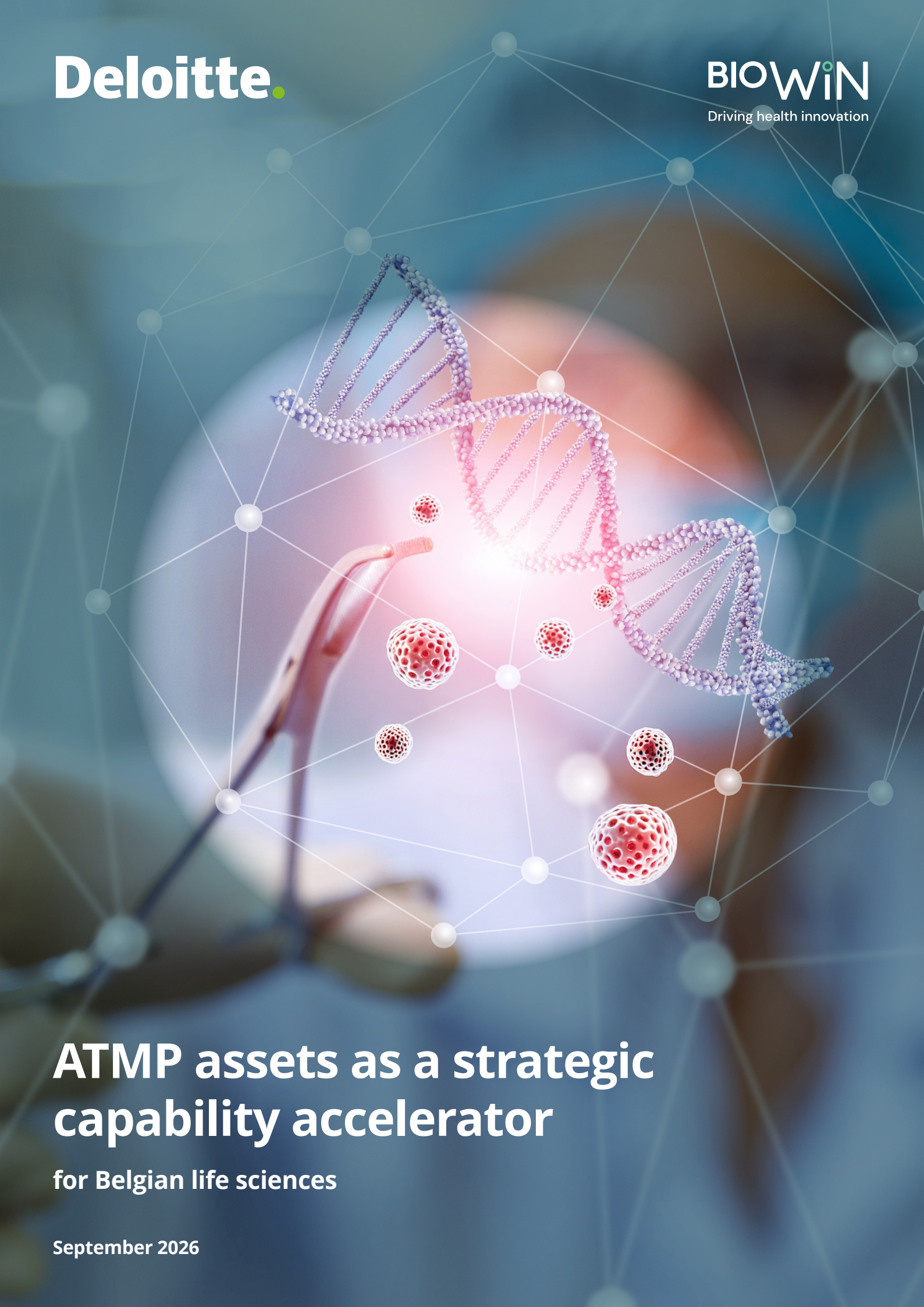
Deloitte.

BIOWIN
Driving health innovation



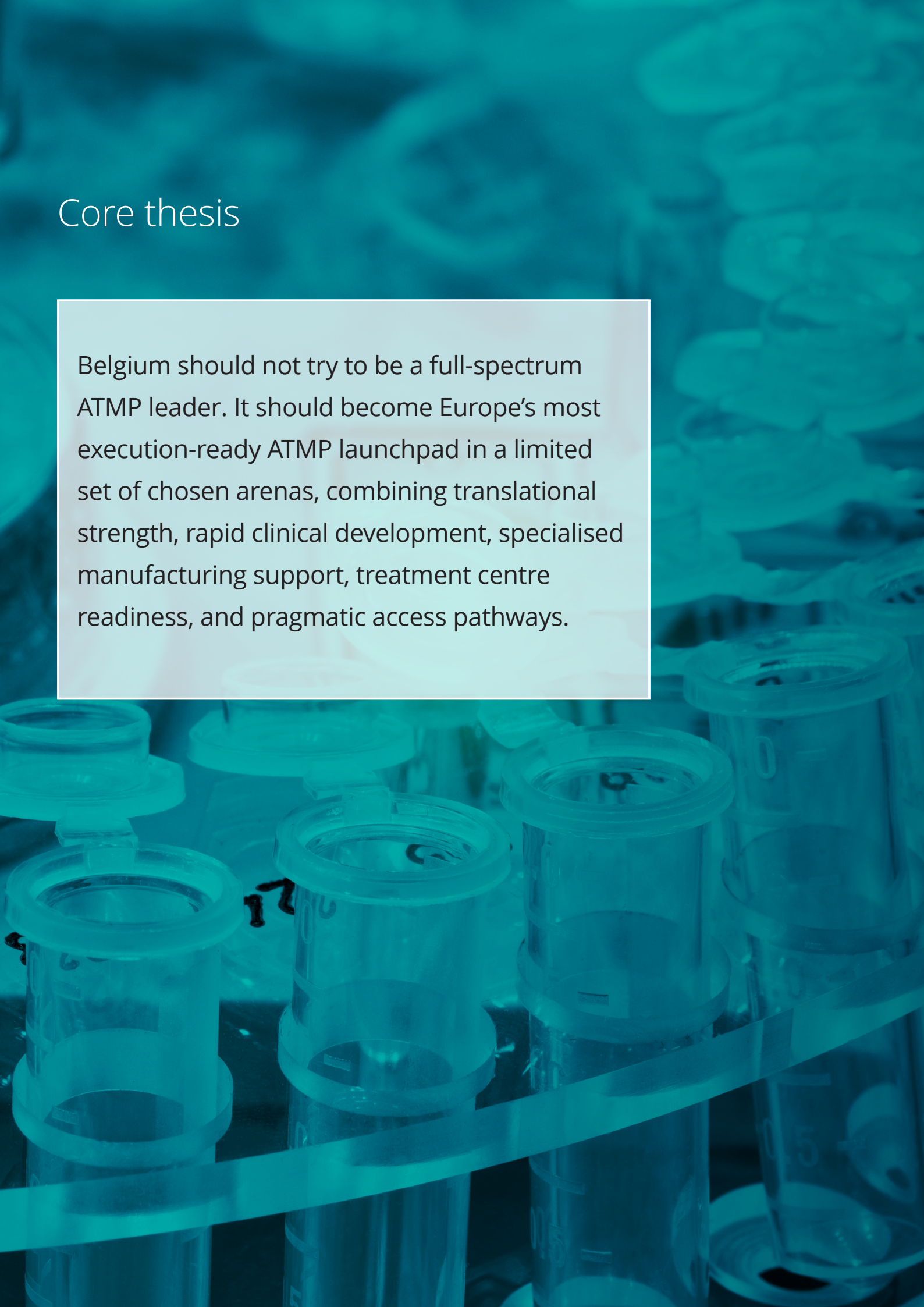
ATMP assets as a strategic capability accelerator

for Belgian life sciences

September 2026

Core thesis

Belgium should not try to be a full-spectrum ATMP leader. It should become Europe's most execution-ready ATMP launchpad in a limited set of chosen arenas, combining translational strength, rapid clinical development, specialised manufacturing support, treatment centre readiness, and pragmatic access pathways.



Contents

0. Executive summary

Belgium has a credible right to win in Advanced Therapy Medicinal Products (ATMPs), but the basis of competition has changed. The 2024 Deloitte/BioWin/Medvia white paper correctly argued that Belgium had many of the ingredients of an attractive ecosystem: academic excellence, a central European location, biomanufacturing heritage, specialist logistics and a collaborative health ecosystem [1]. Two years later, the strategic question is no longer whether Belgium has the ingredients. The question is how Belgium can convert those ingredients into repeatable execution in a strategically limited number of ATMP domains that matter, so that the innovations and investments made in ATMPs are translated into economic, societal, and commercial returns for the ecosystem and the patients.

The broader European ATMP field remains dynamic. The European Medicines Agency (EMA) Committee for Advanced Therapies update of March 2026 shows continuing activity in marketing-authorisation applications, classification requests, scientific advice and PRIME eligibility discussions. The list of authorised ATMPs has also continued to expand through 2025 and early 2026 [2]. The proposed EU Biotech Act, and the Scaleup Europe Fund combined with the rapid emergence of innovation for ATMPs and the need for EU Centres of Excellence make 2026 an important pivotal year for the ecosystem. Yet the commercial reality remains selective: some products have been withdrawn, uptake remains uneven, and operational readiness is now as decisive as scientific novelty. Across Europe, the bottleneck has shifted from proof of concept to industrialisation, delivery, evidence generation and access. In 2021, CGT startups raised an all-time high of ~$8.2 billion across 121 VC deals, but by 2023, funding had fallen to roughly $3.5 billion (65 deals). Investors are only rewarding tangible results in strong clinical data that surpass the standard-of-care, and flawless commercial launch execution through tracked KPIs.

Europe remains a global leader in scientific research, but China and US are moving faster in attracting investment and supporting biotech growth by proposing structural advantages. Belgium starts from a strong position: according to the 2026 pharma.be / Deloitte report based on 2024 data, Belgium remains one of Europe's leading countries in clinical trial authorisations per capita over the last five years. While this data reflects general clinical trial infrastructure rather than ATMP-specifics, it highlights particular strengths in oncology, rare diseases and phase 1 research [3], therapeutic areas that heavily overlap with the ATMP pipeline. At the same time, the report highlights warning signs: start-up timelines remain an issue, first-in-human and phase 1 volumes are under pressure, and other regions are moving faster [3]. Belgium is still attractive, but no longer automatically advantaged. The underlying challenge increasingly appears to be one of orchestration rather than absence of capabilities.

Belgium can remain attractive if it differentiates itself, but only if it chooses a few domains and coordinates them tightly. This paper therefore argues that Belgium should not aim to become a broad-spectrum ATMP leader across all modalities and steps of the value chain. That ambition is unrealistic for a country of Belgium's size and would dilute scarce resources. Belgium should instead aim to become Europe's most execution-ready ATMP launchpad in a limited set of domains where it can combine translational science, rapid early clinical development, specialised manufacturing and release capabilities, treatment centre readiness, innovative evidence, and access pathways (e.g., time from sponsor readiness to first patient enrolled, treatment centre activation rate).

Those domains should be based on demonstrated strength at EU level, and absence of structural barriers that cannot be closed in the short term. The proposed arenas do not intend to be exhaustive nor support any investment decision but suggests a selection of illustrative areas where Belgium can create a competitive advantage based on today's market dynamics. The proposed where-to-play choices are fourfold.

First, Belgium should prioritise cell therapies in oncology and haematology, where its hospital network, investigator base and trial activity are already comparatively strong [3].

Second, Belgium should play selectively in gene therapies for rare diseases and advanced paediatrics, where concentrated patient referral pathways and long-term follow-up capabilities matter. Across Europe, the average diagnostic journey spans five years, with most patients experiencing misdiagnosis and delayed specialist referral. Yet patients referred to centres of expertise experience significantly shorter diagnostic pathways, demonstrating that structured referral systems work. Even though the commercial business case for gene therapies is still to be proven, perhaps Belgium can be the place where technology innovation can broader the case for more patient populations (and so more sustainable for the pharmaceutical industry).

Third, Belgium should position itself in specialised manufacturing, release and logistics to optimise use of specialised resources rather than in undifferentiated volume manufacturing. Post-COVID overbuild has pushed Contract Development and Manufacturing Organization (CDMO) in some plants below 70%, yet 55.9% of sponsors still report difficulty finding a gene therapy CDMO and 55.6% for cell therapy.

Fourth, Belgium should build a clearer bridge from hospital exemption and academic innovation toward scalable late-stage development and broader patient access [4][5]. For that, having shared infrastructure with access to capability and

capacity for small scale productions so the first clinical trials can be executed quickly is a strong enabler for the local biotech and academic ecosystem. Actual CDMOs can play a key role in supporting innovators with reserved capacity. The centralisation rationale makes sense as the number of batches required is low for first phases of CGT trials – having one or two places in consortia with private players where that bridge from research to late stage can be executed will be of high-value for the ecosystem.

How Belgium wins, is as important as where it plays. The recipe should rely on six moves: a visible regulatory and innovation front door; faster trial activation; stronger CMC, quality and specialised manufacturing support (a dedicated scale-up hub); a national ATMP treatment centre network; better outcomes and follow-up data; and pragmatic access innovation. These are not abstract ecosystem aspirations. They are execution choices that can be organised and measured. Belgium will not win by producing the broadest narrative on paper. It will win by being the European ecosystem that sponsors, hospitals, investors and patients experience as the easiest place to advance selected ATMPs from scientific promise to scaled use. These enablers are not specific to ATMPs, these are no regret moves for the life sciences ecosystem in Belgium, for which ATMPs can strongly benefit from. Belgium has reached the maturity to develop a unified national ATMP strategy and governance, and a clear international branding strategy to position and defend its capabilities. Europe does not have the financial depth of US and cost of labour is higher compared to China, but Europe could accelerate its administrative timelines and reduce its procedural complexity to remain internationally competitive.

Europe could put emphasis on its capacity to deliver registrational-quality data in relevant populations while always ensuring transparency, compliance and IP protection. Belgium should publicly invest in specialised manufacturing and logistics, and treatment centre readiness, where shared capabilities create spillovers across multiple programmes. A portfolio approach for technologies of high potential combining targeted milestone-driven funding allocation and administrative flexibility could provide biotech with highly needed financial agility.

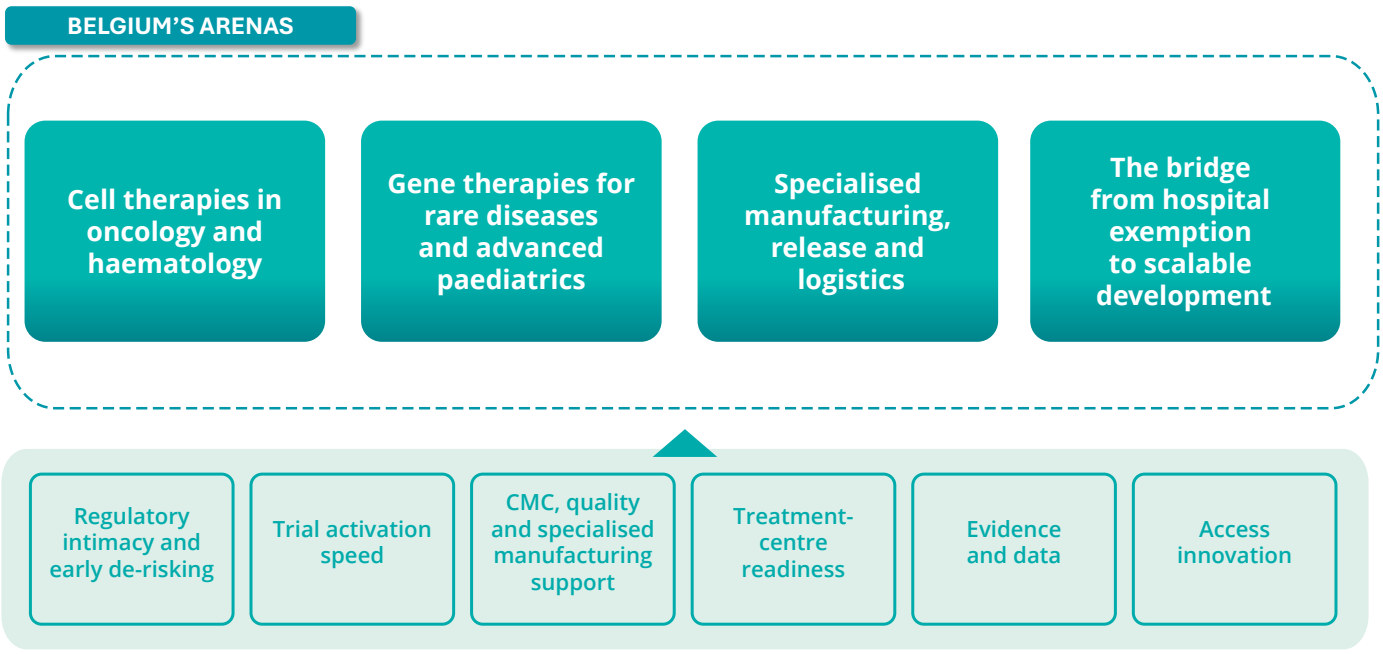


Figure 1: Where Belgium needs to play and how to win (non-exhaustive). Cell therapy is defined in this paper as medicine using autologous or allogeneic cells. Gene therapy is defined as medicine using viral or non-viral gene delivery vehicles to the tissue.

ATMPs have already generated – and can continue to generate – valuable national capabilities well beyond their own value chain, from Good Manufacturing Practice (GMP) and manufacturing to logistics, data, regulatory expertise and talent. The market reset should be a reason for greater focus and selectivity: concentrate on the most promising arenas where Belgium has a genuine right to win, while leveraging the broader spillovers already created.

3 KEY RECOMMENDATIONS

1

Continue to brand Belgium as a true ATMP development and manufacturing powerhouse in the heart of Europe.

- Align ATMP stakeholders around a clear value proposition at country level (e.g., dense end-to-end public private biopharma ecosystem, research institutions and necessary service providers, strong clinical and research sites, both clinical and commercial experience in bringing ATMPs to the patient, regulatory agency with dedicated centre for ATMPs).
- Enhance Belgian visibility in Europe - join large EU initiatives as direct or indirect beneficiaries, create opportunities to escalate Belgian aggregated impact/ needs to policy makers, establish ATMP national governance, organise a national network of accredited Centres of Excellence in priority areas.
- Showcase Belgium capabilities in international events/conferences. Share knowledge and lessons learned across large non-EU national initiatives.

2

Enhance service offering from Industry/Research Centres.

- Create a shared CMC and manufacturing acceleration platform to provide access to academic innovators and early biotech to development expertise, analytics, quality systems support, GMP translation and specialised manufacturing to remove bottlenecks early – so the proof of concept can be executed faster (leveraging Belgian CDMO specific expertise in ATMPs).
- Fast track early phase clinical research processes for the testing of modalities of high potential (e.g., accelerate site contracting, Clinical Trial Agreement (CTA), ethical approval, project management, patient access to clinical trial, patient pre-screening for eligibility (Trial Ready Cohorts), monitoring, reporting).
- Strengthen capabilities to supply bio manufactured Advanced Therapy related products - focus on logistics-by-design (e.g., digital tracking, documentation, temperature monitoring system, Cryo-Chain transport, sustainability).

3

Offer short/medium/long term national growth enablers (and monitor the progress).

- Provide access to agile, milestone driven funding to accelerate the achievement of pivotal milestones for companies developing technologies of high potential.
- Facilitate Public-Private Partnerships (PPPs) between Flanders and Wallonia on strategic research areas needed to support technologies of high potential (aligned with clear and detailed strategic directions from the regional ecosystem).
- Support harmonisation, improvement and acceleration of ATMP-related business processes through digitalisation, AI-driven approaches and sustainable solutions.

1. Why ATMPs (still) matter now: From promise to industrial reality

1.1 ATMPs have moved beyond scientific promise

Advanced Therapy Medicinal Products (ATMPs) are innovative medicines based on genes, cells, or tissue engineering, classified into gene therapy, somatic-cell therapy, and tissue-engineered medicines. These products are designed to treat diseases or repair tissues by inserting recombinant DNA, altering cells for therapeutic use, or modifying tissues for regeneration [6]. They have offered significant improvement for a variety of severe illnesses. Remarkable clinical successes that were almost unimaginable 10–15 years ago, curative outcomes in blood cancers, the first gene therapies reaching patients with genetic disorders, and new delivery technologies emerging, are witnessed.

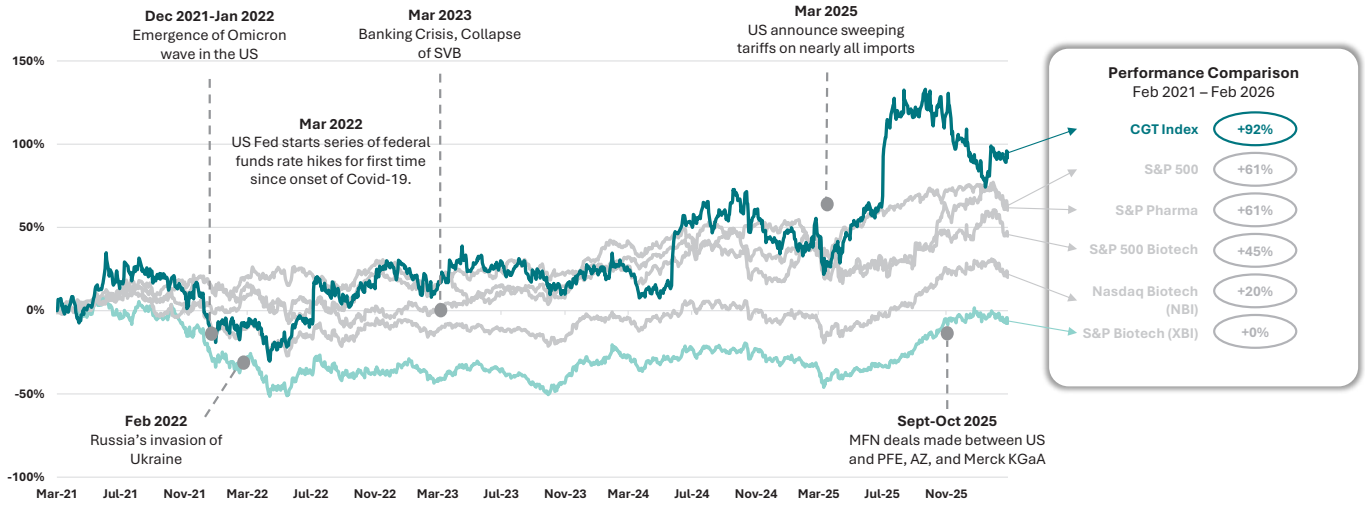
ATMPs have significantly transformed patient care globally, establishing a fast-growing paradigm of innovative treatments that have the potential to cure patients. Globally, a total of 59 distinct ATMPs have been granted a marketing authorisation (MA) by at least one G5, UK, or Swiss regulatory authority. Among these authorised products, gene therapy medicinal products represent the most prevalent modality, with haematology emerging as the primary therapeutic area. For instance, CAR-T cell therapies have fundamentally restructured the clinical landscape for hematologic malignancies, improving hospitalisation rates, infection rates and 3-year survival in relapsed large B-cell lymphoma from 10% with historical care to 59% [41].

1.2 The current ATMP industry has slowed down but the rebound is now

Investor enthusiasm for Cell and Gene Therapy (CGT) has cooled significantly in recent years. Rising interest rates and macroeconomic uncertainty have made investment more risk-averse, favouring lower-risk, near-term opportunities. CGT ventures face headwinds: high technical risk, long development timelines, and substantial infrastructure costs deter capital. Early commercial disappointments and clinical setbacks have further tempered the initial CAR-T euphoria, making clear that CGT is not a guaranteed win. In 2021, CGT startups raised an all-time high of ~$8.2 billion across 121 VC deals, but by 2023, funding had fallen to roughly $3.5 billion (65 deals). Early data from 2024–2025 show the downturn continuing: in the first half of 2024, CGT developers raised only about $0.5 billion in venture rounds. According to recent analyses, Q1 2025 financing for CGT companies was down nearly 50% from the previous quarter – roughly $2.5–3.0 billion raised globally in Q1 2025 compared to $4.4 billion in Q4 2024 [8].

The commercial trajectory of advanced modalities is mirrored by the Deloitte CGT Market Index ™ (Figure 2), which tracks top 50 market cap (> $250 million) pure-play cell and gene therapy developers worldwide (with lead assets past pre-clinical trials) [9]. In 3 years (2023 to 2026), the CGT index doubles, from $77 billion to $126 billion. The first-generation ATMPs faced an initial market downturn. There are some key challenges identified for this downturn (H2'2025). Firstly, the initial CGT successes targeted areas that were, comparatively speaking, "low-hanging fruit." Going forward, CGTs must tackle more complex diseases that present new challenges. Furthermore, even when science succeeds, high price tags and labour-intensive delivery have led to slower adoption of approved products than expected, while manufacturing scale and cost remain significant barriers. Regulatory uncertainty and access pressures add further friction.

Nevertheless, the index experienced a rebound from late 2025 through early 2026. Market sentiment has shifted positively as clinical innovations, such as in-vivo therapeutic delivery, begin to de-risk commercial scalability. Backed by this technological pivot, the index continues to outperform classic biotech benchmarks, proving the sector's resilient investment appeal.



Sources: Capital IQ, Deloitte Research, EIU Economic Outlook, Indices are Rebased to 100 for discussion purposes only

Figure 2: Deloitte CGT Market Index ™ (2021-2026)

CGTs potential remains compelling, but the market and investors demand clear differentiation, cost discipline, and faster paths to commercialisation. New case study analyses confirm what the top performers demonstrate (Figure 3) [9].

Investors are only rewarding tangible results in strong clinical data that surpasses the standard-of-care, and flawless commercial launch execution through tracked KPIs (e.g., new patient starts, site activation rates, reimbursement coverts, expanded market access). While there is a clear understanding of the complexities of CGTs, investors reward progress.

Investor's focus from clinical to commercial

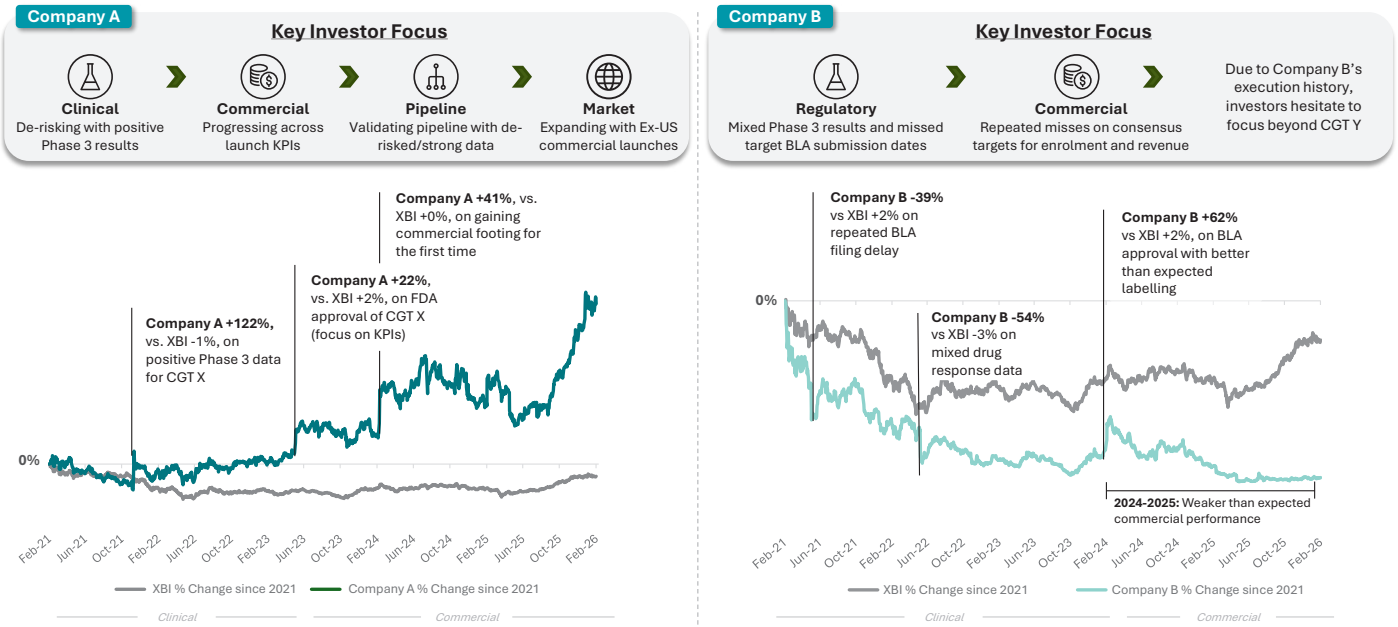


Figure 3: Deloitte CGT Market Index™ use cases (2021-2026)

1.3 The technical beyond the market volatility

First-generation ATMPs face manufacturing and development challenges that explain the industry slowdown. Translating early innovation into GMP-compliant manufacturing processes remains technically demanding. Manufacturing itself presents a myriad of challenges: potential contamination and impurities, variable starting materials (autologous therapies), out-of-specification final drug products, scaling difficulties, packaging challenges, stability concerns, and time-consuming quality control testing.

A fundamental tension also exists between cost and customisation. Large-scale manufacturing usually reduces per-unit costs and broadens patient access, but customised manufacturing, needed for precision medicine, demands higher capital investment and specific diagnostic criteria (e.g., personalised screening tests). However, next-generation ATMPs, such as in-vivo therapies, allogeneic products, and gene editing, are being designed to address these challenges, offering promises for more scalable, cost-effective, and accessible therapies.

1.4 Moving forward, the Next Generation of ATMPs have huge potential

Companies are pivoting to new use cases, in-vivo CAR-Ts being one of the new frontiers. Current approved CAR-T therapies require ex-vivo manufacturing whereas NextGen in-vivo CAR-T approaches deliver CAR instructions directly into the patient avoiding the bespoke manufacturing. In addition, bi-specific CAR-T and multi-modality approaches are expanding the therapeutic scope beyond blood cancers into solid tumours and chronic indications. Recent deals like AbbVie's $2.1 billion acquisition of Capstan Therapeutics and AstraZeneca's $1 billion EsoBiotec deal underscore pharma's strategic commitment to in-vivo platforms.

From mid-2025 to mid-2026, Big Pharma has spent $13 billion positioning around in-vivo platforms, a technology whose clinical profile is still being written (Figure 4), although a meaningful share of these acquisitions looks defensive. To put that into perspective, the original ex-vivo CAR-T M&A wave that built the entire cell therapy industry (i.e., Novartis-Penn, Gilead-Kite, Celgene-Juno, etc.) totalled roughly $21 billion over a period of six years.

The years to come will reveal whether this $13 billion investment will pay off, with two plausible scenarios. One where in-vivo CAR-T becomes the therapy's mainstream modality, and another where it remains a niche delivery technology. Strategic positioning is being done now, based on evidence that does not yet exist. Only data between 2028 and 2032 will decide which scenario unfolds. Investors are only betting on the promise of these platforms, not on any clinical evidence.

Notably, Belgium's established expertise in RNA therapeutics and lipid nanoparticle platforms (integrated components of in-vivo CAR-T) positions the country as a natural hub for participating in this next-generation ATMP wave, leveraging its existing biotech infrastructure to capture value in the emerging in-vivo CAR-T ecosystem.

Company / Asset	Stage	Target & Indication	Patients Treated	Efficacy	Safety
Legend Biotech LB2501 [10]	**Phase 1**	CD19 and CD20 (dual) Non-Hodgkin lymphoma	6 at the top dose level (12 across the full study)	100% OVERALL RESPONSE RATE: all six patients at the top dose responded and five reached a complete response.	Clean so far; no dose-limiting toxicities, serious adverse events, or neurotoxicity. Grade 1 to 2 cytokine release syndrome.
Kelonia Therapeutics KLN-1010 [11]	**Phase 1**	BCMA Multiple myeloma	18 across three dose levels (mMyCAR study)	100% OVERALL RESPONSE RATE: all evaluable patients showed no detectable disease at one month, and the first patient remains in response beyond ten months.	Manageable Toxicity described as consistent with conventional CAR-T, with low-grade cytokine release syndrome.
EsoBiotec ESO-T01 [12]	**Phase 1 enrollment paused**	BCMA Multiple myeloma	5 single-arm study in China	80% OVERALL RESPONSE RATE: four of five patients responded, including three complete remissions by Day 60.	Being characterised; three of five patients had Grade 3 cytokine release syndrome. Further study underway as program continues.
Umoja Biopharma UB-VV111 [13]	**Phase 1**	CD19 Released or refractory B-cell malignancies (large B-cell lymphoma, chronic lymphocytic leukemia)	Enrolling INVICTA-1 study; patient numbers not yet disclosed	No clinical efficacy data have been disclosed. FDA Fast Track designation granted.	No clinical safety data have been disclosed.
Sana Biotechnology SG293 [14]	**Preclinical**	CD19, delivered to CD8 T cells Non-Hodgkin lymphoma	None yet non-human-primate data, clinical trial planned	Preclinical Potent CAR-T generation and deep B-cell depletion in non-human primates.	Preclinical only Cell-specific delivery designed to avoid the liver, engineered to work without lymphodepletion.

Figure 4: Clinical data is catching up to the deal size of in-vivo CAR-Ts (non-exhaustive, 2025-2026)

This paper is focusing on CGTs as fastest growing and bigger market in ATMPs. However, **tissue engineered products (TEP) are bifurcating** [15] [16] [17]. The therapeutic side is finally producing approvable, off-the-shelf products after 25 years of false starts, but revenue remains concentrated in unglamorous orthopaedic and wound grafts. FDA approved Symvess, the first acellular tissue-engineered vessel, for extremity arterial injury (Dec 2024). The non-therapeutic side (organoids, organ-on-chip) is the faster, lower-risk monetisation path, and it just received a regulatory tailwind that changes the investment case (e.g., FDA's April 2025 roadmap promotes organoids and organ-on-chip to reduce animal testing, EU funds New Approach Methodologies (NAMs) through Horizon Europe Work Programme 2026-2027/4.Health). Orthopaedic and musculoskeletal applications hold 41% of the market, hospitals and surgical centres 60% of revenue, and North America 45% of share, with APAC the fastest-growing region at ~14% CAGR. **Soon**, **we could expect TEP to catch-up** the growth rate and market potential of CGTs which represents a real opportunity for the Belgian actors already active and world-class leader in this field.

2. The position of Europe

ATMPs hold great potential but face challenges in the clinical development and the regulatory process. There exists substantial variation between regulatory agencies in the number of ATMPs with marketing authorisation.

Globally, on January 1, 2025, a total of 59 different ATMPs had been granted an MA by at least one regulatory agency such as those in USA, EU, Japan, UK, Canada, Australia and Switzerland. Amongst these, gene therapy medicinal products made up 42% of the approvals, and haematology was the leading therapeutic area at 44% [18]. Nevertheless, while 59 unique ATMPs have been approved globally by at least one major regulatory agency, less than one-third of these therapies have achieved MA from more than one agency. This clearly demonstrates that widespread international distribution remains a critical barrier for the majority of ATMPs.

While the EMA has approved 33 ATMPs since 2009, their post-approval journeys have been selective. Eight approved ATMPs have withdrawn from the EU market or failed to renew their marketing authorisations, including Glybera (2017), Zalmoxis (2019), Skysona (2021) and more recently Beqvez (2025). These withdrawals reflect both commercial viability challenges and the stringent long-term follow-up requirements assessing potential delayed, long-lasting safety or efficacy issues [19].

CGT investments in EU also have undergone a significant shift since 2021, with China being the new hub for biopharma innovations (Figure 5), with massive Chinese business development (BD) licensing deals those last 2 years [20].

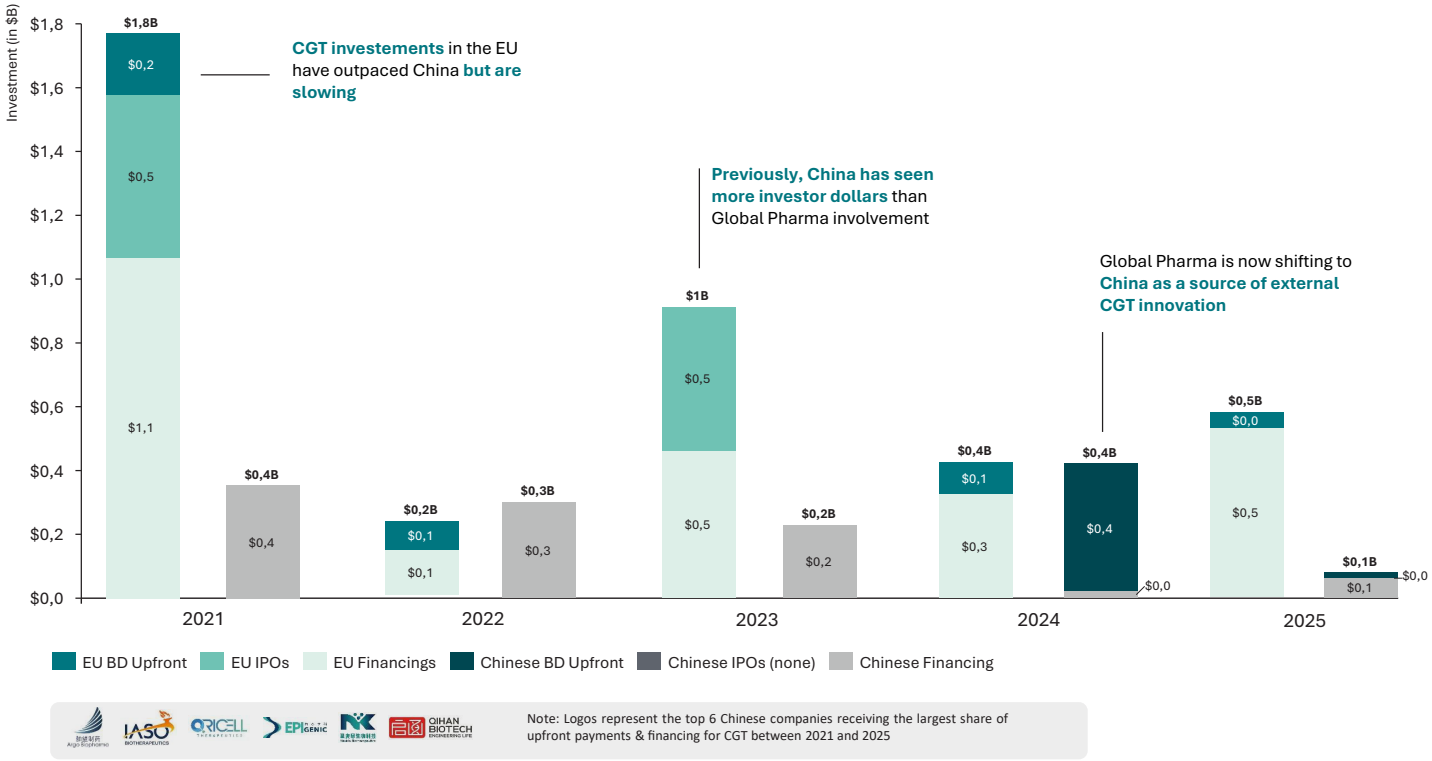


Figure 5: Evolution of CGT investments in EU and China (Deloitte analysis)

2.1. The rise of China as CGT innovation house

While Europe remains a global leader in scientific research, the US and China are currently moving faster in attracting life sciences investment and supporting biotech growth. Clinical trials and patent filings have slowed in EU. Operating costs and regulatory complexity deter both large pharma and startups, a trend underscored by the fact that 66 of 67 EU biotech IPOs since 2020 listed outside the EU.

Considering global dynamics, China has increasing influence in advanced therapies, hosting around 2,000 ongoing cell therapy trials, roughly one-third of global activity (Figure 6). China's credibility and attractiveness as destination for CGT clinical trials has continued to grow due to three main advantages: the availability of a large number of eligible patients for CGTs, cost efficiencies (e.g., lower labour cost) and China's dual-track regulatory framework for CGTs.

The dual-track regulatory framework was implemented in 2017 to provide clear and distinct pathways and requirements for investigator-initiated trials (IITs) under the supervision of the National Health Commission (NHC) on one hand and industry-sponsored trials, regulated by the (NMPA), on the other. The NHC Track results in a cell therapy being classified as a Category III medical technology **for clinical use**, the NMPA track alternatively, aims to eventually authorise a cell therapy as a pharmaceutical product **for commercial use**.

The outstanding feature of China's dual system are the IITs. These studies, sponsored and conducted by a qualified

investigator and their academic medical centre, or hospital, aim to answer the question "is this technology worth pursuing?" rather than assessing its commercial value as well. The interesting characteristic is that these are not regulated by the national drug regulator (NMPA) and thus do not require a formal Investigational New Drug (IND) authorisation (in contrary to IITs in EU requiring Clinical Trial Authorisation). Chinese IITs are currently the fastest and most cost-efficient human proof-of-concept to de-risk a technology for larger financial and regulatory investments before entering the NMPA Track, and for CGTs highly innovative technologic advancements, that carries significant value.

Next to that, the Chinese CGT market focuses significant effort in optimising the CGT manufacturing cost structure. This is driven by process innovation, automation and robotics across multiple manufacturing steps, creating a potential competitive edge for global market entry. Moreover, China prioritises end-to-end localisation of manufacturing activities. Instead of importing raw materials, some CDMOs and CGT developers start to build the required in-house capabilities to self-supply the most critical raw materials.

China being the source of technological research innovation is clear and widely accepted by the ecosystem. However, we might question the sustainability of the model for development, i.e., whether the country will become the (only) place to-go for the early phase trials. Capacity might become a bottleneck at a certain point of time, forcing trials from non-local biotech to be executed in regional centres where the quality of execution and the competency for complex therapies (such as CGT) might not be at the same level as the state-of-the-art hospitals that are currently being used (e.g., to manage adverse effects).

China's Negative List legislation restricts foreign investment in CGTs and mandates partnerships with local Chinese players. This appeared initially appeared to be constraining for the Chinese ecosystem, but functions as another stimulant for local innovation as it accelerates technology transfer from foreign CGT developers to the Chinese ecosystem [20].

In summary, China's primary role in the CGT market is as an early-phase clinical hub, allowing companies to de-risk assets and technologies quickly and cost-effectively.

IITs generate early proof-of-concept data that can accelerate investor interest, but they sit outside the formal drug-approval pathway and do not substitute for the pivotal trials required to support marketing authorization. EU & US regulators require clinical data from a demographically representative population, spanning age, sex, race, and ethnicity, to approve commercialization. Because the US and Europe remain the largest commercial markets, global companies continue to rely on these regions for late-stage (Phase 2/3) pivotal trials to secure marketing authorization, meaning early-stage China-based trials alone will not suffice. Cross-border transfer of clinical data from China has historically required formal government approval under its Human Genetic Resources framework, though a 2026 draft rule signals a move toward streamlining this process for standard international trials not involving genetic-resource export. For now, Europe and US maintain a strong competitive edge in the race for clinical trials, though China's regulatory trajectory on data-sharing is one worth monitoring closely.

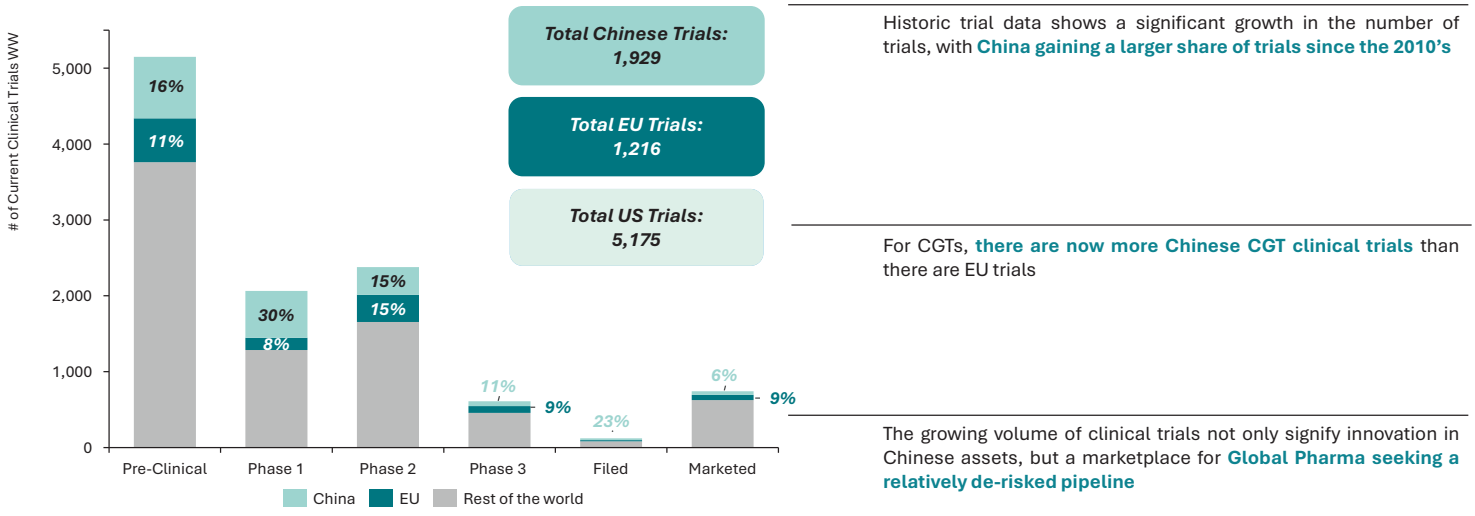


Figure 6: CGT clinical trial landscape (Deloitte analysis)

2.2. US powerhouse

The United States remains the default jurisdiction for CGTs because many capital and administrative advantages compound together rather than merely coexist [21-26]. US is known for huge capital and the largest commercial market for pharmaceutical products. The sector raised $11.1 billion across 216 financings in 2025, and CGTs absorbed roughly 18% of all biotech venture dollars, up from about 15% in 2024, a concentration no other region matches. The National Institutes of Health (NIH) is the world's largest public funder of biomedical research, deploying a budget of nearly $48 billion, of which close to 82% flows extramurally to universities and research institutions, meaning the riskiest science is de-risked on public money before private capital arrives.

US has also an academic-founder model that promotes entrepreneurship. The Bayh-Dole Act of 1980 let institutions retain title to inventions made under federal funding, and the resulting norm is that biotech's scientific founders are typically professors who keep their principal-investigator roles in academia while being paired with seasoned pharma operators in founding management. The professor can therefore combine parallel academic and private mandates. The system produces more than 1,000 university spinouts a year and sustains a standing population of nearly 7,000 companies built on university research.

There is also near-zero formation friction to create a new company. Delaware imposes no minimum capital requirement to incorporate, offers same-day and even one-hour filing options, and is chosen by 81% of US-based IPO issuers, a founder can go from term sheet to legal entity in days, with no notarial deed and standardised documentation investors already trust. Layered on top is a regulator that has actively built the category and shaped future policies to accelerate and increase access to CGTs (e.g., CBER has approved close to 50 CGT products over the past decade and in January 2026 issued explicit CMC flexibilities for CGT products).

2.3. EU recent tactical actions

As an effort to narrow the gap between Europe and the US and China, the European Commission (EC) has invested €1.33 billion in the Horizon Europe – Health Work Programme 2026-2027 to establish the EU as a global leader in health innovation and reduce dependency on non-EU suppliers. The approach is directed toward SME support, multi-stakeholder engagement, and coordinated value-chain development to create a competitive ecosystem while ensuring equitable, sustainable healthcare across Europe. The Work Programme includes significant investments (>€300 million) in CGTs and Personalised Medicine. In addition, The EU Biotech Act, was proposed in December 2025. This includes clinical trial reforms, streamlined regulatory timelines, and increased public and private funding commitments. It aims to simplify pathways, shorten time-to-market, and foster innovation.

Europe possesses the scientific assets to compete, but the Biotech Act's impact on competitiveness will remain limited without complementary measures that strengthen the broader commercial environment (i.e., the willingness of Europe to pay for the real price of innovation) [27].

To further support the strong European scientific excellence and robust startup pipeline, a Scaleup Europe Fund was launched in August 2026, targeting €5 billion. The fund aims to reverse this trend of high-potential firms looking abroad to scale by supporting scale-ups across ten strategic technology areas including biotechnology and medical technologies, involving ATMP investments. Novo Holdings has been selected as one of the institutional backers for the EU Fund. This initiative benefits both sides: innovators gain domestic capital to compete globally, while investors access Europe's pipeline of highly innovative startups [28].

It is also expected that Western startups will increasingly adopt a "China strategy" whether it is conducting proof-of-concept trials or partnering for technology exchange. Rather than treating China as pure competition, the EU can collaborate strategically: access well-selected Chinese partners at lower cost to de-risk platforms, while ensuring the EU will not become obsolete. Legend Biotech exemplifies this model: the Chinese biotech partnered with Johnson & Johnson to develop Carvykti, a BCMA-targeted CAR-T approved in the US/EU in 2022, the first Chinese-discovered cell therapy to achieve Western regulatory approval [8]. In that context, Belgium could perhaps build strategic partnership corridor and systems with China to create a small portfolio of pre-selected Chinese preferred partners (CRO, CDMO, diagnostic, ...) that could become the "go-to" for Belgian developers to de-risk their assets.

3. Belgium's position: Genuine strengths, structural constraints

3.1 The ecosystem narrative needs to mature

Although now considered legacy schemes, Belgium is still offering an attractive layered tax incentive framework to Life Science companies. As of 2026, the key mechanisms include: Innovation Income Deduction (IID), R&D Investment Deduction or Tax Credit, Payroll Withholding Tax Exemptions, and Special Tax Regime for inpatriate executives and researcher. These incentives can be combined with regional grants and EU funding, providing government support across the entire lifecycle of R&D investments. To reach the next level, stronger incentives are needed for companies to anchor and commercialize their R&D outcomes in Belgium [29].

Belgium should approach the new ATMP trends less as a sector-promotion exercise and more as an exercise in industrial policy for high-complexity medicine. ATMP ecosystems succeed when each handoff across the value chain is reliable: from discovery to first-in-human trial, from trial to process scale-up, from regulatory advice to dossier quality, from product arrival to hospital administration, and from administration to clinical outcome tracking. That sequence is where Belgium can still differentiate itself, but only if it chooses a few domains and coordinates them tightly.

The 2024 white paper described this as a paradigm shift. That remains true, but the update for 2026 is that the field is now far enough advanced for execution failures to become visible alongside scientific successes. It also made a compelling case that Belgium had the ingredients to become a biomanufacturing gateway and an innovative advanced-therapy ecosystem [1]. That framing was useful because the sector still needed mobilisation.

Today, we keep the optimism but sharpen the argument. Having the right ingredients is not the same as having a winning recipe.

3.2 Belgium remains a strong clinical-research country, but the edge is under pressure

Belgium's starting point remains favourable. The 2026 pharma.be / Deloitte report states that Belgium has been ranked second in clinical trial authorisations (CTAs) per inhabitant over the last five years, behind Denmark, and that it continues to hold a leading position on several selected trial types [3]. Oncology represents 32% of Belgian CTAs and rare diseases almost 24%, with both categories growing faster than the total CTA increase from 2023 to 2024 [3]. Those data matter for ATMP strategy because oncology, haematology, paediatrics and rare diseases are precisely the domains where ATMP development is most active (Figure 7 and Figure 8) [30]. However, relative to the EU, Belgium is losing momentum, with the US and China capturing increasing share of ATMP development activity.

The same report contains the cautionary signal. Sponsors rate Belgium strongly on regulatory and scientific expertise and on the quality of research centres, but start-up timelines remain a weak point and the country shows long-term pressure on phase 1 and first-in-human activity [3]. In practical terms, Belgium is strong enough to compete, but not so dominant that it can rely on reputation alone. Time, coordination and site capacity are now central competitiveness issues.

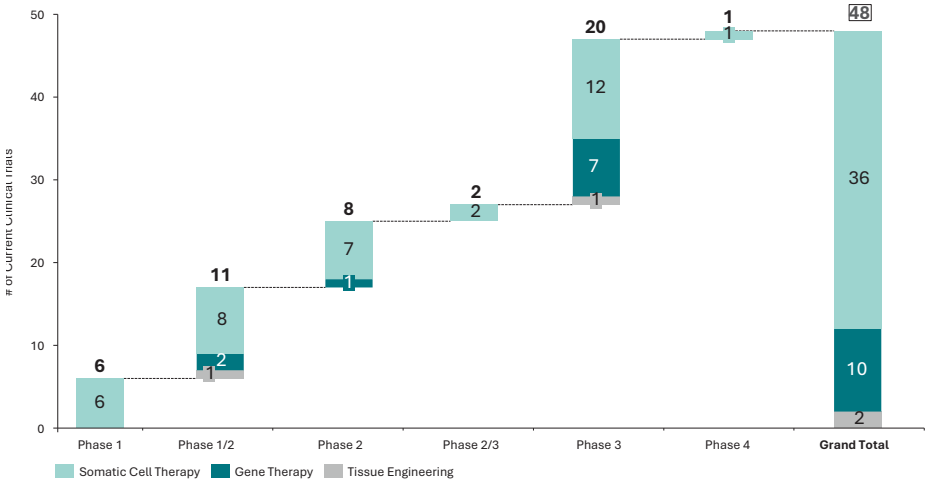


Figure 7: The Belgium ATMP pipeline of clinical trials phase per modality (Deloitte analysis)

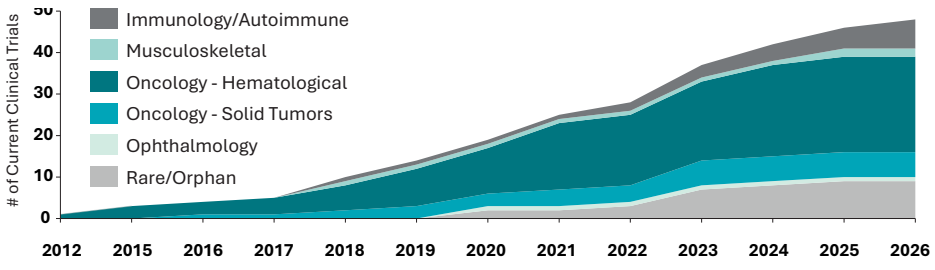


Figure 8: The Belgium ATMP pipeline of clinical trials per disease area (Deloitte analysis)

3.3 Belgium's genuine strengths

Belgium's core strengths in life science remain credible and should be stated confidently. **First**, it combines strong academic hospitals, dense clinical networks and a long-standing culture of clinical research. This multidisciplinary expertise creates a fertile ground for innovation and positions the ecosystem as a recognised centre of excellence.

The availability of advanced technological platforms and infrastructure, such as clean rooms and specialised production facilities, reinforces the country's capacity to develop and validate advanced therapies. Particular strengths were identified in emerging modalities such as tissue-engineering (e.g., Novadip), exosomes and extracellular vesicles (e.g., EXO Biologics and ConvEyXo), as well as in RNA technologies (e.g., Ziphius), and lipid nanoparticle platforms (e.g., eTherna), which together form a solid foundation across the ATMP value chain. That matters disproportionately in ATMPs because patient pathways, investigator experience and site capabilities are as important as abstract R&D capacity.

Second, Belgium benefits from compact and central EU geography. For therapies requiring coordinated referral, apheresis, manufacturing, release and administration, distance and fragmentation matter. Belgium's size can be turned into an operational asset. Moreover, the multilingual and internationally accessible environment of Belgium represents an additional strength, facilitating international collaboration and integration into global networks.

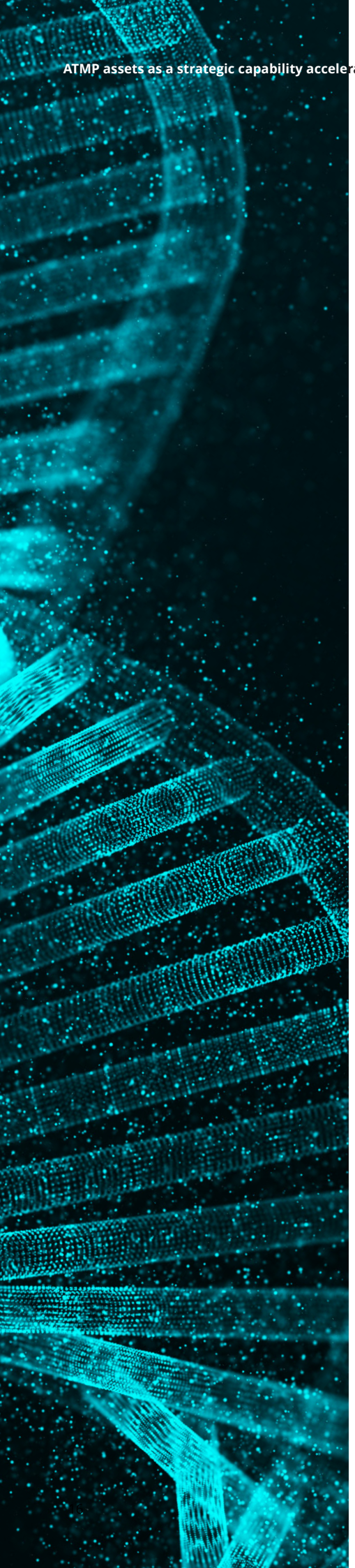
Belgium's translational strength is also visible in the way some academic, clinical and manufacturing capabilities are physically and operationally connected. At Antwerp University Hospital, for example, the Centre for Cell Therapy and Regenerative Medicine provides multidisciplinary cell-processing capabilities supporting the handling, preparation, storage and distribution of cellular therapies alongside clinical studies. This is complemented by specialised entities such as Anicells, which supports the clinical development and GMP manufacturing of cell-therapy products. Such models reduce hand-offs between research, manufacturing and patient care and illustrate the type of integrated translational environment that is particularly valuable for ATMP development.

Belgium has also demonstrated its ability to organise critical mass around gene therapy technologies. GT4Health brings together five Belgian universities, a research centre and industrial partners around viral-vector and lipid-nanoparticle technologies, providing a collaborative foundation that connects fundamental research, enabling technologies and industrial translation.

Third, the ATMP logistics Belgium has in place are a key strength. Continuous investment and strong collaboration in this field are crucial to further establish Belgium as a hub, as logistics represent critical process flows where ATMPs differentiate hugely from small molecules - often causing companies to struggle due to personalised or cryo requirements. Belgium hosts a specialised ATMP logistics hub anchored by the ATMP Logistics Excellence Centre, part of the at.las ecosystem, which pioneers supply chain innovation through live pilot testing and international standards development. The centre partners with global players including Pharma.Aero, Brussels Airport, and Air Cargo Belgium. Brussels Airport has established itself as Europe's preferred pharma gateway for temperature-sensitive shipments, while Liège Airport is expanding its cold chain infrastructure with a €500 million investment in GDP-compliant facilities.

Fourth, Belgium has meaningful regulatory assets. The Federal Agency for Medicines and Health Products' (FAMHP) National Innovation Office offers national scientific, technical and regulatory advice for medicines in development and specifically supports SMEs, spin-offs, academic hospitals and research centres in the preparatory phase of advice requests [31]. That creates a practical entry point for early-stage innovators, provided it is packaged as part of a broader national offer.

Lastly, Belgium has real manufacturing and quality heritage. The ATMP GMP environment is demanding, and both FAMHP and the European framework make clear that specific GMP requirements apply to authorised products, investigational products and products manufactured under hospital exemption [5]. This means Belgium's experience in quality systems, release discipline and regulated biomanufacturing is a relevant strategic asset, not just an industrial background fact.



3.4 Belgium's structural constraints

Belgium is a relatively small market with limited patient volumes. That makes it unsuitable as a scale market for every ATMP business model and limits its ability to influence commercial outcomes through domestic demand alone. The country is also institutionally fragmented, with federal and regional responsibilities split across health, innovation, investment and industrial policy. That fragmentation can slow decision-making precisely where ATMPs require cross-functional speed. Additionally, while collaborations exist, they are not always sufficiently structured or sustained over time, and differences in incentives, particularly within academia (e.g., publication-driven research) may hinder translation toward industrial applications. Barriers to collaboration also persist across institutional or regional boundaries, limiting the ability to fully leverage collective strengths. At the same time, the region faces challenges in attracting international talent and lacks sufficient global visibility, despite its strong scientific capabilities.

Belgium also does not have the scale to compete everywhere in manufacturing. ATMPs require specialised and often small-batch capabilities, but large industrial capacity plays are capital intensive and exposed to international competition. Belgium's manufacturing proposition should not be understood solely in terms of the number of GMP facilities available. Its stronger differentiator is the breadth of specialised capabilities already present across the country. These include academic GMP manufacturing at CHU Liège, cell-therapy manufacturing capabilities such as Anicells and Cellistic, RNA and lipid-nanoparticle development and manufacturing at eTheRNA, exosome production and characterisation through ExoXpert, viral-vector expertise associated with the former Henogen activities now within Thermo Fisher Scientific, and dedicated gene-therapy process-development and clinical-manufacturing capabilities at UCB. Together, these assets form a specialised manufacturing toolbox that is better aligned with Belgium's strategy than a broad push for undifferentiated manufacturing scale.

Funding constraints represent another major bottleneck. While early-stage funding is relatively accessible, there is a significant gap when it comes to financing the transition toward clinical development, not only in Belgium but also in Europe. ATMPs, in particular, require substantial investment and longer development timelines compared to traditional therapies, and the European venture capital landscape remains fragmented and less mature than in the US. This creates a structural challenge for scaling innovations and bringing them to market.

Regulatory complexity further compounds these challenges. Long response times and uncertainties associated with regulatory processes, especially for novel modalities, are unsustainable for small and medium-sized biotech companies. Delays, such as several months, to obtain product classification can have a critical financial impact. In addition, the lack of regulatory expertise within project teams in an early stage limits the ability to anticipate requirements and accelerate development. However, as of January 2026, the FAMHP committed to shorten clinical trial evaluation timelines by nearly 50% and introducing fast-track procedures for ATMPs, hence ensuring acceleration of ATMP development.

Finally, hospital readiness and access pathways remain uneven. Even when the science and regulatory landscape are favourable, the real-world use of ATMPs depends on referral discipline, training, budget handling and longitudinal follow-up. These are not automatically solved by being a good research country. They require intentional design.

3.5 Our 2024 recommendations and their status today

In 2024, we made strategic recommendations to strengthen Belgium's ATMP ecosystem. We have now evaluated their status today to understand what progress has been made and where gaps remain. Changes in policies and structural actions take time, but it is important to keep monitoring them and adapt where needed as the CGT market is evolving very rapidly.

Manufacturing Infrastructure.
First, we recommended investing in flexible, automated, SME-accessible ATMP manufacturing capacity. Belgium had 25+ GMP sites, but most were either large pharma facilities or limited in automation and scalability. The ecosystem needed decentralised, modular manufacturing hubs to serve smaller innovators. There are multiple hubs such as Nucleus Ghent, Biopark Charleroi and Légiapark Liège providing GMP capacity, but these do not operate as a shared and dedicated ATMP hub for Belgium, meaning there is still a problem of fragmentation and lack of coordination. Additionally, SME accessibility remains limited. Shared, decentralised manufacturing infrastructure are not yet operational, and most capacity remains concentrated in large facilities. On the funding side, limited resources from private equity and venture capital remain a challenge for the Belgian ecosystem specifically for manufacturing scale-up.

Regulatory & Market Access.
We recommended accelerating and harmonising ATMP regulatory and reimbursement pathways through the development of a centre of regulatory excellence for seamless interactions with regulatory authorities. Belgium has fast clinical trial approvals, but market access and the regulatory landscape is complex with regional and local guidelines. Today, FAMHP maintains and even sharpens its reputation for efficiency and expertise on trial approvals. The regulatory agency also created a dedicated spearhead for ATMPs, representing a strategic venue in which FAMHP aims to lead, innovate and set high standards by concentrating expertise and resources. However, market access remains complex and early parallel advice with payers is not yet standard practice in Belgium.

Collaboration & Governance.
In 2024, we recommended strengthening national ATMP governance and cross-region collaboration. Governance fragmentation nevertheless remains a strategic constraint. Belgium still lacks an institutionalised national ATMP governance mechanism, a common operational entry point and a sufficiently visible joint international positioning. However, the situation should not be interpreted as an absence of cross-regional building blocks. Regional initiatives such as ATMP-PIT [32], ATMP-Wal [33] and ATMP XB [34] and more specific inter-regional collaborative projects for therapeutics development have already demonstrated the ability to organise stakeholders around common objectives. In addition, recent Belgian efforts to strengthen cross-regional coordination around ATMPs, together with the European push towards a network of ATMP Centres of Excellence, provide an opportunity to further connect regional capabilities into a more coherent national framework.

International Positioning.
Finally, we recommended creating a single brand for the Belgian advanced therapy ecosystem, a biomanufacturing gateway that promotes its capabilities to both domestic and international audiences. Belgium's per-capita R&D was strong, and the country hosted 10% of European ATMP company headquarters, but its global visibility and market share were declining relative to competitors (Boston, Basel, Singapore, UK). Today, Belgium maintains high per-capita R&D and continues to host significant ATMP activity. However, global visibility and EU market share remain limited. International partnerships are growing organically (e.g., the ATMP XB initiative), but a unified international branding and communication strategy has not been launched. Belgium's position as a gateway remains more potential than realised.

Strategic Implication.
The underlying challenge increasingly appears to be one of orchestration rather than absence of capabilities. Belgium has continued to generate projects, infrastructure, training initiatives and specialised networks, but these assets are not yet consistently managed as components of a common national strategy. The next step should therefore be less about creating additional isolated initiatives and pockets of excellence, and more about connecting existing assets around a small number of shared priorities, common KPIs and an explicit national roadmap. The strategic implication is straightforward: Belgium's advantage lies in being coordinated, specialised and fast, not in being comprehensive or massive. The country should lean into its density, proximity and quality culture. It should avoid strategies that require very large domestic patient pools, broad reimbursement capacity across many products at once, or generic manufacturing scale. This lens is what should guide the where-to-play choices in the next chapters.

To benchmark Belgium against other European ATMP hubs, each was evaluated across eight investment-attractiveness dimensions, weighted according to where developers, CDMOs, and investors actually build capacity, not where they eventually commercialise (Figure 9). Market access was intentionally de-emphasised in this analysis, as it reflects commercial launch appeal rather than capacity location decisions. [35-43]

The conclusion is clear: Belgium ranks as a top-tier ATMP hub for speed and cost-efficiency, but a second-tier hub for manufacturing scale.

This positioning validates our focus on Arenas 1-2 (speed-dependent) and Arena 3 (specialised, not scale-dependent), while ruling out commodity manufacturing plays.

EUROPEAN HUB	TRIALS	MFG*	TALENT	FISCAL	CAPITAL	REGULATORY	LOGISTICS	ACCESS	WEIGHTED SCORE / 5
United Kingdom (UK)	5	5	5	4	5	4	4	3	4.6
Switzerland (CH)	4	5	5	4	5	4	4	4	4.5
Belgium (BE)	5	4	4	5	3	4	5	4	4.3
Germany (DE)	4	4	5	3	4	5	4	5	4.2
Netherlands (NL)	4	4	4	4	3	4	5	4	4.0
France (FR)	4	4	4	4	4	3	4	3	3.9
Denmark / Sweden (DK/SE)	5	3	4	3	4	4	4	4	3.9
Spain (ES)	5	3	3	3	2	4	3	3	3.4
Ireland (IE)	3	3	3	5	3	3	3	3	3.3
Italy (IT)	4	3	3	3	2	4	3	3	3.2

*MFG: Manufacturing

1 - Lagging 5 – Best-in-class

Figure 9: European ATMP benchmark (Deloitte analysis, non-exhaustive)

4. Where Belgium can credibly play in ATMPs

4.1 Methodology to identify where Belgium can play

4.1.1 A selection framework is required – the five criteria

The intent of this strategic framework is to (A) illustrate where Belgium holds genuine strengths, and (B) highlight that selectivity and focus are prerequisites for remaining competitive in CGTs. These areas are not intended to be exhaustive, nor to advise on investment or portfolio decisions by public or private organisations.Any subsequent development, prioritisation or implementation of the directions outlined in this paper will remain subject to the appropriate regional, federal and ecosystem governance processes and does not presuppose the involvement of any specific external adviser.

A country-level ATMP strategy must begin by narrowing the field. Belgium cannot and should not choose areas solely because they are scientifically exciting. The better question is where the country can create an advantage that is difficult to replicate and relevant to sponsors, providers and patients. A disciplined selection framework should therefore test each possible arena against five criteria: scientific depth, concentration of patients and referral pathways, Belgium's trial strengths, specialised manufacturing and logistics capabilities, and feasibility of evidence and access implementation.

This framework pushes Belgium away from broad modality claims and toward a portfolio of arenas where the whole chain can work. A modality might be attractive scientifically but weak in Belgium if patient pathways are too diffuse. A disease area might be promising clinically but unattractive strategically if treatment requires large-scale manufacturing where Belgium has no clear edge.

Criterion	Operational definition	Measurable proxy	Concrete example
C1 - Scientific depth	Belgian research groups and translational programmes with international standing in the specific modality-disease pair, not in ATMPs in general.	Number of Belgian academic centres running translational programmes in that pair; principal-investigator standing in the indication.	Haematology-oncology groups in Belgian university hospitals with established CAR-T investigator experience.
C2 - Demand concentration	Whether those who need the offer can be reached through a small number of identifiable channels. For therapy arenas this means patients and referral pathways; for capability arenas it means sponsors and programmes.	Number of centres that would treat 80% of eligible patients; existence of a reference-centre structure; presence of cross-border referral.	CAR-T eligible patients already route to a handful of accredited centres. Prevalent-disease populations, by contrast, sit diffusely across primary and secondary care.
C3 - Trial-strength fit	Alignment of the arena with the therapeutic areas where Belgium has demonstrated trial volume and sponsor-rated quality.	Share of Belgian clinical trial applications in the therapeutic area, and its growth rate against the total.	Oncology is 32% of Belgian CTAs and rare disease almost 24%, both growing faster than the total increase from 2023 to 2024; Belgium ranks second in Europe for CTAs per inhabitant.
C4 - Manufacturing and logistics fit	Whether the arena's CMC and supply profile matches small-batch, high-complexity, chain-of-identity operations rather than large-scale volume production.	Batch size; autologous against allogeneic; cryogenic requirement; vein-to-vein time constraint; qualified person (QP) release complexity.	Autologous cell therapy requires cryogenic logistics and per-patient release, which is Belgium's profile. Commodity vector production requires volume scale, which is not.
C5 - Evidence and access feasibility	Whether outcomes can be captured with available registry infrastructure, and whether a payer pathway is plausible given budget impact and patient numbers.	Annual eligible patients multiplied by price point; registry availability in the disease area; precedent of a managed-entry agreement.	One-shot high-cost rare-disease therapies carry long-term follow-up obligations with no established Belgian payer model. This is the binding constraint on Arena 2.

Table 1: Illustrative definitions of the five where-to-play criteria.

4.1.2 The key dimensions that structure a candidate arena

Belgium's choices can be structured along four dimensions.

The first is modality: gene therapy, cell therapy and tissue engineering each create different demands on manufacturing, logistics and follow-up.

The second is disease area: oncology, haematology, rare diseases, paediatrics and regenerative medicine have very different patient flows and evidence expectations.

The third is value-chain position: Belgium may be stronger in translation, early trials, specialised manufacturing or treatment delivery than in global-scale commercial operations.

The fourth is business model: some opportunities are better suited to a hub-and-spoke treatment network, others to platform services, and others to partnerships with larger international players.

This multidimensional view matters because Belgium does not necessarily need to dominate a full therapeutic category to create value. It can also win by becoming the best partner location for a critical stretch of the value chain. That is particularly relevant for SMEs and spinouts that need integrated support from regulatory advice through early development and manufacturing readiness.

4.1.3 What the selection framework rules out

The framework also rules out several attractive sounding but weak strategic positions. Belgium should not attempt to brand itself as the European leader for all ATMP modalities. It should not define success as maximising the number of ATMP-related announcements or facilities. It should not focus public investment on broad commodity-like capacity without a differentiated demand case. And it should not treat hospital exemption as a substitute for scalable development and access.

In short, the discipline of where-to-play selection is valuable precisely because it makes the strategy narrower than the opportunity set. For a small country, credibility is created by selectivity.

4.2 Priority arenas: Belgium's best where-to-play bets

The framework earns its keep only when it is applied to a real candidate list, including the options Belgium decides against. Nine proposed candidate arenas were scored from 1 to 5 on each criterion, where 5 means a demonstrated strength at European level and 1 means a structural barrier that cannot be closed within a short horizon.

One rule does most of the work. Any arena scoring 1 on any single criterion is disqualified regardless of its total, because an ATMP proposition fails at its weakest link: excellent science with no viable access pathway does not reach patients, and concentrated demand with no manufacturing fit does not reach Belgium.

	Candidate arena	C1	C2	C3	C4	C5	Total	Screening result
A1	Cell therapies in oncology & haematology	5	5	5	4	3	**22/25**	**SELECTED**
A2	Gene therapies in rare disease & paediatrics	4	5	4	3	2	**18/25**	**SELECTED**
A3	Specialised manufacturing, release & logistics	3	4	4	5	4	**20/25**	**SELECTED**
A4	Hospital exemption to scalable development bridge	4	3	4	3	3	**17/25**	**SELECTED**
Screened out								
B1	Broad tissue engineering / regenerative medicine	3	2	2	2	2	**11/25**	**Below threshold**
B2	Large-scale commodity vector & plasmid manufacturing	2	3	2	1	3	**11/25**	**Gated out**
B3	In-vivo gene therapy for prevalent diseases	3	1	3	2	1	**10/25**	**Gated out**
B4	Allogeneic off-the-shelf cell therapy at commercial scale	3	4	4	1	3	**15/25**	**Gated out**
B5	Hospital exemption as a standalone parallel supply model	4	3	2	2	1	**12/25**	**Gated out**

Table 2: Arena scoring matrix. Scores of 1 are shown in red and trigger the gating rule (qualitative assessment, non-exhaustive).

The four selected arenas all clear both thresholds, none of the five rejected options clears the capability threshold. Two rejections are worth reading carefully because they score respectably in aggregate. Allogeneic off-the-shelf cell therapy at commercial scale (B4) scores well on demand and on trial fit and is disqualified only on manufacturing: Belgium should host trials for these products under Arena 1, but should not chase the commercial-scale manufacturing behind them. Large-scale commodity vector and plasmid production (B2) fails on the same criterion for the same underlying reason. The framework is therefore not rejecting the science; it is rejecting a specific position in the value chain.

A1 Cell therapy, oncology & haematology
A2 Gene therapy, rare disease & paediatrics
A3 Specialised manufacturing, release, logistics
A4 Hospital-exemption to development bridge

B1 Broad tissue engineering/ regenerative medicine
B2 Large-scale commodity vector & plasmid manufacturing
B3 In-vivo gene therapy for prevalent disease
B4 Allogeneic off-the-shelf cell therapy at commercial scale
B5 Hospital exemption as a standalone parallel supply model

Scores 1-5 per criterion. Gating rule: any criterion scored 1 disqualifies the arena regardless of total score.

Figure 10: Arena screening and selection (Deloitte analysis, non-exhaustive).

4.2.1 Arena 1: Cell therapies in oncology and haematology

This should be Belgium's primary arena. Oncology already accounts for the largest share of Belgian CTAs (Figure 11) [30], and the country has strong university hospitals, specialised clinical teams and established trial culture in haematology and oncology [3]. These are precisely the settings where cell therapies require multidisciplinary coordination, sophisticated site capabilities and rapid access to eligible patients. Belgium currently operates eight authorised CAR-T therapy treatment centres, 11 active GMP suites (two academic and nine non-academic) and five vector or cell-processing facilities distributed across Flanders, Wallonia, and Brussels [44].

Belgium's right to win here is not based on being the largest market. It is based on being a dense network where early development, treatment centre readiness and post-treatment follow-up can be organised with less friction than in more fragmented systems. The strategic ambition should therefore be to make Belgium the preferred European launchpad for selected oncology and haematology cell therapies, from early clinical development through first commercial centres.

4.2.2 Arena 2: Gene therapies for rare diseases and advanced paediatrics

Belgium should also prioritise selected gene therapies in rare diseases and paediatric settings. The rationale is not broad disease prevalence; it is the concentration of specialist expertise, referral pathways and long-term patient management, reflected by the number of trials being made in our country (Figure 12) [30]. Rare disease and paediatric ATMPs place a premium on accurate diagnosis, coordinated referral, registry-quality follow-up and trusted relationships between centres and families. Those are areas where small, well-networked countries can punch above their weight. Belgium has already a track record in world-firsts and pioneering programs such as Spinal Muscular Atrophy (SMA) newborn screening, a three-year pilot ran in Southern Belgium. Moreover, UZ Leuven treated the first Belgian patient with Luxturna, the first EMA-approved gene therapy for hereditary retinal disease with reimbursement now in place nationally. There are also eight approved genetic centres nationally and rare diseases (e.g., RaDiOrg) foundations to connect patients and ensuring that their voice is heard by policymakers [45]. While the use cases are showing the high unmet needs that gene therapy can address, the sustainability of the commercial business model is still unproven. Costs are high, but technological innovation and platforms could unlock broader therapeutic potential and enable a profitable business for biotech and

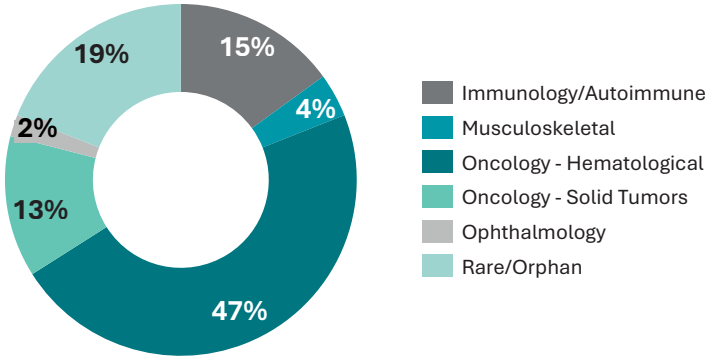


Figure 11: ATMP pipeline of clinical trials in 2026 with Belgian involvement (Deloitte analysis)

pharmaceutical companies. In addition, we have seen companies using FDA Priority Review Voucher (PRV) to cash-in money to progress their pipeline. The FDA Rare Paediatric Disease PRV program incentivizes drug development for rare paediatric diseases by granting vouchers that can expedite FDA review of another drug or be sold to other sponsors. The primary incentive is the ability to accelerate FDA review for another product, which can bring a drug to market faster and potentially increase revenue. Additionally, the vouchers are transferable or sellable, creating a secondary market where vouchers have historically sold for tens to hundreds of millions of dollars, providing a significant financial incentive for developers. For example, Acadia Pharmaceuticals sold a PRV for $150 million in 2024.

The where-to-play discipline matters here as well. Belgium should not claim all rare-disease ATMPs. It should identify subdomains where specialist centres already have credibility, patient pathways are manageable, and the evidence-generation burden is feasible. This could include ultra-specialised areas where Belgian centres already attract cross-border referrals or have meaningful research profiles.

4.2.3 Arena 3: Specialised manufacturing, release and logistics

Belgium should position itself in specialised manufacturing, quality and logistics rather than in undifferentiated volume manufacturing. The Belgian Walloon region has been (and still is) a strong hub for ATMP manufacturing (and more broadly for next generation therapies including biologics and radiotherapeutics), with massive past investment into CDMOs, from small to large scale manufacturing capacities.
The country's opportunity is strongest where the value lies in high trust and technical complexity: process development, analytical characterisation, quality control (QC), QP release, cryogenic logistics, chain of identity/custody, and flexible small-batch operations [5].
The ecosystem is built around a network of 7 academic hospitals, 10 universities

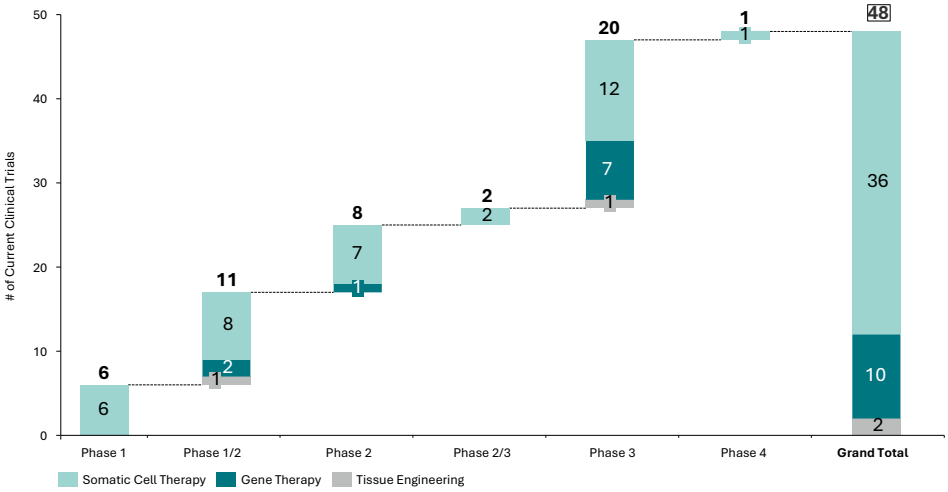


Figure 12: Ongoing clinical trials of Gene Therapy per disease area with Belgian involvement (Deloitte analysis)

with internationally recognised life science departments, and over 50 pharmaceutical and biotech companies active in biomedical research and development and clinical development of ATMPs (Figure 13). This comprehensive ecosystem includes also several high impact global players, such as Legend Biotech, which is building the largest CAR-T provider in Europe, Etherna, which is listed in the top 10 Gene Therapy Medicinal Product (GTMP) patent applicants in the past few years, and UCB which recently made a €200 million investment for a new gene therapy development facility.

This focus is more realistic than aspiring to become the default location for manufacturing across many ATMP classes. It aligns with Belgium's industrial heritage and geography, while avoiding the capital intensity and demand risk of commodity capacity plays. It also complements the clinical and regulatory strengths outlined in earlier chapters.

As we have seen recently, some companies have either terminated their CGT business or closed their doors, and Belgium is not the only example [46].
The Belgian biotech company Galapagos discontinued its cell therapy business this year. The biotech company pursued an innovative decentralised manufacturing model, outsourcing the production to regional CMOs and hospitals with GMP manufacturing capabilities, to reduce the vein-to-vein time significantly. This illustrates that CGT developers are seeking to find more effective manufacturing strategies, however no clear-cut answer has been found yet. Global examples of companies terminating their CGT business are Charles River Labs as well as Resilience and SK Pharmteco. One potential reason is that the volume of manufacturing that was built for CGT drugs has not come to pass with the larger volume drugs being manufactured inhouse. So, the question is: "what is the future of specialised CDMOs in Belgium for CGTs?".

Looking at demand and supply forecast data, the peak is yet to come (Figure 14). The combination of the growth of commercial products approved today (through indication expansions and earlier lines of treatments) with the increasing volume of phase 3 trials testing large cohort of patients, we estimate the steepest growth within two years from now. It means that for Belgium, we have a window to capture that volume and be ready to absorb that peak. Having the right logistic processes in place, upgrading actual capacity to state-of-the-art digital and automation infrastructure, removing end-to-end frictions from the reception of the starting material to the

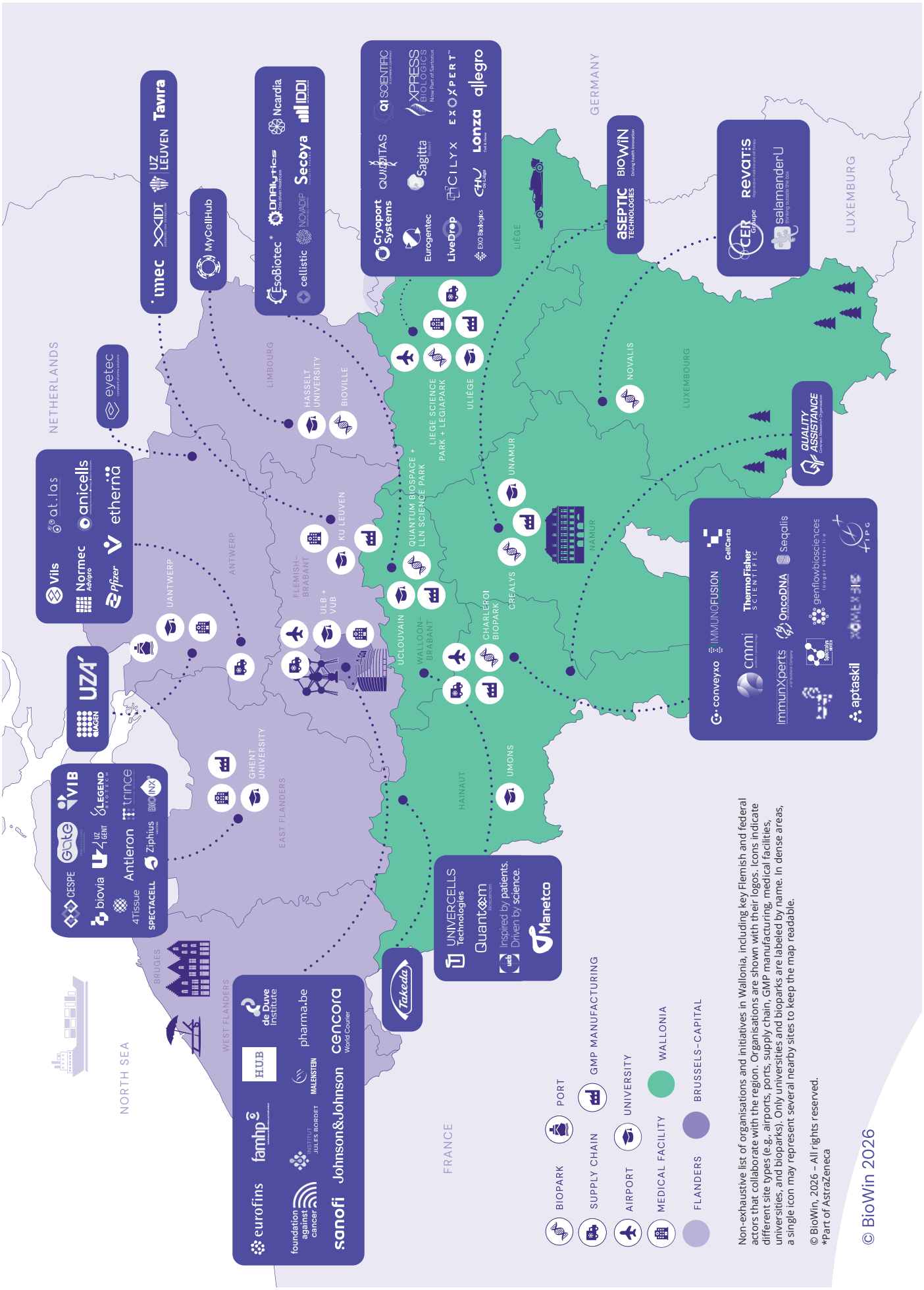


Figure 13: Map of Belgium's ATMP landscape

delivery of the final drug product to the patient, and being able to provide enough continuous energy to our manufacturing and logistical centres.

For CDMOs, it means:

1. **Sell scarce expertise, not square metres.** The paradox defines the market: post-COVID overbuild has pushed utilisation in some plants below 70%, yet 55.9% of sponsors still report difficulty finding a gene therapy CDMO and 55.6% for cell therapy [47]. Each product's vector, cell type and potency requirements demand tailored processes that deviate from standard platforms. Price and market the analytical/potency-assay and regulatory dossier capability, capacity is the commodity.
2. **Build the plan around portfolio volatility, not take-or-pay.** Sponsors have shifted to pipeline hygiene, fewer programs, single asset focus, which is itself a driver of CDMO underutilisation. Long reservation contracts are now a negative selection filter. Win on modular slot booking, guaranteed IND-enabling timelines, and a costed exit clause.
3. **Contract as co-developer, not vendor.** The differentiating behaviour is explicit: programs advance fastest where developer and CDMO share data early, stress-test assumptions together, and adapt when results demand it. Practically, joint CMC governance, named scientific lead, open batch data.

The shift from capacity arbitrage to capability arbitrage, and the asset base is being repriced underneath it. In- vivo CAR-T became a large-pharma priority across 2025, early 2026 (AbbVie, AstraZeneca, BMS, J&J, Kite), with differentiation now driven by delivery, vector design, targeting, payload, scale-up. That moves demand away from patient-scale cell processing suites toward lentiviral/LNP and sterile fill-finish.

4.2.4 Arena 4: The bridge from hospital exemption and academic innovation to scalable development

Hospital exemption is a translational asset that must be intentionally bridged toward scalable development, not left as a parallel system. FAMHP specifies that, from September 2017, a hospital exemption application is required for ATMPs without marketing authorisation, prepared on a non-routine basis, under specific quality standards (GMP), for use in Belgium in a hospital under the exclusive professional responsibility of a physician for an individual patient [4]. This is important because academic centres and hospitals can generate clinically meaningful innovation before a full commercial pathway is established.

Up to date, the hospital exemption has been granted by AFMPS only once in 2019 [48]. The rare usage of this regulatory exemption can be explained by the requirement to prepare the therapy in compliance with the GMP standard, requiring robust infrastructure and capabilities, and the high production costs while reimbursement of the therapy by the national health insurance is not guaranteed.

Hospitals are increasingly stepping beyond clinical care. For example, the new ATMP facility at KU Leuven aims to increase patient access, especially for rare diseases where industry faces difficulties with economic feasibility. Academic centres can focus on high-risk research and process development but ultimately needs the industry for scalingup. Therefore, the collaboration with regulators and policymakers is essential to develop new economic models for rare disease therapies. The future of CGT entrepreneurship hinges on building collaborative models that align science, funding and patient access.

However, hospital exemption should not become a parallel system that traps innovation locally. The policy goal should be to use it where appropriate for patient need and translational learning, while creating clear pathways toward broader development, stronger evidence packages, quality maturity and, where relevant, commercial or multicentre expansion. Belgium can differentiate itself if it becomes the country that helps academic ATMP innovation cross that bridge (i.e., from university research centres/academic hospitals to patient) rather than stall on it. Having shared infrastructure for first GMP batches (e.g., system like the UK CGT Catapult, see 5.3), using our existing footprint from CDMOs, will also help academics and early biotech to test their products quickly without investing large amount of CAPEX for their own infrastructure.

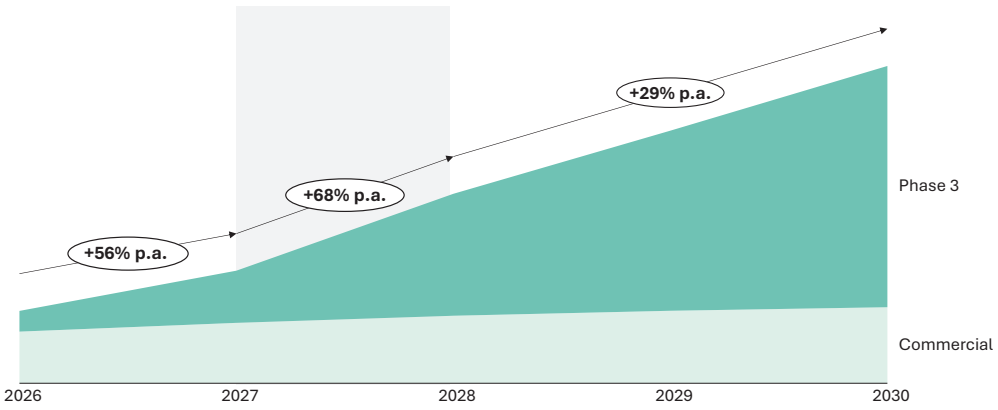


Figure 14: Uptake of CGTs in Europe, defined as number of therapies being administered (GlobalData 2026, Deloitte analysis)

5. How Belgium can win

5.1 Win on regulatory intimacy and early de-risking

Belgium should make its regulatory offer visible, coherent and easy to access. The FAMHP's National Innovation Office already provides national scientific, technical and regulatory advice and specific pre-submission support for SMEs, spin-offs, academic hospitals and research centres [27]. The strategic opportunity is to turn this into a recognisable front door for ATMP innovators, linked to cluster support, trial-site intelligence and manufacturing expertise.

In practice, this means a "Belgian ATMP concierge": one joined-up pathway that directs companies and academic teams to the right experts, flags likely development bottlenecks early and aligns advice across regulation, clinical development, manufacturing and quality. For developers, reducing ambiguity early can be as valuable as later funding.

The UK's Integrated Licensing and Access Pathway (ILAP) exemplifies this approach. It provides a single integrated platform where medicine developers collaborate with the regulator (Medicines and Healthcare products Regulatory Agency), health technology assessment bodies, and the National Health Service from early clinical development stages. By aligning regulatory, clinical, and health system requirements upfront, ILAP accelerates patient access to transformative medicines, a model Belgium could adapt to enhance its competitive advantage in ATMP innovation.

> ***ATMP concierge:*** *one joined-up pathway that directs companies and academic teams to the right experts, flags likely development bottlenecks early and aligns advice across regulation, clinical development, manufacturing and quality.*
> *e.g., ILAP (UK)*

To retain technologies in EU, Belgium could also consider allowing IITs for de-risking ATMP assets under the supervision of an independent committee and through a collaborative national hospital network, without compromising on safety but allowing some agility to developers (e.g., administrative efficiency, phase-appropriate GMP expectations, fast-track ethical committee). Another option could be to provide specific government support (e.g., tax credit) for conducting early-phase clinical studies in Belgium, a mechanism already in place in Australia allowing the net cost of in-country studies to become competitive against the Chinese offering.

5.2 Win on trial activation speed

Belgium's white paper should treat speed to site activation as a national competitiveness metric. Sponsors continue to value Belgium's regulatory and scientific expertise, but the 2026 pharma.be / Deloitte report underlines declining attractiveness on start-up timelines [3]. In ATMPs, delays are particularly costly because manufacturing slots, patient windows and international portfolio decisions are highly time sensitive.

A national fast-start pathway for selected ATMP studies would therefore be high impact. It could include standardised documents, contracting support, trial project management, site-readiness checklists and a limited number of high-priority pilot studies. The goal should not be a generic promise of speed; it should be a measured reduction in time from sponsor readiness to first site activation.

England's National Institute for Health and Care Research (NIHR) Industry Hub demonstrates this approach in practice. As the national delivery and accountability platform for commercial clinical trials, it is explicitly designed for speed, predictability, and performance.

> ***Fast-start pathway:*** *a structured, national regulatory and operational framework designed to accelerate the initiation of ATMP clinical studies.*
> *e.g., NIHR Industry Hub (UK)*

5.3 Win on CMC, quality and specialised manufacturing support

ATMP programmes often fail not because the biology is weak, but because manufacturing, comparability, potency assays, QC or release become bottlenecks. Belgium should position itself as the place where those issues can be solved earlier and more reliably. **Its role need not be full end-to-end manufacturing ownership; it can also be platform support for SMEs, hospitals and translational teams.**

A shared CMC and manufacturing acceleration platform could provide access to development expertise, analytics, quality systems support, GMP translation and external manufacturing partnerships. This would be more useful than scattering investment across multiple under-scaled assets and more realistic than competing for very large generic capacity.

The UK's Cell and Gene Therapy Catapult is a good example of this platform approach. As an independent innovation organisation, it supports the ATMP sector by providing shared infrastructure, expertise, and resources focused on four critical areas: new therapeutics, lower cost of goods, manufacturing at scale, and healthcare system uptake. By collaborating with academia, industry, and healthcare providers, the CGT Catapult removes manufacturing and CMC bottlenecks early.

> ***A shared CMC and manufacturing acceleration platform:*** *a platform that could provide access to development expertise, analytics, quality systems support, GMP translation and external manufacturing partnerships.*
> *e.g., UK CGT Catapult*

5.4 Win on treatment centre readiness

Commercial success for ATMPs depends heavily on the centres that identify patients, manage referrals, prepare administration and run long-term monitoring. Belgium should create a national network of accredited ATMP centres of excellence in its priority arenas. Accreditation should include referral rules, staffing, pharmacy and logistics readiness, patient-information standards, adverse-event management and follow-up capabilities.

A hub-and-spoke approach would fit Belgium's geography well. A small number of highly prepared hubs could serve a broader network of referring centres, reducing duplication while preserving access. This is especially relevant in oncology, haematology and paediatric rare diseases.

Catalonia's Blood and Tissue Bank demonstrates the effectiveness of this approach. Its hub-and-spoke network that has one core processing centre that centralises cell-therapy logistics while the network integrates seven ATMP manufacturers across academic hospitals, enabling rapid patient access and clinical support.

A hub-and-spoke approach: *a small number of highly prepared hubs can serve a broader network of referring centres, reducing duplication while preserving access.*
e.g., Catalonia's Blood and Tissue Bank

5.5 Win on evidence and data

Because many ATMPs are high-cost and often one-time interventions, outcomes evidence and long-term follow-up are central to both access and trust. Belgium should invest in registries and outcomes infrastructure for the disease areas it selects. The aim is not to build a generic data vision, but to **create disease-linked evidence pathways that support patient identification, long-term monitoring and payer dialogue**.

This is an area where Belgium's size can again become an advantage. If referral pathways are concentrated and centre participation is aligned, registry completeness and longitudinal learning can be stronger than in more fragmented markets.

This is done in the Netherlands with a program 'Follow that CAR', a national tumorboard and registry. As a prospective observational cohort study, it evaluates CAR-T cell therapy eligibility for patients with haematological B-cell malignancies, following patients from referral through 30 years of follow-up. The registry captures comprehensive data—medical history, disease characteristics, treatment outcomes, adverse events, and patient-reported experiences—while supporting quality-of-care evaluation and patient education.

Disease-linked evidence pathways: *pathways that support patient identification, long-term monitoring and payer dialogue.*
e.g., 'Follow that CAR' program (Netherlands)

5.6 Win on access innovation

The last mile for ATMPs is often reimbursement and budget handling rather than regulation. Belgium should therefore pilot pragmatic access mechanisms for priority ATMPs, including evidence-linked reimbursement, staged funding, centre-related support and outcome-based elements where feasible. The goal is not to create a one-size-fits-all payment model; it is to avoid losing strategically important therapies because the system has no structured way to test alternatives.

An ATMP access sandbox would create a controlled environment for such pilots. It would also signal that Belgium understands launch readiness as a whole-system challenge, not as a matter left entirely to developers or payers in isolation.

This system readiness is now an absolute necessity due to major shifts in global pharma policies, specifically the expansion of the US Most Favored Nation (MFN) model. MFN ties US drug prices to the lowest prices in European reference countries, and pharmaceutical companies face a massive commercial incentive to delay or completely bypass launches in smaller European markets like Belgium to protect their highly profitable US revenues. This risk is highest for ATMPs, where revenue depends heavily on maintaining a high price rather than generating large volumes. The impact is already visible, with a 25% decline in EMA drug applications in early 2026. To prevent Belgium from losing ground in both patient access and life sciences investment, the country can no longer rely on a static, wait-and-see pricing approach. Instead, Belgium must use structured frameworks like a sandbox to demonstrate it is ready to value innovation and commercialize these advanced therapies at scale.

Belgian experience with ATMPs such as Kymriah, Yescarta, Tecartus, Carvykti, Zolgensma, and Upstaza demonstrates the viability of tailored reimbursement approaches. Our analysis shows substantial variation across products, both in the structure and evolution of reimbursement agreements and in access timelines, which

ranged from approximately 9 months to almost 3 years for the oncology ATMPs analysed. Agreements combine different mechanisms, including financial discounts, expenditure caps and, in selected cases, performance- or evidence-linked elements, reflecting the need to tailor reimbursement to the characteristics and uncertainties of each therapy. This diversity provides a strong foundation for Belgium to test more structured and flexible access models through an ATMP access sandbox.

Pragmatic access mechanisms:
including evidence-linked reimbursement, staged funding, centre-related support and outcome-based elements, where feasible.
e.g., EU5 experience with Kymriah and Yescarta

5.7 What "winning" should mean in practice

Belgium should define winning operationally rather than theoretically. Winning means more Belgian-supported ATMP programmes progressing into quality clinical development, more predictable activation timelines, more treatment centres genuinely ready to administer priority therapies, more credible outcomes data, and a handful of visible cases where Belgium becomes the preferred European site for a critical ATMP step. Those are the outcomes that would validate the strategy. To maximise its chances of success Belgium needs to selectively invest in Scientific Excellence (and perhaps accepting to invest significant amount of money in few high-potential and high-impact projects instead of spreading the same amount to as much project as possible). Using a governance model including management control systems and relevant KPIs, Belgium should focus its investments on balanced project portfolios having a cohesive vision, direction, and evaluation system to drive that strategy forward. Projects could be selected for advanced funding and "de-risking" if they have a strong IP strategy, achievable Proof of Concept metrics, and a high commercial interest vetted alongside venture partners.

6. The enablers Belgium should leverage, connect and scale

6.1 Talent

ATMPs require talent that cuts across disciplines: cell processing, vector analytics, bioinformatics, GMP operations, QA/QP, translational regulatory affairs, trial management and specialist nursing. Belgium has depth in parts of this system but not necessarily enough scale in all of them. The Deloitte/OFI 'Talent in the Biopharma sector' study estimated that Belgium has a Biopharma talent gap of 27%, mainly in R&D and manufacturing and supply chain. However, given the fast-growing digitisation, there is expected to be a growing need/gap for data scientists. This gap was expected to grow even larger in the next 5 to 10 years if considering also the indirect and induced employment, as well as the outflow.

Vector Talent's 2026 industry market analysis reveals a critical talent shortage in biomanufacturing. The scarcity is most acute for professionals holding GMP qualifications and hands-on experience in biologics or advanced therapy manufacturing. Belgium's shift towards domestic manufacturing has been driven by CDMO development and a wave of investment in additional production capacity, but the existing candidate pool hasn't kept pace.

A practical strategy should identify scarce roles and build targeted training and mobility programmes, rather than assuming life-sciences talent is interchangeable. Flanders and Wallonia are already moving in this direction, launching initiatives through for example ViTalent that focus on specific topics such as targeted training programmes and non-traditional talent development pathways.

Belgium should build on an existing but still fragmented ATMP-specific training base. Advanced Therapies Training micro-credentials already combine knowledge of cell and gene therapy, tissue regeneration and personalised medicine with practical laboratory and quality-control skills. The GMP for ATMP Summer School adds practice-oriented exposure to manufacturing processes, quality systems, aseptic techniques and cleanroom operations, while interdisciplinary European doctoral networks involving Belgian academic and industrial actors are developing expertise in areas such as immune-cell therapies, advanced delivery systems and scalable manufacturing.

These initiatives are valuable because they address a specific feature of the ATMP workforce challenge: specialised talent cannot be generated through scientific education alone. Operators, analysts and researchers must understand GMP constraints, quality systems and industrial reproducibility as well as the underlying biology. Belgium should therefore move towards a coordinated competency framework that maps scarce profiles, connects existing training providers and allows curricula to evolve rapidly with emerging technological needs. The objective should be to make specialised ATMP talent development itself part of Belgium's competitive proposition.

6.2 Quality & logistics

The specific GMP environment for ATMPs is a strategic capability in its own right. European and Belgian guidance make clear that ATMPs, including investigational products and hospital exemption products, are subject to specific GMP expectations [5]. Belgium should therefore invest not only in facilities and hub (ATMP-XB), but also in the people and routines that make quality systems robust and inspection-ready.

For personalised and time-sensitive therapies, logistics are not support functions; they are part of the product itself. Belgium's compact geography can help, but only if chain of identity, chain of

custody, cryogenic transport, scheduling and exception management are designed as system capabilities. A multistakeholder debate convened by Johnson & Johnson identified Belgium's unique capability to efficiently deliver the complete "vein-to-vein" process, enabled by well-functioning infrastructure and Brussels Airport's strategic role as a global pharma hub [49]. This is one of the most tangible areas in which Belgium can become execution ready.

6.3 Digital traceability and data infrastructure

A credible ATMP ecosystem needs interoperable traceability and outcomes capture. Current barriers are substantial. A Tiro Health survey found that structured data integration remains rare in Belgian healthcare, with 72% of clinicians unfamiliar with European Health Data Space requirements [50]. Real-world evidence (RWE) collection for cell and gene therapies (e.g., registries) is particularly challenging: there is a lack of a structured system for collecting RWE and patient follow-up, ambiguity regarding the responsibilities for maintaining data infrastructures and insufficient dedicated hospital funding. Physicians face time constraints and lack financial incentives, which can lead to gaps in patient assessments [51].

Belgium should not over-promise a universal digital backbone. It should instead build fit-for-purpose traceability and registry capabilities in priority disease areas and connect them to treatment centre workflows and payer evidence needs (e.g., CAR-T registry linked to treatment centre workflows in oncology).

6.4 Patient, referral and access

Many ATMPs fail to scale because eligible patients are not identified early enough or not referred consistently. Rare disease patients exemplify this challenge: across Europe, the average diagnostic journey spans five years, with most patients experiencing misdiagnosis and delayed specialist referral. Yet patients referred to centres of expertise experience significantly shorter diagnostic pathways, demonstrating that structured referral systems work [52]. Belgium can address this by developing disease-specific referral pathways, centre criteria and awareness programmes in its priority arenas. This is particularly important in rare disease and paediatric settings, where fragmented referral can undermine both access and evidence quality.

ATMPs place unusual pressure on budget management, contract design and outcomes tracking. Belgium should develop institutional capability in those areas rather than treating each product as a bespoke exception. Belgium's system has a longstanding structural weakness of bespoke, case-by-case negotiation but is actively reforming its early/fast-access procedures [53] [54]. For certain innovative therapies, Belgium allows early and fast access and reimbursement even before they have received market authorisation by the EMA [55]. From January 1st, 2026, new procedures were introduced. The access sandbox proposed in chapter 5 should therefore be supported by legal, payer and health-economics expertise.

7. A pragmatic investment case for Belgium

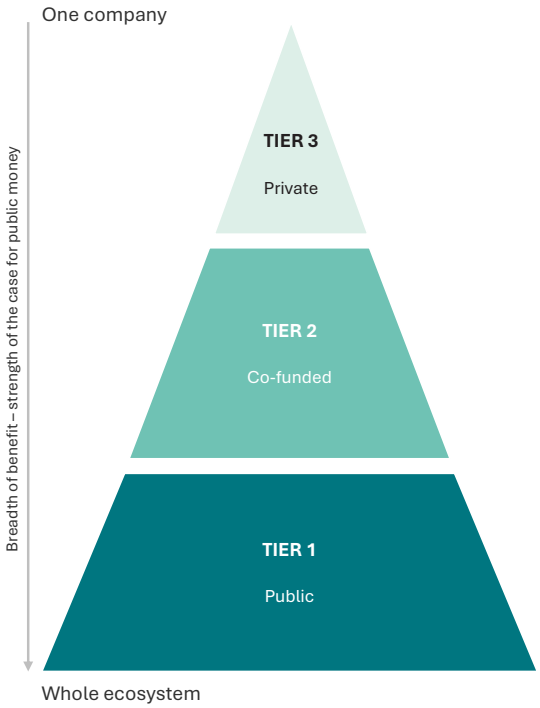
ATMP strategy should be backed by an investment logic, not just by sector ambition. Belgium should prioritise investing where shared capabilities create spillovers across multiple programmes and where public intervention de-risks private participation. The best examples are regulatory navigation, shared CMC support, treatment centre readiness, outcomes infrastructure and targeted training. These are classic coordination failures: individually important, but hard for any one actor to fund alone.

By contrast, Belgium should be careful with large irreversible capacity bets that depend on uncertain demand. Public support should be catalytic, linked to selected arenas and tied to measurable use and aligned with Smart Specialisation Strategies (S3) for clear EU positioning. In many cases, Belgium's winning model will involve partnerships with larger manufacturers, technology providers or investors (public private partnership is a good example, such as the ATMP-PIT).

A pragmatic investment case should also distinguish three layers to support top ATMP players. First, shared national goods: regulation, data, talent and network design. Second, selectively supported platforms: CMC/manufacturing acceleration, specialised logistics and centre readiness. Third, company-specific investment, which should mostly remain private unless justified by clear strategic spillovers. This structure helps prevent the strategy from becoming an unfocused subsidy catalogue.

Examples of investment logics for ATMPs in other countries can be used to decide what should be publicly funded or not. The Netherlands, for example, backed a national cell-and-gene therapy pilot factory with €56 million in government investments, explicitly targeting the same "shared infrastructure" logic as Tier 1/Tier 2, de-risking scale-up and manufacturing capability that no single company would build alone [56].

In Sweden, the ATMP Path2Patient project is introduced to accelerate the development and commercialisation of ATMPs. The project has a budget of SEK 36 million, with the majority of funding coming from the Swedish Agency for Economic and Regional Growth (Tillväxtverket) and Region Skåne. The Path2Patient project is led by Lund University's innovation office and



TIER 3	Company-specific investment	Mostly private
Covers	Individual company assets, proprietary pipelines and firm-level capacity.	
Funding logic	Private. Public co-investment only where a strategic spillover can be named in advance – not asserted afterwards.	
Test question	Would this still be worth funding if only one company benefited?	

TIER 2	Selectively supported platforms	Co-funded, conditional
Covers	CMC and manufacturing acceleration, specialised logistics, treatment-centre readiness.	
Funding logic	Co-funded and tied to the priority arenas. Catalytic, with tranches released against measurable use, not capacity built.	
Test question	Do several programmes draw on this, and does usage – not construction – trigger the next tranche?	

TIER 1	Shared national goods	Publicly funded
Covers	Regulatory navigation, outcomes data infrastructure, talent, network and referral design.	
Funding logic	Public. These are classic coordination failures: individually important, but hard for any single actor to fund alone.	
Test question	Would any one actor fund this by itself?	

Outside the pyramid	Large irreversible capacity bets that depend on uncertain demand. The objective is not to subsidise industrial scale for its own sake – where scale is needed, the winning model is partnership with manufacturers, technology providers or investors.

Figure 15: ATMP Investment logic for Belgium (illustrative). The three tiers set out where public support is justified, where it should be conditional, and where it should not go. Each tier carries a test question so that allocation decisions can be argued rather than asserted.

executed in partnership with venture hubs, innovation centres, and regional ATMP facilities. The initiative builds more efficient ecosystems for turning academic research into patient-ready therapies [57].

Belgium has relevant experience with portfolio-based public investment that can inform this model. For instance, ATMP-Wal was established under the regional Smart Specialisation Strategy to connect research, clinical capabilities, industrial development and public-support mechanisms, and was reported to encompass 35 active projects in 2025. Within this broader framework, GT4Health has concentrated public investment around enabling technologies for gene therapy while ATMP-PIT represents a major portfolio investment across cell therapy, gene therapy and emerging modalities. ATMP-PIT also illustrates how such an approach can combine strategic ambition with financial discipline. Approximately €40 million of public funding was initially committed to the three-year programme, but disbursement is linked to project progress and the achievement of defined milestones rather than being automatically spent. This milestone-based approach provides an important basis for a more agile use of public funding: resources can follow progress and evidence rather than being locked into fixed allocations from the outset. However, this model should come with administrative flexibility regarding programme/budget modifications, so money is not lost but redistributed within the portfolio in case an asset or a work package needs to be deprioritised, abandoned or adapted.

The lesson is broader than the individual projects. Public investment can create greater strategic value when projects are managed as a portfolio rather than as a series of independent grants. Indeed, portfolio management makes it possible to identify common bottlenecks, mutualise infrastructure, connect complementary technologies, stop duplicative investments and direct additional resources towards programmes that demonstrate the strongest translational or industrial potential. Given a flexible administrative structure, portfolio-based public investment could provide biotech with a highly needed financial agility. This approach would also provide a clearer framework for assessing the economic and patient impact generated by public investment over time, and to maximise it.

The next generation of public support should therefore shift progressively from funding individual ATMP projects towards managing a strategic pipeline: feeding high-quality early innovation, building shared enabling capabilities, and creating explicit pathways for the strongest programmes to progress towards clinical, industrial and commercial maturity. Having large professional private investors with deep technical expertise (or so called the "Smart Money") establishing themselves in Belgium would be a highly needed addition to the ecosystem. Facilitating mechanisms, including fiscal advantages and/or public co-investment could be leveraged to attract them, but would need to be justified by sufficient offer in strong investments cases of sufficient maturity (and market size).

Overall, the strategic value of investing in ATMPs goes well beyond the direct ATMP market itself. ATMPs are an important capability-building engine for the broader Belgian life-sciences ecosystem and generate significant spillovers in broader areas (Table 3). This is particularly important from a public-investment / industrial-policy perspective. Although important, the return on investment should not be measured only through the revenues or jobs directly generated by individual ATMP products or companies. Shared investments in ATMP capabilities can strengthen the competitiveness and attractiveness of the entire Belgian biopharma ecosystem.

Category	Technological and Capability Improvements
Manufacturing & Quality	Advanced GMP, QA/QC and regulatory capabilities
Process Innovation	Automation, digital manufacturing and advanced process technologies
Supply Chain	Specialised and cryogenic logistics, chain-of-identity and chain-of-custody
Data & Evidence	Health data, traceability, registries and real-world evidence
Human Capital	Highly specialised talent and new professional profiles
Clinical Infrastructure	Clinical trial capabilities and treatment centre readiness
Ecosystem Development	Entrepreneurship, spin-off creation, licensing, partnerships and M&A attractiveness
Cross-Therapeutic Spillovers	Technologies and capabilities that can subsequently benefit RNA, biologics, vaccines, precision medicine and other complex therapeutic modalities
Patient Impact	Improved patient pathways and earlier access to innovative therapies

Table 3: Technological and capability improvements generated through ATMP investment in Belgium (non-exhaustive).

8. Conclusion

8.1 Belgium's strategic choice

Belgium does not need another generic statement that ATMPs are important. That is already clear (Figure 16). **The more difficult and more pragmatic task is to define the narrow set of battles Belgium can win and the concrete moves required to win them**. This update therefore recommends a more selective and more operational strategy than the 2024 white paper. The Belgian ambition should be the overarching external proposition, with Wallonia contributing a differentiated set of capabilities to that national ambition, alongside Flanders and Brussels.

Belgium should aim to become Europe's most execution-ready ATMP ecosystem in selected niches, not the broadest ecosystem on paper, but the one most capable of converting science into scalable and flexible patient access in a cost-efficient way. That means choosing a handful of arenas, building the capabilities that matter at the handoffs, and measuring outcomes ruthlessly over the next 24 months.

What does it mean to position Belgium on the European map? It means (1) strengthen our international branding and visibility, (2) position itself as a European leader in specific ATMP niches, and (3) build stronger global partnerships.
If Belgium makes those choices now, it can still turn its combination of trial strength, regulatory know-how, geography and quality culture into a durable ATMP advantage. If it does not, it will remain scientifically relevant but strategically diffuse. The difference between those futures lies in coordinated execution.

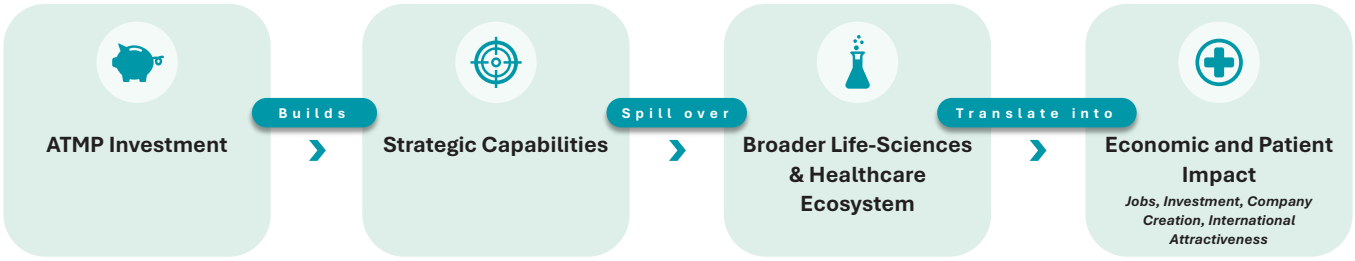


Figure 16: From initial ATMP Investment to system-wide economic and patient returns

8.2 Wallonia's differentiated contribution to Belgium's ATMP competitiveness

In parallel with the Belgian analysis developed in this white paper, BioWin facilitated a five-year vision exercise with Walloon ATMP stakeholders, with methodological support from Deloitte. This vision reflects the ambitions expressed by the Walloon ecosystem and should therefore be understood as a regional contribution to a broader Belgian positioning, rather than as a nationally agreed vision [58].

The exercise identified three priorities for Wallonia over the next five years: strengthening international visibility and attractiveness; consolidating excellence in selected ATMP capabilities and niches; and developing stronger national, European and global partnerships. The objective is not to build a standalone regional proposition, but to better connect, leverage and selectively strengthen existing assets so that they can contribute more effectively to Belgium's competitiveness in advanced therapies.

Wallonia can bring differentiated capabilities in collaborative R&D, translational science, specialised manufacturing and emerging therapeutic modalities, supported by initiatives such as ATMP-Wal, ATMP-PIT and GT4Health. Equally important, the creation, attraction and retention of highly specialised scientific, technical and entrepreneurial talent is itself a strategic asset for the region. In advanced life sciences, such expertise takes years to build, is internationally mobile and is difficult and costly to recreate once lost. Preserving this "brain capital" is therefore an important part of the long-term value generated by ecosystem investment.
Ultimately, Wallonia should be considered one of the regional building blocks of a stronger Belgian ATMP proposition, alongside complementary capabilities in Flanders and Brussels. Further national alignment will require continued engagement across the regions and with relevant federal stakeholders, with the objective of translating regional strengths into a clearer, more coordinated and internationally visible Belgian offer.

Acknowledgements

We would like to thank everyone who contributed to the development of this white paper, especially our partner BioWin, Jiri Keirsse and the other external experts for their guidance, trust and support. We also acknowledge BioVia for providing input on the map of Belgium's ATMP landscape. In addition, we thank all our Deloitte colleagues who provided valuable insights on the Advanced Therapy landscape including members of our Global Next Gen and Life Sciences Community, Amit Agarwal, David Xie, Liedewij Vandewal, Marte Dennes and Antje Bossuyt.

Authors

Kevin Missault
Life Sciences & Healthcare Strategy
Senior Manager
kmissault@deloitte.com

Annie Marie (Anny) Fortin
Life Science - Global Investment and Innovation Incentives
Senior Manager
afortin@deloitte.com

Karen Seghers
Life Sciences Regulatory & Compliance Manager
karseghers@deloitte.com

Thomas Terryn
Life Sciences and Healthcare Strategy
Senior Consultant
tterryn@deloitte.com

Contacts

Marc Abels
Life Sciences & Healthcare Industry Lead Deloitte Belgium
Partner
mabels@deloitte.com

Pieter Sauwens
Life Sciences & Healthcare Strategy
Partner
psauwens@deloitte.com

Julie Jadoul
Life Science - Global Investment and Innovation Incentives
Director
jjadoul@deloitte.com

Burçak Aydin
Life Sciences & Healthcare Strategy
Director
buaydin@deloitte.com

References

1. Deloitte and BioWin. Advancing Advanced Therapies in Belgium: A Belgian Recipe for an Innovative Ecosystem. October 2024 (Link)
2. European Medicines Agency. CAT quarterly highlights and approved ATMPs. March 2026 (EMA/53733/2026) (Link)
3. Deloitte Belgium for pharma.be. Belgium as clinical trial location in Europe – Report 2024 (published 2026; data year 2024) (Link)
4. Federal Agency for Medicines and Health Products (FAMHP). Hospital exemption for advanced therapy medicinal products in Belgium. National guidance and webpage.
5. Federal Agency for Medicines and Health Products (FAMHP) and European Commission. GMP guide and Part IV requirements applicable to advanced therapy medicinal products.
6. European Medicines Agency. Advanced therapy medicinal products: Overview. National guidance and webpage. (Link)
7. Kordbachech, T. et al. "Improved Survival and Health Care Use with CAR-T vs Historical Care in Relapsed/Refractory Large B-Cell Lymphoma, " Blood Advances 10, no. 7 (2026): 2304. (Link)
8. Invivo Partners. Future trends in cell and gene therapies (2026-2030): Crisis, opportunity, or both? – September 2025. (Link)
9. Deloitte CGT Market Index ™. Capital IQ, Deloitte Research, EIU Economic Outlook
10. Legend Biotech. Clinical proof-of-concept for LB2501 (CD19/CD20 in vivo CAR-T), R/R B-cell non-Hodgkin lymphoma. EHA 2026 Congress, late-breaking session, Abstract LB5006, June 14, 2026.
11. Kelonia Therapeutics. Updated first-in-human data, Phase 1 in MM yCAR study of KLN-1010 (in vivo BCMA CAR-T), R/R multiple myeloma (NCT07075185). ASCO 2026 Annual Meeting, May 2026.
12. EsoBiotec / AstraZeneca. Phase 1 data for ESO-T01 (in vivo BCMA CAR-T), R/R multiple myeloma. Nature Medicine, 2026.
13. Umoja Biopharma. UB-VV111 (CD19 in vivo CAR-T) receives FDA Fast Track designation; INVICTA-1 Phase 1 trial (NCT06528301). September 2025.
14. Sana Biotechnology. Preclinical data for SG293 (CD8-targeted, CD19-directed in vivo CAR-T), non-human-primate study. ASGCT 2026 Annual Meeting, May 12, 2026.
15. Mordor Intelligence. Tissue Engineering Market Size & Share Report 2026–2031, April 2026. (Link)
16. U.S. Food and Drug Administration (FDA). FDA Approves First Acellular Tissue Engineered Vessel to Treat Vascular Trauma in Extremities. Press Announcement. December 20, 2024. (Link)
17. U.S. Food and Drug Administration (FDA). FDA Announces Plan to Phase Out Animal Testing Requirement for Monoclonal Antibodies and Other Drugs. Press Announcement. April, 10 2025. (Link)
18. Cramer, J. "Advanced therapy medicinal products (ATMPs) – An analysis of the global regulatory status." British Journal of Clinical Pharmacology. Wiley Online Library. April 30, 2026. (Link)
19. European Medicines Agency. CAT Quarterly Highlights and Approved ATMPs (EMA/147429/2026)
20. Deloitte. "Cell and Gene Therapy and China's Precision Medicine Initiative." Deloitte Insights. May 5, 2020. (Link)
21. Alliance for Regenerative Medicine. State of the Industry Briefing 2026. Jan 2026.
22. National Institutes of Health (NIH). Office of Budget. CRS Report R43341.
23. Association of University Technology Managers (AUTM). Licensing Activity Survey. National Science Foundation National Center for Science and Engineering Statistics (NSF NCSES).
24. LifeSciVC (Bruce Booth). Moving From Academia To Successful Biotech.
25. Delaware Division of Corporations. 2024 Annual Report.
26. U.S. Food and Drug Administration (FDA), Center for Biologics Evaluation and Research (CBER). "Flexible Requirements for Cell and Gene Therapies" January 11, 2026.
27. European Federation of Pharmaceutical Industries and Associations (EFPIA). Europe has the foundations to lead in biotech – now is the time to build on them. June 18, 2026. (Link)
28. European Commission. Scaleup Europe Fund to start making investments. August 4, 2026.
29. Deloitte. Future of R&D in Belgium - Belgium at the Crossroads: A Decade of Growth, A Change of Course Required. March 31, 2026. (Link)
30. ClinicalTrials.gov as of August 2026, Deloitte Analysis.
31. Federal Agency for Medicines and Health Products (FAMHP). Scientific, technical and regulatory advice meetings. National Innovation Office page, updated December 2025.
32. Biowin. The ATMP-PIT Portfolio, an ATMP collaborative project initiated in Wallonia. January 28, 2024. (link)
33. S3 Wallonie. IIS ATMP Wal, Stratégie de Spécialisation Intelligente 2021-2027. (link)
34. Interreg Vlaanderen-Nederland. ATMP XB. (link)
35. FMA/CAT annual reports.
36. Alliance for Regenerative Medicine (ARM) sector data.

37. UK Cell & Gene Therapy.
38. Catapult GMP & investment reports 2024–25.
39. AseBio/AEMPS. Essencia & BCG: "Belgium, the health and biotech valley". 2023.
40. FAMHP applied timelines.
41. EFPIA. WAIT Indicator 2025.
42. BioIndustry Association. 2025.
43. Company disclosures: Galapagos, Bone Therapeutics, BioSeniC
44. EudraGMDP. GMP Certificates database (Link)
45. UZ Leuven. New gene therapy for congenital blindness. January 13, 2023. (Link)
46. Lakefront Biotherapeutics. Galapagos Announces Intention to Wind Down Cell Therapy Business as Part of the Company's Ongoing Transformation. October 21, 2025. (Link)
47. Contract Pharma. "The CDMO Capacity Crunch Persists. (Link)
48. Fagg. Hospital exemption for ATMPs. February 19, 2024. (Link)
49. Johnson & Johnson. ATMP White Paper: From Plant to Patient. October 2025. (Link)
50. Tiro.Health. "Structured Data in Belgian Healthcare: 5 Findings from 847 Professionals." December, 24 2025. (Link)
51. Pharma.be and PwC Belgium. "Challenges Associated with the Funding of Medical Acts Related to Advanced Therapy Medicinal Products in Belgian Hospitals." White Paper. November 2025. (Link)
52. EURORDIS-Rare Diseases Europe. "Major Survey Reveals Lengthy Diagnostic Delays for Rare Disease Patients." News article. May 2024. (Link)
53. Belgian Health Care Knowledge Centre. How to Improve the Belgian Process for Managed Entry Agreements? An Analysis of the Belgian and International Experience. KCE Report 288. Brussels: KCE, 2017. (Link)
54. Neyt, M. et al. "An Evaluation of Managed Entry Agreements in Belgium: A System with Threats and (High) Potential if Properly Applied." Health Policy 124, no. 9 (2020): 959–964. (Link)
55. Inovigate. Modernising Early and Fast Access for Patients in Belgium: A Collaborative Path Forward. Policy Report, commissioned by Novartis. September 2025. (Link)
56. Invest in Holland. "How the Netherlands Allows Cell and Gene Therapy Businesses to Scale-up." News article. February 10, 2022. (Link)
57. Lund University (LU Innovation). "Major Investment Accelerates Advanced Therapies Research for Patients." News article. Accessed August 21, 2026. (Link)
58. BioWin. "Belgium's ATMP Strategy: A Roadmap to Strengthen Belgium's Position in Advanced Therapies." August 19, 2026. (Link)

Deloitte.