

CGT Commercialization Will Succeed Or Fail On Operational Readiness

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Kevin Land of Vitalant explains why logistics, decentralized collection networks, and scalable infrastructure are becoming the defining factors in bringing cell and gene therapies to more patients.



Cell and gene therapies have demonstrated remarkable clinical potential, but translating scientific breakthroughs into widespread patient access remains a complex operational challenge. As developers move from clinical trials to commercial scale, issues such as collection capacity, logistics, manufacturing coordination, and care delivery are emerging as critical determinants of success. **In this interview, Kevin Land, Executive Medical Director Biotherapies and Vice President of Clinical Services at Vitalant,** shares insights on why infrastructure planning must begin early in development and how lessons from the blood sector can help create a more scalable, reliable, and equitable future for advanced therapies.

Why do you believe logistics and infrastructure planning remain underestimated in CGT commercialization strategies?

Because the field grew up in academic research settings where the focus, appropriately, was on science and clinical outcomes. In that environment, a handful of patients could be managed through heroic individual effort. But commercial-scale therapy delivery is a systems problem, not a science problem.

When you move from treating 50 patients in a clinical trial to treating 5,000 across a country, the limiting factor is rarely the biology. It is whether you can collect the starting material, transport it under controlled conditions, manufacture on time, and deliver the finished product back to the clinical site before the patient's condition deteriorates. It is also about cohesive clinical and PI oversight. These are operational challenges that require operational expertise.

The blood services sector has been solving exactly this class of problem for decades. We collect 13.6 million units of whole blood annually in the United States alone, process and test every one of them, and deliver them to hospitals within tightly

controlled timeframes. Many already participate in multi-site, multi-state clinical trials with heavy data demands. That is the operational baseline CGT commercialization strategies need to account for.

What are some of the most common mistakes therapy developers make when designing vein-to-vein workflows?

The most common mistake is designing the workflow around the manufacturing process and treating collection and infusion as afterthoughts. In reality, the patient's clinical trajectory sets the timeline. A patient with aggressive disease cannot wait weeks for scheduling, collection, and shipping logistics to be sorted out. In hospitals, healthier patients get bumped for sicker patients when it comes to collection but cells from healthier patients performed better. This happens when demand outstrips capacity.

A second mistake is assuming that any hospital can collect a leukapheresis product. Collection requires trained apheresis staff, validated equipment, and a quality system that meets the sponsor's specifications. Many community hospitals do not have these resources, and the gap creates access disparities for patients outside major metropolitan areas. Or these resources are only for heme/onc patients and not for other conditions like autoimmune disease.

A third mistake is underinvesting in data systems and standardized formats of traceability, chain of identity, and chain of custody. They are the foundation of patient safety at scale. Developers who treat them as administrative details rather than clinical requirements will face problems at scale.

How early should manufacturing and care delivery considerations be integrated into therapy development programs?

From the beginning. By the time a product reaches Phase II trials, the collection method, processing specifications, transport requirements, and site capabilities should be well defined. Retrofitting these elements after the science is locked creates unnecessary risk and delay.

This is where blood centers can add value early. We understand the practical realities of collecting cellular starting materials from sick patients and healthy donors, maintaining product integrity during transport, and operating under the regulatory frameworks that govern these activities. Engaging with organizations that have this experience during protocol design, not after commercial launch, saves time, reduces variability, and ultimately gets therapies to patients faster.

The most forward-thinking developers we work with already do this. They involve collection and processing partners in their IND submissions and build site feasibility assessments into their trial design. That early collaboration pays dividends throughout the product lifecycle.

In your view, what role will decentralized collection and regional manufacturing models play in the next phase of CGT growth?

A central (sic) one. The current model, where patients travel to a small number of academic centers for collection and the product is shipped to a single manufacturing facility, works for small patient volumes. It does not work at scale, and it does not work equitably.

Decentralized collection brings leukapheresis and other starting material services closer to where patients live. Regional manufacturing reduces transport distances and turnaround times. Together, they create a more resilient system that is less vulnerable to capacity constraints at any single site.

Vitalant operates in 27 states with clinical apheresis capabilities distributed across the country using our hub and spoke model. That footprint is not something you can build overnight. It took decades of investment in facilities, people, and quality systems. As CGT volumes grow, organizations with established distributed networks will be essential to keeping pace with demand and ensuring that patients in rural and underserved areas have the same access to these therapies as patients coast to coast, border to boarder.

How can the blood sector's operational experience help reduce cost, variability, and delivery delays in advanced therapies?

Cost, variability, and delay are all symptoms of the same underlying problem: a lack of standardized, scalable infrastructure.

The blood sector addressed this decades ago by building national networks with standardized collection

procedures, validated cold chain logistics, and rigorous quality systems. We did not eliminate variability by relying on individual expertise. We reduced it through process discipline, training, and continuous improvement across hundreds of sites.

That same approach applies directly to CGT. When collection protocols are standardized, patients are collected early in their disease course, product quality becomes more consistent, and manufacturing failure rates decline. When transport logistics are managed by organizations with established cold chain networks, delivery delays decrease. When quality systems are already in place and regularly inspected, the cost of compliance goes down.

None of these are theoretical. These are operational realities that blood centers manage every day. The opportunity for the CGT field is not to reinvent these systems but to leverage them.