

EXPANDED ACCESS PROGRAM • ONCOLOGY

Helping a Sponsor Scale Up an EAP to Fulfill Increase in Demand for Promising Oncology Product

How WEP Clinical helped an oncology Sponsor scale an Expanded Access Program from 14 to 34 countries — meeting growing demand while maintaining patient access and operational control.

PROGRAM SNAPSHOT

Therapeutic Area
Oncology

Program Type
Expanded Access Program
(EAP)

Country in Scope
34 globally

BACKGROUND

The Sponsor is an emerging biopharmaceutical company based in the United States and focused on designing and developing precision therapies for cancer, rare diseases, and immunotherapy. In 2017, the Sponsor established an Expanded Access Program (EAP) to provide access to one of its lead oncology products for patients who were unable to enroll in an active clinical trial. The program was designed to provide access across multiple indications and was originally scoped to include 120 patients across 14 countries in the United States and Europe.

THE CHALLENGE

Once the EAP was underway, the Sponsor began receiving unsolicited requests from patients in countries that were not included in the original program scope and where the Sponsor had no physical presence. The Sponsor wanted to scale the program so it could respond to these requests, continue addressing unmet need, and support equitable access to the product.

As demand increased, the program needed to expand quickly while maintaining operational control. This created several important challenges:

- Managing growing patient and site demand across additional countries
- Supporting requests across different time zones and regions
- Updating regulatory planning for new countries and indications
- Coordinating supply chain activity across strategic and non-core markets
- Maintaining consistent communication with sites, patients, and the Sponsor
- Adapting country-specific processes to meet local requirements

The key challenge was clear: scale an existing oncology EAP from a focused regional program into a broader global access model without compromising patient access, site support, or supply continuity.

WEP'S SOLUTION

WEP used its flexible delivery model and cross-functional EAP expertise to help the Sponsor manage the increase in demand.

WEP worked closely with the Sponsor to understand where additional requests were coming from and then optimized a cross-functional team across Project Management, Regulatory, and Supply Chain. This team modified the original program processes and added resources where needed to support the increased demand for the Sponsor's oncology product.

WEP'S APPROACH

1

Expanding Project Management Support

As the program expanded into additional regions, WEP increased Project Management resources to help manage global time zones and provide greater availability for sites and patients. WEP also created a centralized email inbox to improve visibility, monitor requests more effectively, and track the status of sites and patients as the program grew. This helped create a more structured communication model and gave the Sponsor better oversight as the program moved beyond its original scope.

WEP Impact: Stronger project management helped the program scale without losing visibility across patient requests, site activity, and regional needs.

2

Updating the Regulatory Plan for New Countries and Indications

WEP updated the regulatory plan to support rapid onboarding of additional countries and new indication requests. WEP used its regulatory database covering 122 countries, managed regulatory submissions for cohort pathways, and supported two primary indications plus several single-case approvals for other indications.

This was important because the program was no longer limited to its initial country footprint. As demand increased, the Sponsor needed a partner that could identify suitable access routes, prepare for country-specific requirements, and help keep new requests moving.

WEP Impact: WEP helped the Sponsor respond to new country and indication requests through a more flexible and scalable regulatory model.

3

Adapting the Warehousing Strategy for New Regions

As the program expanded, WEP adapted the warehousing strategy to support new regions and changing operational needs. The original case study notes that WEP established new warehouse locations outside the US and EU, adjusted inventory management practices, and maintained supply chain integrity and continuity amid regulatory changes.

WEP Impact: WEP helped the Sponsor adapt the supply model as the program expanded geographically and operational requirements changed.

4

Securing Supply into Strategic and Non-Core Countries

WEP worked closely with the Sponsor to understand how new countries aligned with the company's future commercial strategy. This allowed the team to expand logistics and distribution into both strategic markets and non-core regions while supporting consistent supply and minimizing disruption across diverse geographies.

This was especially important because the Sponsor was receiving requests from countries outside its original footprint and without an established local presence.

WEP Impact: WEP helped the Sponsor support access in countries that were both commercially important and outside the original strategic focus.

5

Implementing Country-Specific Strategies

As the EAP expanded, WEP adapted delivery processes to meet local country requirements. One example was the use of Just-in-Time (JIT) labeling in South Korea.

WEP adopted JIT labeling practices to increase flexibility, reduce waste, and meet South Korean regulatory requirements, improving efficiency and responsiveness to local market demands.

This example shows how WEP did not apply a one-size-fits-all model. Instead, the team adapted processes based on local regulatory and operational requirements.

WEP Impact: Country-specific strategies helped the program remain flexible, efficient, and locally compliant as demand expanded.

THE OUTCOME

WEP helped the Sponsor scale its EAP significantly beyond the original scope. The program was initially designed for 120 patients across 14 countries.

The program has now supported:

700+ patients

400 sites

34 countries

By expanding project management capacity, updating regulatory planning, adapting warehousing strategy, coordinating supply into strategic and non-core countries, and implementing country-specific solutions, WEP helped the Sponsor transform a focused EAP into a large-scale global access program.

Most importantly, the Sponsor was able to respond to growing demand and provide access to hundreds of patients across a broad international footprint.

WHY THIS MATTERS

EAPs can change quickly once patient and physician awareness grows. A program that starts with a defined patient and country scope may need to expand rapidly as new requests come in from additional regions.

Without the right operational model, this can create pressure on Sponsor teams, regulatory delays, supply disruption, inconsistent site communication, and inequitable access.

This case demonstrates how WEP Clinical can help Sponsors scale EAPs by combining project management, regulatory planning, supply chain coordination, warehousing strategy, and country-specific execution.

NEED TO SCALE AN EXISTING EXPANDED ACCESS PROGRAM?

Let WEP help you scale your EAP without compromising control or patient continuity.

WEP Clinical supports Sponsors with the project management, regulatory strategy, supply coordination, site support, logistics planning, and country-specific execution needed to scale Expanded Access Programs while maintaining continuity for patients.



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