WEP

With Every Patient.

# CASE STUDY: HOW STRONG PROJECT MANAGEMENT DELIVERED A SUCCESSFUL CELL THERAPY EAP

## Challenge

The Sponsor was receiving unsolicited requests for its lead cell therapy from patients and physicians who were not a part of their active clinical trial. The Sponsor wanted to set up a treatment access program to manage these requests and treat a high unmet clinical need. The Sponsor was aware of existing access pathways but lacked the internal knowledge, experience, and personnel to design and execute the program in-house.

The Sponsor knew they needed to find a vendor that is experienced in the access program space. A key criteria in this search was to find a vendor that also understands the complexities involved in running access programs for cell therapies specifically.

## Why WEP?

WEP has managed access programs for over a decade. The Sponsor decided to partner with WEP due to our proven track-record of successful execution across hundreds of access programs; our exceptional project and site management; and, most importantly, our knowledge and experience in cell therapy treatment and supply chain management.

WEP took the time to understand the Sponsor's overall goals for providing treatment access. This allowed our team to provide strategic recommendations on how best to design and deliver the program.

## We provided guidance on the following aspects of the program:

- Program scope
- Regulatory pathways
- Patient eligibility criteria
- Site support requirements
- End-to-end supply chain mapping and risk mitigation
- Data collection
- Monitoring
- Site payments
- Patient request management
- Implications for commercial launch

We also set clear expectations on the requirements for the program, developed robust project and communication plans, and engaged early with all program stakeholders, so that the everyone was aligned and prepared throughout the entire duration of program set up and initiation.

## The Value of WEP Project and Site Management in Cell Therapy

We recognize that access programs for cell therapies are complex and multifaceted. Therefore, we assembled an experienced, purpose-built team to deliver this project, which was spearheaded by our expert cell therapy Project Management Group.

Our Project Managers (PMs) are trained to be proactive, highly detailed, and in control of all moving parts of a program. They ensure that every detail of the WEP solution aligns with a Sponsor's overall program goals and are quick to anticipate and mitigate challenges throughout. These skills make our PM team ideal for managing access programs across the cell therapy space.

Due to the time-critical nature across every step of the cell therapy program, our PM team understood that providing effective site management and clear ongoing communication between all stakeholders would be paramount.

## This meant mobilizing both internal and external teams, including:

### WEP Teams

- Logistics Manager
- Data Team Lead
- Clinical Research Associate
- Regulatory Associate

### Sponsor Teams

- Program Leads
- Logistics Teams
- Quality Assurance Personnel
- Medical Affairs Team
- Medical Science Liaisons

### Treating Sites

- Data Coordinator
- Cell Therapy Lab Personnel
- Regulatory Coordinator
- Finance
- Pharmacy Personnel

Our PMs integrated seamlessly with each component of the supply chain to educate themselves on the complex logistical elements involved in running the program. This included:

- Patient enrollment
- Site visits
- Sample and drug product inventory management
- IP shipments
- IP accountability and final disposal
- Ongoing site management

The PMs overall goal was to operate like an extension of each of the external teams and understand their individual needs and challenges. This helped ensure effective ongoing coordination and continuous improvement of processes throughout the duration of the program.

### To help with this, the team created the following:

- Stakeholder-specific communication templates were created during the planning phase to ensure patient requests were managed efficiently and key parties at different stages were notified appropriately without delay.
- A site start-up tracker was built to track essential document collection, IRB timelines, contract/budget timelines, and general communications with sites during the site setup phase.
- A patient tracker was built to track the multiple steps within the patient journey from the initial interaction with the patient through dosing with the final drug product across multiple patients and sites.

## Conclusion

We have been working with the Sponsor on this program for several years now. The Sponsor has been so happy with WEP's execution and ongoing support, that it awarded our team additional work, following FDA approval of the product. We now manage a second access program for out-of-spec access to the commercial product.

**If you have any questions or want to learn more about WEP capabilities click the button below to send us an email**

**Contact Us**