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Inizio Engage

Overcoming the Challenges in Bringing Cell & Gene Therapies to Market

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Addressing the Gatekeeper Challenges in Cell & Gene Therapy

Cell and gene therapy (CGT) is opening new treatment pathways for rare and orphan diseases. But getting a therapy to patients takes more than clinical success. It also requires treatment centers being willing and able to administer it. Operational complexity, financial exposure, and growing competition are pushing centers to be more selective about which programs they take on.

This white paper examines four challenges shaping treatment center partnerships, and how manufacturers can address each one to build durable, scalable site relationships:

1 **Treatment Center Constraints**



2 **Operational Complexity and Workflow Burden**



3 **Financial Concerns and Reimbursement Exposure**



4 **Market Competition in Clinical Trials and Commercial Applications**



By proactively addressing these challenges, manufacturers can build stronger treatment center partnerships and establish more scalable clinical and commercial models for bringing CGTs to patients.

Challenge 1: Addressing Treatment Center Constraints

The Numbers:



- Industry pipeline trackers put thousands of CGT products in active development, and the global CGT market is forecast to grow at a roughly 24% CAGR from 2026 to 2035, reaching an estimated $232 billion. Competition for qualified treatment centers will only intensify because of this growth.[1]
- As of September 2026, more than 50 CGT products carry FDA approval and are being actively administered through treatment centers, each drawing on the same limited pool of qualified sites and personnel.[2]
- Beyond product-to-product competition, fixed physical constraints, including beds, ICU capacity, procedure slots, and trained staff, cap how fast any single center can realistically scale to take on a new therapy.

Closing the Gap:

- Forecast demand early, but keep the forecast flexible, so site resources are sized to real patient demand rather than a static launch-day estimate.
- Design the therapy's workflow around each center's existing practices rather than asking them to conform to yours; favor outpatient or hybrid administration models where clinically and operationally appropriate.
- Support center staff directly, rather than leaving them to absorb the extra work. Offer one accessible point of contact and training that's modular enough to fit around their existing workload.
- Keep the supporting technology simple and centralized, with a straightforward process for things like password resets, so it removes friction rather than adding to it.
- Build relationships with the center's stakeholders early and map out who will be involved across both the trial and commercial phases so the relationship carries through the transition.

Footnotes:
[1] Towards Healthcare, Cell and Gene Therapy Market Size to Hit US$232.22 Billion by 2035, Dec 2025.
[2] FDA, Approved Cellular and Gene Therapy Products.

Challenge 2: Operational Complexity and Workflow Burden

CGT administration involves many interconnected stakeholders, each with its own ordering, training, and reporting requirements, which creates redundancy and real risk of error at every handoff. For autologous products chain of identity (CoI) and chain of custody (CoC) tracking must guarantee that a patient's own cells return to that same patient, which demands rigorous documentation, labeling, and technology support throughout the process. Some allogeneic products also require similar rigor to ensure coordinated timely delivery.

Key process categories to align on:

Cell collection	**Order management process**
Shipping logistics	**Technology support**

Tracking platforms should be easy to use and, where possible, integrate directly into the treatment center's existing systems rather than requiring staff to learn a new one. Getting this right also means resolving, upfront, needed SOP changes and where the manufacturer and center will need to share ownership of the process. Wherever possible, the processes built for the clinical trial should transition cleanly to support commercialization rather than being rebuilt from scratch.

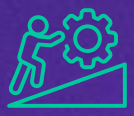
Reducing the Burden:

- Minimize add-on tests and process steps beyond what the center already does day to day. Every extra requirement is friction the center has to absorb.
- Solidify scheduling and cancellation policies early in the relationship, so there's a clear, agreed-upon process for handling delays that mitigates waste or potential product issues.
- Offer modular, role-specific training that survives staff turnover, backed by a dedicated troubleshooting contact so problems get resolved quickly rather than stalling the process.
- Connect treatment centers with their peers for shared learning, so lessons from one site's experience can carry over to the next.

By understanding the roles stakeholders play and engaging them early and throughout the partnership, manufacturers deliver a better patient and site experience while strengthening the product delivery process end to end.

Case Study: Designing an End-to-End Therapy Order Management Process

The Challenge



Pharma manufacturer launching its first autologous cell therapy product.

Being new to the cellular therapy space, there were no well-defined approaches or processes related to coordinating the order intake, payment process, and product delivery for a complex, individualized medicine.

- Lack of historical precedence within the organization
- Disparate cross-functional teams working in silos
- Differing development timelines associated with key components of the end process (e.g. distribution, manufacturing, IT, etc.)
- Unfamiliarity with the lift associated with creating needed order management platform (e.g. years vs. months)

The Goal



Leverage existing thinking across teams and combine with Nuvera's historical expertise in cellular therapy order management processes to capture, map, and facilitate cross-functional alignment on the end-to-end process for treatment centers to leverage an ultra-specialized therapy.

The Solutions



- Broad collection of all current thinking and process requirements
- Detailed mapping and alignment to an end-to-end process
- Roles & responsibility development and articulation of key enablers

The Results



Single Source of Reference

Created a strategic planning and alignment asset which carried through the entire process build effort



"While we had a lot of very smart people working on our order management process, we were having a difficult time coordinating across teams and aligning on an optimal approach – Nuvera was critical in helping us bring together our experts in developing a single source of truth relating to what we needed to do!"

Commercial VP, Cell and Gene Therapy Manufacturer

Challenge 3: Financial Risk & Reimbursement Exposure

Cell and gene therapies carry a significant cost burden, and where that burden lands shifts the moment a product moves from trial to commercial. During clinical trials, the manufacturer absorbs the cost of the therapy itself, so the treatment center's financial exposure is limited mainly to the operational side of administering it. Once a product reaches commercial approval, that dynamic changes. The center itself often becomes financially responsible for acquiring the therapy before it ever sees reimbursement.

Many centers operate on a "buy and bill" model, purchasing the treatment upfront, often $1 million or more per treatment, and then billing the patient's insurer after the fact. That upfront purchase ties up a substantial amount of working capital, and there's no guarantee the payer will approve the full amount without pushback, additional documentation requests, or an outright denial. Payment terms that lag 60 to 90 days post-billing compound the exposure, and a single delayed or denied claim is far harder for a center to absorb on a million-dollar therapy than it would be on a lower-cost one. For centers already weighing limited resources against competing priorities, this financial exposure can become the deciding factor in whether they take on a new CGT program at all, or how many patients they're willing to treat at once.

How Manufacturers Can Help:

Specialty pharmacy option: When the pharmacy bills the insurer directly, the center never has to carry that financial exposure in the first place.

Hands-on reimbursement support: Practical help with prior authorization, medical necessity documentation, and billing/coding guides makes the approval process far less burdensome for center staff.

Ongoing payer follow-up: Patient support programs can track down payer delays and keep individual cases moving instead of leaving the center to chase them alone.

Challenge 4: Market Competition in Clinical Trials and Commercial Applications

Established centers of excellence often run several trial and commercial programs at the same time, competing for the same limited staff, infrastructure, and even the same pool of patients. The bottleneck isn't just physical beds. It's the specialized resources every CGT program needs: apheresis suites, cell processing labs, trained infusion nursing, and pharmacy built for handling these products. Because only a relatively small number of centers have that full set of capabilities today, several manufacturers are often courting the exact same sites at the exact same time, and a center's calendar fills up fast.

Bringing a brand-new center online instead takes significant time to reach certification. Staff need to be trained on the specific handling and administration requirements of the therapy, workflows must be built and tested, and the center typically needs to run through the process before it's ready to treat a real patient, all of which adds months before a new site can start contributing. That means outreach must start well before the therapy is anywhere near launch, not after. Centers may lean toward favoring clinical trials over commercial launches in the meantime, since trial costs are covered by the manufacturer and the center gets more direct support, while commercial launch comes with the payer uncertainty and administrative burden described in the financial risk challenge above.

How to Compete Effectively:

- Design the trial process so it carries over cleanly into commercial launch, rather than requiring the center to relearn a new workflow later.
- Articulate the therapy's value beyond clinical differentiation. Show concretely how the workflow eases staff burden rather than adding to it.
- Engage sites early and invest in relationships that span the full arc from trial to commercial, not just the initial launch window.
- Demonstrate portfolio depth wherever possible; a center is far more likely to prioritize a manufacturer offering multiple products over a one-off engagement.





As treatment centers become more selective, access will increasingly favor manufacturers who reduce burden, de-risk participation, and operate as true partners. Winning in CGT commercialization will depend less on the number of activated sites and more on the depth, durability, and viability of site engagement.

As a leading partner to life science manufacturers, **Nuvera**, an **Inizio Engage HCP and Patient Experience Brand**, has successfully addressed the planning needs of emerging and large pharma in autologous and allogeneic therapies. From strategy to execution, Nuvera uniquely uncovers and diagnoses the most critical challenges an organization and its brand faces and then develops the strategies and operational know-how to build, maintain, and optimize them.

Building from environmental awareness, operational excellence, customer engagement and experience design methodologies, Nuvera works with its client partners to establish and operationalize plans that redefine launch success in CGT.

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