WEP

With Every Patient.

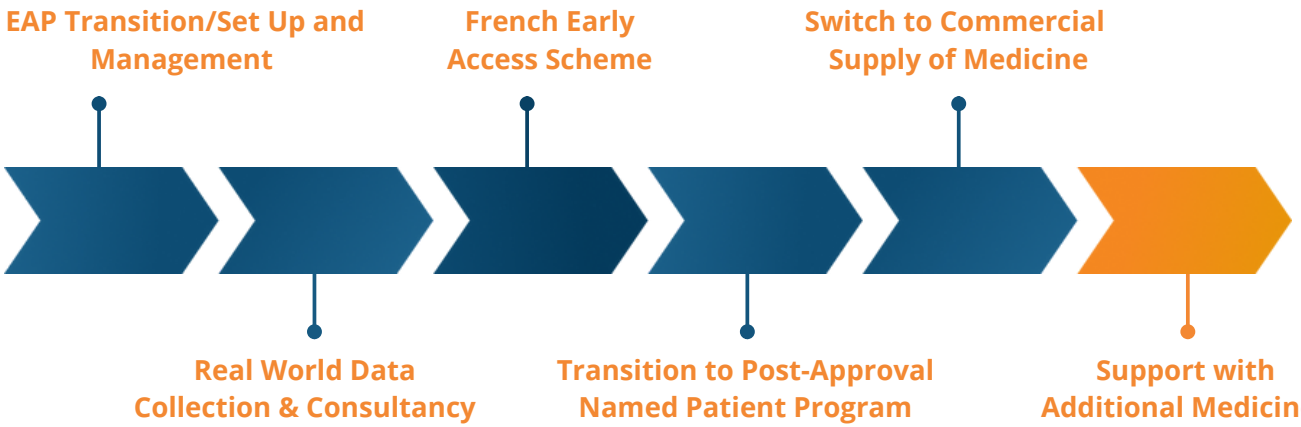
CASE STUDY: SUPPORTING A MEDICINE THROUGHOUT THE DEVELOPMENT JOURNEY

WEP Clinical creates bespoke treatment access solutions for the pharmaceutical industry through the breadth of services we provide. We focus on supporting our clients and their products, from drug development all the way through approval and commercial supply. Our internal team of experts are tasked with continuously nurturing relationships with our clients in order to understand their evolving needs. This allows us to provide additional services and support, which scale alongside our clients growth.

Real World Example

Below is an example of how we delivered our portfolio of service offerings to a global biopharmaceutical company developing medicines for patients with rare and life-threatening diseases. Our partnership began when the Sponsor approached WEP to assist with transitioning an active Expanded Access Program (EAP), after they acquired the product from another manufacturer. We successfully managed the complex transition across multiple continents, ensuring there was no disruption to treatment for patients previously enrolled in the EAP. WEP then worked with the Sponsor to enable new patients to enroll, thus allowing greater access for patients in need of the therapy.

Because WEP offers our partners additional key services to support their medicine on its journey towards global regulatory approvals and launch, we built an integrated program which included Real World Data collection, French Early Access, post-approval named patient supply and commercial medicine supply. The diagram below illustrates our partnership journey.



Supporting the Sponsor at Every Stage

EAP Set Up and Management

- WEP handled all elements of transitioning from the existing program and then setting up and managing new EAP.
- This included the development of a transition and project plan, defining the new program scope, site and physician support, regulatory management, data management, and product warehousing and delivery.

Real World Data Collection & Consultancy

- WEP helped Sponsor understand how to set up a data collection program for its EAP in specific countries to help fortify the drug safety and efficacy profile
- We recommended using a series of patient and physician questionnaires and supported the Sponsor through the whole set up and roll out process.

French Early Access Scheme

- WEP helped the Sponsor navigate the new French Early Access Scheme, tailored specifically to their product and on-going EMA regulatory submission.
- We advised on the access strategy, secured Exploitant services, prepared and submitted relevant dossiers, set up Real World Data collection, and liaised with HAS & ANSM throughout.

Transition to Post-Approval Named Patient Program (PA-NPP)

- In preparation for product approval in the US, WEP helped the Sponsor set up a PA-NPP to provide access to patients ex-US on a paid for basis.
- This provided a mechanism for patients to access the US products in countries where the medicine had not yet been approved.

Switch to Commercial Supply of Medicine

- The product then received approval in additional countries outside the US.
- At this time, WEP managed the process of switching EAP patients and PA-NPP patients to commercial, reimbursed product supply in a way that ensured no patient missed treatment.

Support with Additional Medicine

- WEP has proven itself as a true partner on the journey of a medicine from development to launch, offering the highest levels of service.
- As a result, the Sponsor asked WEP to manage the commercial supply and distribution of additional products in its portfolio.

Sponsor Testimonial

"Finding a partner like WEP who helped us provide access to investigational products for those who are unable to participate in clinical trials has been crucial for our company. It has allowed rare disease patients to have access to a much-needed therapeutic option we're working tirelessly to bring to reality."

EXECUTIVE MEDICAL DIRECTOR, CLINICAL RESEARCH