

EXPANDED ACCESS PROGRAM • ONCOLOGY

How Strong Project Management Delivered A Successful Cell Therapy EAP

How WEP Clinical helped an oncology Sponsor operationalize and scale a complex US cell therapy EAP – building a structured model for site activation, patient access, and program oversight.

PROGRAM SNAPSHOT

Therapeutic Area
Oncology

Program Type
Expanded Access
Program (EAP)

Advanced Therapy
Yes

Country in Scope
United States

ABOUT THE SPONSOR

The Sponsor is an oncology-focused biopharmaceutical company developing an advanced cell therapy for patients with significant unmet medical need.

The Sponsor needed an experienced access program partner to help operationalize a US-based Expanded Access Program (EAP) that could support eligible patients outside of the clinical trial setting while maintaining clear coordination across the Sponsor, treating physicians, sites, and internal program stakeholders.

THE CHALLENGE

Cell therapy EAPs are operationally complex. They require strong coordination across patient eligibility, site readiness, physician communication, program documentation, treatment timelines, and Sponsor oversight. For this program, the Sponsor needed to support access across a broad US site footprint while ensuring participating sites had the information, tools, and guidance needed to manage requests efficiently.

The scale of the program created several important operational priorities:

- Supporting a large number of potential patients
- Activating and coordinating with multiple treatment sites
- Maintaining consistent communication with physicians and site teams
- Tracking patient access requests through each stage of the pathway
- Giving the Sponsor clear visibility across program activity
- Supporting eligible patients without adding unnecessary complexity for sites

The key challenge was clear: build a scalable US cell therapy access program model that could support eligible patients while coordinating effectively across a large network of oncology sites.

WHY WEP CLINICAL

The Sponsor selected WEP Clinical because of our experience designing and managing access programs, our project and site management expertise, and our understanding of the additional coordination required for cell therapy programs.

For a program of this scale, the Sponsor needed more than administrative support. They needed a partner that could bring structure, communication, oversight, and practical tools to help keep the program moving across multiple sites and patient requests.

WEP'S SOLUTION

WEP Clinical supported the Sponsor by helping establish a structured operating model for the Expanded Access Program. Rather than treating the program as a series of individual requests, WEP created a coordinated approach across site activation, patient access, stakeholder communication, documentation, and ongoing program oversight.

This gave the Sponsor a clearer framework for managing the program while helping sites understand how to participate and support eligible patients.

WEP'S APPROACH

1

Establishing a Clear Program Model

WEP worked with the Sponsor to define the operating model for the program, including roles and responsibilities, communication pathways, documentation expectations, escalation routes, and reporting processes. This helped ensure that all stakeholders understood how requests would be managed and how information would flow between the Sponsor, WEP, sites, and treating physicians. For a cell therapy EAP, this structure was especially important because timelines, coordination requirements, and site readiness can all affect the patient access pathway.

2

Supporting Site Activation

A key priority was building a strong site network for the program. The program included 70 sites in scope, with 50 sites activated to date. WEP supported the site activation process by helping ensure participating sites had the guidance, documentation, and communication needed to engage with the program effectively. This helped create a broader operational footprint and allowed the Sponsor to support access across a larger US site network.

3

Creating Practical Project Management Tools

To help keep the program organized, WEP created practical tools that supported site activation, patient tracking, stakeholder communication, and Sponsor oversight. These included:

- Stakeholder-specific communication templates
- A site start-up tracker to follow documents, IRB timelines, contracts, budgets, and site communications
- A patient tracker to follow each step of the patient journey from request through treatment
- Structured reporting tools to help the Sponsor maintain visibility across program activity
- Clear escalation pathways for site questions, patient requests, and operational issues

These tools helped bring consistency to the program and gave both the Sponsor and participating sites a clearer view of program progress.

4

Coordinating Patient Access

The program was scoped to support 170 patients, with 93 patients supported to date and 56 patients currently receiving access. WEP helped manage the coordination required to support patient access in a structured and consistent way. This included keeping program activities organized across sites, stakeholders, and Sponsor requirements. The focus was on making the access pathway clearer for sites and more manageable for the Sponsor, while keeping patients at the center of program delivery.

5

Maintaining Sponsor Visibility

As the program scaled, the Sponsor needed clear visibility into program activity, site progress, and patient access status. WEP provided a coordinated view of program delivery, allowing the Sponsor to understand progress across the access pathway without needing to manage every operational detail directly. This helped reduce internal burden while keeping the Sponsor informed and engaged at the right level.

THE OUTCOME

WEP helped the Sponsor operationalize a US oncology cell therapy EAP, creating a clearer and more scalable model for managing site participation and patient access.

To date, the program has supported:

150+ Patients

70 sites

US program operationalized

By supporting site activation, patient access coordination, stakeholder communication, project tracking, and Sponsor reporting, WEP helped the Sponsor manage a complex cell therapy access pathway across a broad US site network.

Most importantly, the Sponsor was able to support eligible patients through a more structured access program model while maintaining visibility across program activity. Following successful execution of the program and FDA approval of the product, the Sponsor awarded WEP additional work, including management of a second access program for out-of-specification access to the commercial product.

WHY THIS MATTERS

Cell therapy access programs can be complex to manage, especially in oncology, where patients may have urgent treatment needs and sites require clear guidance to participate effectively. When multiple sites and patient requests are involved, Sponsors need more than basic program administration. They need a partner that can create structure, maintain communication, coordinate stakeholders, track progress, and keep the program moving.

This case demonstrates how WEP Clinical can help Sponsors operationalize advanced therapy access programs in a way that supports patient access, site engagement, and Sponsor oversight.

NEED TO BUILD OR SCALE AN ACCESS PROGRAM?

Let WEP help you build and scale access programs designed for the demands of complex therapies

WEP Clinical supports Sponsors with the strategy, project management, site engagement, program coordination, stakeholder communication, and operational oversight needed to deliver structured access programs for complex therapies.



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