



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 U.S, 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, that was now coming to an end. It also wanted to better understand the opportunities for funding for its 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 and 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) which approved access for current, as well as new patients and granted 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



For more information:
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