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Designing an enterprise operating model for cell and gene therapy

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EXECUTIVE SUMMARY

Cell and gene therapy (CGT) is entering a new phase of growth. Advances in therapeutic technology, manufacturing, and precision medicine are expanding the potential role of CGT beyond its earliest clinical applications. While Bone Marrow Transplant (BMT), cellular therapy, malignant hematology, and oncology programs provided the natural foundation for early CGT delivery, the next wave of therapies is expected to reach a broader range of diseases, specialties, care settings, and patient populations.

That evolution demands a strategic answer: health systems must determine now whether their operating model can support CGT safely, consistently, and sustainably as therapies move beyond the departments and infrastructure where they first developed. Traditional disease-specific models often worked well when CGT volume was limited and concentrated in oncology and transplant programs. As CGT expands, however, fragmented models can lead to duplicated workflows, inconsistent patient access, unclear accountability, avoidable delays, and uneven financial visibility.

Vizient's work with health systems across the CGT landscape — from early-stage programs to mature enterprise platforms — reveals a consistent pattern: organizations that design their operating model deliberately, rather than by default, deliver safer care, protect margin, and scale faster. This paper translates those insights into a practical framework leaders can act on now.

The purpose of this paper is to review common CGT operating models and equip health system leaders to identify which approach best aligns with their organization's current capabilities, strategic goals, patient population, and anticipated growth. Decentralized, hybrid or federated, and centralized models can each be effective when designed intentionally. The advantages and limitations of each model depend on factors such as program maturity, therapy volume, specialty participation, infrastructure, financial risk, governance needs, and executive alignment. The best practice principle is not that every organization should adopt the same structure, but that the chosen model should be deliberate, aligned to the patient and cell or product journeys, and supported by the capabilities required for safe, sustainable growth.

A scalable CGT operating model requires five core capabilities: a multidisciplinary care model, early financial risk and margin management, standardized infrastructure and operating procedures, clear acute-phase ownership, and enterprise governance tied to growth planning. When these capabilities are designed deliberately, health systems can build on the expertise of BMT, cellular therapy, and oncology programs while creating the infrastructure needed to support future CGT expansion across additional diseases, specialties, and care settings.

WHY CGT DELIVERY REQURIES REEVALUATION NOW

CGT is no longer a narrow area of innovation limited to a small number of highly specialized indications. The field now includes approved therapies, a rapidly expanding clinical pipeline, and ongoing research across a broader range of diseases. As new therapies continue to emerge, health systems are being asked to support not only greater volume, but also greater diversity in modalities, disease states, care settings, and operational requirements.

This evolution matters because CGT is not operationally equivalent to most other specialty therapeutics. These therapies often require close coordination across physicians, advanced practice providers, nursing, pharmacy, laboratory services, apheresis, finance and revenue cycle, managed care, informatics, quality, legal, regulatory, and patient-support functions. Some therapies involve months of planning, patient screening, procurement logistics, and monitoring. Others require specialized product handling, manufacturer coordination, site-of-care decisions, or long-term follow-up obligations.

The effect is cumulative: each new therapy introduces its own level of complexity, but the entire portfolio creates a much broader need for durable infrastructure, shared processes, and enterprise-wide coordination. New products drive organizations toward more distributed clinical workflows — connected to a centralized CGT core or shared operating infrastructure.

Just as importantly, the challenge is not limited to the therapies being delivered today. The near-term pipeline suggests continued expansion in approved indications, earlier-line use cases, and eligible patient populations across both malignant and non-malignant diseases. As therapies move beyond highly specialized academic environments and into broader clinical

practice, many organizations are likely to see patient demand increase over a relatively short period of time. Health systems that delay operational planning will become reactive. Patient volumes, manufacturer requirements, and infrastructure demands are accelerating simultaneously — and the window to prepare is closing.

The way most organizations are structured helps explain why this issue has become so pressing. Large health systems often organize care through service lines, in which specialties such as oncology, orthopedics, pediatrics, cardiology, or neurology manage much of their clinical, operational, and financial activity within their own domains. Other functions, such as radiology, laboratory services, pharmacy, revenue cycle, and information technology operate more broadly across the enterprise. As **Figure 1** illustrates, CGT sits between these two models. It may originate within a single specialty, but successful delivery depends on coordinated support from enterprise-wide functions, often across multiple settings of care. That makes CGT fundamentally different from a therapy that can be fully absorbed within the boundaries of one department or one traditional service line.

Figure 1. CGT sits at the intersection of specialty-based clinical ownership and enterprise-wide support functions

From BMT and oncology roots to enterprise CGT structure

In many organizations, CGT developed in exactly the right place: within BMT, cellular therapy, malignant hematology, and oncology programs. Those teams already had experience with high-acuity patient monitoring, complex care coordination, specialized laboratory and pharmacy workflows, and the clinical infrastructure needed to manage intensive cellular therapies.

When the first wave of commercial CGT entered routine practice, therapies focused primarily on oncologic diseases. BMT programs typically live within larger oncology service lines and have the deepest experience with highly specialized therapies, established relationships with laboratory and apheresis teams, and the strongest operational foundation for managing complex, high-touch care. Extending that foundation into early commercial CGT was both practical and efficient.

Organizations with strong transplant and autologous cell therapy foundations often had a substantial head start compared with institutions building CGT capabilities more recently. They were already accustomed to coordinating patient evaluation, collection, cell processing, infusion, toxicity management, and follow-up. They also had clinical teams familiar with managing patients through high-risk treatment episodes and multidisciplinary infrastructure that could be adapted for commercial therapy delivery.

The challenge is that the field has not remained within those clinical boundaries. Today, prescriber interest in CGT may emerge in specialties that have little or no historic exposure to cell therapy operations. A specialty team may know it wants to offer a therapy but still lack established processes for storage and handling, reimbursement strategy, manufacturer engagement, scheduling, monitoring, documentation, and patient-flow design. In those settings, the organization is no longer

solving only a specialty-specific problem. It confronts a broader operating-model question that reaches across functions, departments, and cost centers.

The next stage of CGT maturity should build on the expertise developed by existing programs rather than displace it. The strategic question is how to leverage that expertise across a broader enterprise model so that new specialties can access established infrastructure, governance, and operational support without recreating the same capabilities independently.

Following the patient and product journeys

A useful way to evaluate CGT infrastructure is to follow both the patient journey and the cell or product journey. The patient journey spans referral, evaluation, financial clearance, pretreatment planning, treatment, toxicity monitoring, follow-up, and transition back to longitudinal disease management. The cell or product journey may include ordering, collection, manufacturing coordination, procurement, chain-of-identity and chain-of-custody requirements, storage, release, administration, tracking, and post-treatment reporting.

Fragmentation becomes problematic when no single model has visibility across both journeys. A patient may move between a referring specialty, a treatment program, an infusion area, inpatient services, financial navigation, pharmacy, laboratory services, and follow-up care. At the same time, the product may move through manufacturer requirements, procurement processes, storage conditions, chain-of-custody documentation, and administration workflows. If those activities are not coordinated through a clear operating model, the health system may rely on local workarounds, informal relationships, or individual expertise rather than durable system design.

Organizing around these journeys also helps leaders distinguish clinical ownership from operating-model ownership. Disease-specific teams should remain central to diagnosis, treatment selection, longitudinal management, and specialty-specific expertise. However, many CGT capabilities repeat across therapies and disease states. These include therapy onboarding, benefits verification, payer strategy, product handling, apheresis or cell-processing coordination, toxicity readiness, patient navigation, quality reporting, and implementation planning. The more consistently these repeatable capabilities are designed, the easier it becomes to support growth across specialties.

When the operating model is working well, patients experience coordination rather than fragmentation. Clinical teams know where accountability sits during each phase of care. Operational teams understand when and how they are engaged. Financial stakeholders have earlier visibility into payer and reimbursement risk. Leaders can evaluate growth not as a series of isolated therapy launches, but as a portfolio requiring shared infrastructure and planned investment.

When disease-specific models become fragmented

Most fragmented CGT models did not arise from poor decisions. In many cases, they reflect thoughtful, pragmatic choices made by teams responding quickly to new therapies with the resources, expertise, and structures already in place. That is how many mature programs begin. Health systems built from where capability already existed, often within oncology, hematology, and blood and marrow transplantation (BMT) programs. As new therapies became available, those teams adapted existing workflows, staffing models, and support structures, while supporting departments contributed where needed to create a workable path to treatment. When the field was narrower and concentrated in a limited number of disease areas, that approach was both practical and effective. It leveraged established expertise, avoided unnecessary restructuring, and allowed organizations to respond to early commercial demand without building an entirely new model from the ground up. The challenge is recognizing when those same structures begin to constrain future growth.

Over time, however, what begins as adaptation can become duplication. Disease-specific clinics may build parallel processes for prior authorization, patient education, toxicity readiness, care coordination, manufacturer engagement, and patient follow-up. In many organizations, that evolution also leads to similar operational, financial, navigation, and coordination roles being developed across multiple service lines, with each team solving many of the same problems independently.

These structures, however well-intentioned, increase administrative cost, create ambiguity in roles and responsibilities, and make it harder to scale efficiently as therapy volume grows. Financial clearance may vary by specialty or care setting. Pharmacy and operational partners may be engaged later than they should be. Responsibility can shift depending on where the patient is in the journey, leaving no single team accountable for the full picture from referral through acute recovery and transition back to disease-specific care. These conditions do not always prevent care delivery, but they create friction that becomes harder to manage as more therapies and more specialties enter the field.

In established disease areas, fragmentation often appears as inconsistency rather than outright dysfunction. Two programs may be treating clinically similar patients with very different levels of coordinator support, different financial workflows, or different expectations for handoffs and follow-up. The experience for staff can vary just as much as the experience for patients. One team may feel highly supported, while another may be relying on partial effort from already stretched personnel. The organization may appear functional on the surface, but beneath that surface many of the same operational problems are being solved repeatedly in different ways.

Over time, this can also reinforce dependence on a small number of highly experienced individuals to move best practices forward. Those individuals may know how to navigate manufacturer requirements, payer issues, cell-processing logistics, patient flow, and internal escalation pathways. However, if the model depends too heavily on individual expertise, the organization remains vulnerable to turnover, growth pressure, and inconsistent execution across programs.

In newer clinical areas, the limitations of fragmentation become even more apparent. A specialty launching its first commercial CGT may struggle with fundamental implementation questions: how care should be coordinated, how the high-cost drug process should be navigated, who owns site-of-care decisions, how workflows should be built, how reimbursement and legal pathways should be managed, and what infrastructure must be in place before the first patient is treated.

Without a broader operating model, the team typically has two choices. It can attempt to build the infrastructure from scratch, or it can rely informally on support from an existing CGT-capable group such as BMT, cellular therapy, or oncology. Either approach may work in the short term. Neither represents an efficient or sustainable long-term strategy for a growing enterprise portfolio.

The cumulative effect of fragmentation is not always dramatic, but it is consequential. It shows up in repeated work, inconsistent processes, avoidable delays, diffuse accountability, limited financial visibility, and increasing dependence on informal relationships to move patients through care. As the CGT landscape continues to expand, these limitations become harder to absorb within traditional disease-specific structures alone.

The goal, therefore, is not necessarily to remove specialty ownership. The goal is to determine which capabilities should remain close to the disease-specific team and which should be standardized, shared, or governed at the enterprise level.

EVALUATING CGT AS AN ENTERPRISE OPERATING MODEL

The most useful shift in perspective is to stop viewing CGT solely as a departmental or product-level issue and start evaluating it as an enterprise operating model. In this paper, the term CGT operating model refers to the way a health system organizes the clinical, operational, financial, governance, and support capabilities required to deliver CGT. This may or may not take the form of a formal service line or center.

This does not mean every therapy requires identical workflows, nor does it mean every organization must establish a standalone center. It does mean that leaders should assess where the core work of CGT repeats across specialties and therapies and where shared infrastructure would reduce both friction and risk.

Thinking in operating-model terms changes the questions leaders ask. Instead of asking only whether a therapy can be onboarded, the organization begins asking whether it has a reusable approach to intake, readiness review, financial clearance, patient coordination, acute-phase ownership, and quality oversight. Instead of allowing ownership to remain wherever it historically sat, leaders can ask whether the current model aligns with the patient and product journeys or whether it reflects a collection of legacy departmental boundaries.

Common repeatable functions for leaders to assess

- Referral intake and triage
- Therapy onboarding and readiness review
- Benefits verification and prior authorization
- Payer contracting and single-case agreements
- Product procurement, storage, and handling
- Chain-of-identity and chain-of-custody processes
- Apheresis and cell-processing coordination, when applicable
- Site-of-care decision-making
- Patient navigation and education
- Toxicity management readiness
- Inpatient and outpatient care transitions
- Quality reporting and outcomes tracking
- Long-term follow-up obligations
- Financial reporting and margin visibility

This enterprise framing also enables health systems to build on what has already worked. Many of the strongest CGT capabilities in the market were built through oncology, transplant, and cellular therapy programs. Those foundations should not be discarded. They should be leveraged. The question is how to take the expertise, workflows, and specialized labor that were developed in those areas and create a model capable of supporting therapies wherever they emerge across the health system.

The practical value of the enterprise model is especially clear when a new therapy appears in a nontraditional specialty. In a more coordinated model, the prescribing team does not have to begin from zero. Site-of-care questions, toxicity management principles, storage and handling requirements, coordination workflows, legal agreements, contracting needs, payer pathways, and financial inputs can all be mapped with support from experienced stakeholders who have already solved similar problems elsewhere in the system. That shifts the burden away from individual prescriber teams and toward a broader organizational capability.

COMPARING DECENTRALIZED, HYBRID, AND CENTRALIZED DESIGNS

No single operating-model design is right for every health system. Organizational structure should reflect community needs, institutional culture, leadership alignment, physical infrastructure, payer environment, clinical ambition, and the organization's broader ambition for CGT. Some health systems may be focused primarily on the reliable delivery of approved therapies. Others may already operate within a highly specialized service model, such as a cancer-focused enterprise. Still others may be considering a broader platform that includes clinical trials, manufacturing, translational science, or expansion into additional specialties and care settings. The right design depends, in part, on what the organization is trying to become.

A **decentralized design** typically allows functions and specialties to retain historical ownership. This often makes implementation easier in the short term. Departments can move quickly within familiar structures, local decision-making is preserved, and less immediate organizational change is required. The limitation is that decentralized models may perpetuate fragmented access, repeated workflows, inconsistent communication, and weaker enterprise-wide visibility into the full patient journey and financial picture. These constraints become more pronounced as more therapies and more specialties enter the field. Decentralized models work in lower-volume or early-stage programs — when strong communication, clear standards, and committed cross-functional collaboration are in place.

A **hybrid or federated design** creates some centralized control while preserving localized ownership in selected areas. For many organizations, this can be a practical intermediate state. It allows certain capabilities — such as governance, financial planning, onboarding review, quality oversight, or operational readiness assessment — to become more coordinated without immediately moving every related function into one entity. Hybrid models can improve growth planning and bring greater structure to a fragmented environment, but they do not eliminate complexity. Depending on what remains distributed, they may still leave leaders managing diffuse accountability and uneven operational maturity across the portfolio. Many current CGT programs operate in some version of a hybrid or federated model.

A **centralized or integrated CGT platform** places core capabilities under a single integrated operating model or distinct CGT entity. The potential advantages are substantial: more standardized patient access, clearer ownership, streamlined internal communication, stronger patient centricity, and better ability to scale as therapies and volumes grow. The tradeoff is that centralization requires more deliberate change management, stronger executive sponsorship, and more thoughtful handling of budgets, cost centers, reporting structures, resource allocation, and stakeholder trust. Centralization may offer the clearest route to long-term scalability for some organizations, but it also requires the greatest near-term investment in organizational alignment.

It is helpful to view these models as points along a maturity spectrum, not fixed categories. Some organizations may remain decentralized by design. Others may evolve over time, strengthening governance first, centralizing selected functions next, and formalizing a broader CGT platform only when growth and complexity justify it. The more important question is not which model sounds best in theory, but which model best aligns with the organization's current realities and future direction.

Table 1. Comparing CGT operating-model designs

Design	Best fit	Defining characteristics	Strengths	Risks to manage
Decentralized	Early-stage or lower-volume programs with strong informal collaboration and limited near-term CGT expansion	Functions remain within historical service lines and departments.	Easier to launch initially; preserves specialty autonomy; aligns with legacy structures.	Duplicated workflows, fragmented access, weaker enterprise visibility, inconsistent communication, and greater difficulty scaling over time.
Hybrid / federated	Growing programs with multiple specialties, multiple care settings, or increasing need for shared governance	Selected capabilities are centralized while others remain in historical homes.	Improves planning and coordination while preserving some local ownership.	Accountability may still be diffuse; complexity remains if too many capabilities stay fragmented or standards are inconsistently applied.
Centralized / integrated platform	Mature or high-growth programs with broad CGT strategy, expanding portfolio, and need for scalable enterprise infrastructure	Core capabilities are organized through a single integrated model or distinct CGT entity, with dedicated CGT-specific resourcing.	Clearer ownership, more standardized patient journey, stronger patient centricity, and greater ability to scale.	Requires more change management, executive sponsorship, deliberate resource alignment, budget clarity, and stakeholder trust.

CORE CAPABILITIES AND FUNCTIONS REQUIRED FOR SCALE

Regardless of organizational structure, scalable CGT models tend to rely on a consistent set of core capabilities. The first capability is a truly **multidisciplinary care model**, ideally supported by leaders with direct CGT experience. In lower-volume environments, a single individual may be responsible for more than one function. Even so, the underlying capabilities still need to be present: clinical leadership, coordination, pharmacy support, nursing expertise, financial navigation, laboratory and apheresis integration, quality oversight, and an established operational cadence.

Programs that treat CGT as a team-based capability — not a series of isolated consults — build expertise faster, reduce variation, and sustain growth. More mature models also tend to include dedicated operational leadership with deep CGT subject matter expertise — or direct access to that expertise — to help coordinate across clinical, financial, and administrative functions as the program grows. In practice, this kind of leadership becomes the connective tissue between strategy and execution, ensuring that decisions about infrastructure, staffing, readiness, and patient flow are informed by both operational realities and the unique demands of CGT.

The second capability is **financial risk and margin protection**. CGT programs often win or lose financially long before billing occurs. Early benefits verification, prior authorization, payer-specific pathways, site-of-care optimization, denial prevention, and length-of-stay management all shape whether therapy can proceed efficiently and whether the organization can protect margin over time. In more fragmented environments, these activities may be distributed unevenly across departments or engaged too late in the process. More mature models bring financial review closer to referral and treat reimbursement strategy as a core operating function rather than a downstream administrative step.

The third capability is **standardized infrastructure**. Pharmacy operations, risk evaluation and mitigation strategy (REMS) processes, storage and chain-of-identity requirements, chain-of-custody documentation, apheresis and cell-processing coordination, clinical pathways, and business functions such as contracts and single-case agreements are not one-time issues. They recur across therapies. Organizations that repeatedly rebuild these capabilities by specialty absorb unnecessary cost and complexity. Organizations that standardize them where appropriate create a much stronger foundation for scale.

The fourth capability is **clear ownership of the acute phase**. During evaluation, treatment planning, infusion, toxicity management, and early monitoring, explicit accountability matters. A model that clearly defines who owns the patient during the highest-risk period — and how care transitions back to the referring team — is more resilient than one that depends on informal understanding. This principle becomes even more important as therapies move into specialties that may be less familiar with CGT, where the risk of handoff gaps is higher.

The fifth capability is **enterprise governance and growth planning**. Steering structures, onboarding pathways, and regular multidisciplinary operational cadence create a forum for aligning stakeholders before a therapy goes live. This distinction is critical: approving a therapy for use is not the same as being operationally ready to deliver it. Formulary review can establish clinical appropriateness and address some financial implications, but operational readiness requires additional work. Labor, scheduling, infrastructure, quality review, contracting, payer pathways, patient-flow design, and ownership must all be addressed explicitly rather than assumed.

More mature models also connect governance to longer-range planning, including labor, capital, and resource allocation, so that growth can be supported intentionally rather than reactively.

Table 3. Five core capabilities of a scalable CGT operating model

Core capability	Why it matters	Representative functions
Multidisciplinary care model	CGT depends on coordinated expertise rather than ad hoc consultation.	Physicians and APPs, coordinators, pharmacists, nursing, financial navigators, laboratory and apheresis integration, recurring operational meetings
Financial risk and margin protection	Programs often win or lose financially long before billing occurs.	Benefits verification, prior authorization, payer pathways, site-of-care optimization, denial prevention, length-of-stay management, margin visibility
Standardized infrastructure and operating procedures	Rebuilding the same workflows therapy by therapy creates friction and inconsistency.	REMS processes, storage and chain-of-identity, chain-of-custody, cell-processing coordination, regulatory readiness, clinical pathways, contracts, single-case agreements
Acute-phase ownership and patient-flow design	The highest-risk segment of care requires explicit accountability and coordinated handoffs.	Evaluation, treatment planning, infusion, acute toxicity management, monitoring milestones, escalation pathways, transition back to the referring team
Enterprise governance and growth planning	Scale requires a mechanism to review readiness, align stakeholders, and plan labor and capital.	Steering committee structure, onboarding workflow, resourcing plans, outcomes tracking, financial reporting, prioritization, implementation readiness review

These capabilities require participation from a broader group of stakeholders than many organizations initially expect. Representative stakeholders in CGT operating-model design may include the following groups.

Table 2. Representative stakeholders in CGT operating-model design

Stakeholder group	Representative roles
Clinical leadership	Practicing physicians, physician leaders, advanced practice providers, disease-specific program leaders
Pharmacy	Pharmacy leaders, clinical pharmacists, specialty pharmacy teams, medication-use support teams
Nursing and patient coordination	Nurse leaders, patient coordinators, navigators, social work, case management
Laboratory support	Laboratory, cellular therapy lab, cell processing, blood bank, and apheresis teams
Quality and regulatory	Quality, regulatory, data management, clinical process improvement
Financial support	Finance, revenue cycle, payer strategy, managed care contracting teams
Operational support	Legal, compliance, informatics, analytics, cybersecurity, strategic planning, operations leaders

FINANCIAL AND GOVERNANCE IMPLICATIONS OF OPERATING MODEL CHOICE

CGT operating-model design is inseparable from financial design. Financial design is often where the limitations of fragmented CGT models become most visible. One of the most important lessons from more mature programs is that organizations need to evaluate the economics of CGT holistically rather than through isolated departmental silos. Apheresis, laboratory services, infusion capacity, inpatient support, pharmacy, revenue cycle, managed care, and ancillary operations all contribute to the total impact of the program.

If each function is evaluated only within its own cost center, the organization underestimates the broader value the service line creates — and underinvests in the very capabilities that enable growth. Holistic financial evaluation does not require every cost to be moved into a single budget. It does require leaders to understand how decisions made in one part of the journey affect revenue capture, denial risk, inpatient utilization, ancillary revenue, labor needs, and overall contribution margin across the full episode of care.

That is why the phrase “revenue cycle starts at referral” is so useful in this context. Early benefits verification, prior authorization, payer-specific pathways, site-of-care optimization, single-case agreement needs, denial prevention, and patient financial counseling are not downstream administrative tasks. They are foundational operating functions that shape whether therapy can proceed efficiently and whether the organization can protect margin over time. In many fragmented environments, these processes are owned unevenly or engaged too late. A more mature operating model brings financial review closer to the beginning of the patient journey.

Governance helps connect those pieces. A steering committee or similar cross-functional structure aligns clinical, operational, and financial stakeholders around readiness, accountability, timelines, and resource needs — before launch. In decentralized organizations, governance may function as the bridge across formal reporting lines. In more centralized organizations, it may serve as the mechanism for prioritization and portfolio oversight. In either case, governance gives the organization a way to assess not only whether a therapy is desirable, but whether it is supportable.

Governance should also create a clear distinction between therapy approval and implementation readiness. Clinical review, formulary approval, and contracting decisions are necessary but insufficient. Leaders also need to understand whether the organization has the staff, scheduling pathways, care setting, product-handling procedures, revenue cycle workflows, toxicity management plans, documentation tools, and quality reporting processes required to deliver the therapy safely and sustainably.

Longer-range labor planning is another financial and governance issue that should not be overlooked. If the organization waits until bottlenecks become acute, staffing decisions will remain reactive. More mature models increasingly pair growth projections with tiered labor planning, volume modeling, and dedicated resourcing. This does not require every institution to use identical staffing ratios. It does require acknowledging that scalability depends on dedicated expertise and that labor should be treated as part of the growth strategy rather than simply a response to operational strain.

A PRACTICAL ROADMAP FOR CGT OPERATING MODEL DESIGN

For leaders beginning this work, the first question should not be whether the organization needs a distinct center. The more useful starting point is to ask what problem the organization is actually trying to solve. Is the primary challenge duplication within existing BMT, cellular therapy, or oncology pathways? Is it preparing the organization to support new specialties entering CGT for the first time? Is it better alignment across commercial delivery, clinical trials, laboratory functions, and supporting operations? Or is it the need for a broader strategic platform that can scale over multiple years?

The design decision becomes much clearer once the organization defines the problem with precision and begins to map a practical path from current state to future state.

1. Assess current and future demand

Leaders should begin by evaluating current and anticipated patient demand, approved therapy volume, clinical trial activity, specialty interest, therapy pipeline, physical space, outpatient footprint, inpatient capacity, and operational constraints across the organization. This assessment should include both existing CGT activity and emerging areas where CGT may become relevant over the next three to five years.

Demand planning should also account for the organization's referral patterns, payer mix, regional market position, manufacturer relationships, and potential site-of-care implications. The goal is to understand not only what the organization is delivering today, but what it may be asked to support next.

2. Define the strategic ambition

The next step is to clarify what role CGT should play in the organization's broader strategy. Some organizations may seek reliable access to approved therapies for their existing patient population. Others may pursue regional growth, clinical trial expansion, earlier-line treatment access, pediatric-adult integration, manufacturing partnerships, translational science, or broader platform development.

Different ambitions require different levels of infrastructure. An organization focused on selective delivery of approved therapies may not need the same model as one seeking to become a regional referral destination or a comprehensive advanced therapeutics platform. The operating model should reflect the organization's desired future state rather than simply its historical structure.

3. Map the patient and product journeys

Leaders should map how patients and products currently move through the system. This includes referral intake, eligibility assessment, financial clearance, payer authorization, pretreatment planning, product ordering or collection, manufacturing or procurement logistics, storage and handling, infusion or administration, acute monitoring, toxicity management, transition back to disease-specific care, and long-term follow-up.

This exercise often reveals where duplication, bottlenecks, unclear ownership, and financial risk occur. It also helps distinguish between work that must remain specialty-specific and work that could be standardized, shared, or governed at the enterprise level.

4. Identify capability and governance gaps

Once the current state is mapped, leaders can compare it with the capabilities required for scale. This includes multidisciplinary coordination, financial clearance, payer strategy, standardized infrastructure, pharmacy and laboratory readiness, acute-phase ownership, quality oversight, operational readiness review, and growth planning.

This step should also evaluate whether existing governance structures are sufficient. A health system may have strong clinical review processes but limited mechanisms for assessing operational readiness. It may have committed clinical champions but no clear process for prioritizing labor, capital, scheduling, contracting, or data needs. Identifying those gaps allows the organization to strengthen the model before growth pressure becomes unmanageable.

5. Select and phase the operating model

After assessing demand, ambition, journeys, and capability gaps, leaders can determine whether a decentralized, hybrid, or more centralized design is most appropriate. The output should not be limited to an organizational chart. It should include a staged operating plan that defines governance, labor, infrastructure, financial visibility, stakeholder alignment, and therapy implementation readiness.

For many organizations, the right answer may be phased evolution: strengthening governance first, centralizing selected functions next, and formalizing a broader CGT platform only when scale and complexity justify it. The key is to ensure that the model is intentional rather than accidental.

Cultural and change management considerations

Operating-model decisions are never just structural — they are deeply cultural. We know that asking teams to rethink long-standing ownership, resources, and accountability can feel like a loss of control rather than a path forward. A more coordinated CGT model may require teams to rethink long-standing assumptions about ownership, resources, and accountability. In some settings, the challenge is not whether a centralized or hybrid model could work operationally, but whether the organization is prepared to build trust across specialties and support functions.

That makes change management, stakeholder engagement, and early demonstration of value just as important as the formal design itself. Leaders should clearly articulate what the model is intended to solve, what will remain with specialty teams, what will be shared, and how success will be measured. Without that clarity, even a well-designed structure may be perceived as disruptive or as a loss of local control.

The strongest models continue returning to the patient and product journeys. Patient centricity is not a separate design principle. It is one of the clearest measures of whether the operating model is working. When the system is organized well, the patient experiences coordination rather than fragmentation, and the care team experiences structure rather than repeated reinvention.

CONCLUSION

Cell and gene therapy has reached a stage where health systems can no longer rely on legacy departmental structures alone. The programs best positioned for growth are not necessarily those with a single design, but those that have intentionally aligned CGT governance, infrastructure, financial accountability, and patient-flow ownership to the realities of a growing therapeutic portfolio.

For many institutions, the foundation built by BMT, cellular therapy, malignant hematology, and oncology programs remains a major strength. The next challenge is to determine how that expertise can support a broader set of therapies, specialties, and care settings without requiring each team to recreate the same infrastructure independently. Some organizations will strengthen a decentralized model. Others will require a hybrid or federated structure. Still others may benefit from a centralized CGT service line or integrated enterprise platform.

For organizations earlier in their CGT journey, particularly those building a program without an established BMT or cellular therapy foundation, progress may also depend on learning from peer institutions, established treatment centers, and experienced external partners. The complexity is real — and Vizient's expertise, data, and cross-health-system network mean it does not have to be navigated alone. We bring the operational intelligence, benchmarks, and implementation experience to accelerate the path from current state to a scalable CGT enterprise.

The fundamental question is not simply how to deliver the next therapy. It is how to build a model that can support many therapies, many specialties, and many future decisions while maintaining safety, consistency, financial sustainability, and patient-centered care. When done well, CGT operating-model design creates clearer accountability for teams, a more coordinated experience for patients, and a stronger foundation for sustainable innovation across the health system.

KEY TAKEAWAYS

Treat CGT as an enterprise capability, not a single-therapy issue.
As therapies expand beyond traditional BMT, cellular therapy, and oncology settings, health systems need operating models that can support growth across specialties, sites of care, and patient populations.

Start with the patient and product journeys.
Operating-model design should account for referral, authorization, treatment planning, product handling, administration, acute monitoring, follow-up, and handoffs back to disease-specific care.

Scalability requires shared infrastructure and clear ownership.
Organizations are better positioned for growth when they standardize recurring functions, clarify acute-phase accountability, and reduce duplications across service lines.

Financial performance should be evaluated across the full episode of care.
CGT economics are distributed across departments and cost centers. Leaders need visibility across the entire service line to understand value, protect margin, and allocate resources effectively.

Governance should distinguish therapy approval from implementation readiness.
Clinical appropriateness alone does not ensure operational readiness. Mature models assess labor, infrastructure, contracting, financial clearance, quality oversight, and supporting capabilities before launch.

There is no single correct design, but there should be an intentional one.
Decentralized, hybrid/federated, and centralized models can all be viable. The critical question is whether the model has been deliberately designed to support the future state of CGT strategy.

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