

# **CELL AND GENE THERAPY**

What is the right digital strategy?

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## LEVERAGING DIGITAL TO MANAGE COMPLEXITY AND CREATE A COMPETITIVE ADVANTAGE WITHIN CELL AND GENE THERAPY DELIVERY

In recent years, advances within the Cell and Gene Therapy sector have created incredible excitement about how these potentially curative treatments can transform the health of individuals and society as a whole.

However, complexities within the lifecycle of the delivery model—from the patient, to the manufacturing process, and back to the patient require pharmaceutical and biotechnology companies to address significant and unique challenges associated with Cell and Gene Therapy development. This bold pursuit requires new operating models, systems, partners, and investments; the revolutionary nature of these therapies must also be matched by a transformative approach within the business. For companies that enter this class of treatment there is the added pressure of a rapidly growing playing field. By 2030, the Cell and Gene Therapy sector is expected to increase almost 700%, with the market valuation surging from just over \$4 billion today to more than \$34 billion. With thousands of new therapies in development, increased competition will only heighten the need to differentiate by outcome, patient experience, affordability, and other attributes.

In this paper, we explore how organizations entering the Cell and Gene Therapy sector must transform their business to support the development of the therapy itself and deliver it in a human-centric way.

## Projected growth of the Cell and Gene Therapy market

Today **\$4.39B**  By 2030



<sup>1</sup>Sources: Global Cell and Gene Therapy Market Report 2021, BusinessWire.



# EXPLORING THE UNIQUE CHALLENGES WITHIN THE CELL AND GENE THERAPY SECTOR

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## 1.1 Increased complexity at every stage of the delivery lifecycle

Unlike traditional pharmaceuticals, which follow a made-to-stock model, Cell and Gene Therapies are currently made-to-order. In the case of autologous and ex vivo therapies, one therapy is developed for each individual. In the case of allogeneic cell therapies, a range of development options exists, from drug products closely matched between donor and patient to off-the-shelf approaches. This adds complexity within the delivery lifecycle and requires personalized interaction with the patient at both the beginning and end of the delivery cycle.

Further, because Cell and Gene Therapies are derived from living cells taken from a patient or donor, organizations must ensure those cells are handled properly and remain viable. This creates new and complex chain of custody (COC) and chain of identity (COI) requirements that are not present in traditional pharmaceutical development.



Figure 1: Comparing the traditional pharma and Cell and Gene Therapy care model

Discovery/R&D	Clinical Trials	Commercial Manufacturing	Supply Chain	Patient Outcome Management
<ul> <li>Target selection</li> <li>Assay development</li> <li>Mechanism of action</li> <li>Clinical research site selection</li> <li>Credibility with key opinion leaders</li> </ul>	<ul> <li>Study design</li> <li>Patient eligibility criteria</li> <li>Safe starting and escalating doses</li> <li>Efficacy endpoints</li> <li>Therapy standardization for all patients and phases</li> <li>Therapeutic duration and long-term effects</li> </ul>	<ul> <li>100% product quality required</li> <li>Contamination- free manufacturing processes</li> <li>Strict turnaround time while maintaining GMP compliance</li> <li>High cost of goods sold</li> <li>Compliance of process specifications</li> <li>Manufacturing investment decisions</li> <li>Limited supply of starting materials</li> </ul>	<ul> <li>Chain of Identity and Chain of Custody</li> <li>Capacity management and patient scheduling</li> <li>Quality and resilience of supply chain networks</li> <li>Clinical site consistency</li> <li>Optimal manufacturing capacity and reagent replenishment policy</li> <li>Integration with systems due to patient privacy requirements</li> </ul>	<ul> <li>Lack of universal standard measurement of cell quality or product potency</li> <li>Temperature controls, storage and transportation quality and consistency</li> <li>Market access and reimbursement coverage</li> <li>Access to advanced healthcare facilities and medical centers</li> <li>Patient journey support and tools</li> <li>Long-term follow up and monitoring</li> </ul>

Table 1: Challenges within the Cell and Gene Therapy development cycle by phase

## 1.2 Seamless integration and management of the digital ecosystem to deliver Cell and Gene Therapies

As seen in Figure 1, the Cell and Gene Therapy care model requires the manufacturer to coordinate the entire supply chain, as well as other stakeholders such as patients, health care providers (HCPs), payors, and authorities. In addition, various systems, processes, and teams will need to be integrated to ensure therapies remain viable and that compliance standards are met.

Figure 2 maps the ten-part process of the Cell and Gene Therapy Journey in a linear fashion, focusing on autologous therapies. The figure identifies the underlying systems required to complete the cycle. In visualizing the journey in this way, we understand how steps within the process are not just sequential, but interdependent.



Figure 2: The Cell and Gene Therapy Journey

## 1.3 Enabling information access across the lifecycle through analytics to make real-time decisions and sustainable improvement

The end-to-end delivery of Cell and Gene Therapies is extremely time sensitive. At each point within the process, organizations and networks need to capture and produce real-time data and make insights derived from that data visible to relevant stakeholders.

Most obviously, companies need to know where the cells are at any given time to protect quality, confirm the cells are still viable, and ensure that they've been through the necessary quality checks to proceed to the next stage of the manufacturing process.

To do this, organizations must consider all the different contingencies needed to complete the process. Are the raw materials readily available to produce the therapy? Is there an available manufacturing slot? Are there any disruptions that will affect the availability of the manufacturing team itself? Can quality control release the intermediate product to the next manufacturing step? If not, at which step can the process be restarted? Even seemingly benign issues like public holidays or weather events may impact the ability to ship the therapy, which may in turn impact the success of the treatment.

Compounding complexity is the fact that the data needed to make such decisions must be compiled from a variety of internal and external sources. This means that companies must not only connect their own systems and processes, but also ensure all partners within the ecosystem, such as treatment centers or shipping partners, are integrated seamlessly. Since different steps might be outsourced, logistics will be external, but must remain accessible.

### Patient privacy and security

Cell and Gene Therapy development raises important concerns about patient privacy and data security. Even when the data set is anonymized, it is still possible to analyze different data points, such as the device used or IP address, and cross reference it with other data from third-party data brokers, to identify the patient. For this reason, organizations must follow strict protocols to protect their data and also avoid sharing the data set, or a portion thereof, with other parties. Security is an especially complex undertaking in today's increasingly distributed, remote work settings.

### **Regulatory compliance**

Data access also raises important issues around regulatory compliance. Put simply, the more parties that have access to data, the higher the risk of non-compliance.

Organizations must make sure they comply with all relevant patient and other stakeholder privacy regulations, which vary from region to region. For example, In the EU, companies are required to delete consumer data upon request. To comply, organizations need to be able to erase not just the original data set but any copy or segment that was shared with a partner or stakeholder and any subsequent instances thereafter. If the organization cannot ensure that they have a complete and accurate view of where patient data is across the ecosystem, then they should not grant access to external stakeholders.

Regulatory compliance is a complicated and nuanced situation that our team will explore in more detail in a subsequent article.



# USING DIGITAL TO ACCELERATE CELL AND GENE THERAPY DEVELOPMENT CAPABILITIES AT SCALE

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"You have to start on your digital roadmap pretty early...it's very important to balance your 3- to 4-year vision with what you need fit for purpose now."

## **CHRISTOPHE SUCHET**

VP, Global Head of IT, InstilBio

For some Cell and Gene Therapy manufacturers, building the technology set and infrastructure needed to deliver therapies has taken a backseat to developing the treatments themselves. While that approach may seem logical, it is far from ideal.

When organizations attempt to develop infrastructure and implement technology ad hoc, it leaves open the possibility of gaps or silos that put the entire process at risk. This is why traditional pharmaceutical companies and established organizations, in particular, must develop and implement a comprehensive digital transformation strategy that enables all aspects of the business – people, processes, systems and technologies – to overcome gaps and unite the Cell and Gene Therapy development cycle. They must also consider how other factors, such as organizational culture, leadership, governance, and change management, will enable the transformation strategy.

## 2.1 Positioning digital as the foundation

The challenges facing Cell and Gene Therapy developers can be partially or fully solved by digital—which includes capabilities such as cloud, data, automation, user experience, and process re-engineering, all deployed in an effective, efficient, and sustainable way.

However, just as with any business transformation initiative, technology is an enabler, not the solution. Organizations must develop a comprehensive and connected digital strategy, underpinned by a robust and scalable data platform, cloud technology and automation, to advance the maturity of digital capabilities, enable appropriate access to timely insights, support end-to-end Cell and Gene Therapy delivery, and ensure data security and privacy.

Further, integration of the disparate solutions and systems within the cycle is particularly challenging. Organizations must contend with a large ecosystem of vendors across an ever-changing technology and solution landscape. There is also a very specific issue of integrating vendors of specialized biopharma solutions with traditional, out-of-the box enterprise solutions.

## 2.2 Using digital to enhance the competitive position

For most organizations, Cell and Gene Therapy development is a new line of business that requires new resources. While this introduces new costs for the organization, it also unlocks new opportunities. For example, organizations that master their data strategy can gain a competitive advantage through the use of sound, timely, and accurate insights, which can be used to optimize business operations, proactively identify pain points within the cycle, and enhance the customer experience.

Another important benefit of digital transformation is the improved cost position of the Cell and Gene Therapy manufacturer. For example, current manufacturing processes are often manual, which drives up the cost of goods sold. Innovations supported by digitization, such as artificial intelligence, smart factory automated processes, and real-time decision-making, can help organizations both reduce costs and increase Cell and Gene Therapy yield.

Since reimbursement remains an important and contentious issue that can contribute to the success of a Cell and Gene Therapy, an improved cost position will increase the chances of market acceptance.

Leveraging a digital platform across the complete value chain can help minimize or eliminate disruptions, as well as maximize service levels. This, in turn, can have a positive impact on the availability, or market access, for patients.

Organizations can also leverage new insights from the Cell and Gene Therapy cycle to enable and reinforce valueor-evidence-based reimbursement models for novel therapies. This would connect payment not just to delivery but also the success of the treatment based on patient outcome or side effect data. Leveraging such insights to unlock new reimbursement models can help organizations both enhance market authorization processes and increase the affordability of the therapy.

Data from across systems can also be cross referenced and used to create real-time alerts to proactively address issues within the cycle and improve operations. It can also be used to produce insights to improve the patient or caregiver experience and create value within the business.

## Digital infrastructure will play a key role in the successful delivery of Cell and Gene Therapies

#### **Company requirements**

- Long-term vision
- Documented end-toend processes
- 5-year digital roadmap
- Implementation plan
- Agile and flexible digital partners

## **Patient imperatives**

- Overall quality assurance
- Ensured privacy and data security
- Patient and Health Care Provider omnichannel experience
- Timely delivery as demanded by patient enrollment
- Manufacturing excellence for high-quality therapy (order management)
- Enhanced real-time quality control and product release
- Supply chain accuracy and optimization
- Ecosystem integration

#### Business values and outcomes

- Quality therapies
- Agile decision making
- End-to-end operational efficiencies
- Cost structure improvements
- Regulatory compliance
- Competitive advantage

Table 2: Digital infrastructure and successful delivery of Cell and Gene Therapies

# 3 KEY CONSIDERATIONS FOR SUCCESSFUL DIGITAL TRANSFORMATION





"Organizations must remember that applying a technology is merely part of the equation and not the solution itself."

SALAH AZIZI Cell & Gene Therapy CoE Lead Capgemini Invent

Developing a successful Cell and Gene Therapy program requires organizations to have markedly different capabilities across people, processes, technology, and data within the business, as well as effective coordination and collaboration with a broad partner ecosystem.

In this section we explore how organizations can develop the optimal business and technical architecture to ensure a successful and scalable Cell and Gene Therapy strategy, as well as key considerations as they create and deploy a customized Cell and Gene Therapy program.

## 3.1 Developing an optimal business architecture

### Enabling a comprehensive and connected end-toend Cell and Gene Therapy journey

Since autologous and ex vivo therapies are developed using cells from patients, there is a finite window of viability for development. The efficacy of the treatment depends not just on the therapy itself, but the developer's ability to connect all aspects of production, delivery, administration or infusion, and monitoring. This means the developer must have accurate insight into all stages of the manufacturing cycle at all times to ensure success.

As such, organizations need to think about the Cell and Gene Therapy delivery cycle as one cohesive process that begins and ends with the patient. This includes determining all system requirements, integration points and contingencies across the cycle, from the patient and HCP experience all the way through the enterprise resource planning (ERP) system and data foundation.

### Offering an intuitive and effective user experience

As the Cell and Gene Therapy landscape becomes more competitive in the coming years, the user experience will become an important differentiator for manufacturers. While treatments will be chosen primarily based on their projected impact on the patient, companies cannot discount the importance of an accessible, intuitive connected delivery experience for HCPs, patients, and their caregivers. Further, a clear and intuitive experience can directly impact performance indicators, including drop-out rates, adherence, monitoring and more, which can in turn help drive program success or identify opportunities for early intervention.

To that end, developers need to consider the end-toend supply chain and determine how to best engage HCPs, patients, and caregivers at every stage of the journey. This includes ease of registration, data coordination, patient updates, and coordination of virtually every other task within the cycle. Post infusion, it also includes patient monitoring and communication.

## Optimizing business processes to enable system efficiency and ensure future scalability

While organizations must take the wide lens and enable an end-to-end journey, they must also consider how to optimize each task and process within that broader chain to ensure the organization can execute at the speed required for Cell and Gene Therapy treatments. In practical terms, this means reevaluating how core, recurring tasks are completed and determining if that process still serves the purpose in an efficient and effective way.

For example, in the past, a large pharmaceutical company may have required nine steps to approve a purchase order (PO). In today's digital world, companies may be able to eliminate some portions of that sequence and automate others to create leaner, more agile processes, which will help enable a more responsive, efficient business.

## Executing a change management strategy to drive success

As in every case of business transformation, success depends not just on the implementation of tools or creation of new processes, but people's willingness to embrace a new way of working. Cell and Gene Therapy development requires a new mindset and culture that must be embraced by all stakeholders across the business. It also will provide the opportunity for automated processes and real-time decision making, which requires having a workforce that is skilled in digital technologies that can leverage these new capabilities.

Organizations must remember that applying a technology is merely part of the equation and not the solution itself. For established companies in particular, part of every Cell and Gene Therapy strategy should include developing a change management program that focuses on human-centric understanding and design. Ultimately, the organization should aim to achieve a fast, high adoption rate and demonstrate value to users so that people will continue to use the solution over time.

# SOLUTION SPOTLIGHT

## CELL AND GENE THERAPY IS A GAME CHANGER IN THE PHARMA AND BIOTECH INDUSTRY AND GIVES HOPE TO SO MANY PATIENTS

Judith Koliwer, Principal Consultant Cell and Gene Therapy Software  $\begin{pmatrix} K \ddot{O} R B E R \end{pmatrix}$ 

The processes in Cell and Gene Therapy (Cell and Gene Therapy) often require many manual steps and high flexibility – especially the autologous cell therapies with their highly variable starting material and/or process development during the journey to commercialization. The Cell and Gene Therapy/ATMP (Advanced Therapy Medicinal Products) industry is growing extraordinarily fast and training of personnel that is involved in these complex processes is extensive, which leads to them being a bottleneck for manufacturing.

Electronic Batch Recording (EBR), such as provided by Werum PAS-X MES from Körber, can support by facilitating the documentation, e.g. by allowing the operators to scan barcodes instead of recording values manually or automatically collecting time stamps. The effort that operators, supervisors and QA are using to correct date formats or signature definitions alone can be used for so much better purpose – like scaling up the manufacturing.

Data management in Cell and Gene Therapy can be particularly challenging, as the regulatory guidelines are updated upon development of the industry. Digital data are easily available and can be used directly not only for the batch release, but also for process analysis, optimization and validation. Thus, the reduction of time to market can be significantly improved.

Furthermore, EBR supports operator guidance. Thus, calculations can be done by the system and existing algorithms and AI can be used for automatic decisions – e.g. when it's time to harvest the cells. This again leads to a reduction of efforts and increased safety of the procedure. On the other hand, the required flexibility of the process still needs to be ensured. Key seems to be to find the right balance between automated decisions, manual decisions by operators or supervisors and definition of alternative pathways, resulting in recipe design and execution, which reflects the variability of the process and in which deviations are automatically recognized.

Cell and Gene Therapy is a game changer in the pharma and biotech industry and gives hope to so many patients. By supporting the manufacturers in their digitization initiatives, we at Körber are delighted to be able to contribute to making the processes safer and increase availability of these therapies.

## 3.2 Developing a robust and interoperable technical architecture to integrate solutions and data layers

## Business process standardization and harmonization

While Cell and Gene Therapy development is highly customized in terms of the treatment itself, the underlying systems and processes that enable the development and delivery of those treatments must be standardized and harmonized in order to achieve scale.

In looking at the process landscape across the Cell and Gene Therapy development cycle, developers should follow what is commonly referred to as the 80/20 scenario. This means that roughly 80% of core processes should be standardized across the organization, regardless of geography or business unit. This applies to common, recurring tasks, such as taking orders, issuing POs, moving materials, or other activities that do not require much deviation and therefore will not benefit from specialization.

The remaining 20% of processes can be considered "non-core" or variable. This is where organizations can adapt standard systems and processes at the geographic or site level to account for different market or business nuances. For example, a relatively small biopharma organization may have the need to agree to supplier terms set by a large, dominant partner in certain markets because not doing so would delay or jeopardize the company's ability to go to market.

It is important for Cell and Gene Therapy developers to understand when to standardize and when to harmonize their processes. While some companies may attempt to customize core systems and processes as a way to drive innovation and enrichment, doing so can actually have the opposite effect when customizations occur within the core. Such changes can slow the pace of technology development and make future upgrades and integrations infinitely more complex, which diminishes the business's ability to respond to market changes, introduce new products, or integrate acquisition targets.

In working with our client partners, we recommend that all process enhancements are made outside the core, or at the edge. These enrichments can be made to peripheral functions and processes – such as last mile delivery – which will vary from market to market or by business unit. Such customizations enable the business to enrich their processes and drive value, while also preserving the core. This helps ensure that any future updates, upgrades, or integrations will be relatively simple.

#### Designing a flexible and scalable ecosystem

Flexibility is an important consideration for Cell and Gene Therapy companies given that the nature of the business all but requires the need to accommodate major events, such as spinning off a division, acquiring a new company, introducing a new product, or entering a new market. The system landscape and platform should be able to accommodate and support those changes with relative ease. This can be achieved, in part, through process standardization and harmonization, as discussed above.

Ecosystem orchestration is also an essential capability for Cell and Gene Therapy developers. The ability to interface with all systems across all stakeholders, both internal and external, throughout the journey is essential when it comes to ensuring that treatments remain viable and that they can reach patients in time. Put simply, each component of the ecosystem must work flawlessly for the entire system to work effectively.

In developing the ecosystem, it's important to determine the degree to which the system can scale to support increased volume and growth in a short span of time.

# WHAT DOES SUCCESS LOOK LIKE?

Organizations that successfully develop a transformation strategy that leverages digital can expect a multitude of benefits, including:

### 1. Improved patient experience and outcomes

- Lower dropout rates
- Higher patient satisfaction
- Reduced scheduling and administration
- Improved efficacy
- Improved manufacturing with faster product delivery timelines
- Higher quality of care

### 3. Enhanced business performance and improved reputation

- Resource optimization
- Enhanced efficiency
- Lower cost of goods sold
- Improved profitability
- Enhanced reputation
- Improved adoption

### 2. Increased healthcare provider referrals

- Reliability and trust in delivery timing and quality
- Lower complexity of Cell and Gene Therapy administration
- Increased ease of use
- Harmonized processes for order and delivery

### 4. Scalability and business transformation

- Access to new business models
- Ability to invest in new capabilities and resources

## 3.3 Executing the Cell and Gene Therapy strategy: Three considerations for designing a successful and scalable Cell and Gene Therapy program

## #1: Prioritize system and solution deployment to maximize impact

Every IT department has thousands of initiatives, many of which compete with one another for resources and attention. Determining which programs to approve and execute, as well as the deployment sequence, will be determined based on the portfolio strategy and the need to balance quick win projects with long-term initiatives. In creating the transformation roadmap, Cell and Gene Therapy developers must determine their longterm goals and then identify those initiatives that will help the company achieve the vision.

## #2: Tailor the Cell and Gene Therapy strategy

It's important to note that each of the challenges explored within this paper will manifest differently in each pharmaceutical manufacturer or developer based on the company structure and level of maturity. For example, large pharmaceutical companies will need to run their Cell and Gene Therapy program as a new line of business and therefore may need to develop internal capabilities or acquire them. New entrants, on the other hand, may have an immediate need to create scalable capabilities for clinical operations and commercialization. To that end, the Cell and Gene Therapy strategy and plan will need to be tailored to the company's unique position, capabilities, and goals.

## #3: Identify the optimal solution partners

Cell and Gene Therapy development requires partnerships across many different functions – from patient engagement and healthcare provider coordination to treatment delivery and administration. No company – no matter how established in the market – will be able to deliver the Cell and Gene Therapy strategy independently.

Compounding complexity is the fact that Cell and Gene Therapy development is a new market segment of novel therapies. Unlike traditional drug development, where there are long-standing leaders and reputable niche players, the Cell and Gene Therapy sector has yet to produce mature solutions. There is no market leader for the core technologies and systems that will support the development and delivery cycle. To that end, the transformation strategy must also include the deliberate evaluation and selection of vendors and developing a careful list of requirements and benchmarks for each partner, system, and tool.





## AN END-TO-END APPROACH TO ACCELERATE AND DE-RISK DIGITAL TRANSFORMATION FOR CELL AND GENE THERAPY COMPANIES

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## 4.1 Enabling the Cell and Gene Therapy transformation journey with Capgemini

The challenge organizations in the Cell and Gene Therapy sector are facing, is not to just accelerate time to care – but to do so at scale. To that end, the industry must go beyond simple process optimization and incremental changes and instead embrace a bold vision of the future – one marked by a reinvention of the entire digital value chain to enable better care, improve operations and enhance compliance.

The question is: How will Life Sciences organizations implement an enterprise-wide, scalable, sustainable digital transformation to get the future they want?

Capgemini helps Cell and Gene Therapy developers become intelligent and renewable enterprises that can improve customer outcomes through the delivery of personalized solutions at scale and as a service. We work with clients to help them develop an ecosystem of partners and enhance their digital supply chain and smart factory capabilities to improve agility and responsiveness within the market.

Discovery/R&D	Clinical Trials	Commercial Manufacturing	Supply Chain	Patient Outcome Management
<ul> <li>Provide proprietary tools and accelerators to expedite program launch</li> <li>Data-driven R&amp;D</li> </ul>	• Intelligent & Decentralized Clinical Trials	<ul> <li>Manage the complexities of quality, cost, and turnaround times</li> <li>Assess bottlenecks and determine key features and system integrations (LIMS, MES, ERPs, etc.) to overcome them</li> <li>Prioritize and define a roadmap based on capacity and ambition</li> <li>Smart Factory</li> </ul>	<ul> <li>Identify supply chain bottlenecks</li> <li>Define an action plan to optimize the supply chain with defined anticipated gains</li> <li>Intelligent Supply Chain</li> </ul>	<ul> <li>Understand pain points and opportunities for patients, physicians, treatment centers, pharmacists and caregivers</li> <li>Deliver an exhaustive journey mapping blueprint for key personas</li> <li>Develop a targeted action plan and recommended initiatives to increase omnichannel experience</li> <li>Connected Health</li> </ul>



In the coming decade, Cell and Gene Therapies are poised to revolutionize how we treat chronic diseases, cancer, and other complex diseases.

At the same time, the development of the therapy is but one part of the delivery model. To realize the promise of this exciting class of treatment, organizations must reconsider virtually every aspect of the business to address the significant and unique challenges associated with Cell and Gene Therapy development.

Digital plays a crucial role in solving these challenges, though the underlying technologies, systems, and processes must be carefully planned and orchestrated to enable the end-to-end development cycle and deliver a personalized, intuitive user experience to all stakeholders.

With the health of millions of people at stake, organizations must take bold and decisive steps to make the promise of Cell and Gene Therapy a reality. "Organizations must take bold and decisive steps to make the promiseof Cell and Gene Therapy a reality."

## **OLIVIER ZITOUN**

Global Life Sciences Industry Lead, Capgemini

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## About Capgemini

Capgemini is a global leader in partnering with companies to transform and manage their business by harnessing the power of technology. The Group is guided everyday by its purpose of unleashing human energy through technology for an inclusive and sustainable future. It is a responsible and diverse organization of 325,000 team members in more than 50 countries. With its strong 55-year heritage and deep industry expertise, Capgemini is trusted by its clients to address the entire breadth of their business needs, from strategy and design to operations, fueled by the fast evolving and innovative world of cloud, data, AI, connectivity, software, digital engineering and platforms. The Group reported in 2021 global revenues of €18 billion.

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