Cell & Gene Therapy

When Logistics Become a Strategic Advantage in CGT Trials

Chain of custody, manufacturing coordination, and site workflows that keep cell and gene therapy studies moving

1 The Logistics Challenge

In CGT trials, logistics can directly affect enrollment timing, manufacturing cadence, and study momentum. **These challenges create risk across every handoff.**

Chain of identity (COI) and custody (COC)
Every handoff increases the risk of mismatch, mislabeling, or broken traceability.

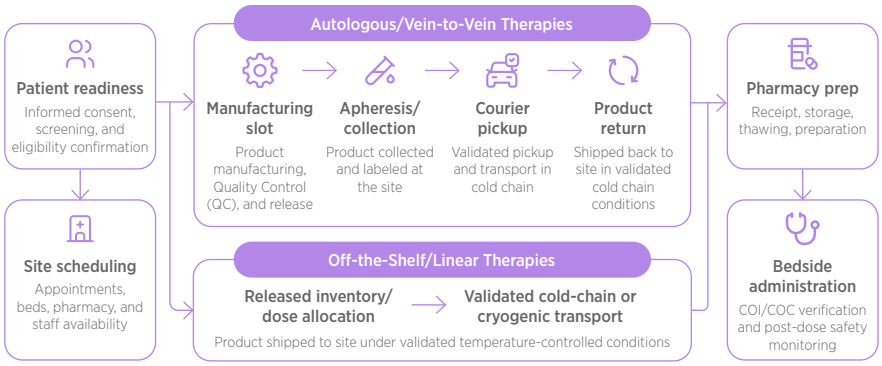
Manufacturing slot limitations
Limited capacity can slow enrollment.

Courier coordination and cold chain requirements
Temperature-sensitive products require flawless transport.

Multi-stakeholder scheduling
Misalignment across teams can delay dosing.

A missed collection, shipment delay, manufacturing issue, or temperature excursion can disrupt the entire study and delay treatment for patients.

2 The Trial Design Response



The product cannot wait for the patient — and the patient cannot wait for the product.

Questions to Ask a Logistics or CRO Partner

- How are manufacturing slots coordinated with enrollment and patient readiness?
- What contingency plans exist for shipping disruptions, missed courier windows, or temperature excursions?
- What systems provide real-time visibility into product location, temperature status, and expected arrival?
- How is chain of identity and chain of custody tracked from collection to infusion?
- Who owns logistics coordination across the sponsor, site, manufacturer, courier, and CRO?

3 The Readiness Response

Five areas of logistics readiness reduce risk and keep your study on track.

- **Digital Traceability**
- **Site Standardization**
- **Logistics Orchestration**
- **Risk-Based Planning**
- **Pharmacy-to-Bedside Workflow**

Why it matters

CGT logistics failures do not just create operational noise. They can result in catastrophic product loss, compromise patient safety, increase site burden, and derail timelines for decision-ready data.

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