

CASE STUDY:

HELPING A SPONSOR PROVIDE ACCESS TO PROMISING INVESTIGATIONAL DRUG OUTSIDE OF THEIR CLINICAL TRIAL

About the Sponsor

The Sponsor is a global biotech company focused on designing and developing precision therapies for cancer, rare diseases, and immunotherapy. With headquarters in the US, the Sponsor has a diverse portfolio of newly FDA and EMA approved products, as well as promising investigational drugs in its pipeline.

The Challenge

The Sponsor started receiving unsolicited requests for one of its investigational oncology products from patients who were unable to enroll in the active clinical trial. The Sponsor needed to find a way to manage and review these requests without disrupting focus on the clinical trial. Due to the high demand for its drug and the Sponsor's limited internal resources and knowledge of Expanded Access, the Sponsor needed to quickly find a flexible partner with experience providing drugs on an unlicensed basis. See product details below:



Condition

Drug being developed to treat several rare Gastrointestinal Tumors



Development Status

Investigational medicine being studied in phase 2 clinical trials



Treatment Options

There are currently limited treatment options for this disease

WEP Solution

The Sponsor partnered with WEP Clinical to provide a global Expanded Access Program (EAP). This program allowed patients, contingent on meeting a predetermined inclusion criteria, to access the drug outside the clinical trial.

A dedicated WEP Lead Project Manager (PM) and supportive PM team were assigned to the Sponsor at the beginning of the program. WEP's PM team developed an in-depth understanding of the program requirements, nuances, and overall goals in order to develop a strategic project plan. Elements of the plan are listed below:

Scope Confirmation

- Agreed on countries in scope, developed inclusion criteria and developed EAP Policy

Physician Request Management Set Up

- Created program-specific contact details, appropriate documentation/templates, and a process flow for managing requests

Regulatory Management

- Developed a regulatory plan, handled all interactions with local regulatory bodies and submitted any required regulatory documentation

Product Management and Delivery

- Managed all elements of warehousing and transportation of the drug to physician sites and clearing through customs

Physician & Patient Support

- Provided and maintained open communication channels with physicians and sites to ensure patient needs were continuously met throughout the program

Program Outcomes

The WEP team has been providing treatment to patients through this EAP, on behalf of the Sponsor, for over five years. We continue to work closely with the Sponsor's internal team to ensure that the program continues to meet patient needs around the world.



739

739 patients have been approved into the EAP



8000

Over 8000 units of drug have been shipped



35

Patients in 35 countries* across 5 continents

**Argentina, Australia, Austria, Belgium, Brazil, Canada, Croatia, Estonia, Finland, France, Germany, India, Indonesia, Ireland, Israel, Italy, Kuwait, Lithuania, Luxemburg, Netherlands, New Zealand, Norway, Oman, Poland, Russia, Serbia, Singapore, South Korea, Spain, Sweden, Switzerland, Taiwan, Turkey, UK, and US.*

WEP has continued the relationship with this Sponsor, both by supporting additional EAPs and also by assisting the company transition certain countries to commercial supply as the treatment gained European approval.