WEP

With Every Patient.

CASE STUDY: ACTING AS A STRATEGIC ACCESS PROGRAM PARTNER – GOING ABOVE AND BEYOND THE STANDARD VENDOR APPROACH

Background

Over the past two years, WEP Clinical has partnered with a global biopharmaceutical company developing innovative treatments for serious pulmonary diseases. What began as a rescue effort to transition struggling access programs away from an incumbent vendor has evolved into a long-term, strategic collaboration spanning multiple products and differentiated access programs.

Together with the Sponsor, we have worked to understand real-world patient demand, navigate complex regulatory and market access landscapes, and design sustainable access models that support both patient needs and Sponsor goals. This case study outlines how our role has grown from operational support to a true access program partnership, guiding decisions and implementing value-driven projects across the Sponsor's clinical development pipeline.

Stage 1: Providing Tailored, Dedicated Support to Rescue Struggling Access Programs

First, we transitioned three programs away from the initial access program vendor:

- Post-Trial Access (PTA) program for a drug developed to treat a chronic pulmonary condition.
- Compassionate Use Program (CUP) for a drug developed to treat serious pulmonary infections.
- Post-Approval Named Patient Program (PA-NPP) for the same drug developed to treat serious pulmonary infections.

We worked closely with the incumbent vendor and the Sponsor team, across all three programs, to:

- Communicate the change of program ownership to all treating sites; introduce WEP to site staff; and provide adequate training and support on new program processes, documentation, and channels of communication.
- Oversee the secure transfer of all project documentation and patient data from the incumbent vendor to WEP, ensuring accuracy, reconciliation, and compliance with applicable data protection requirements.
- Plan and map logistics so that by the time patients received their last shipment from the incumbent vendor, WEP had stock available at our warehouse – packaged, labeled, and ready to send out – ensuring no treatment gaps.
- Identify any regulatory submissions held by the incumbent vendor, in all countries where applicable, and update them so they were held by the Sponsor instead.

Stage 2: Helping to Scale the PTA Program to Fulfill Patient Needs and Support Sponsor Goals

Once all three programs were transitioned over to WEP, we worked with the Sponsor to expand the scope of the PTA program. Through our early conversations with the Sponsor team, we understood the Sponsor was particularly unhappy with the incumbent vendor, as it had been unable to operationalize the PTA program on a global scale. The program had originally been setup to include just half of the countries the Sponsor wanted to provide continued supply in.

WEP's Regulatory and Project Management teams worked together to:

- Conduct a country-by-country feasibility and regulatory assessment to clarify PTA requirements, importation rules, data privacy obligations, and any local adaptations needed to program documentation.
- Prepare and submit the necessary regulatory and ethics notifications/approvals to extend the PTA program into new countries, updating program materials (e.g. request forms, informed consent, patient information) as required.
- Standardize global operational processes, including eligibility review; supply request handling; safety reporting; and documentation. This allowed us to ensure consistent experience for treating sites and patients across all participating countries.

- Onboard and support new sites, providing tailored training on workflows and acting as the main point of contact for day-to-day questions, so that the expanded PTA program could run smoothly and scale.

Stage 3: Offering Strategic Recommendations to Maximize Product Potential

Discussions around the expansion of the PTA program also led to us offering dedicated support with French Early Access, including Autorisations Accès Compassionnel (AAC) and L,Accès Precoce (AP). Regulated by the French National Agency for the Safety of Medicines and Health Products (ANSM) and the French Health Authority (HAS), pre-approval access schemes in France serve as a key strategic step for companies aiming to ensure timely patient access while building a strong market foundation.

After speaking with our expert in-house Market Access team, the Sponsor was keen to benefit from patient access opportunities in France. The benefits included early revenue generation, Real World Data (RWD) collection, early clinical engagement and stakeholder buy-in, with the potential for accelerated market entry.

Our Market Access team provided end-to-end support in optimizing strategy and execution, which included:

- Defining the optimal access scheme design and positioning in line with ANSM and HAS requirements, including program objectives; eligible patient populations; prescriber criteria; data collection strategy and alignment with the Sponsor's broader European launch strategy.
- Developing the value and access narrative to support French stakeholder engagement, including articulation of unmet need; expected clinical benefit; and the potential impact on healthcare resource use.
- Guiding pricing and reimbursement considerations within the patient access framework, helping the Sponsor understand implications for early revenue generation, rebate and Montant M payments, and future Pricing & Reimbursement (P&R) negotiations.
- Designing the Real World Data (RWD) and evidence plan to capture meaningful insights from patients via the Therapeutic Use Protocol, supporting both ongoing clinical development and future market access discussions.

- Coordinating operational implementation with the Sponsor and relevant French stakeholders, ensuring compliant patient enrollment, supply management, and reporting throughout the duration of the program.

Stage 4: Integrating Additional Access Programs to Bridge to Commercial Launch and Continue Adding Value

As the medicine progressed towards FDA approval, WEP proposed the addition of a Post-Approval Named Patient Program (PA-NPP), broadening patient access to benefit more patients beyond the existing PTA program. The PA-NPP also provided a bridge from the first approval and launch in the US to further approvals in other countries worldwide. This approach allowed the Sponsor to provide quality controlled, compliant access for new patients, across selected countries where permitted, and recover a portion of costs to support long-term program viability.

We worked cross-functionally with the Sponsor to:

- Map and prioritize countries based on the Sponsor's commercial roadmap and launch sequence. We also took into consideration local frameworks that allow funded access to reduce out-of-pocket burden, where feasible.
- Build a country-by-country supply and logistics plan that indicated pack presentations and pack pricing aligned to staggered approvals; established compliant trade routes, with clearly defined product flow, title (ownership) transfer, and financial flows; and outlined which local stakeholders to engage with and when to meet importation and distribution requirements.
- Develop a detailed project plan for running the PA-NPP. This covered end-to-end operations such as eligibility confirmation; site invoicing and payment processing; supply request handling; shipment coordination; reconciliation; and periodic sales and activity reporting to the Sponsor.

Stage 5: Supporting with Access Programs for Additional Products

As the Sponsor had additional promising products in its pipeline, the WEP team worked closely with the Sponsor's clinical operations, commercial, and senior leadership teams to embed the learnings from our existing pre-approval access strategies to deliver integrated patient access programs for new medicines in earlier development.

As a result of that initiative, we now provide two new PTA programs for one of the Sponsor's investigational drugs being developed to treat an additional serious, progressive, rare pulmonary disease. Our goal when working with all of our clients is to serve as a long-term access program partner, providing recommendations and support across their full clinical development pipelines.

Our collaborative and forward-thinking approach to partnership allows us to:

- Offer continued strategic recommendations and support over time so that programs can evolve to meet new demands and add value
- Anticipate additional opportunities to benefit patients and support Sponsor clinical development and commercialization goals.
- Become an extension of the Sponsor's team to help them think holistically about how to fully maximize pipeline potential.

Key Takeaways

Through our work across multiple phases and products, WEP Clinical's relationship with this Sponsor has grown far beyond that of a traditional vendor. By combining regulatory, operational, and market access expertise, we have helped the Sponsor rescue and scale existing programs, unlock new access opportunities, and create a framework that guides decision-making for future clinical and commercial asset launches.

Today, we continue to act as an extension of the Sponsor's organization – proactively identifying new ways to support timely, compliant access for patients while keeping clinical development and commercialization priorities in view. This collaborative, long-term approach is how we aim to work with all of our clients, serving as a strategic access program partner across the full product lifecycle.