



With Every Patient.

## CASE STUDY: HELPING A SPONSOR RESCUE AN EXISTING EAP 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 set-up an EAP to provide treatment access to patients living in countries outside the US who were unable to enroll in the clinical trial for one of the company's high valued rare disease therapies.

### The Challenge

The Sponsor found that the initial EAP vendor did not provide adequate attention or support to program sites. The lack of attention created confusion with the Sponsor and the sites, which caused inefficiencies and frustration within the EAP. It also meant there was an increased level of involvement and oversight necessary from the Sponsor's team.

The Sponsor's priorities were focused on supporting their pending US commercial approval and ongoing ex-US clinical trials. The Sponsor, therefore, needed a company to take over the program, ensuring effective project management and better customer service to sites. The program had to run more smoothly so the Sponsor could refocus attention to their launch and ongoing trials.

The Sponsor chose to partner with WEP and tasked us with transitioning patients from the existing EAP into a new program, which would be wholly managed by WEP. On the next page, we will provide insight into how we did this.



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[www.wepclinical.com](http://www.wepclinical.com)



Reach out to us:  
[info@wepclinical.com](mailto:info@wepclinical.com)

## WEP Solution

WEP assigned a dedicated and highly experienced Project Manager (PM) to oversee and manage the transition of the ongoing program. The PM along with our internal teams worked closely with the Sponsor to develop an in-depth understanding of their EAP requirements and align on overall goals and expectations for the program.

We outlined the new program scope and developed a bespoke transition and project plan so that patients were seamlessly transitioned to the WEP-led EAP without any disruption to their ongoing treatment. The details on how we accomplished this, together with the Sponsor, are outlined below:

- **Analysis:** Conducted a detailed analysis of the current program, which included a gap analysis, risk assessment, root cause of current issues, and stakeholder impact.
- **Project Plan:** Created a transition/implementation plan that included roles and responsibilities, transition and milestone timelines, document requirements, training requirements, and KPIs.
- **Communication Plan:** Alongside the transition plan, WEP developed a comprehensive communication plan which covered interactions between WEP, the Sponsor, the program sites, and all external stakeholders involved. This plan outlined how often formal meetings would occur as well as how daily and adhoc communications would be handled across all parties involved in the program.
- **Site and Physician Support:** Provided proactive site and physician support to ensure all treating Healthcare Providers (HCPs) were aware of the upcoming transition and were comfortable with the new WEP program plan and processes. The sites involved in the program had differing levels of experience with and knowledge of Expanded Access, so our team tailored our support accordingly to each site.
- **Logistics:** Received and stored drug in our warehouse facilities so we could manage inventory, distribution, and customs clearance for all countries in the scope of the program.

- **French Early Access:** Set up and managed a French Early Access (AC) component to the program. This had been delayed under the previous vendor due to lack of expertise which led to submission deadlines being late. WEP Clinical's Market Access and PM teams have in-depth knowledge and experience with the French Early Access Scheme and managed all elements of Exploitant services, dossier preparation & submissions, Real World Data collection, and all ANSM and HAS interactions on behalf of the Sponsor.
- **PV Solution:** As the Sponsor required PV support with this program, our dedicated PV team was brought in to support our PM and Sponsor with a tailored PV solution.

## The Outcome

WEP adopted a flexible and proactive approach when working with the Sponsor, which allowed for a quick transition of the EAP from the incumbent vendor. Our team developed the transition and project plans in a way that allowed us to work in an autonomous manner, while keeping the Sponsor updated on milestones and defined KPI's at set intervals. The Sponsor was able to quickly turn attention back to their commercial launch, which proved to be successful, as well as their clinical trials in countries outside of the United States.