WEP

With Every Patient.

CASE STUDY: PROVIDING DRUG IN FRANCE THROUGH REVISED LEGISLATION FOR AAC COMPASSIONATE USE ACCESS

About the Sponsor

The Sponsor is a pharmaceutical company, headquartered in the US, which is dedicated to researching and developing specialist therapies for seizure disorders and rare epilepsies. The medicines the Sponsor develops provide hope for patients around the world.

The Challenge

After receiving FDA approval for its drug, the Sponsor wanted to ensure continuity of treatment for patients in France, who had previously been treated via a clinical trial which was now coming to an end. It also wanted to better understand the opportunities for funding for their treatment, pre-Licence, in France. The Sponsor did not have the expertise to manage this in-house and so needed a partner to help support them with the pre-approval access schemes in the country.

WEP Solution

Using our expertise in early access regimes, WEP Clinical helped the Sponsor provide Compassionate Use access for the existing patients in France, under the 2021 revised legislation for AAC Compassionate Use access. WEP Clinical also developed the full clinical dossier & the PUT (Therapeutics Use Protocol) for the client to be submitted to the Agence nationale de sécurité du médicament et des produits de santé (ANSM) who approved access for current, plus new patients and the opportunity to collect Real World Data (RWD) prior to launch in the EU.

The Outcomes

Continued treatment access for patients

Funding from the ANSM was granted

Early engagement with KOLs in France

New patients could also access treatment