WEP

With Every Patient.

CASE STUDY:

HELPING A SPONSOR SCALE UP AN EAP TO FULFILL INCREASE IN DEMAND FOR PROMISING ONCOLOGY PRODUCT

Background

The Sponsor is an emerging biopharmaceutical company, based in the US, which is focused on designing and developing precision therapies for cancer, rare diseases and immunotherapy.

In 2017, the Sponsor decided to setup an Expanded Access Program (EAP) to provide access to one of its lead oncology products for patients who were unable to enroll into their active clinical trial. The program was designed to provide access to patients with multiple indications and was originally scoped to include 120 patients in 14 different countries across the US and Europe.

The Challenge

Once the program was up and running, the Sponsor began receiving unsolicited requests from patients in countries that were not included in the initial program scope and where the Sponsor had no physical presence. The team wanted to find a way of scaling up the EAP to provide access to these patients so they could continue to address the unmet need and ensure equitable access to their drug.

The Solution

The WEP team used our extensive experience and flexible delivery model to develop a comprehensive solution to manage these additional requests.

We worked closely with the Sponsor's team to understand where the additional patient requests were coming from. We then promptly optimized a cross-functional WEP team, including Project Management, Regulatory, and Supply Chain. This group worked together to modify the original program's processes and add additional resources where necessary to support the unprecedented increase in demand for the Sponsor's drug.

Below we have outlined some of the steps our team took:

Added Resources to the WEP Project Management (PM) Team

- Expanded PM team to manage global time zones and ensure greater availability and support for sites and patients in additional regions.
- Created a centralized email inbox to better monitor and track the status of sites and patients as the program expanded.

Updated the Regulatory Plan to Ensure Rapid On-Boarding of Additional Countries and New Indication Requests

- Utilized our Regulatory database of 122 countries.
- Managed regulatory submissions for cohorts pathways.
- 2 primary indications & several single case approvals for other indications.

Adopted Warehousing Strategy to Accommodate New Regions

- Established new warehouse locations outside of the US and EU and adjusted inventory management practices to ensure seamless operations.
- Maintained supply chain integrity and continuity amidst regulatory changes.

Secured the Supply Chain into Strategic and Non-Core Countries

- Worked with the Sponsor team closely to understand how new countries would fit into their future commercial strategy.
- Expanded logistics and distribution to both key strategic markets and non-core regions.
- Ensured consistent supply and minimized disruptions across diverse geographical areas.

Implemented Certain Country-Specific Strategies to Ensure Local Success in Each Country – For Example, Just-In-Time (JIT) Labelling for South Korea

- We adopted JIT labelling practices in South Korea to increase flexibility and reduce waste.
- We customized labelling processes to meet South Korean regulatory requirements, which improved efficiency and responsiveness to market demands.

The Outcome

Our team has helped the Sponsor exponentially increase access to their product, year after year. In year 1, there were 14 countries included in the scope of the program. By year 5, we had 33 countries included across the US, Europe, South America, Asia, and Oceania.