



We are **With Every Patient**,
as we believe every patient should have access to treatment

CASE STUDY: HELPING A SPONSOR TRANSITION AN EXISTING EAP OVER FROM ANOTHER VENDOR

About the Sponsor

The Sponsor is a global biopharmaceutical company headquartered in the US and focused on researching, developing, and commercializing medicines for orphan, autoimmune and severe inflammatory diseases. The Sponsor's mission is to provide clinically meaningful therapies for patients with unmet clinical needs.

The Challenge

At the time the Sponsor approached WEP Clinical, it was already working with another vendor to provide an Expanded Access Program (EAP) for one of its high-priced rare disease therapies. See details of the product below:



Condition

Developed to treat a
rare, progressive
autoimmune condition



Approval

Approved and
commercially available
to patients in the US



Landscape

The only approved
treatment available for
this condition

The EAP had been set up to provide treatment access for patients living in countries outside the US. However, the Sponsor was dissatisfied with the service being provided by the initial vendor. It wanted to find a company that could take over the program and provide better customer service for physicians and the client and ensure more effective project management moving forward.

The Sponsor chose to work with WEP and tasked us with transitioning patients over from the existing EAP into a new program, set up and managed by WEP.



WEP Solution

Through WEP's Project Management focused delivery model, we assigned a dedicated Project Manager (PM) and supporting team to work directly with the Sponsor to develop an in-depth understanding of the EAP requirements, nuances, and overall goals, as well as the shortcomings of the initial program.

Our PM team then defined the new program scope and developed a bespoke transition and project plan, so that patients could be seamlessly switched over to the WEP-led EAP, without any disruption to their treatment. The elements of this are outlined below:

- Active site and physician support was required, to ensure treating HCPs were aware of the upcoming transition and comfortable with the new WEP program plan.
- We had to prepare to receive and store the Sponsor's product at our warehousing facilities, so that we could then manage delivery and customs clearance in the countries in scope and manage all product inventory moving forward.
- Using our expertise and experience working in France on the Early Access Scheme, our team set up and managed an Early Access scheme in France. This included Exploitant services, dossier preparation and submissions, Real World Data collection and all HAS and ANSM interactions on behalf of the client.
- As the Sponsor required PV support with this program, our dedicated PV team was brought in to support the WEP PM with a bespoke PV solution.
- We liaised closely with the Sponsor team throughout the whole process and provided monthly progress reports.

As a result of WEP's invaluable support with this initial product, the Sponsor has awarded WEP additional work with another of its portfolio products. For this second product, we provide a number of services including:



**PA-NPP Set Up
& Management**



**Support with the
French Early
Access Scheme**



**Real World Data
(RWD) Collection**



**Transition from PA-
NPP to commercial
supply**

