Expert View

CELL AND GENE THERAPY DIGITAL INFRASTRUCTURE: REPLACING FRAGMENTATION WITH STANDARDISATION

Dr Akshay Peer examines why bespoke digital systems for cell and gene therapies are reaching a saturation point, how clinicians experience this fragmentation on the ground and why a shift towards standardisation is becoming essential for enabling safe, scalable and sustainable delivery of these innovative treatments.

Cell and gene therapies (CGTs) are highly personalised treatments that are redefining what is possible in modern medicine. By transforming patient cells into living therapeutics or using targeted genetic modifications to correct diseases at their molecular roots, CGTs can offer curative possibilities for conditions previously considered untreatable. However, this promise comes with intense operational complexity. A single therapy's journey can involve collecting patient materials, transporting them under strict temperature controls, manufacturing the product, co-ordinating data across multiple teams and maintaining a tight chain of identity and custody at every step.

Managing these processes requires an ecosystem of digital infrastructure capable of supporting precision, transparency and speed. This contrasts with today's CGT operating model, which remains fragmented and slow. Most treatment centres must juggle multiple digital portals, each built independently by individual therapy developers, to order therapies, co-ordinate manufacturing slots, track logistics and manage patient journeys. The resulting digital landscape is inefficient and increasingly unsustainable as the number of approved therapies grows.

FRAGMENTATION AT CGT TREATMENT CENTRES

The CGT digital environment has evolved to be fragmented. In the earliest days of commercial autologous therapies, when few CGTs were in production, individual developers built customised portals to manage their proprietary processes. These first platforms were logical and necessary innovations at the time – purpose-built tools to manage a new class of therapies with unprecedented supply chain constraints.

However, with the number of therapies having multiplied and major regulatory bodies anticipating a significant wave of novel CGT approvals, the problems with this "portal per product" model are more evident. Clinical and operational teams are now required to manage a patchwork of systems, each with its own nomenclature, its own workflow and its own login credentials. In many centres, staff rely on binders full of URLs, passwords, process guides and technical contacts simply to treat patients across different therapies.

Healthcare professionals consistently express frustration with the practical challenges created by today's fragmented digital landscape. Although each therapy manufacturer promotes its portal as cutting-edge, extra features matter far less in a clinical environment than having a system that is fast, intuitive and easy to use. What staff ultimately need is the ability to log in quickly, place an order, complete essential tasks and move on to the next patient without disruption.

Teams often have to manage purchase orders through a mix of inconsistent processes – some fully digital and others still dependent on paper forms, faxing or third-party systems. This lack of uniformity complicates training and creates frequent opportunities for error, particularly when new staff join or when multiple therapies are in play.

These issues are only intensifying as treatment centres expand their CGT programmes and as interest grows in

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delivering certain cell-based therapies beyond major academic hospitals, especially in the case of administration at local- and community-level healthcare centres. Each additional therapy typically brings another portal, workflow and terminology set, adding to an already heavy cognitive load. The sheer number of IT platforms and communication channels required has the potential to overwhelm site staff. With care teams already stretched thin, layering more digital complexity onto their daily workflow is neither sustainable nor scalable. This phenomenon is now widely known in the community as "portal fatigue".

THE CHALLENGES OF BESPOKE PORTALS IN A SCALING CGT INDUSTRY

High Development Costs and Long Timelines

Custom systems require extensive engineering effort, including:

- Requirements gathering
- User experience (UX) design
- Back-end development
- Integrations
- Testing
- Validation
- Hosting
- Cybersecurity
- Ongoing maintenance.

When regulations evolve or supply chain models shift, these portals must be updated, revalidated and redeployed. This creates perpetual cost and technical debt for therapy developers.

What begins as a tool to support a single product often evolves into a long-term software commitment that requires ongoing investment. As more CGT products enter the market, duplication of these costs across dozens of companies has become economically inefficient for the entire sector.

User Experience Shortcomings That Risk Patient Safety

Most bespoke portals were designed for a single therapy workflow and do not incorporate universal UX principles or broad user input from diverse clinical settings. As a result, they often include:

- Inconsistent navigation
- Unclear labelling or terminology
- Unintuitive use steps
- Redundant data entry
- Interfaces that do not reflect real-world clinical scenarios.

Under clinical pressure, these inconsistencies can slow staff or lead to mistakes. Each additional interface compounds cognitive load, increasing the risk of miscommunication or error – issues that can directly affect treatment timelines and outcomes.

Integration Bottlenecks Across the Multi-Stakeholder CGT Network

The CGT network requires seamless co-ordination across:

- Hospitals and authorised treatment centres (ATCs)
- Community clinics
- Apheresis centres
- Manufacturing facilities
- CDMOs
- Quality assurance and quality control labs
- Distributors and depots
- Logistics providers
- Payers.

Each bespoke portal must integrate separately with these partners, resulting in dozens of redundant point-to-point integrations across the industry. Maintaining these connections is costly and slow.

Limited Flexibility as CGT Science Evolves

The pace of innovation in CGT development requires digital systems that evolve just as quickly. Bespoke portals often cannot adapt fast enough, especially when new clinical or operational workflows are introduced.

PORTAL FATIGUE: A BARRIER TO ACCESS, QUALITY AND EQUITY

The most significant consequences of portal fatigue are felt directly in the care setting. The need to navigate multiple systems introduces substantial administrative burden, consuming time that clinicians could otherwise devote to patients. Staff often have to juggle different login processes, unique terminology, various methods for requesting manufacturing slots, multiple documentation upload procedures and separate points of contact for troubleshooting. In some cases, clinicians report managing well over 10 systems at once, relying on physical lists of credentials – an approach that creates both operational inefficiency and security concerns.

This complexity also creates a significant training burden. Each new therapy brings its own portal and workflow, requiring dedicated training for every staff member involved. Treatment centres already face high turnover rates, so the constant need to onboard new personnel into a growing number of platforms only amplifies the challenge.

The impact extends beyond workflow efficiency. Fragmented data, manual transcription and inconsistent processes create opportunities for missteps or delays, which is particularly problematic given the time-sensitive nature of many autologous treatment journeys. Even small errors in scheduling, documentation or communication can have meaningful consequences for patient care.

These issues become even more pronounced as the industry seeks to expand CGT delivery into community settings.

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While this shift is critical for improving access, many community clinics have limited IT resources and cannot feasibly manage a proliferation of portals. Without greater standardisation, the push towards broader, more equitable access to CGTs risks slowing down or stalling altogether.

STANDARDISATION AND BUILDING A SUSTAINABLE DIGITAL ECOSYSTEM

For CGTs to scale responsibly, the sector must shift from bespoke, siloed portals towards standardised, interoperable orchestration frameworks that support multiple therapies across diverse sites.

Interoperability by Design

Rather than building one-off integrations for each therapy, a standardised architecture could enable "plug-and-play" connections through open application programming interfaces, shared data models and harmonised process steps. A successful standardised platform would be able to exchange data seamlessly with:

- Electronic health records (EHRs)
- Laboratory information systems
- Logistics platforms
- Manufacturing execution systems
- Regulatory documentation workflows.

Reduced Cognitive Load for Clinicians

A consistent user experience can reduce training time, minimise errors and give clinical teams confidence navigating workflows. When multiple therapies share similar digital touchpoints, clinicians can focus on patient care rather than portal management.

Scalability for Expanding Global Networks

Standardised systems can help therapy developers to onboard new ATCs, regions, distributors and manufacturing partners with rapid, repeatable deployment methods.

Sustainable Economic Models

Shared digital infrastructure can reduce the duplication of effort across therapy developers and improve cost predictability. In so doing, investments can be shifted from maintaining proprietary systems to enhancing shared, industry-aligned platforms.

Support for Community-Based Delivery

If, rather than bespoke portals, CGTs used standardised systems with intuitive interfaces and unified workflows, community clinics with limited digital support would be able to participate in CGT delivery more confidently and safely.

KEY CONSIDERATIONS FOR FUTURE-READY ORCHESTRATION SYSTEMS

Whether developed internally or implemented through commercial vendors, orchestration systems must be built on a set of foundational principles that ensure that they can support the evolving needs of the CGT ecosystem. Central to this is user-centric design – interfaces should be shaped by continuous input from the people who interact with them every day, both in major treatment centres and community settings. Their insights reflect the real operational pressures of CGT workflows and can help to ensure that digital tools align with practical needs, rather than abstract IT assumptions.

These systems must also offer configurable, modular architectures. As new therapies, technologies and manufacturing methods emerge, digital platforms need to be able to adapt without requiring extensive redevelopment. Flexibility and modularity can help future-proof the infrastructure and support rapid iteration as the field progresses.

Interoperability is another essential requirement. Open integration frameworks allow systems to connect smoothly with EHRs, manufacturing systems, logistics platforms and other critical components of the healthcare and supply chain ecosystem. An interoperable approach would eliminate the need for repeated bespoke integrations and reduce the risk of data silos.

Security and compliance must also be embedded at every level of system design. Given the sensitivity of patient data and the strict chain-of-identity and chain-of-custody requirements in CGT workflows, platforms must meet rigorous global standards for cybersecurity, privacy and auditability.

Finally, long-term stability matters. Therapy developers and treatment centres depend on reliable digital infrastructure, so clear visibility into product roadmaps, update cycles and ongoing support is essential. A system's value is not just in what it delivers today but in the assurance that it will continue to evolve and remain dependable as the CGT landscape continues to grow over the coming years.

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A COLLABORATIVE FUTURE: THE PATH TOWARDS INDUSTRY-WIDE STANDARDISATION

No single stakeholder can solve the fragmentation challenges facing the CGT ecosystem. Meaningful progress depends on a co-ordinated effort among therapy developers, technology providers, clinical centres, logistics partners, regulatory bodies and standards organisations. Each plays a distinct role in shaping a digital environment capable of supporting safe, scalable and efficient therapy delivery.

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To accelerate momentum towards a more unified infrastructure, several collaborative actions will be particularly important, including:

- Harmonising terminology and workflow definitions to reduce variability across platforms, particularly for steps such as slot reservation, product release and chain-of-identity confirmation.
- Strengthening participation in industry boards and cross-stakeholder working groups, ensuring that platform capabilities reflect real-world clinical needs, regulators have insight into operational pain points and manufacturers remain aligned on best practices.
- Adopting and contributing to interoperability standards, such as emerging extensions for CGTs, to support secure, efficient data exchange at scale.
- Shifting from proprietary to compatible infrastructure, recognising that the goal is not uniformity but seamless collaboration among systems developed by different organisations.

Through shared effort, the industry can move closer to a cohesive digital foundation that supports the next generation of CGT therapies.

SECURING THE FUTURE OF CGTS THROUGH DIGITAL MATURITY

CGTs are on a trajectory towards broader indications, larger patient populations and more diverse treatment settings. However, without a fundamental shift in digital strategy, fragmentation will continue to strain clinical teams, inflate operational costs and limit patient access. The industry now stands at an inflection point:

- Bespoke portals supported the first wave of CGT commercialisation, but their limitations are now clear
- Standardised, collaborative and interoperable platforms are essential for the next wave – one defined by scale, sustainability and global reach.

By embracing shared digital infrastructure and prioritising user-centric, interconnected systems, the CGT ecosystem can support the safe, efficient and equitable delivery of life-changing therapies to the patients who need them most.

ABOUT THE COMPANY

TrakCel is a provider of integrated cell and gene therapy software solutions for the orchestration and precise management, control and tracking of cell and gene therapy products. With deployments supporting a wide variety of therapy classes in industry, TrakCel has built a deep understanding of the unique challenges faced by advanced therapy developers globally.

Dr Akshay Peer

Akshay Peer, PhD, is Chief Product Officer at TrakCel. He has many years of experience in creating technology-based solutions for the cell and gene therapy industry. His long-standing tenure in the field reflects a dedicated commitment to advancing innovation and contributing to the industry's growth.

T: (UK) +44 2920 483 729 (US) +1 833 236 2052
E: enquiry@trakcel.com

TrakCel Ltd
11 Raleigh Walk, Brigantine Place, Waterfront 2000, Cardiff, CF10 4LN, United Kingdom
300 Montgomery Street, Suite 1130 San Francisco, CA 94104, United States
www.trakcel.com

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