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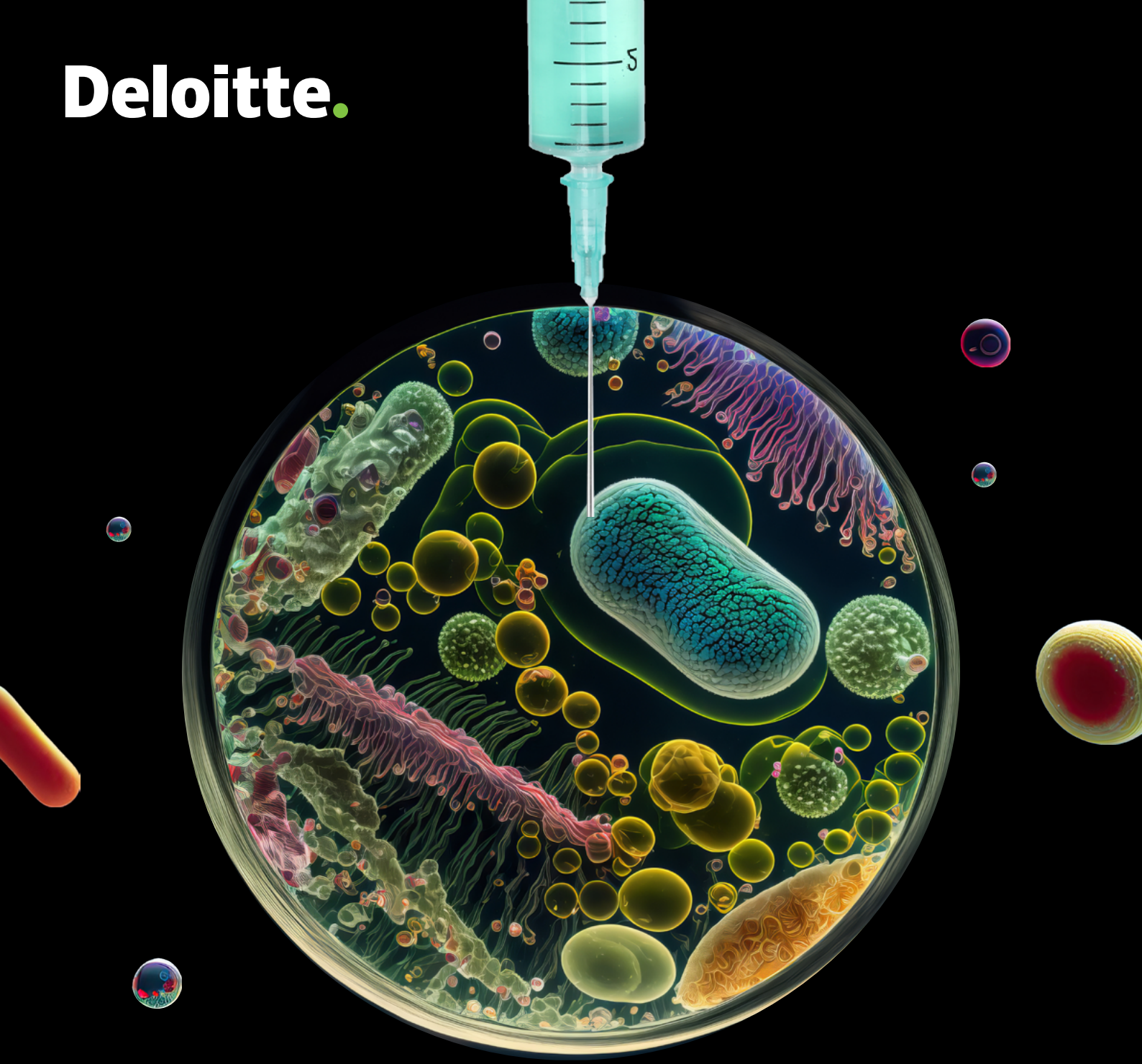


Realising the promise of cell and gene therapies in Asia Pacific

Four imperatives for commercial delivery

June 2023

MAKING AN IMPACT THAT MATTERS since 1845

Contents

Realising the promise of cell and gene therapies in Asia Pacific

Nearly two decades ago, the Human Genome Project concluded a multi-year effort to identify, map, and sequence all the genes in the human genome. The vast amount of information from this landmark initiative led to the development of a common scientific language – that, in turn, opened the door for researchers to identify disease-causing genetic variants, and develop personalised testing, diagnosis, and treatment therapies for patients based on their unique genetic makeups.

Known as next-generation therapies (NGTs), these treatments are poised to transform care across a myriad of therapeutic areas earlier thought to be the domains of the incurable. This new era conceivably began in April 2012, when a six-year-old girl relapsed in her battle with acute lymphoblastic leukaemia after many months of unsuccessful chemotherapy. Unwilling to give up hope, her family enrolled her in a trial for a brand new chimeric antigen receptor (CAR) T-cell therapy product targeted against leukaemia[1].

More than 10 years later, the patient remains cancer-free – and a multi-billion-dollar NGT revolution holding the promise of curative therapy is underway in the global pharmaceutical industry. Leading the charge are cell and gene therapies (CGTs), which are transforming not only the ways in which we treat genetic and intractable diseases, but also the entire pharmaceutical ecosystem as we know it.

Indeed, since the first approval of the first NGT product in 2017, CGTs and other NGTs have been on an explosive global expansion path. Currently, with more than 900 companies focusing on NGTs and over 1,000 CGT clinical trials underway[2], the industry looks set to witness a tsunami of approvals – in the region of 10-20 new therapies per year from 2025 in the US alone[3]. CGTs, in particular, have also expanded beyond their initial oncology focus to include other therapeutic areas, such as neurology and ophthalmology. Taken together, sales in the global CGT market have been projected to reach more than US$11.96 billion by 2025[4].

Closer to home in Asia Pacific, we are also witnessing a wave of regulatory approvals, growing pipelines of CGT products lined up for commercial launch, as well as a surge of innovative solutions, technologies, and players coming onto the scene. The region – which accounted for more than 26% of global CGT revenue in 2021 – is expected to expand at a compound annual growth rate of 21% between 2021 and 2027 to reach a market size of US$4 billion[5], on the back of accelerated approval pathways by governments, growing investments, and increasing health care needs.

Having played a role in the commercial launch of every single CGT product that has been approved to date, Deloitte has had a front-row seat to the global CGT sector's dynamic evolution over the last decade. In this report, we will synthesise some of the learnings that we have accumulated over the years, and provide our perspectives on where the solutions may lie for pharmaceutical companies to realise the promise of CGTs in Asia Pacific.

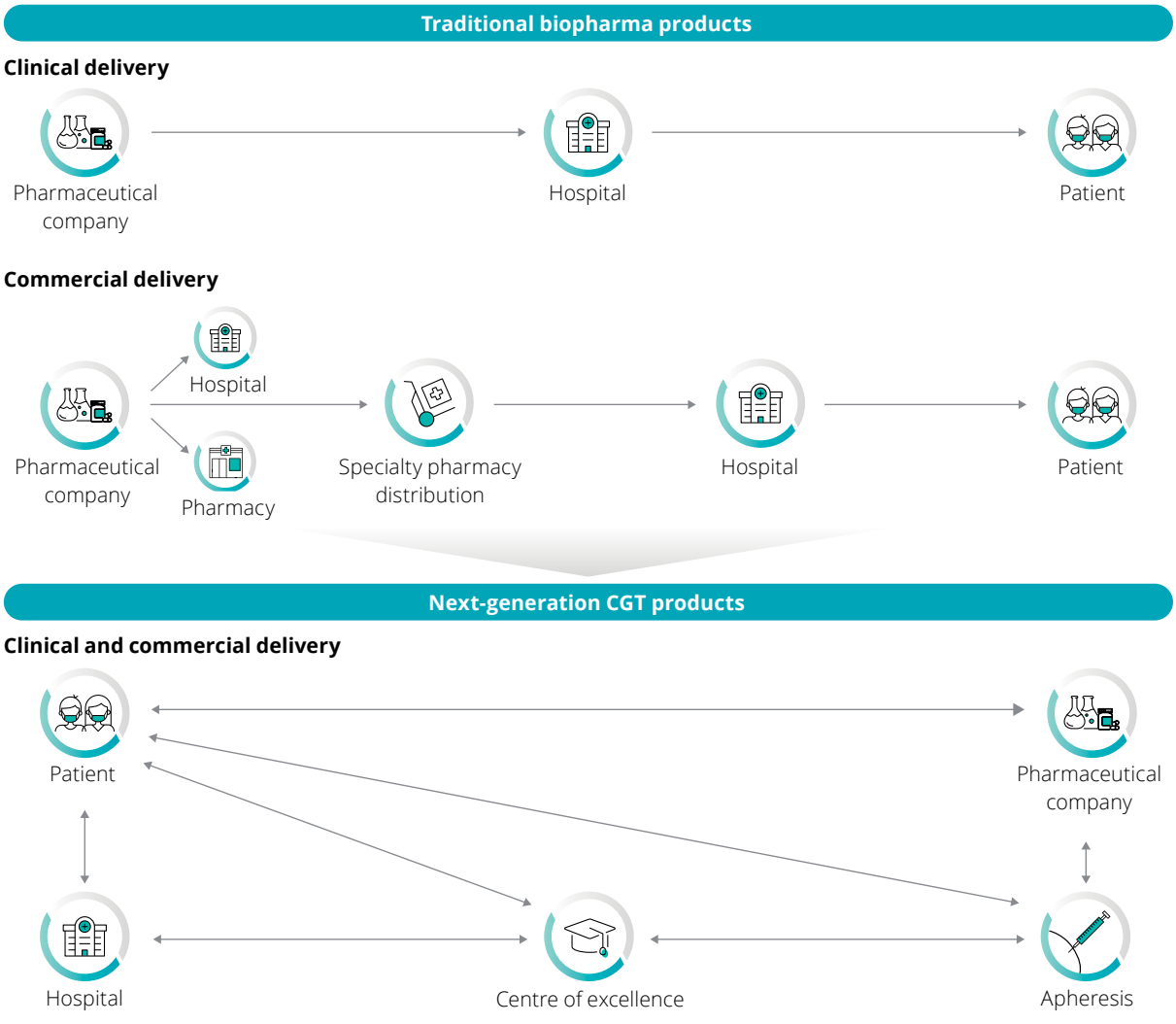
1. "Emily Whitehead, first paediatric patient to receive CAR T-cell therapy, celebrates cure 10 years later". Children's Hospital of Philadelphia. 11 May 2022.
2. "2018 annual report". Alliance for Regenerative Medicine.
3. "Statement from FDA Commissioner Scott Gottlieb, M.D. and Peter Marks, M.D., Ph.D., Director of the Centre for Biologics Evaluation and Research on new policies to advance development of safe and effective cell and gene therapies". US Food & Drug Administration. 15 January 2019.
4. "Global cell and gene therapy market to reach $11.96 billion by 2025". Markets Insider. 6 August 2019.
5. "Cell and gene therapy manufacturing market estimates and trend analysis, 2018 to 2030". Grand View Research.

Four imperatives for commercial delivery

Suffice to say, the next generation of CGTs holds tremendous potential for therapeutic benefits. To realise this promise, however, stakeholders across the value chain – including but not limited to pharmaceutical companies, health care providers, health care payers, and patients – will need to come together to fundamentally recalibrate their commercial delivery modus operandi.

Central to this challenge is the high level of personalisation involved in the end-to-end production and delivery of CGTs, which means that current processes being deployed for traditional biopharma products cannot be easily adapted for use. Rather, what is needed is a multidisciplinary approach to designing a new operating model – one centred around complex, patient-centric journeys – and a holistic understanding of the stakeholder ecosystem to manage the accompanying cultural change (see Figure 1).

Figure 1: A new operating model for the clinical and commercial delivery of CGTs



In the sections ahead, we will discuss four imperatives for the commercial delivery of CGTs in Asia Pacific, distilled from our cumulative experience supporting CGT players in their go-to-market efforts both across the globe and within the region:

1. Shift from a product-centric to a service-centric mindset

Given that CGTs are highly personalised drugs managed through highly controlled logistics processes, the fundamental design principle of a CGT operating model is more likely to resemble that of a service value chain than a traditional manufacturing and distribution supply chain. This service value chain will, in turn, need to be supported by an entirely different model of patient care, with pharmaceutical companies going beyond traditional ways of working to increase the level of collaboration with their ecosystem partners to provide better support for physicians and patients.

2. Design and deploy patient-centric digital ecosystems

Digital ecosystems hold the key to breaking down traditional silos between stakeholders for the delivery of patient-centric experiences, and the transparent end-to-end tracking and traceability of CGT products across the value chain. Integrated systems and data flows also work to serve the needs of different stakeholders through timely and on-demand notifications, enabling different teams to connect on patient and material status, respond to patient and caregiver enquiries, and capture data within the patient's record for long-term follow-up purposes.

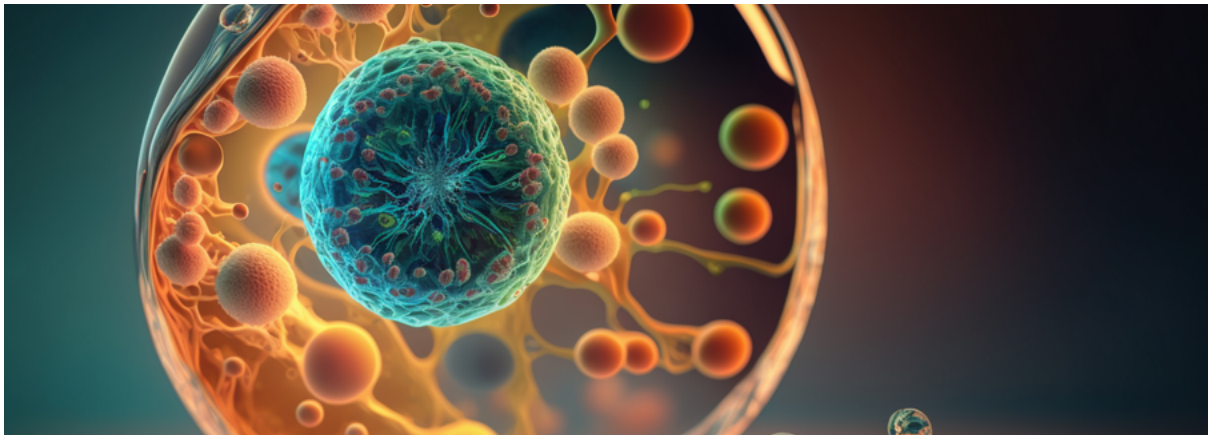
3. Collect and manage mission-critical data

The delivery of CGTs differs significantly from that of traditional biopharma products in that it is heavily reliant on patient-specific data, with data flow processes requiring high levels of interaction from both patient and donor. This introduces a high level of complexity to the value chain, not only from the addition of new risks and variables, but also in the form of more stringent and continually evolving data privacy regulations at the local jurisdictional level.

4. Embrace the unexpected

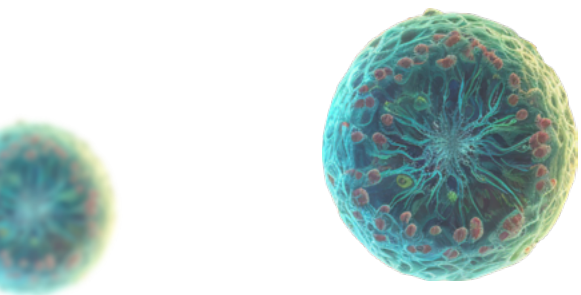
As their operating models evolve, CGTs are likely to present pharmaceutical companies with many 'news': a new unique patient care delivery model; new value chains; new and evolving regulatory norms; and new unexpected risks. Yet, at the same time, the constraints of working with live cells and urgency of treating critical patient populations makes its delivery process a highly time-sensitive one. To manage this dichotomy, CGT players must brace themselves for high levels of variability and volatility, and build a high tolerance for the unexpected within their systems and corresponding vein-to-vein processes.

1. Shift from a product-centric to a service-centric mindset



The clinical delivery of CGTs is a much more complex and multidisciplinary effort than the clinical delivery of pills or biologics. Cell therapy patients are likely to require highly complex care before, during, and after therapy; for example, prior to receiving gene-edited immune cells that have had their specific gene mutations removed, a patient may need to have their immune system ablated, which puts the onus on the care team to reduce and manage risks of infection.

Given that CGT products are manufactured for individual patients, tight coordination between physicians and manufacturers will be required to manage any fluctuations in delivery timelines that may affect the decisions made by physicians. This represents a significant change from the status quo under current pill and biologic regulations, where manufacturers have separate commercial and medical functions, and do not coordinate for individual patients.



Evolving towards a value chain model

Fundamentally, the rise of CGTs implies the need to rethink the roles of pharmaceutical companies, health care professionals, and regulators in serving "a market of one". Deloitte's experience has found this to be a significant challenge for the CGT ecosystem, with many players struggling to commit resources and investments, and reshape operations to align themselves with such a delivery model (see sidebar).

CGT players, in particular, will need to evolve away from the traditional model where they manage all activities from sourcing to procurement, conversion, and logistics, and towards a value chain model where a series of business operations are designed to add value to goods and services through the delivery of enhancements to the patient experience (see Figure 2)[6].

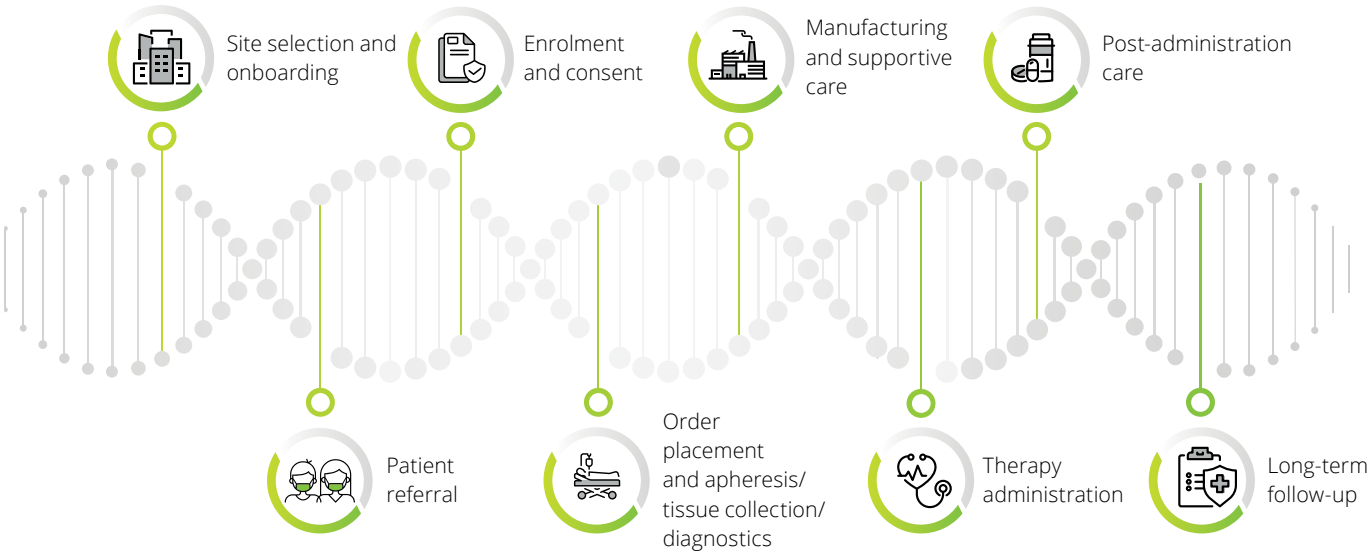
Specifically, unlike traditional supply chains, CGT players need to ensure that their value chains are designed to be high-touch, high-visibility, and closed-loop, with the end-to-end connectivity and involvement of highly specialised stakeholders.

Serving a "market of one"

Each CGT patient has a unique set of needs: some may require the full suite of services, while others may require only limited support as with conventional therapies. The key lies in understanding each patient's individual needs and delivering personalised support.

As a first step to improving the customer experience, CGT players will need to start developing a better understanding of the care team experience and patient experience at each step of the treatment journey.

Figure 2: A typical made-to-order CGT value chain



6. "Cell and gene therapies: Delivering scientific innovation requires operating model innovation". Deloitte. 17 April 2020.

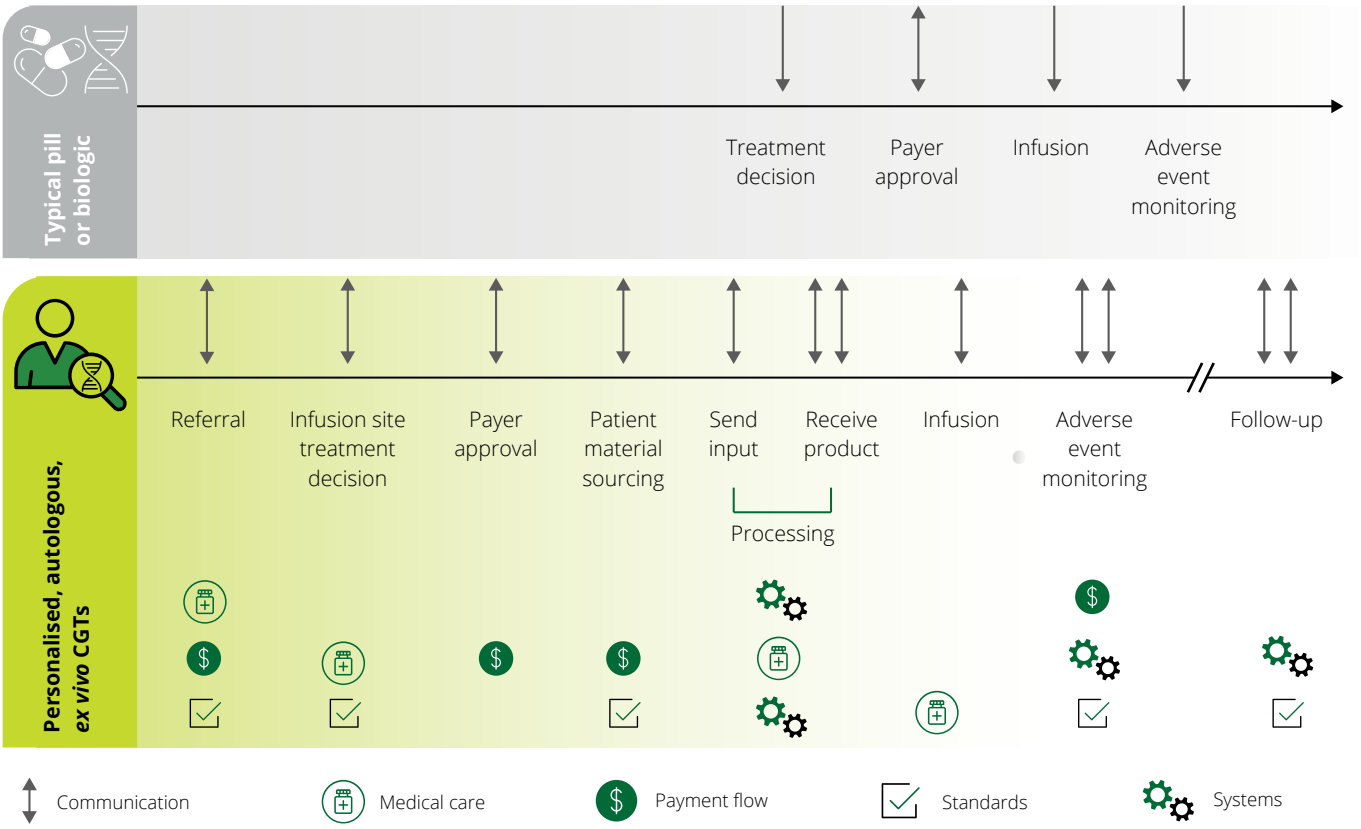
Under a CGT value chain model, three types of flows are critical:

1. Patient flow

Patients must be placed at the centre of the service value chain, as CGTs are unique and personalised to the patient. To ensure a successful commercial launch, it is crucial that CGT players define the specificities of the end-to-end patient journey, including the unique touchpoints, handovers, and stakeholders involved across the entire care pathway as their patients receive the therapy and its associated care.

This is in stark contrast to the current model deployed in the commercial delivery of pills and biologics, which primarily involves only one-way decision-making amongst limited stakeholders (see Figure 3)[7]. Given that the stakes in CGTs are high and timelines are tight, CGT players will also need to adopt a more proactive approach to communication – for example, by providing regular updates on the manufacturing status or order details to care teams and hospital sites to help manage the concerns of both patients and physicians – rather than rely on a reactive approach by simply acting on requests or prompts.

Figure 3: The changing stakeholder interaction model



7. Elverum, K., Whitman, M. "Delivering cellular and gene therapies to patients: Solutions for realising the potential of the next generation of medicine". Gene Therapy 27, 537–544 (2020).

2. Product flow

Unlike traditional products such as pills and biologics for which the role of the pharmaceutical company diminishes upon completion of product manufacturing, CGT products demand a high level of end-to-end involvement throughout the journey from patient enrolment to cell and tissue collection, and just-in-time product manufacturing. When designing their product flow processes, CGT players should therefore consider how they intend to deliver their innovative products to their patient sites in a closed-loop value chain, including the roles and responsibilities of their distribution partners, and supporting technology infrastructure.

Typically, for CGTs, the product flow begins with a diagnostic test – for example, antibody testing for specific viral vectors in the case of gene therapies, or apheresis of cells at the treatment site or specialised apheresis site for autologous therapies. However, as each CGT product is unique and individualised to the patient, every product batch must be monitored and tracked across a closed-loop value chain to maintain a chain of identity (COI) and a chain of custody (COC) leading to the final delivery and infusion (see sidebar).

3. Financial flow

Relative to traditional pills or even targeted therapies, the treatment costs for CGTs tend to be on the higher side. With this higher level of financial risk, a clearly laid out financial flow is therefore required to accompany the cross-border movement of these higher value products from their manufacturing hubs to treatment sites. Briefly, this flow should define how pharmaceutical companies and their external stakeholders exchange payment for CGT products and services, including stakeholder involvement and payment modalities – and form the basis for pharmaceutical companies to plan and execute innovative pricing and contracting models.

Managing transparency through COI/COC

In the context of CGTs, COI and COC should be viewed as distinct from traditional biopharma product serialisation. This is because the patient is a key element of CGT manufacturing and delivery processes, and it is vital that they receive the right therapy to avoid safety issues such as product rejection.

- **COI** enables a product to be traced back to its original donor, and down the lineage to its intended recipient. The raw material (tissue or cells) and the resulting CGT product are associated with the donor's unique identifiers throughout the entire process, from collection and manufacturing to treatment and post-treatment monitoring. For instance, as part of COI, an autologous donor's patient number will be associated with their unique donation number and manufacturing batch number.
- **COC** enables a product to be traced throughout the value chain, from material collection to product administration. Data points include staff handling information, temperature and storage conditions, actions performed, and the associated location, date, and time of these actions.

Following the administration of the therapy, the COI and COC should become encoded into health information systems to provide complete traceability over the patient's lifetime and ensure patient safety across multiple products and doses.

2. Design and deploy patient-centric digital ecosystems

To deliver effective patient and product journeys for CGTs, the collaboration of an entire ecosystem of players is needed. Bringing this concept to fruition, however, will require pharmaceutical companies to invest in the design and deployment of patient-centric digital ecosystems – that is, platforms capable of providing assurance in the form of COI/COC, ensuring alignment in key hand-offs, and enabling the establishment and centralisation of order transparency.

One central requirement for such a digital ecosystem is the existence of an open, trusted digital backbone that connects all ecosystem players – including but not limited to physicians, care teams, pharmaceutical companies, payers, and even global logistics firms and last-mile carriers transporting the therapies – around their contributions to patient outcomes. Based on Deloitte's experience working with CGT ecosystem players across Asia Pacific, we believe that a patient-centric, clinically-connected ecosystem should exhibit six key design principles (see Figure 4).

Figure 4: Six design principles for a digital CGT ecosystem

Designing patient-centric architecture

In all likelihood, there would be no single digital solution or platform capable of managing all end-to-end CGT processes from ordering to scheduling, labelling, billing, and manufacturing (see sidebar). Rather, a mix of multiple digital applications – such as manufacturing execution system (MES), customer relationship management (CRM), treatment portals, middleware, and enterprise resource planning (ERP) systems – will need to be integrated to facilitate CGT lifecycle functions (see Figure 5).

To this end, developers may wish to consider the following high-level best practices as they align their individual digital applications to an overarching CGT digital ecosystem:

- **1. Assess digital roadmap capabilities**
- **2. Consider the design of a role-based architecture for users**
- **3. Deploy a minimum viable product (MVP) approach to balance market needs and out-of-box (OOB) applications**
- **4. Consider requirements for current and future releases**
- **5. Limit integration across applications to reduce churn and application program interface (API) chatter**
- **6. Confirm native combinability for selected applications prior to design**

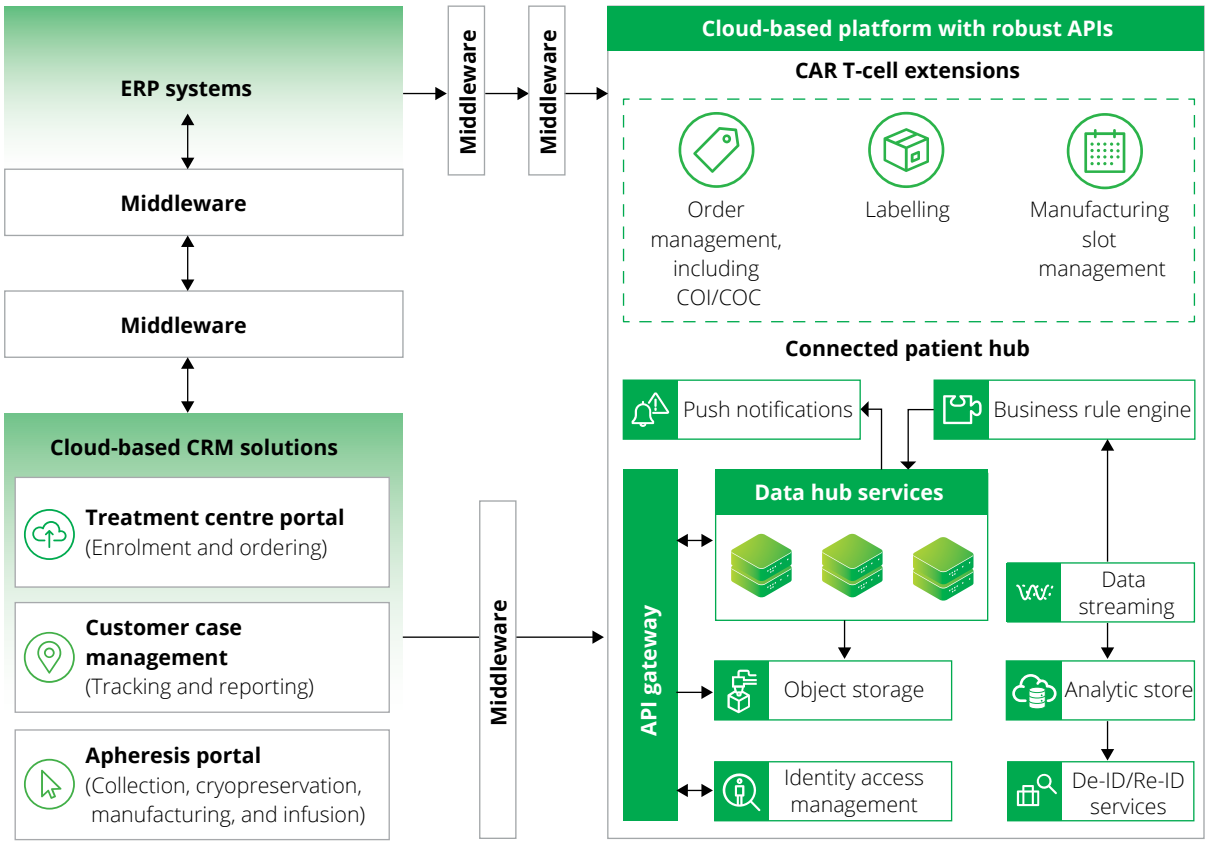
One common platform: can it be achieved?

Having a single, industry-standard portal would be a considerable improvement over the current approach; however, developing such a platform for the global CGT ecosystem is a complex endeavour that would require a central intermediary to bridge the varying requirements and trade-offs faced by different players.

The good news is that several standardisation efforts are already underway. In collaboration with several CGT players, Deloitte launched the NextGen Therapies Industry Working Group (IWG) earlier in 2019 to exchange perspectives, share best practices, and develop solutions to improve the lives of CGT patients.

As its first endeavour, the IWG brought together a group of CGT companies, clinicians, quality and regulatory advisors, and technical solution providers to drive alignment toward standardising the minimum elements required for apheresis end-of-collection labelling. The voluntary group also recently drafted and published a new International Council for Commonality in Blood Banking Automation (ICCBBA) standard.

Figure 5: Illustrative example of a CGT digital ecosystem architecture

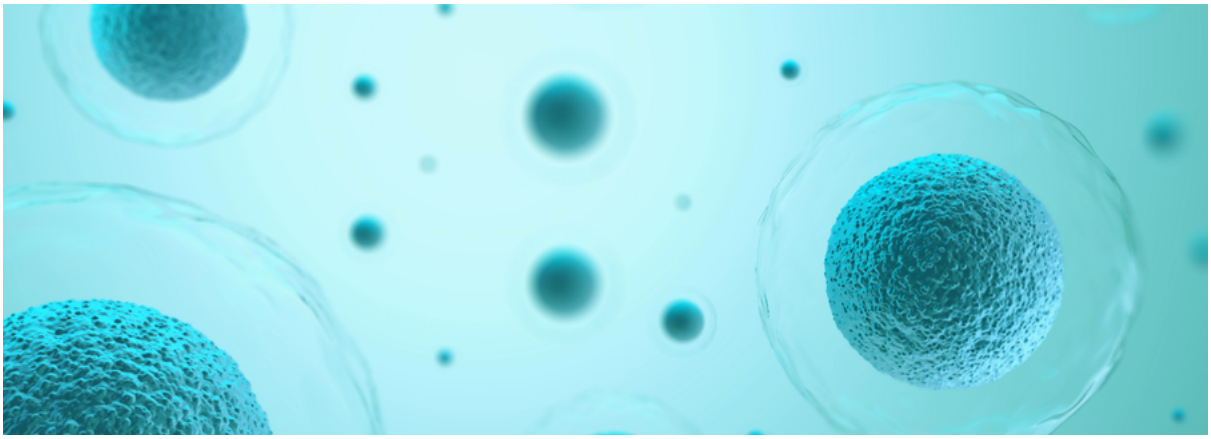


Taking inspiration from the e-commerce and technology sectors

While working with a CGT player in Asia Pacific, Deloitte undertook a reimagination of the digital backbone for an innovative therapy for cancer. By enabling pharmaceutical manufacturers, medical logistics organisations, health care providers, and other stakeholders to collaborate and share data on an intelligent digital platform – which is in turn hosted on an encrypted network – we were able to design a new digital ecosystem to support our client's end-to-end CGT lifecycle.

Inspired by the ability of e-commerce players to deliver consistent reliability and the intuitive digital experiences provided by technology players in the form of new-age operating system engines, we designed a cloud-enabled digital platform to support the quick and safe movement of a patient's cells, while permissioning protocols to ensure that protected health information is only provided to the network participants on an as-needed basis. Network members are consistently updated on treatment status, and the platform also predicts and notifies them of potential issues so that they can be pre-emptively rectified.

3. Collect and manage mission-critical data



For traditional drug products, processes and systems are designed with well-defined patient populations and stakeholder communities in mind. Production and distribution processes adhere to relatively predictable demand and supply schedules, with minimal involvement or input from health care providers, care teams, and patients. When it comes to next-generation, personalised therapies such as CGTs, however, the opposite becomes true.

In a "market of one", the supply chain is built around a single patient, with each dose of the drug product manufactured for an individual either from the patient or a donor's live cells. The patient is, in other words, core to the manufacturing and delivery of CGTs. This characteristic of CGT supply chains – and its corresponding reliance on patient-specific data – is essentially what differentiates CGTs from traditional drug products and other biologics.

This paradigm shift alters not only the type of data that pharmaceutical companies must deal with, but also the fundamental nature of their workflow and how information or data is captured and shared throughout the patient lifecycle from patient identification and enrolment to cell collection, manufacturing, treatment, and long-term follow up. This high volume of highly variable data will, in turn, need to be threaded through an entire ecosystem of players through both internal and external workflows (see Figure 6).

Figure 6: A CGT value chain's dependency on data

	Processes in a CGT value chain				
	Enrolment	**Ordering and scheduling**	**Collection and logistics**	**Manufacturing**	**Infusion**
Illustrative examples of data	• Patient personally identifiable information (PII) • Diagnostic information • Site delivery information • Reimbursement information	• Apheresis collection date • Link to manufacturing or cryo-preservation dates • Link to desired infusion activities	• Patient COI identifier • Packaging and labelling • Shipping inserts and signatures	• COI/COC details • Date and time of manufacturing progress • Deviation prediction • Quality release information • Out-of-specification (OOS) notification	• Proof of delivery • COI/COC match to patient • Date and time of infusion
Key considerations	• Clear definition of COI and related PII • Ease of use for health care provider and/or certified sites • Commercial checkpoints for reimbursement	• Capacity management for manufacturing and cryo-preservation • Availability of rescheduling options	• Standardisation of Good Manufacturing Practices (GMP) documentation • Ease of access	• Maintenance of COI/COC • Notification of delivery dates • Notification of quality release	• Proof of delivery and administration • Legal, contractual, and financial documentation • Availability of long-term tracking options

Streamlining data collection and management

As CGT players face the prospect of collecting and managing a vast amount of highly regulated patient data, they would do well to bear in mind that the key is to collect only the data that is meaningful to the product – that is, data that is "mission-critical". This requires a streamlining of their data collection and management processes, as any disintegration in the information or data architecture is likely to result in the lack of a single source of truth, and consequently, inconsistent audit trails and ineffective decision-making.

At this juncture, it is also perhaps worth emphasising that while some pharmaceutical companies may have found that they have been able to function thus far with a disintegrated or decentralised data architecture, the reality is that the introduction of CGT products and services will require them to deal with such an unprecedented volume and variability of data that their existing systems can easily become overwhelmed and result in process bottlenecks.

Based on Deloitte's accumulated experience working with CGT players in Asia Pacific, we have developed a tried-and-test framework for data collection and management that is anchored by four pillars of focus:

1. Data integrity

To protect data integrity, it is vital to ensure that data is complete, trustworthy, consistent, and accurate throughout the product journey. This requires CGT players to make investments in a digital ecosystem, where systems and solutions can be developed and evolved to manage and control the use of data.

2. Automation of data collection and consolidation

To reduce data workloads and minimise risks of inaccuracy, CGT players should work to continuously automate their data collection and consolidation processes, as well as optimise the specific quantum and data types that they require. This process must be carried out in tandem with the necessary consideration on issues relating to patient consent and relevant regulatory frameworks.

To this end, it would be useful for CGT players to develop a detailed data map with an explicit business purpose and data retention policy. Take, for example, a CGT player who might need to utilise patient data for analytics in the post-transfusion phase. While the use of data in this instance could be deemed as beyond the scope of its primary purpose, the use of data-masking techniques could help to mitigate some of the accompanying compliance risks. Establishing a well-defined data policy, and investing in the right digital tools for data-gathering, consent-recording, and storage will therefore be key to automating the process, while minimising errors and ensuring compliance with regulatory requirements.

3. Process intelligence

With the typical cell journey for a single patient entailing more than 40 different milestones and 140 procedures, the sheer volume of data makes it difficult for CGT players to develop a 360-degree view of their process. While generic data management tools could go some way in alleviating these challenges, much of the data collection and data analytics requires an in-depth understanding of CGTs and their biological processes.

What is needed, therefore, is a process mining capability – one that gives CGT players the ability to connect all the data points across vein-to-vein processes and systems for any single order, enables them to visualise how actual processes are performing, and supports them in performing root cause analysis and suggesting process improvements (see Figure 7).

Figure 7: Deloitte's process mining accelerator for the CGT ecosystem

Through the work that we have delivered for CGT players around the globe and within the Asia Pacific region, Deloitte has developed a proprietary process mining accelerator for the CGT ecosystem capable of:

- Integrating and analysing process data across the CGT ecosystem; and
- Driving process transformation with the integration of artificial intelligence/machine learning (AI/ML) tools

Key benefits of leveraging Deloitte's process mining accelerator

1. Attain new levels of performance by rectifying inefficiencies and recommending best course of action for human intervention

2. Obtain a 360-degree view of the CAR T-cell order execution across the cell journey and system to identify any inefficiencies in execution

3. Leverage built-in AI/ML tools to pinpoint root cause for violations and automate the monitoring of impacts

Figure 8: Deloitte's privacy by design framework

In order to attain operational goals while ensuring compliance with regulatory requirements, it is essential for CGT players to establish a well-defined and transparent data privacy policy setting out the ways in which personal information is being collected, stored, and used, while also investing in the necessary technical infrastructure.

Deloitte's proprietary privacy by design framework helps CGT players to achieve this by building data privacy into the design, operation, and management of any given system, business process, or design specification. Briefly, the framework sets out seven foundational principles of privacy-by-design:

Proactive, not reactive
Anticipate, identify, and prevent invasive events before they happen; this means taking preventive actions before the fact, and not remedial actions afterwards

Ensure end-to-end security
Data lifecycle security means that all data should be securely retained as needed, and destroyed when no longer needed

Lead with privacy as the default setting
Ensure personal data is automatically protected in all IT systems and business practices, with no additional action required by any individual

Maintain visibility and transparency
Assure stakeholders that business practices and technologies are operating according to objectives and subjected to independent verification

Embed privacy into design
Privacy measures should be fully integrated components of the system, not merely add-ons

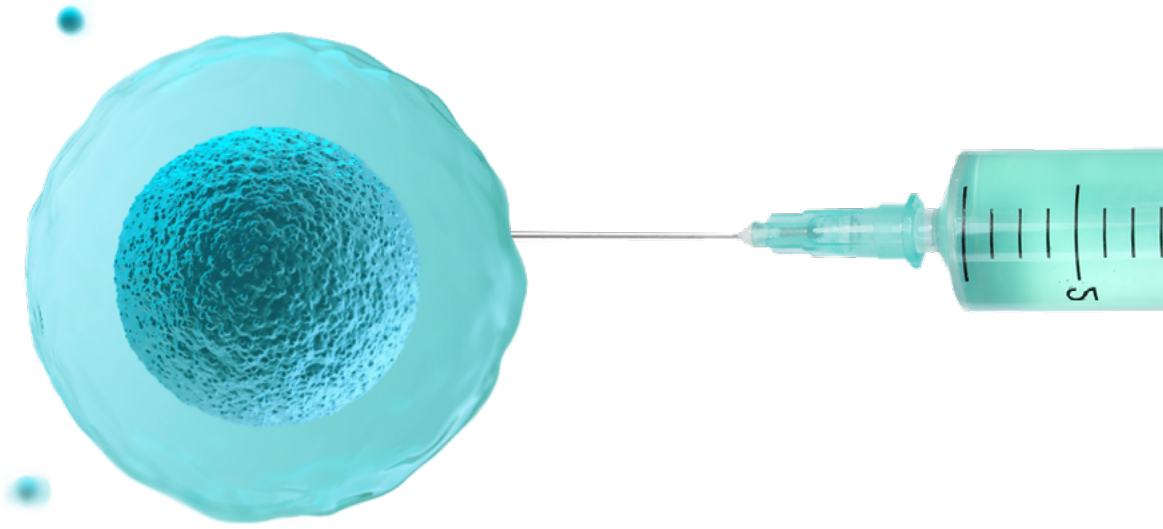
Respect user privacy
Keep things user-centric, and support individual privacy interests with strong privacy defaults, appropriate notices, and user-friendly options

Retain full functionality
Privacy by design is a positive-sum game and not a zero-sum one; a "win-win" approach should be adopted for all legitimate system design goals so that no unnecessary trade-offs are made in order to achieve both

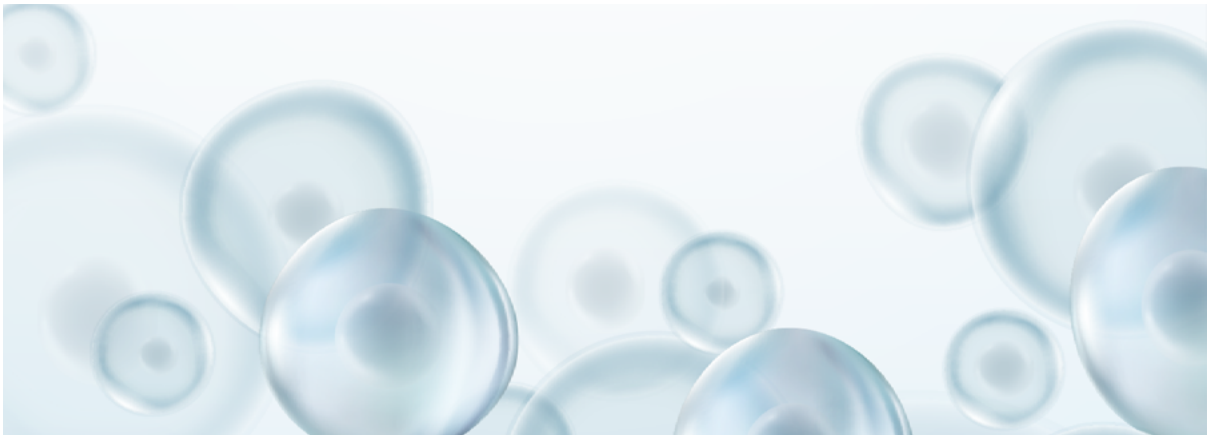
Challenges in cross-border data transfer

CGT players in Asia Pacific are finding themselves increasingly confronted with issues relating to cross-border data transfer, as they expand their networks of collaboration across multiple, varied internal and external stakeholders. One oft-cited challenge is the need to ensure that the data security protocol of each individual stakeholder meets local regulatory standards for personal data privacy – which may in turn limit the volume and types of data transfers, or require overseas processers to adhere to a series of additional procedures and cybersecurity standards.

To mitigate these compliance risks, CGT players will need to augment data security with local autonomy. This could include, for example, adopting a highly localised design for their health care provider-facing platforms, such as front-end systems of websites, applications, and data lakes employed in data analysis. Based on our marketplace observations, we have noted that major CGT players are currently in the process of developing such localised portals as replacements for existing global systems. In addition, many are also deploying the use of local security operations centres (SOCs) to centralise system logs, as well as monitor malicious attacks on the ground.



4. Embrace the unexpected



The stakes are high for CGT delivery: failure to deliver a quality product on time could mean depriving a patient of their only remaining viable treatment option. The primary challenge, however, is that the product fulfilment process – with its closely interwoven upstream and downstream activities – is itself highly variable and volatile.

Managing variability and volatility

Consider the first stage of the CGT product fulfilment process: the patient's cell collection. This stage alone is subjected to many variable factors, including but not limited to the patient's physical condition, travel schedules and logistics, capacity of the treatment centre, and availability of skilled personnel. As the product moves along the fulfilment process, the variability is further compounded along the product fulfilment process by a myriad of manufacturing, transportation, and quality issues – all of which individually and collectively threaten to jeopardise critical supply chain timelines and viability of the cell products.

Based on Deloitte's experience, the probability of having to reschedule an apheresis is almost 40 percent at cumulative order levels. An order could also be delayed for a variety of extraneous and uncontrollable reasons, such as supply disruptions, weather conditions, traffic accidents, and flight cancellations. To cope with these sudden and unforeseen circumstances, CGT players must be prepared to embrace the unexpected.

As they consider the resiliency of their operations for long-term success, we propose that they consider taking the following five actions:

1. Secure the vein-to-vein value chain

CGT players should identify and map out every step in their vein-to-vein value chain to understand each process dependency, including significant hand-off points and the attendant risks. Having such a holistic understanding of the value chain is vital – not least because the CGT model requires apheresis to be obtained from a patient, conveyed through a manufacturing process, delivered to the location, and then returned to the patient, all within a pre-determined period.

2. Build flexibility into the value chain

Given that the commercial delivery of CGTs is a highly complex and intricate process, CGT players should look to build flexibility into their value chains to reduce the likelihood of disruptions. As a start, they should look to identify weaknesses and liabilities within their value chain, before defining and executing measures to improve resilience. Continual monitoring, as well as flexible and rapid decision-making processes, are also key to ensure that the value chain remains robust in the face of evolving circumstances.

3. Standardise COI/COC tracking across the value chain

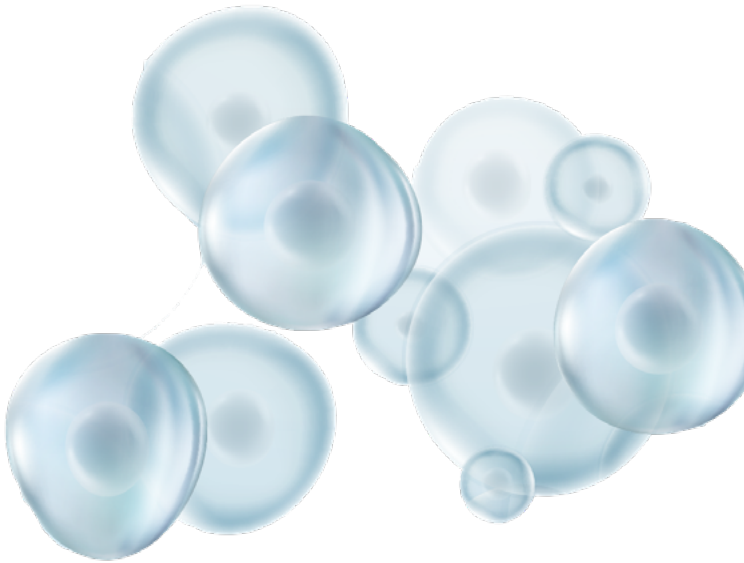
Stakeholders within the CGT ecosystem will need to work collaboratively to standardise the way patient and product information is being captured and recorded throughout the entire value chain, including PII and other critical patient information. For this reason, setting and communicating COI/COC standards upfront can go a long way in mitigating the negative repercussions associated with improper or inaccurate tracking.

To this end, CGT players should also invest in training initiatives to educate their value chain partners – such as physicians, care teams, and manufacturers – on the relevant information and labelling standards, as well as best practices for COI/COC tracking. Ideally, these training sessions should take place before a site's activation to ensure that all stakeholders have a common understanding on COI/COC standard operating procedures.

4. Develop business continuity and disaster recovery plans

CGT players will need to plan for contingencies – in particular, high-impact, high-probability scenarios – in collaboration with stakeholders throughout the value chain, which include, but are not limited to treatment sites, couriers, and contract development and manufacturing organisations (CDMOs). In addition, they should also establish comprehensive and clear guiding principles for the escalation of commonly identified issues, such as product OOS, and where possible, put in place alternative arrangements for transportation and logistics (see sidebar on next page).

To equip them with the skills they need to manage these contingencies, it is vital that all stakeholders are put through immersive, true-to-life scenario training, during which they can practice executing their assigned roles and responsibilities. These sessions could also incorporate the use of gamification techniques to increase motivation, attention, and learning. Based on Deloitte's experience delivering such training programs, we have found that well-designed simulation programs are about twice as effective as traditional classroom trainings at helping teams improve their core decision-making.



Risk assessment of transportation providers

As with all critical supply chains, it is imperative to leave little to chance. The planning process should include a detailed review of all participants, process steps, data processes, as well as check and choke points across the value chain. Given the critical role that they play in the delivery of CGTs, transportation providers should also be included in this risk assessment.

A non-exhaustive list of considerations include:

- Regulatory requirements, including applicable customs and border control
- Trans-shipment points across the chain of custody
- Changes in mode of transportation due to potential environmental hazards
- Weather hazards in shipment and delivery locations
- Resource availability, including personnel and material handling equipment
- Inspection and quality assurance process, including time and data logs

5. Adopt agility and lucidity as guiding principles

In order for CGT players to evolve the right operating model to address the needs of their patients and health care providers, it is critical that they adopt agility and lucidity as guiding principles. Specifically, in addition to real-time visibility capabilities to track and trace orders throughout the journey, CGT players will need to learn to account for the variability of geographical and environmental factors, cultural factors, and even unknown factors in the orchestration of their solution design.

This, in turn, requires them to ensure that their processes and digital tools are sufficiently agile to accommodate real-life scenarios and changes: while some parts of the process intrinsic to a product could nevertheless benefit from standardisation, others such as the ability to switch patients for a given apheresis date could benefit from greater agility.

Furthermore, as CGT business models have compelled pharmaceutical companies to shift away from business-to-business (B2B) models and towards business-to-patient (B2P) models, CGT players will also need to learn to reduce the level of complexity in their processes to create greater lucidity for their patients and health care providers – and thereby, achieve greater differentiation vis-à-vis the competition. Initiatives could include, for example, referral networks that provide platforms for referring physicians to engage certified sites with ease for the purpose of referrals and post-treatment follow-ups.

Looking ahead

By altering a patient's biological core – their DNA – CGTs hold the elusive promise of curative therapy. But to deliver on this unparalleled potential, an equally unparallel commercial delivery model and value chain is required. From manufacturing to infusion and long-term follow-up, the need to ensure the end-to-end traceability of viable cells demands an unprecedented level of transparency into manufacturing processes – and a corresponding rethink of operating models.

Within Asia Pacific, this challenge is further amplified by the heterogeneity of health care systems across the region. Nevertheless, Deloitte's experience has revealed that several common approaches can be deployed to help pharmaceutical companies orchestrate streamlined end-to-end commercial delivery processes for CGTs.

Based on a prior project that we delivered to support a leading pharmaceutical company in developing an operating model and digital ecosystem for its commercial CAR T-cell launch in Asia Pacific, we have developed – and subsequently refined – a five-step methodology to move a CGT product from clinical to commercial readiness (see Figure 9).

Figure 9: Deloitte's five-step methodology to achieve commercial readiness for a CGT product

Discover
Conduct market research with industry leaders and subject matter experts to design a commercial readiness blueprint, and outline capabilities required to maximise value

Design
Design and develop a digital ecosystem backed by leading cloud platforms

Implement
Implement a flexible, integrated digital architecture to support future scalability and growth

Operationalise
Leverage agile methodology to mobilise people, processes, and technology to achieve launch readiness

Improve
Envision future, high-level business needs and priorities to plan for the development of new digital capability enhancements

While each CGT product will likely require a unique or even idiosyncratic path to commercial readiness, it remains clear that the success of its operating model will hinge in large part on the pharmaceutical company's ability to develop and implement a strong digital core – that is, one that is capable of facilitating seamless collaboration across an entire ecosystem of players, and involving patients at every step along the journey.

More importantly, however, as CGT players look towards a horizon of new unknowns, we believe that it will be their tolerance of risk and ambiguity, coupled with a gritty willingness to "roll up one's sleeves" and commit to prompt, data-backed decision-making, that will ultimately make or break their ability to overcome inevitable setbacks on the journey to long-term success.

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