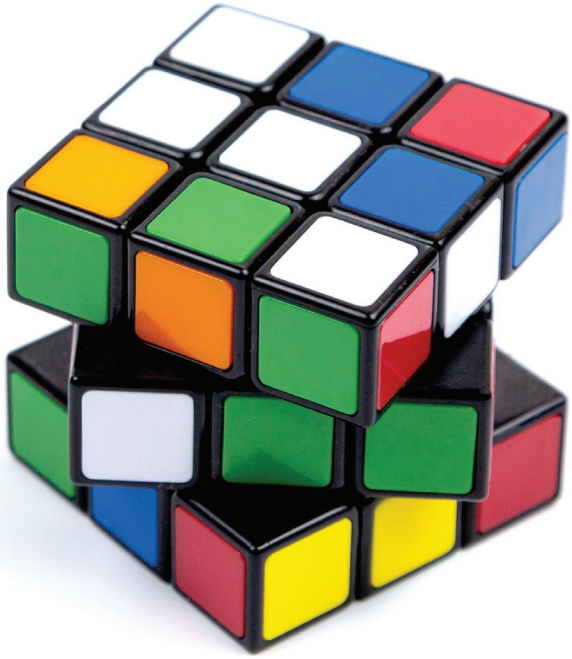
BlueSquared™

CGT is Getting More Complex

Digital Operations Are Struggling to Keep Up

A BlueSquared thesis brief on why the 2017 playbook no longer fits the 2026 portfolio



1 The Ground Has Shifted

When Novartis received the first commercial CAR-T approval in August 2017, the operational problem was bounded. One therapy. One modality. One linear patient pathway. The orchestration platforms, site onboarding workflows, and governance routines designed in that era made sense in that era. They were built to coordinate a single process from apheresis to infusion.

The 2026 portfolio is not that portfolio. **A single sponsor now runs autologous and allogeneic programs in parallel, and the portfolio a team must serve next quarter is not the portfolio it serves today.** Two kinds of complexity now compound on the same operations team. Portfolio complexity, which is a wider, more volatile mix of therapies. Operational complexity, which is everything required to run them in parallel without dropping a patient. Trial readouts reshape priorities inside a week. New modalities enter active coordination while the previous one is still stabilizing.

The digital operating model inherited from 2017 was not designed for either dimension. It was designed for one therapy at a time.

Cell & Gene Therapy at a Glance

1 → 7

annual FDA CGT approvals in 2017 vs. 2024. The portfolio the industry now has to operate.

FDA CBER approval history; ISCT, Jan 2025

45

FDA-approved cellular and gene therapy products in commercial distribution.

FDA CBER, 2025

18

additional CGT products under FDA review or expected to file in 2025.

Alliance for Regenerative Medicine, 2025

6

distinct CGT modality categories now in active commercial coordination. Autologous, allogeneic, gene-edited, in vivo, TIL, engineered TCR.

FDA CBER approved-products register, 2025

Sources. 1. FDA CBER approval history, fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products. ISCT TelegraftHub, Jan 2025, isctglobal.org/telegrafthub. 2. FDA CBER, Approved Cellular and Gene Therapy Products, 2025. 3. Alliance for Regenerative Medicine, 2025 Sector Snapshot, alliancerm.org/sector-snapshots.

2 Why the Legacy Delivery Model Breaks at this Tier

The systems most operators are running were specified against a portfolio that no longer exists. They were scoped for a single therapy, funded on the assumption that the next therapy would look broadly similar, and implemented in a window when the industry still believed orchestration was a one-time build.

None of those assumptions survived contact with the 2026 portfolio. The therapies diverged. The modalities multiplied. The build never finished. What launched as infrastructure now functions as a ceiling on operational capacity.

Portal Sprawl

Each new program bolts on its own portal. Every credential set, every data model, every assumption about where the source of truth lives is slightly different, and the clinical team carries the reconciliation cost.

Calcified capability investments

Infrastructure was locked in before the portfolio stabilized. The portfolio never stabilized. The infrastructure cannot be unlocked without a multi-year re-platforming cycle the program cannot afford.

Pivot-Blind Governance

Governance assumes a stable build plan. Trial readouts pivot the portfolio in days. The governance layer cannot move at that pace, so the program stalls. Releases hold. Slot allocation freezes. Operations absorbs nothing. Someone has to hit the brake while the team rebuilds the plan in a Slack channel and a parallel spreadsheet.

The legacy delivery model is not wrong. It is out of date.

3 What the 2017 Playbook Cannot Absorb

The gap between the 2017 operating model and the 2026 portfolio is not a maturity-level delta to be closed with more training. It is a structural mismatch between what the systems were scoped to handle and what the portfolio now demands of them.

Three shifts describe the distance, and each one breaks a different assumption the 2017 playbook was built on.

	2017	2026
Modality scope	One therapy at a time. Autologous CAR-T for B-cell malignancies. A single operational pattern, replicated.One therapy at a time. Autologous CAR-T for B-cell malignancies. A single operational pattern, replicated.	Autologous, allogeneic, gene-edited, in vivo, TIL, and engineered TCR programs share the same commercial coordination layer. Each requires a different operational pattern under it.
Patient pathway	Linear. Apheresis → manufacture → infusion, executed by one team, captured in one system.	Branching. Patient eligibility and slot allocation depend on which trial is still recruiting, which therapy has a readout pending, and which modality the site is credentialed to deliver this quarter.
Build cadence	One-time. Select a platform, configure it for the lead therapy, sign a multi-year contract, move on.	Continuous. Every trial readout reshapes the portfolio in days. The build never finishes because the portfolio never stabilizes.

The operational symptoms (portal load, vein-to-vein drift, access-pathway failures) are the shape these shifts take on the ground. Each is documented in detail, with program-level data, in the BlueSquared CGT Orchestration Maturity Model whitepaper accompanying this brief.

4 What Adaptive Operations Look Like

Adaptive is not a posture.. At this scale, it is a specific capability stack, and most CGT operators are missing it in at least one dimension. The June 11 panel is built around the three capabilities that separate operators who keep moving when the portfolio shifts from operators who stall.

Modality-Agnostic Coordination

One operating layer, not a new portal, data model, or SOP package every time a new modality enters the pipeline. Autologous, allogeneic, and gene-edited programs share that layer. The coordination logic is the asset, not the therapy-specific wrapper built around each new product.

Pivot-Capable Governance

Governance that absorbs a trial-readout pivot in days, not quarters. Decision rights, escalation paths, and audit trails designed for a volatile portfolio rather than a static one. The governance model is measured by how fast it metabolizes change, not how tightly it controls the last plan.

Ecosystem Without Portal Sprawl

Integration, not accumulation. Adding a therapy does not mean adding infrastructure. The ecosystem expands by connecting what already exists rather than stacking another portal on top of a clinical team already managing twenty.

The June 11 Panel

A 60-minute conversation with senior operators from commercial CGT programs, moderated by Phacilitate's Becky Johnson. Anthony Roth, BlueSquared's CEO, co-hosts alongside three senior operators drawn from leading sponsor and center-of-excellence programs, confirmed ahead of the event. Each capability above is tied to a working question the audience will leave able to answer:

- What does modality-agnostic coordination look like when autologous and allogeneic run side by side?
- How does governance absorb a trial-readout pivot without grinding operations to a halt?
- How do you stop adding portals and start shrinking the ones you have?

REGISTER

Join the June 11 Conversation

The BlueSquared and Phacilitate co-hosted panel is a 60-minute working session, not a product pitch. If you run, build, or govern CGT digital operations, this is the room.

Event details

Thursday, June 11, 2026

11:00 ET · 16:00 UK · 17:00 CET

60 minutes · Crowdcast (Phacilitate-hosted)

Moderated by Becky Johnson, Phacilitate / Clarion Events

About BlueSquared

BlueSquared is a CGT digital operations firm working with sponsors and centers of excellence to rebuild orchestration for the portfolio the industry actually has, not the portfolio it had when the original playbooks were written.

blue-squared.com