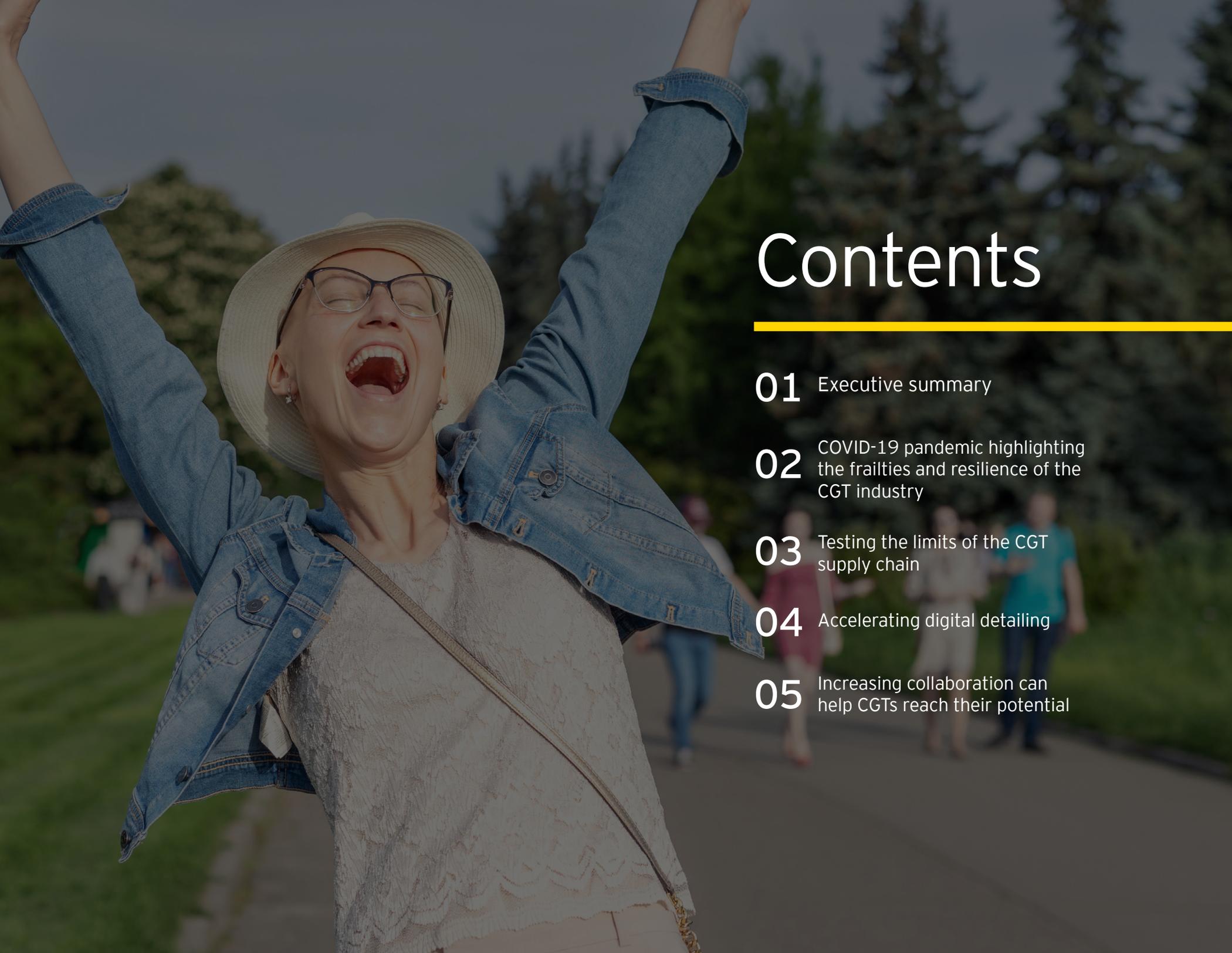




How collaboration
will strengthen the
future of cell and
gene therapies

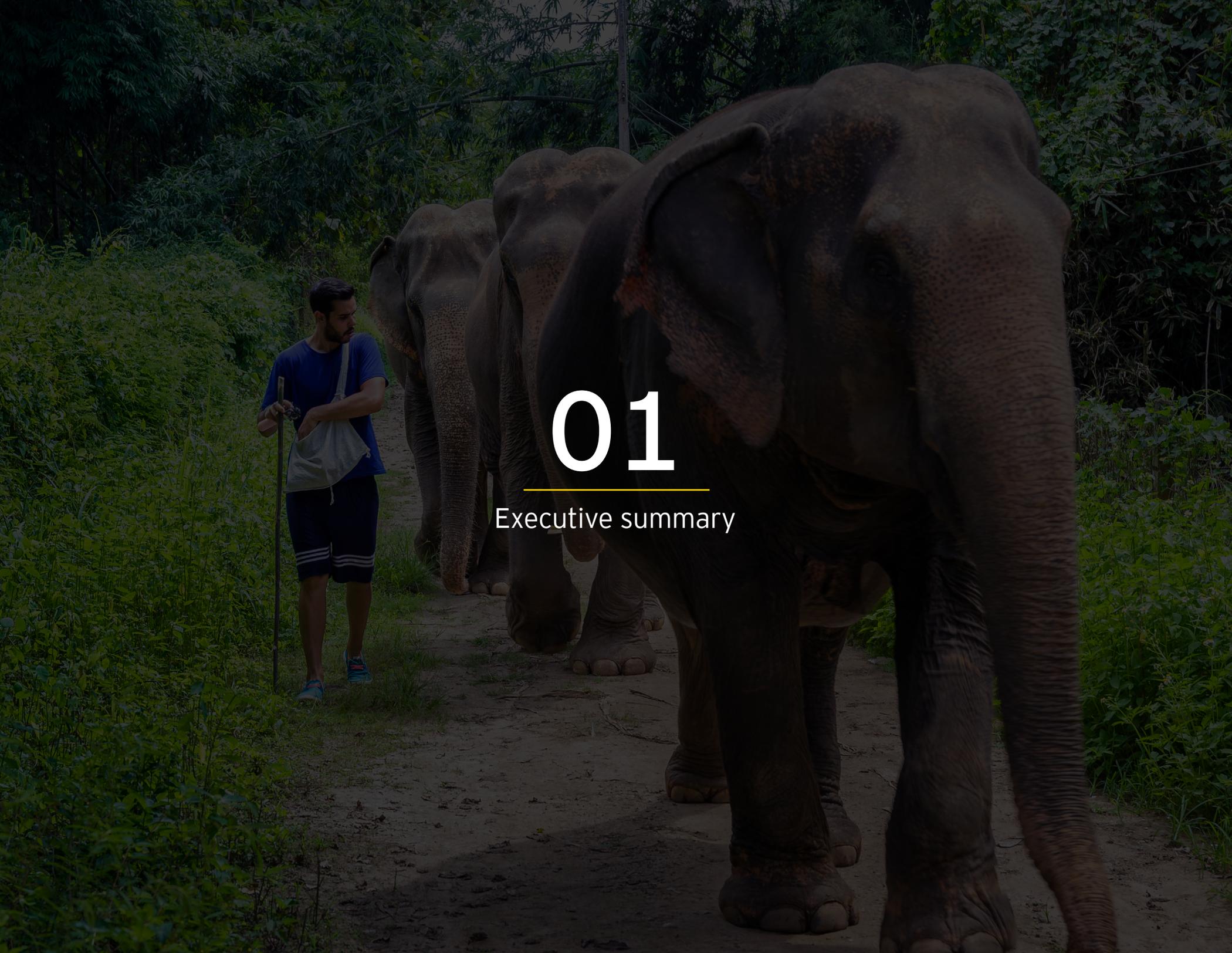
EY

Building a better
working world

A woman wearing a straw hat, glasses, a denim jacket, and a lace top is cheering with her arms raised in a park setting. The background shows other people and trees.

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A man in a blue t-shirt and dark shorts is herding a line of elephants on a dirt path through a lush, green forest. The man is holding a long stick and has a bag slung over his shoulder. The elephants are walking away from the camera, with the largest one in the foreground. The scene is dimly lit, suggesting early morning or late afternoon.

01

Executive summary



Adlai Goldberg

Pointellis Solutions Lead
EY Global Digital, Social and Commercial
Innovation Health Sciences and Wellness Leader

Cell and gene therapies (CGT) are ushering in a transformative era in medicine, with the goal of changing the course of relentless diseases such as inherited genetic disorders and cancers. But is the health care industry ready? To help ensure that these life-changing therapies can benefit all those who need them, much has to be accomplished in a short period of time.

The CGT global market will significantly outpace the pharmaceutical global market, from an estimated US\$3 billion annually in 2021 to an estimated US\$50 billion annually in 2027. But

these highly specific therapies come with their own set of challenges. They are difficult and expensive to manufacture and administer. And their short-term treatment and curative-intended outcomes currently translate into higher-than-average prices.

EY teams are working with the CGT industry to provide the services and solutions needed for these treatments to reach their true potential. *How collaboration will strengthen the future of cell and gene therapies* explores the threats to the developing but fragmented CGT industry - highlighted by the COVID-19 pandemic - and how a connected ecosystem of stakeholders working together can overcome them.

The pandemic tested the limits of the current CGT ecosystem, underscoring vulnerabilities in manufacturing and delivery, research and development and commercialization. Central to the problem is that CGT supply chains require the seamless orchestration of time-sensitive materials and information across a diverse set of organizations and systems. Today, this process is largely managed by people and therefore subject to human error, as well as travel delays, lab

closures, etc. Imagine digitalizing this end-to-end process with real-time tracking and tracing across the full CGT value chain, allowing for early indications of problems and speedy course corrections.

Another key issue is cost. Before CGTs can be commercially available at scale, they have to be made more affordable. Payers will balk at the prospect of footing the bill for a much larger CGT patient population at today's prices. Are there different economic models? And will data be the key to proving which ones work best?

Delivering on the promise of CGT will take an unprecedented level of cooperation, a willingness to share information and a high degree of trust. It will also require combining advances in clinical science with the power of data and technology. No one in health care - no matter how smart or well-funded - can do this alone.

Working together, we have the chance to build a secure digital infrastructure that will help make treatments available to more patients globally. It is a recipe for resilience that can withstand crises and the test of time.



02

COVID-19 pandemic highlighting the frailties and resilience of the CGT industry

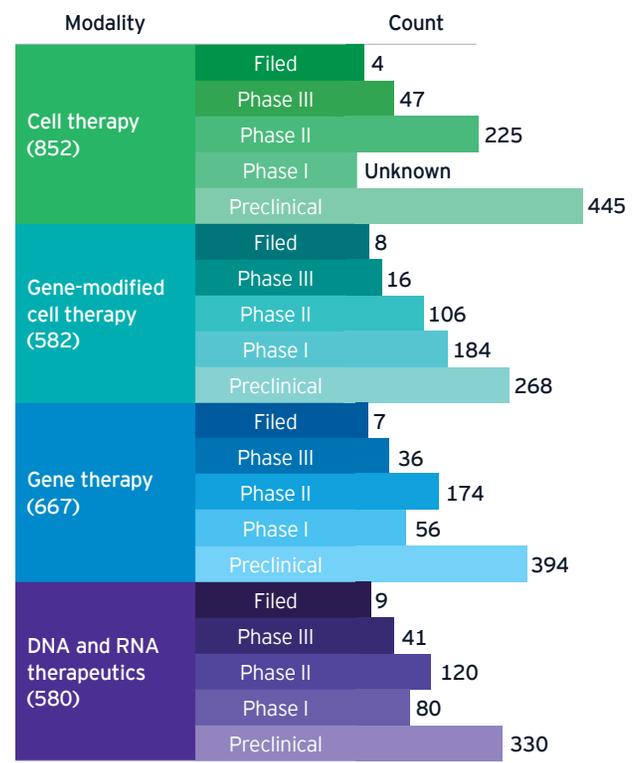


In his first eight years of life, Sam had never seen the stars in a clear night sky. The Canadian boy had been diagnosed with a form of genetic retinal degeneration called retinitis pigmentosa, a condition that lead to his blindness. Sam's sight was severely hindered, and in 2019, his parents took him to the US so he could receive a novel gene replacement therapy. One year later, Sam can now see the stars at night and can dress himself and function as a healthy, active child.¹

We are living in a golden age of medical discovery. CGTs have the power to transform medicine, creating tailored treatments for patients who are living with difficult and even incurable diseases² such as inherited genetic disorders and cancers. People who have lost their vision are regaining their sight. Cancer patients that were thought to be out of treatment options have new hope; many are cured.

After more than four decades of advancements – in cell, molecular and structural biology, biochemistry, immunology, oncology, virology, engineering and biotechnology³ – cell-based therapies, gene-based therapies, or a convergence of the two, are now center stage in modern medicine. With the continuous influx of emerging clinical science in the pipeline and strong financing, EY teams expect the CGT global market to grow exponentially faster than the total pharmaceutical global market, from an estimated US\$3b annually in 2021 to an estimated US\$50b annually in 2027. The more than 2,600 CGT clinical trials in different modalities at different stages of maturity signal a potential wave of product approvals between 2022 and 2027. In the US alone, this translates into 10 to 20 different gene therapy approvals every year, starting in 2025, according to former U.S. Food & Drug Administration (FDA) Commissioner Scott Gottlieb.⁴

Figure 1: CGT clinical trials in different modalities at different stages of maturity



2,681 total CGT pipeline (2020)

Source: "Pharma Commercial Intelligence, News & Analysis" published on 1 October 2020



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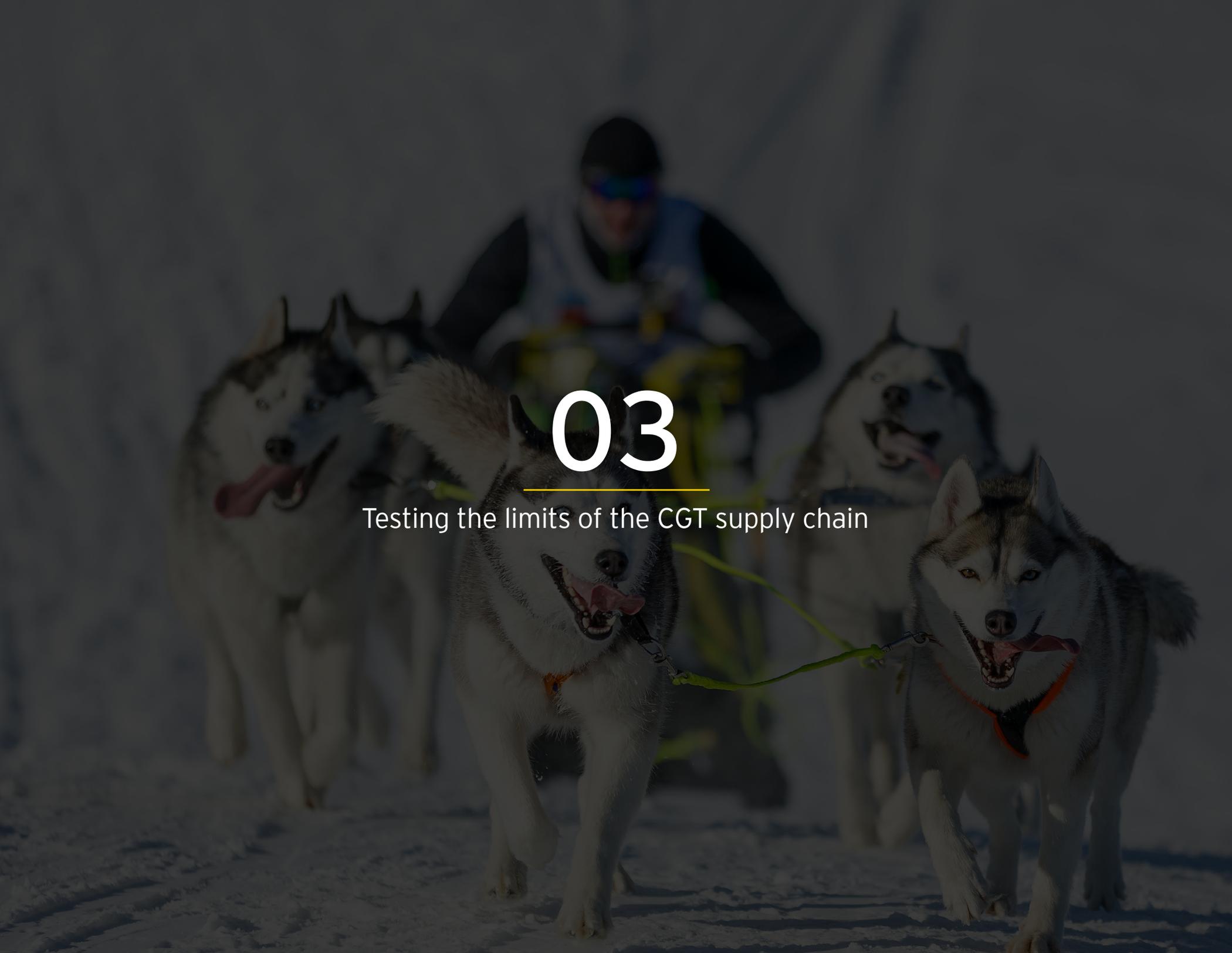
As Orlando Serani, Program Lead, Advanced Cellular Therapies Supply Chain at Johnson & Johnson, put it during a recent OCTS Cell Therapy Summit panel discussion hosted by the EY organization, “We need to collaborate at the speed of science.” For CGT, this translates into using the power of data and technology to enable an unprecedented level of cooperation, a willingness to share information and a high degree of trust – in other words, a recipe for resiliency that will serve patients and the industry now, next and beyond.

Orlando Serani, Program Lead, Advanced Cellular Therapies Supply Chain, Johnson & Johnson

While all transformational medicines come with their own set of challenges, these revolutionary treatments are unlike any other therapies in significant ways. First, they cannot be mass manufactured; they must be tailor-made for small numbers of people or a specific individual as part of a complex process that varies mightily for each instance. Second, CGTs are difficult and expensive to administer, limiting their current availability to a small population. Third, their manufacture and delivery offer zero room for error. The challenges will multiply as CGT options and their usage increase.

Recently, the COVID-19 pandemic shined a light on the existing frailties in the current CGT ecosystem. Shifting regulatory, R&D and point-of-care priorities. Clinical trial delays and shutdowns. Lab closures. Travel bans. Heightened risks for immunocompromised patients. These were some of the pandemic byproducts that threatened the research, development, manufacturing and delivery of CGTs, with no immediate changes in sight.

How can CGTs be made available and affordable at scale so that they can benefit as many people as possible? If the pandemic has taught us anything, it is that this endeavor cannot be accomplished in silos. As science continues to deliver on the promise of CGTs, the only way to make them a reality at scale is to create an ecosystem of stakeholders working together – patients, health care providers (HCPs), health services companies, insurers/payers and the biopharmaceutical industry. No single player – regardless of how smart or well-funded – can do this alone.

A musher wearing a blue and white winter jacket and goggles is pulling a team of huskies on a snowy trail. The dogs are running and pulling a sled, with their tongues hanging out. The scene is set in a snowy, outdoor environment.

03

Testing the limits of the CGT supply chain

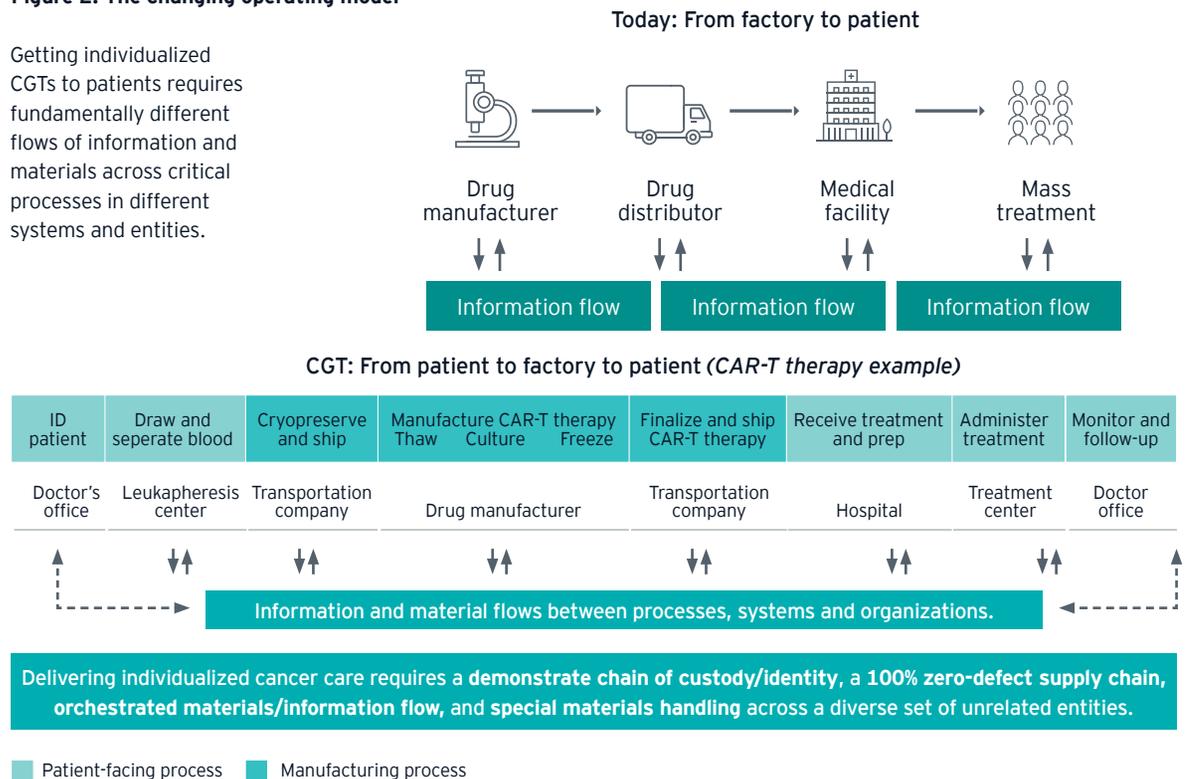


The COVID-19 pandemic has tested the limits of the current CGT ecosystem, underscoring vulnerabilities in this nascent industry's manufacturing and delivery, research and development and commercial operations.

The evolving CGT treatment paradigm from a mass market (1-for-Many) to an individualized approach (N of 1) requires a 100%, zero-defect supply chain with seamless orchestration of the movement and sharing of time-sensitive materials and information across a diverse set of disparate organizations and systems.

Figure 2: The changing operating model

Getting individualized CGTs to patients requires fundamentally different flows of information and materials across critical processes in different systems and entities.





This is a significant departure from today's chemotherapy model, which involves the simple movement of the drug from the manufacturer to the distributor to the medical facility, where the same product may be administered to multiple cancer patients. In contrast, CAR-T therapy, where the patient's own T cells are extracted, modified, activated, expanded, purified and returned to the patient⁵, requires nearly double the number of steps – from doctor to leukapheresis center (where blood is drawn and separated) to shipping company to drug manufacturer to shipping company to hospital to treatment center.

Pandemic-related travel delays and cancellations negatively impacted the movement of time-critical CGTs, which are typically transported on commercial flights. Border restrictions in some EU countries resulted in couriers being deterred or stopped. In addition to shipping-related problems and quarantine restrictions, lab closures and fear affected both allogeneic (donor) and autologous (patient) cell collection. Furthermore, as these immunosuppressive therapies require complex and prolonged hospital visits, some physicians and their patients elected to delay their administration.

Trial delays and shutdowns threaten progress

Likewise, the pandemic took a serious toll on clinical trial programs worldwide. ClinicalTrials.gov data indicates that more than 200 interventional oncology studies were suspended in March and April because of the pandemic.⁶

Factors such as redirected resources, new guidance from regulatory agencies, impaired patient access and travel restrictions initially affected the ability to advance many CGT clinical research programs. With patients unable or unwilling to attend trial sites, and provider resources stretched thin, multiple trials were deferred or canceled.

Reduced HCP bandwidth hinders commercial operations

With the focus on the COVID-19 pandemic, disruptions to the commercial operations of CGT companies have been widespread, including reduced contact with HCPs, who have had limited bandwidth. This has impacted product detailing and patient and payer engagement.

New demands from regulators could delay CGT candidates

Efforts to manage the ongoing public health crisis caused by the COVID-19 pandemic have become the priority for many policymakers, regulators and public sector payors. New demands from regulators in particular could exacerbate delays for CGT candidates with the focus on therapies in the COVID-19 space.

Peter Marks, FDA's Center for Biologics Evaluation and Research (CBER) Director, when speaking at the Alliance for Regenerative Medicine's (ARM) Meeting on the Mesa, noted that before COVID-19 he spent about 75% of his time on CGTs, but the pandemic has forced him to shift priorities. As Dr. Marks noted, "At this point in time it's probably 80% of my time on COVID-19-related activities."⁷

Wilson Bryan, CBER's Office of Tissues and Advanced Therapies (OTAT) Director, echoed Dr. Marks' sentiment. "We all know we've had delayed meetings and we've had to delay review of some applications because of giving priority to the pandemic." However, Bryan said they are getting their balance and working to catch up on some of the delayed activities.⁸



The silver lining: CGT financing continues despite pandemic

To date, CGT companies have continued to attract investors and raise significant financing for their programs. The ARM *Global Regenerative Medicine & Advanced Therapy Sector Report* states that fundraising by CGT developers during the first half of 2020 more than doubled compared with the first half of 2019. Between January and June, these companies raised US\$10.7b globally – a 120% increase over last year, per Biomedtracker.⁹

For potential acquirers, that means there are a number of new companies with promising pipelines to track. Peter Behner, EY Global Health Science & Wellness Strategy and Transactions Leader, notes that many biopharmaceutical companies are determined not to miss out on what they believe is the industry’s next wave of innovation and because of this, they have accelerated their CGT investments. “The companies believe these medicines, which promise increased therapeutic precision and potentially curative outcomes, are transformative not just for patients but also for their businesses.”

Sustaining clinical trials

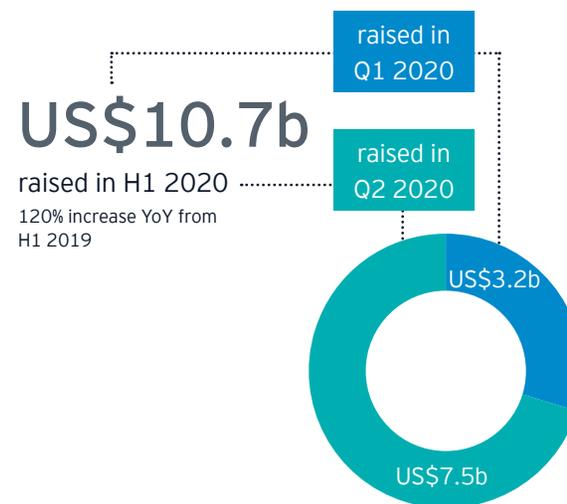
Once things have stabilized concerning the COVID-19 pandemic, there is every expectation that the life sciences business environment will look very different than pre-pandemic times. According to Behner, “For CGT companies, the pandemic provides the burning platform to sharpen data strategies and refine business models.”

EY recently held a virtual roundtable to discuss in more detail the impact of the pandemic on clinical trials with the professionals in the fold. There was general consensus among participants (biopharma, HCPs, contract research organizations and technology companies) that clinical trial sponsors and other stakeholders need to find creative, collaborative and decentralized ways to make trials sustainable, resilient and agile now, and for years to come. Recommendations gleaned from the roundtable include:

- ▶ More flexible assessment protocols
- ▶ Baked-in resilience against disruption
- ▶ Digital acceleration

- ▶ Decentralization and telehealth as the defaults rather than the exceptions
- ▶ Regulatory openness to protocol streamlining and wider liberalization of the rules
- ▶ Collaboration between stakeholders, including industry and regulators

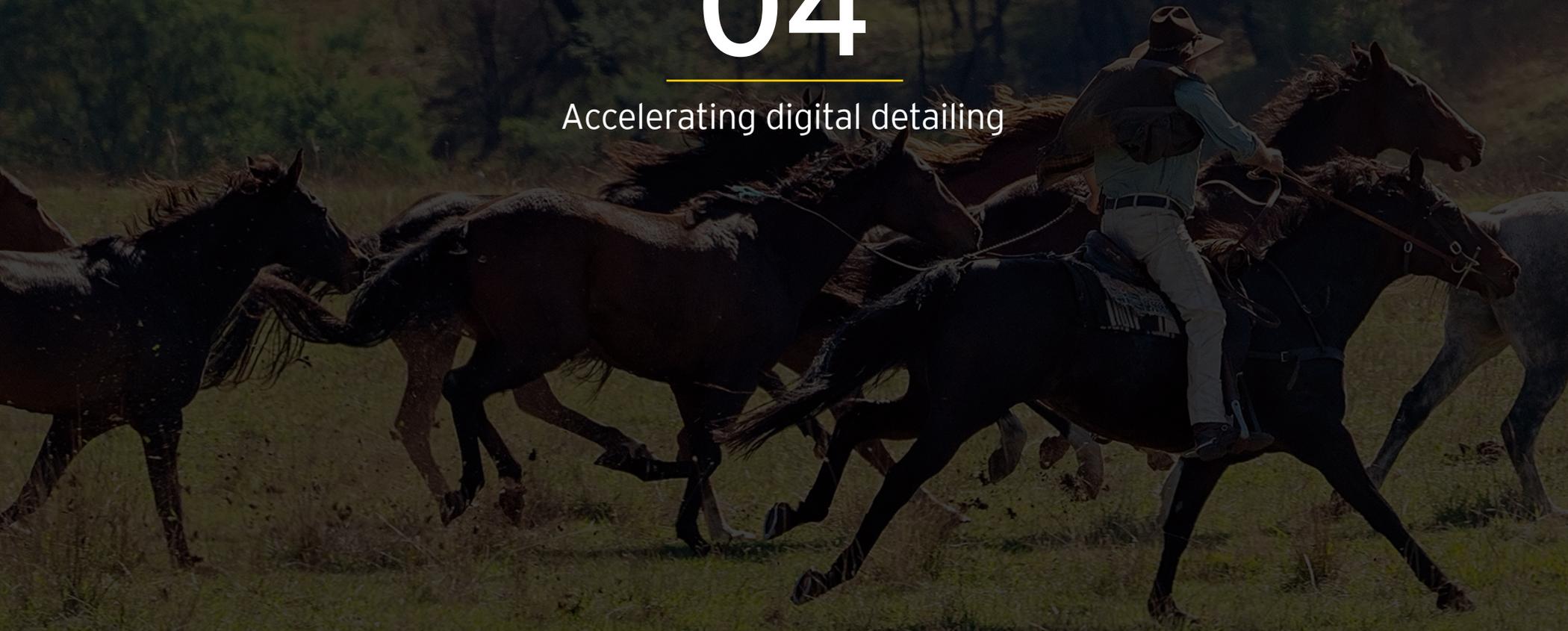
Figure 3: Total global financing



Source: “Innovation I the Time of COVID-19. ARM Global Regenerative Medicine & Therapy Sector Report, Alliance for Regenerative Medicine (2020).”

04

Accelerating digital detailing





“

Improved reimbursement models should be tied to patient outcomes, align incentives across the value chain and help spread the significant costs of these treatments across multiple years. This type of payment innovation is a significant shift from today’s payment models and will take time to develop.

Sarah Dye, Senior Vice President of Oncology at Optum (part of UnitedHealth Group)

Even before the pandemic, life sciences companies have been experiencing declines in face-to-face detailing, fueled by increasing restrictions at doctors’ offices and hospitals. As a result, they have been exploring customer-centric, cross-channel, data-driven digital solutions to complement personal promotion, improve the HCP experience and drive better relationships. With the “new normal” imposed by the pandemic, and the next “new normal” yet to be determined, this trend is expected to pick up speed and acceptance.

Alternative payment models

Life sciences companies and all involved in the health and wellness ecosystem have to ask and keep asking: “What is the value of a one-time, potentially curative treatment?”

Highly specific CGT are characterized by complex manufacturing, short-term treatment

and curative-intended outcomes, all of which translates into higher-than-average prices. But their duration of treatment remains unknown and current models of drug pricing, which are based on utilization, don’t work.

During an EY-hosted panel discussion on scaling CGTs at the recent OCTS Cell Therapy Summit, Sarah Dye, Senior Vice President of Oncology at Optum (part of UnitedHealth Group), stressed the need to establish new models of reimbursement for CGTs.

In the meantime, several innovative payment and risk-sharing approaches are being developed and considered. These include outcomes-based contracts (OBCs), which tie a product’s performance to emerging evidence of improved patient outcomes, and even “drug mortgages” that would allow patients and payers to stretch out payments of a value-based price over a set period of time.¹⁰

Stakeholders remain concerned that OBCs are too risky, too complex to design and measure, and too difficult to replicate across multiple parties. But through discussions, data and research on the subject, EY believes leveraging new digital technologies that make it easier to collect and share data will eliminate some of the long-standing frictions associated with OBCs. Some of the ongoing obstacles include: growing health data, including from consumer devices and the expanding internet of health care things (IoHT); readily available computational power and data storage, which help to create the infrastructure to manage and use health data in secure, scalable and low-cost ways; and application program interfaces that limit administrative burden and allow aggregation of longitudinal data from a range of sources. Following the patient journey will require data portability across years of treatments, and even changing payors and providers.



Shoring up the supply chain

If CGTs cannot reach patients, their efficacy is irrelevant. Plain and simple, CGTs are based on patient outcomes.

The current supply chain processes for CGTs are highly fragmented and subject to fracture. These models cannot handle commercial scale production and delivery, particularly of the most complex of the CGTs, which are derived from a patient's own cells. Meanwhile, traditional mechanisms used to communicate and coordinate with different stakeholders are woefully inadequate, especially since patients and caregivers are now embedded in the supply chain, with many managing their own treatments and advocating for themselves when they are most vulnerable.

The CGT manufacturing community, including drug manufacturers, contract development and manufacturing organizations (CDMOs), and lab supply and equipment providers, are exploring strategies to improve supply chain resilience and address bottlenecks in the current processes. These strategies

include advancements in next generation engineering and manufacturing technologies; expanded manufacturing capacity through acquisitions and collaborations; and the move to de-centralized or bedside manufacturing when possible.

But improvements in manufacturing procedures alone are not enough to solve the complex challenges in successfully delivering these therapies at scale. Supply chain and logistical challenges and concerns around data integrity will intensify as more therapies enter the market and cross international borders. For example, in the case of autologous therapies, a clear chain of identity must be maintained from starting material to final therapy delivery at the patient's bedside. Any patient-therapy mismatch could pose dire consequences. The industry needs a proven mechanism to integrate and share information and data across the CGT value chain, to fully ensure the right patient gets the right treatment at the right time.

Sean Harapko, EY Americas Supply Chain & Operations Solution Leader, says, "One of the most important factors in successfully scaling CGTs will be

real-time tracking and tracing across the full CGT value chain, allowing for early indications of any problems and speedy course corrections."

Collaboration at the speed of science

A cross-functional EY team studied each step and the connectivity points along the CGT value chain. It asked: What issues could arise? What changes are required to address them? The team leveraged multidisciplinary capabilities and diverse geographies and experiences across EY to further define and solve these complex and evolving problems.

EY also conducted market research of more than 400 professionals in the health sciences and health care ecosystem (practicing oncologists, oncology thought leaders, HCPs, payers and other stakeholders) across multiple geographies (the US, France, Germany and Spain) to better and more fully understand the current care management paradigm and determine needed behavioral and process changes from patient, health care, manufacturing, intermediary and reimbursement standpoints.



“

And EY LLP worked with Microsoft to address the critical technology challenges. Data and technology can help deliver personalized, life-altering therapies at scale and with security, accessibility and reliability. We are working to solve the challenge of seamlessly ingesting and enriching any volume, variety or velocity of health care data from one system to another to ensure that patients receive the right treatment, at the right place, at the right time.

David Rhew, M.D., Microsoft Chief Medical Officer & Vice President of Healthcare, Worldwide Commercial Business (WCB)

The result is Pointellis™ – an open, trusted data exchange and the digital backbone that links all the key players in the CGT ecosystem that have a stake in patient outcomes: doctors, hospitals, drug makers, payers, even the logistics firms that move the therapies along the value chain. Pointellis™ liberates everyone in the ecosystem from building duplicative data systems that create siloes, so they can focus their personnel on developing and delivering new and effective therapies and keeping

patients and health providers connected, informed and engaged. By connecting each participant and forming a sharing, collaborative stage, Pointellis™ serves to speed up the delivery of vital, potentially life-saving therapies, minimizes costly errors and makes cutting-edge treatments more widely available to everyone who can benefit from them.

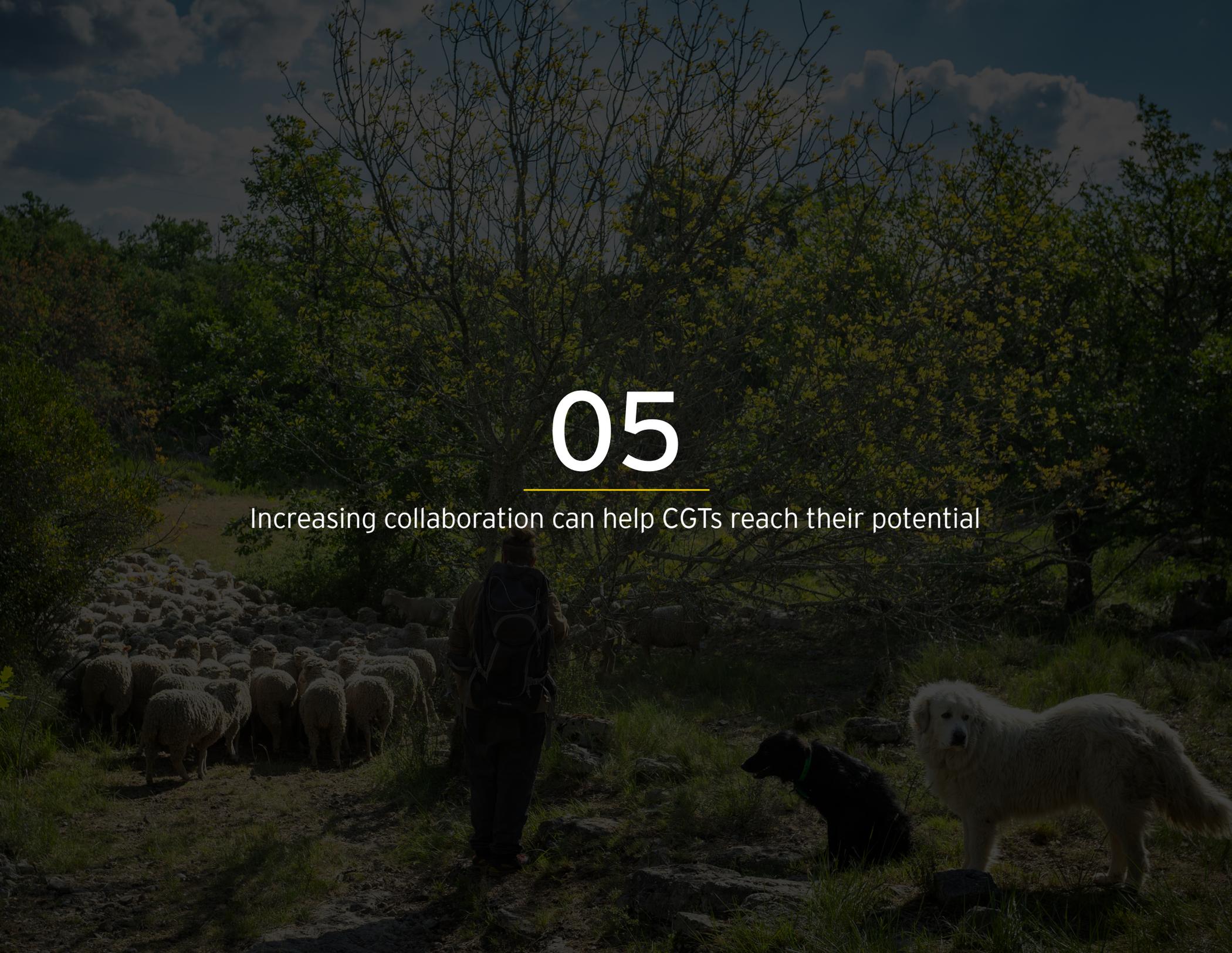
Pointellis™ is positioned to become the industry standard utility that will enable the CGT ecosystem to collaborate in unprecedented ways.



[EY Pointellis™ solutions page](#)

05

Increasing collaboration can help CGTs reach their potential



The World Health Organization estimates that by 2030

This translates to a yearly estimated cost of

23.6m

people a year will be diagnosed with cancer or other mutation-based diseases.

US\$1.16t

in medical expenses and loss of productivity from cancer alone.

And then there is the emotional toll of these illnesses, for which no figure can do justice.



“

The global disruption caused by the pandemic has demonstrated that resiliency, agility and innovation are more possible with digitally enabled business models that have data at their core. It has also served as a “hinge moment” by transforming the focus to be more patient-centric, with a growing understanding that patients expect to own their own data and access it through secure platforms.

Pamela Spence, EY Global Health Sciences and Wellness Industry Leader and Life Sciences Industry Leader

What could that world look like with a supportive digital ecosystem and how will patients benefit?

A reliance on data and connectivity

In CGT, that translates into a digital ecosystem that: supports data collection, management and sharing; evolves and expands to manage rapid growth; and becomes the foundation for delivering value.

Starting with chain of custody, which is the backbone of the CGT value chain, it will lead to additional modules that support improvement of stakeholder processes. This digital ecosystem will deliver a wide range of functional capabilities, information, services, data and analytics that will be phased in over time as the CGT market and patient base expands. The end result will

be a fully digital, cloud-based supply chain that focuses on reducing turnaround time, enhancing efficiency and enabling delivery of on-demand, individualized therapies with high levels of control and traceability to a wider audience.

New collaborations will be developed to combine and share data in ways we never considered before. This heightened level of coordination will help ensure every player in the value chain knows where a therapy is at any given moment, providing greater transparency to the patients themselves. It will also allow and fuel a teaming spirit that is open to the insights and value-adding modifications offered by all involved.

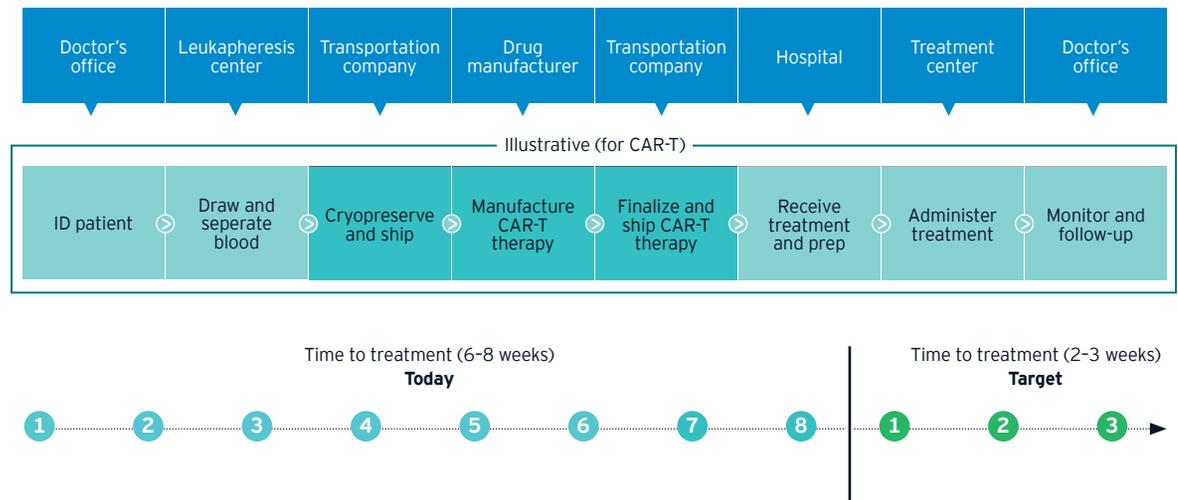


Success redefined through collaboration

Fluidity versus silos. Data sharing versus data ownership. Process and algorithm versus product. The ecosystem of the future will be connected and open, blurring traditional distinctions among the players in the CGT value chain. Organizations will focus less on owning and monetizing data and more on connecting and combining it to drive valuable insights that can transform health care. CGT manufacturers will rethink their approach to intellectual property, as the focus will shift from chemical or pharmaceutical patents to patents related to the process required to create on-demand, made-to-order therapies. The ultimate goal is to become a more responsive, flexible and resilient ecosystem that allows each member in the ecosystem to be more proactive and be better able to forecast needs rather than reacting to them.

Figure 4: Improving CGT lead times

Industry professionals agree that **lead times can, and need to, be reduced by up to 75%** to help realize the full potential of CGTs.



Source: EY primary research; *Cell Therapy Manufacturing Market (Second Edition), 2018-2030*, Root Analysis, 2018.



“

There has never been a better time to reimagine health care, with cloud-based tools like Pointellis™ that facilitate highly personalized care. This marriage of science and technology inspires trust, confidence and collaboration that will inevitably lead to better patient experiences and outcomes.

Elena Bonfiglioli, Microsoft Regional Business Leader, Health and Life Sciences EMEA

Access, empowerment and hope

The patients and caregivers in the CGT value chain are steadily becoming “super consumers,” demanding and deserving convenient, seamless care. They desire integrated applications that minimize turnaround time and maximize end-to-end reliability of novel therapy development. They want communication of highly complex processes in terms they can understand and real-time updates that make them feel confident and hopeful, and part of the process. And they seek secure data that protects their privacy, and coverage information and assistance that preempts billing.

Apart from addressing the challenges and needs of the complicated CGT value chain, an open digital platform, such as Pointellis™, provides an opportunity to create value for patients, now and

in the future. HCPs will have resources to help them advance patient care without adding extra work, including: transparent communications within the supply chain that improves handoffs; real-time data to manage and improve the specifics of patients’ treatment; and a forum for easier provider-patient communications. Providing this system for managing all that data is key.

Shared information, trust and an unprecedented level of collaboration among the players will mean faster, more efficient and accessible treatments, as organizations dramatically increase success rates, lower costs and expand their offerings. More successes will also lead to different treatment options that will offer patients more choices specific to their needs, both medically and financially.

Moreover, CGT patients will be more empowered and informed than ever before, with a highly personalized and supported patient-centric experiences through seamless access to tailored, up-to-date and complete information regarding their treatment and progress.

The Pointellis™ Mission

At EY, we want to help make CGTs available to every person and family that can benefit. By harnessing the transforming power of data, technology and stewardship of information, we can allow everyone else in the ecosystem to focus on what they do best – from developing new science, to delivering outstanding logistics, to giving patients the best medical care possible. This is how we’re building a better working world.

Please visit [Pointellis™](#) to learn more.

End notes

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About EY Health Sciences and Wellness

The rise of the empowered consumer, coupled with technology advancements and the emergence of digitally focused entrants, is changing every aspect of health and care delivery. To retain relevancy in today's digitally focused, data-infused ecosystem, all participants in health care today must rethink their business practices, including capital strategy, partnering and the creation of patient-centric operating models.

The EY Health Sciences and Wellness architecture brings together a worldwide network of 34,000 professionals to build data-centric approaches to customer engagement and improved outcomes. We help our clients deliver on their strategic goals; design optimized operating models; and form the right partnerships so they may thrive today and succeed in the health systems of tomorrow. We work across the ecosystem to understand the implications of today's trends, proactively finding solutions to business issues and to seize the upside of disruption in this transformative age.

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