinical trial may still have an urgent need for treatment. However, providing access across multiple countries requires more than making product available. Sponsors must navigate different regulatory pathways, coordinate sites and supply, respond to evolving patient demand, and plan for what happens as approvals and commercial availability change. Without the right operational plan and infrastructure, these demands can divert valuable time and resources away from clinical development. This case demonstrates how an experienced EAP partner can help a Sponsor successfully set up and deliver an access globally – while allowing the Sponsor to remain focused on its development and launch priorities.

NEED TO PROVIDE TREATMENT ACCESS OUTSIDE OF A CLINICAL TRIAL?

Let WEP help you build an access program designed for real-world global delivery.

WEP Clinical supports Sponsors with the strategy, regulatory coordination, site engagement, supply and logistics, program management, and commercial transition planning needed to provide treatment access across countries. Contact us to learn more:



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