WEP
With Every Patient.

Case Study

POST-TRIAL ACCESS PROGRAM • MARKET ACCESS STRATEGIC CONSULTING

Establishing a Post-Trial Access Centre of Excellence

How WEP Clinical helped a global biopharmaceutical company establish a consistent, compliant, and scalable approach to Post-Trial Access across its clinical development portfolio.

BACKGROUND

A global biopharmaceutical company sought to establish a consistent, scalable approach to Post-Trial Access (PTA) across its entire clinical development portfolio.

While individual study teams were making PTA decisions, the organization lacked a unified strategy, standard governance model, and operational framework to ensure decisions were made consistently, compliantly, and proactively throughout the development lifecycle.

The client needed to understand how PTA should be operationalized across functions, clarify organizational responsibilities, and develop a repeatable model that could support both current and future clinical programs while meeting evolving regulatory and ethical expectations.

WEP'S APPROACH

WEP partnered with the client to design a PTA Center of Excellence (CoE), designing and implementing an end-to-end operating model that combined strategic guidance, decision-making frameworks, and operational execution. Our methodology included:

1. **Current-State Assessment:**
Conducted a comprehensive review of existing PTA processes, decision-making pathways, and cross-functional responsibilities to understand how post-trial access was currently being managed across the portfolio.

2. **Regulatory and Ethical Baseline:**
Established a common understanding of global post-trial access regulations, ethical guidance, industry standards, and sponsor obligations. This provided the foundation for consistent decision-making across therapeutic areas and geographies.

3. **Strategic Positioning:**
Worked with senior stakeholders to define the organization's post-trial access philosophy, principles, and decision framework. Where appropriate, this included flexibility to accommodate asset- or program-specific approaches while maintaining enterprise-wide consistency.

4. **Gap Assessment:**
Facilitated structured interviews and workshops with stakeholders across Clinical Development, Medical Affairs, Regulatory, Supply Chain, Legal, Ethics, and Patient Access to identify operational gaps, governance challenges, decision-making bottlenecks, and opportunities for process optimization.

5

Target Operating Model Design:

Developed a comprehensive framework covering:

- Strategic decision-making principles
- Governance structure and accountability frameworks
- Standardized operational processes
- Cross-functional roles and responsibilities
- Escalation pathways and decision gates
- Supporting tools, templates, and documentation

6

Validation and Implementation:

Socialized the proposed framework through cross-functional workshops, incorporating stakeholder feedback before supporting implementation and embedding the model within existing clinical development processes.

SOLUTION DELIVERED

WEP delivered a comprehensive Post-Trial Access Center of Excellence framework that provided a single, enterprise-wide framework for planning, governing, and operationalizing PTA. The framework enabled:

A consistent approach to PTA decision-making across the clinical portfolio.

Clear governance, ownership, and accountability across functions.

Standardized processes integrated into clinical development planning.

Improved alignment between internal policies, ethical commitments, and external company positioning.

Practical tools and guidance to support study teams throughout the trial lifecycle.

Greater organizational readiness to respond to evolving regulatory and stakeholder expectations.

BUSINESS IMPACT

By implementing a structured Post-Trial Access Center of Excellence, the client transformed PTA from a decentralized, study-level activity into a strategic organizational capability. Study teams were equipped to make informed decisions earlier in the development lifecycle, governance became more transparent, and operational execution became more consistent across programs.

Most importantly, the new framework enabled the organization to deliver continued treatment access to eligible patients in a compliant, efficient, and patient-centric manner, while reducing operational variability and supporting long-term portfolio scalability.