

MULTI-PROGRAM ACCESS PARTNERSHIP • PULMONOLOGY

Acting as a Strategic Access Program Partner – Going Above and Beyond the Standard Vendor Approach

How WEP Clinical helped a global biopharmaceutical Sponsor transform complex access needs into a scalable, long-term strategy spanning multiple programs, markets, and stages of the product lifecycle.

PROGRAM SNAPSHOT

Therapeutic Area
Pulmonology

Program Type
Multi-Program
Access Partnership

Pediatric
Yes

Country in Scope
29 globally

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 models.

Together with the Sponsor, WEP has 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. The partnership initially focused on transitioning three programs away from the incumbent vendor:

- **A Post-Trial Access (PTA) Program** for a drug developed to treat a chronic pulmonary condition
- **A Compassionate Use (CUP) Program** for a drug developed to treat serious pulmonary infections
- **A Post-Approval Named Patient Program (PNNP)** for the same drug developed to treat serious pulmonary infections

The relationship has since grown from operational rescue support into a broader access program partnership across the Sponsor's clinical development pipeline.

THE CHALLENGE

The Sponsor needed more than a transactional access vendor. The incumbent vendor had struggled to provide the level of coordination, responsiveness, and global operational support required across multiple access programs. This created risk across site communication, patient continuity, logistics, regulatory ownership, documentation transfer, and program expansion.

At the same time, the Sponsor's access needs were evolving. The team needed to rescue existing programs, expand PTA coverage, consider French Early Access opportunities, prepare for post-approval named patient access, and apply learnings to additional products in the pipeline.

The key challenge was clear: Transition and stabilize multiple access programs, then evolve the relationship into a strategic access partnership capable of supporting future clinical and commercial goals.

WEP'S APPROACH

1

Rescuing and Transitioning Existing Access Programs

WEP first worked closely with the incumbent vendor and the Sponsor team to transition all three programs into WEP management. This required careful coordination across sites, documentation, patient data, regulatory submissions, inventory, labeling, packaging, warehousing, and communication planning. WEP supported the transition by:

- Communicating the change of program ownership to all treating sites
- Introducing WEP to site staff and providing training on new program processes
- Supporting sites with documentation requirements and communication channels
- Overseeing secure transfer of project documentation and patient data
- Reconciling transferred information for accuracy and compliance
- Planning logistics so WEP stock was available, packaged, labeled, and ready to ship when patients received their final shipment from the incumbent vendor
- Identifying regulatory submissions held by the incumbent vendor and updating them so they were held by the Sponsor instead

This ensured patients could continue receiving treatment while program ownership moved to WEP.

WEP Impact: WEP stabilized three struggling access programs while helping prevent treatment gaps during vendor transition.

2

Scaling the PTA Program to Meet Patient and Sponsor Needs

Once the three programs were transitioned, WEP worked with the Sponsor to expand the PTA program.

Early conversations showed that the Sponsor had been unhappy with the incumbent vendor because the PTA program had not been operationalized globally. The original program had only included around half of the countries where the Sponsor wanted to provide continued supply.

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

- Conduct country-by-country feasibility and regulatory assessments
- Clarify PTA requirements, importation rules, data privacy obligations, and local documentation needs
- Prepare and submit regulatory and ethics notifications or approvals to extend the PTA program into new countries
- Update request forms, informed consent, patient information, and other program materials where needed
- Standardize eligibility review, supply request handling, safety reporting, and documentation
- Onboard and support new sites with tailored training and day-to-day guidance

WEP Impact: WEP helped turn an underperforming PTA program into a scalable access model across patients, sites, and countries.

3

Expanding Into French Early Access and Market Access Strategy

Discussions around PTA expansion led WEP to identify an additional opportunity: dedicated French Early Access support.

This included support for **Autorisations d'Accès Compassionnel (AAC) and Accès Précoce (AP)**. These French pre-approval access schemes, regulated by ANSM and HAS, can be strategically important for Sponsors seeking timely patient access while building a stronger market foundation.

After speaking with WEP's in-house Market Access team, the Sponsor was interested in the opportunity to benefit from patient access in France.

The potential benefits included:

- Early revenue generation
- RWD collection
- Early clinical engagement
- Stakeholder buy-in
- Potential for accelerated market entry

WEP's Market Access team provided end-to-end support, including:

- Defining the optimal access scheme design and positioning in line with ANSM and HAS expectations
- Clarifying program objectives, eligible patient populations, prescriber criteria, and data collection strategy
- Aligning the French access approach with the Sponsor's wider European launch strategy
- Developing the value and access narrative for French stakeholder engagement
- Supporting pricing and reimbursement considerations, including rebate and Montant M implications
- Designing an RWD and evidence plan through the Therapeutic Use Protocol
- Coordinating operational implementation with the Sponsor and French stakeholders

WEP Impact: WEP helped the Sponsor move beyond access program delivery and begin using early access as part of a broader market access and launch-readiness strategy.

4

Preparing a Post-Approval Named Patient Program Strategy Ahead of Approval

The PA-NPP was designed to broaden access for new patients beyond the existing PTA program. It also provided a bridge between first approval and launch in the United States and future approvals in other countries.

This approach allowed the Sponsor to provide quality-controlled, compliant access in selected countries where permitted, while recovering a portion of costs to support long-term program viability.

WEP worked cross-functionally with the Sponsor to:

- Map and prioritize countries based on commercial roadmap and launch sequence
- Identify local frameworks that could support funded access and reduce out-of-pocket burden where feasible
- Build a country-by-country supply and logistics plan
- Align pack presentations and pricing with staggered approvals
- Establish compliant trade routes, product flow, title transfer, and financial flows
- Identify local stakeholders and timing for importation and distribution requirements
- Develop an end-to-end PA-NPP project plan covering eligibility confirmation, site invoicing, payment processing, supply request handling, shipment coordination, reconciliation, and activity reporting

WEP Impact: WEP helped the Sponsor prepare a more sustainable post-approval access pathway that aligned patient need with launch planning and long-term program viability.

5

Supporting Access Programs for Additional Products

As the Sponsor's pipeline continued to develop, WEP worked with clinical operations, commercial, and senior leadership teams to embed learnings from the existing access programs into planning for new medicines. As a result of this broader collaboration, WEP now provides two new PTA programs for one of the Sponsor's investigational drugs being developed to treat an additional serious, progressive, rare pulmonary disease.

This demonstrates how the relationship evolved beyond one program or one product. WEP became an extension of the Sponsor's team, helping identify new opportunities to support patient access, clinical development, commercialization goals, and pipeline strategy.

WEP Impact: WEP's role expanded from rescuing existing programs to supporting strategic access planning across future assets.

THE OUTCOME

WEP helped the Sponsor transition, stabilize, scale, and evolve multiple access programs across a growing pulmonary portfolio.

To date, the partnership has supported:

500+ Patients | 140 sites | 29 countries | 2 additional PTA programs

Countries Included:

Europe & Eurasia: Austria, Belgium, Denmark, France, Greece, Hungary, Ireland, Italy, Latvia, Netherlands, Poland, Portugal, Serbia, Spain, Turkey, United Kingdom

Asia-Pacific: Australia, Malaysia, New Zealand, South Korea, Thailand

North America: Canada, United States

Middle East: Israel

Latin America: Argentina, Brazil, Chile, Mexico, Peru

By combining project management, regulatory strategy, supply coordination, market access expertise, RWD planning, and long-term pipeline thinking, WEP helped the Sponsor move from reactive program rescue to proactive access program partnership.

Most importantly, the Sponsor gained a strategic partner capable of supporting patient access across the full product lifecycle, from post-trial access and compassionate use through post-approval access and future launch planning.

WHY THIS MATTERS

Access programs rarely stay static. As products move through development, Sponsors may need to manage treatment continuation, new patient demand, country expansion, regulatory changes, launch planning, RWD needs, and cost-recovery considerations at the same time.

A traditional vendor may be able to execute predefined tasks, but complex access programs often require a partner that can see across the full lifecycle and proactively identify what should happen next.

This case demonstrates how WEP Clinical can act as a strategic access program partner, helping Sponsors rescue existing programs, scale delivery, identify new access opportunities, and align patient access with clinical and commercial goals.

NEED A STRATEGIC ACCESS PROGRAM PARTNER?

Let the WEP team help scale patient access with a strategy built for every stage of the product lifecycle

WEP Clinical supports Sponsors with access program strategy, project management, regulatory coordination, PTA, Compassionate Use, PA-NPP, French Early Access, Market Access, RWD planning, supply coordination, and long-term lifecycle access planning.



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