A Strategic Roadmap towards World-Leading European Regenerative Medicine

Novo Nordisk Foundation

Catenion

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This report (published June 2026) provides an overview of that analysis and conclusions, and was developed by Catenion and the Foundation in collaboration.

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Access a slide deck with more information about the analysis here:

https://novonordiskfonden.dk//app/uploads/EU-RM-Bioclusters-Slide-Deck.pdf

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Abstract

Regenerative medicine promises transformative therapies that cure, reverse, or halt disease. Yet after two decades of investment, the field has delivered only a handful of approved therapies, private capital has decreased substantially, and Europe in particular lacks the critical mass of well-funded companies needed to change this situation. The field currently sits in a "trough of disillusionment". Without a trigger moment – a transformative clinical success that establishes platform potential and commercial viability – it will most likely remain there.

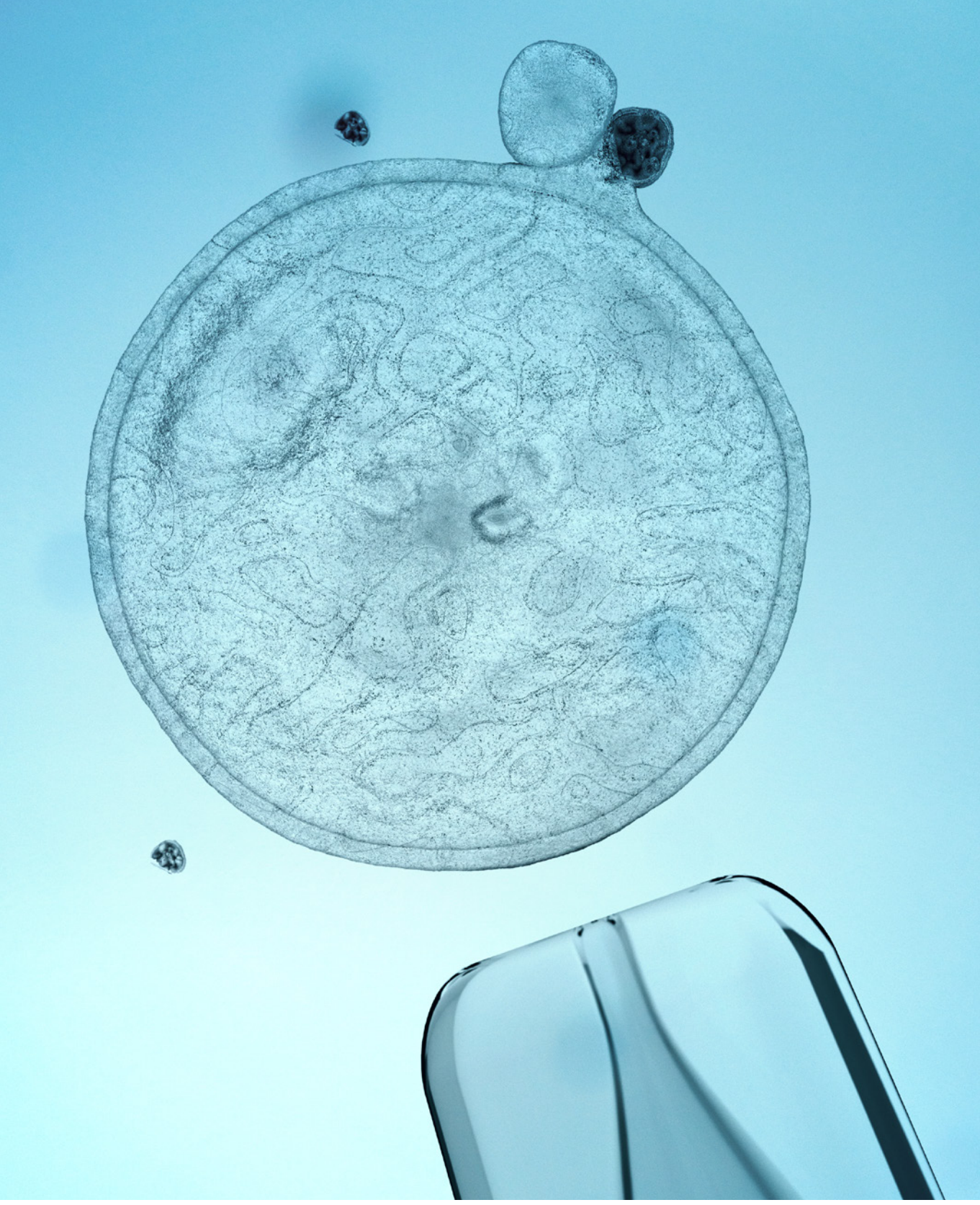
The EU Biotech Act I proposal and the Draghi Report describe the need and commitment to build momentum in Europe to advance life science competitiveness. With the aim to deliver a data-driven strategic roadmap for Europe to advance the field and become a global leader within regenerative medicine, we carried out a multi-parametric analysis of all European and leading global bioclusters within regenerative medicine[1], supported by more than 30 expert interviews.

The analysis confirms that Europe's science is world-class, and policy momentum is building. However, this strength still does not translate into a critical mass of regenerative medicine companies and late-stage programmes. In contrast, leading clusters within regenerative medicine (e.g., Boston and San Francisco) have come further due to risk-tolerant capital, tight integration of science and business, and deliberate efforts to build critical mass.

Our analysis identified four strategic priorities to improve European regenerative medicine performance: achieving critical mass by concentrating efforts in already existing high-potential hubs; attracting investors by embedding strategic and commercial thinking early; improving manufacturing efficiency and shared infrastructure; and applying rigorous strategic prioritisation.

We urge European stakeholders to adopt these priorities to catalyse clinical and commercial trigger moments needed to restore investor confidence and attract talent, ultimately enabling regenerative medicine to deliver meaningful patient impact.

1 Regenerative medicine is here defined as pluripotent and multipotent stem cell therapies and tissue engineering–based solutions, including bioengineered organs. See textbox 1



Introduction

Regenerative medicine promises durable solutions for chronic diseases

Regenerative medicine (RM) offers a unique value proposition compared to other modalities: functional restoration or even cure rather than lifelong disease management. Its potential spans across multiple high-burden indications, including degenerative disorders and organ failure, where transplantation is currently the only option. If realised at scale, RM could help address growing healthcare costs, improve healthspan for the ageing population, and provide a cure for many indications lacking disease-modifying options.

Momentum is growing in the EU for advanced modalities: the EU Biotech Act I[1] proposal signals renewed commitment to life science competitiveness with pan-European activities emerging. The Draghi Report emphasises the importance of translating research excellence into economic impact and improving on the well-documented lag in Europe in translating high-quality research into competitive startups and biotech companies[2]. National advanced therapy medicinal product (ATMP) strategies in Germany, the UK, and other countries align academic institutions with industrial priorities. Local initiatives within bioclusters (e.g., ATMP-PIT in Belgium) are also emerging to accelerate the translation of academic research into an innovative pipeline.

Textbox 1
RM DEFINITION

Our RM definition encompasses pluripotent and multipotent stem cell therapies and tissue engineering–based solutions, including bioengineered organs. It excludes immune cell–based therapies (e.g. non-induced pluripotent stem cell (iPSC)-derived chimeric antigen receptor T-cell (CAR-T) products) and *in vivo* gene delivery approaches.

Specific challenges of regenerative medicine

Despite well-intended initiatives and two decades of investment, however, only a handful of RM therapies have reached late-stage development in Europe. Already in the early stages of the research and development (R&D) value chain, the challenges with RM products differ from those for classical modalities.

Small molecules and biologics have lower, more predictable manufacturing costs and well-established supply chains, making their risk profile well understood and attractive for industry and investors. For RM, the process and the product are still highly interdependent and the reliable production of a living therapy with consistent potency, predictable performance, and low cost of goods remains a challenge. The transition from lab-graded cells to large production methods for clinical application can pose challenges for comparability between products in clinical trials or animal studies[3]. There is thus a clear technological manufacturing gap that needs to be closed.

However, the challenges are not limited to manufacturing. Advancing RM therapies requires coordinated progress across multiple stages from clinical to regulatory and commercial. Hospitals must manage short-lived cellular products with diverse administration requirements. Regulators must adapt frameworks to evolving technologies, and commercial viability requires managing high cost of goods and developing new payment models. The current reality is that development remains capital-intensive and reliant on tacit trial-and-error knowledge. The long and irregular development timelines for RM are poorly aligned with conventional venture capital funding cycles.

The current European RM efforts seem insufficient to overcome the challenges of the field. Instead, clear coordinated European activities may be required to give the field the push it needs towards scalable clinical and commercial success.

"For complex cell therapies, discovery, process design, and manufacturing are inseparable. That's why breakthrough manufacturing approaches have to be developed alongside the biology."

CEO of a high-profile RM startup

"Currently it costs at least €1,000 per litre per day to maintain iPSCs. Processes of converting iPSCs to differentiated cells can take two weeks - iPSC-derived cardiomyocytes are some of the shortest [cell types], neurons take longer, immune cells take three to four months. At a 5,000-litre scale, this translates to tens to hundreds of thousands of euros."

Globally recognised stem-cell biologist and translational leader

Reigniting the field

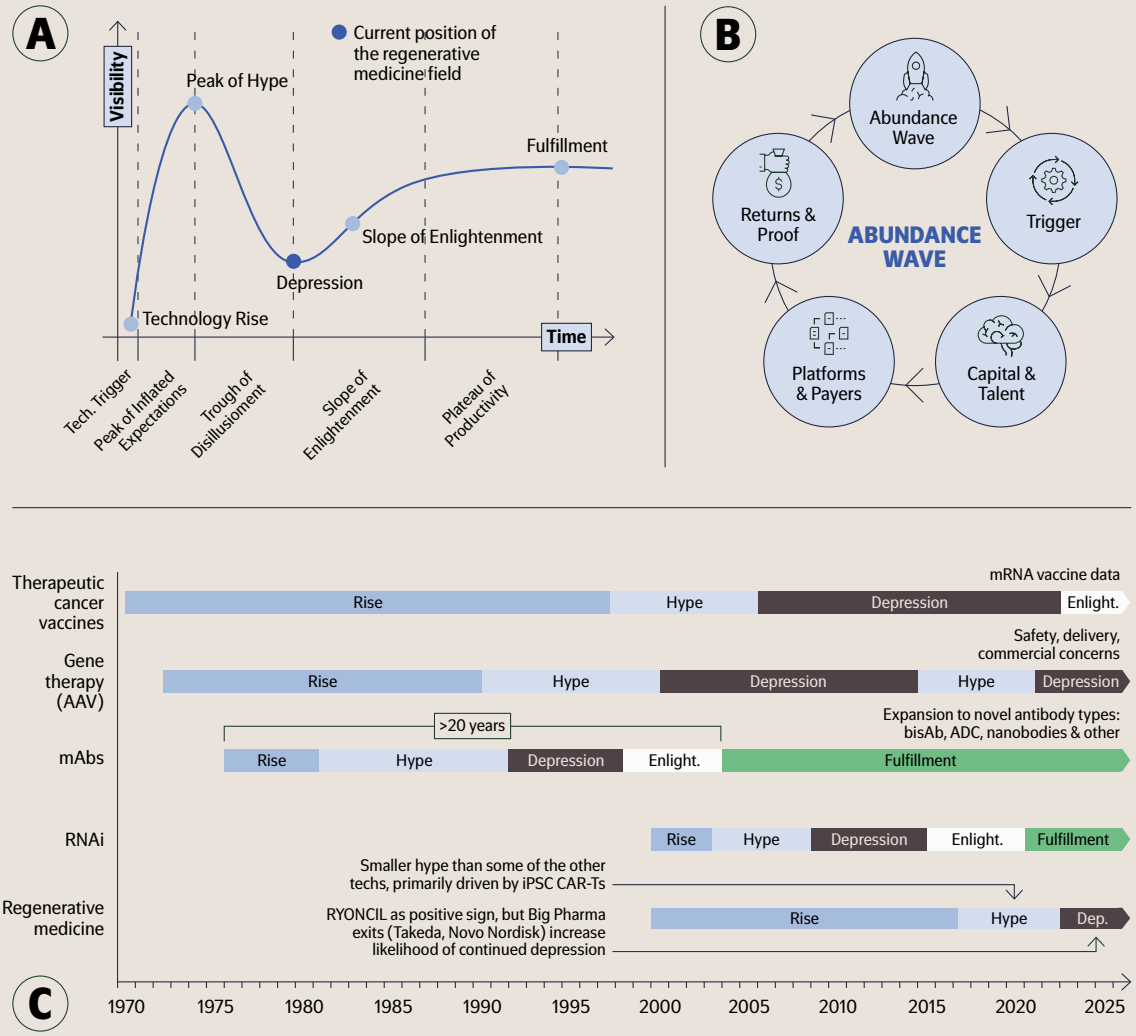
Understanding trigger moments

Novel and transformative technologies will almost always pass through a difficult phase. The Gartner Hype Cycle describes a common trajectory: initial enthusiasm drives a peak of inflated expectations, followed by disillusionment when reality fails to match the hype, and then a gradual climb toward productivity as the technology matures[4] (Figure 1).

Antibody-drug conjugates (ADCs) illustrate how long it can take to reach a trigger moment. It took nearly two decades from initial approval by the US Federal Food and Drug Administration (FDA) to a trigger moment. MYLOTARG[5] (approved in 2000) proved the ADC concept but failed commercially due to toxicity and technical limitations, even before its 2010 withdrawal. Next-generation ADCs, primarily ENHERTU and PADCEV addressed these limitations, and their FDA approvals in 2019 helped unlock the modality by demonstrating transformative efficacy and multibillion-dollar market potential[6].

RM currently sits in the trough of disillusionment of the Gartner Hype Cycle. First-generation mesenchymal stromal cell therapies largely failed to deliver transformative clinical outcomes, dampening the initial hype. While Mesoblast's RYONCIL

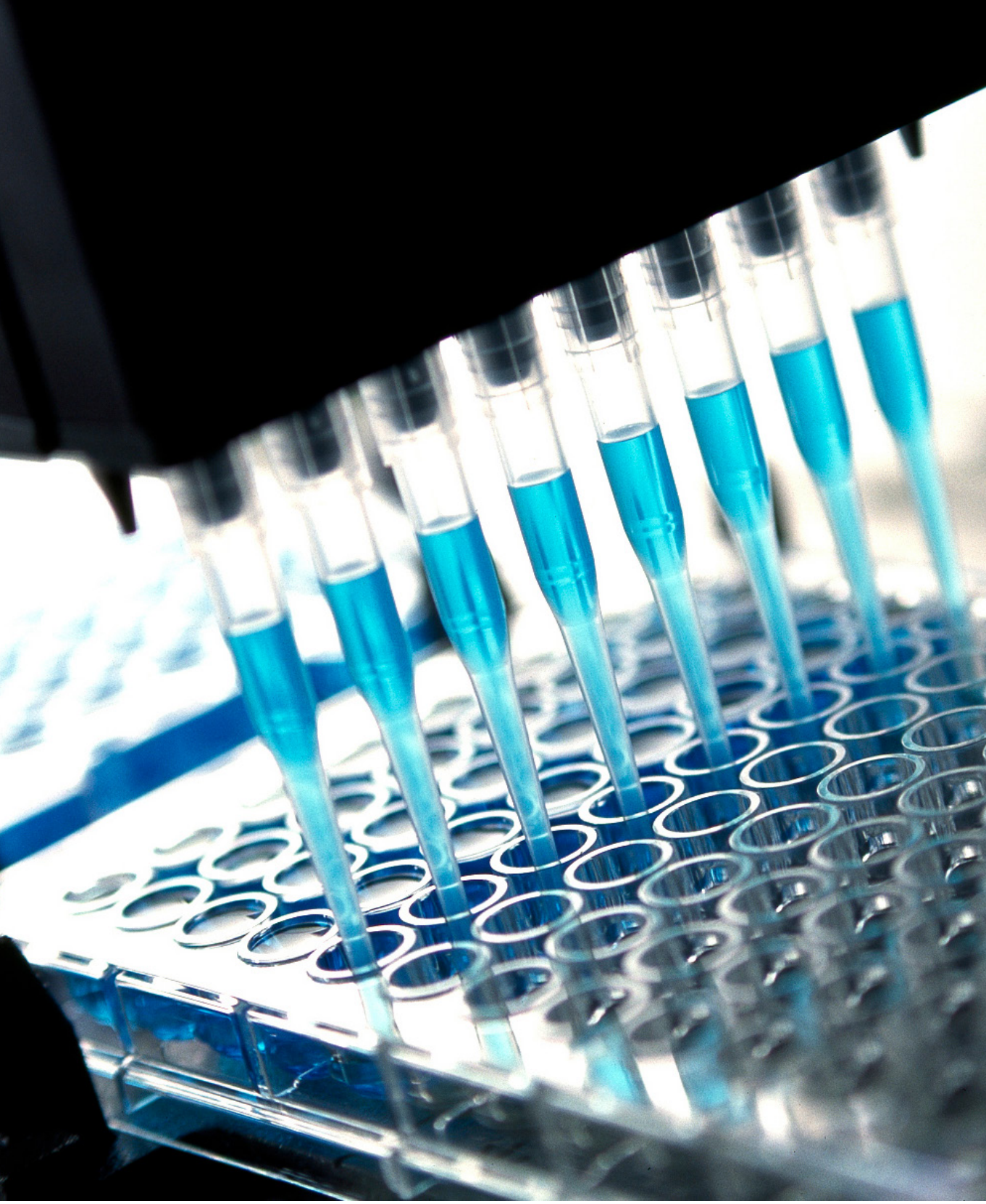
FIGURE 1
What it takes to unlock regenerative medicine in Europe – a trigger moment



A A schematic representation of the Gartner Hype Cycle of Emerging Technology, illustrating the current position of regenerative medicine in the post-hype "depression," where early clinical feasibility has been demonstrated but scalable manufacturing, reproducibility, and commercial models remain unresolved. Progression toward the slope of enlightenment and long-term fulfillment requires system-level maturation beyond first-generation approvals.

B Conceptual "Abundance Wave" framework highlighting the interdependent enablers required to generate a self-sufficient virtuous cycle of technology. A field-level trigger moment, including platform-level clinical proof, aligned payer pathways, access to capital and skilled talent, and coordinated ecosystem infrastructure reinforce the investment in the field.

C Historical maturation timelines of selected advanced therapeutic modalities (e.g., mRNA therapeutics, AAV-based gene therapy, monoclonal antibodies, RNAi), contextualising regenerative medicine relative to prior innovation cycles that required decades to transition from initial hype to widespread clinical and commercial fulfillment.



"There was a lot of investment in this area a few years ago and those investors have kind of moved away [...] I think those investors believed that in two years, for example, they were going to get to the clinic, but really they weren't any closer to the clinic"

Senior leader of a cell therapy development and commercialisation non-profit

reached approval in December 2024 and according to some market analysts has blockbuster potential[7], investors remain cautious and still do not see broad platform potential beyond the initial successes. Major pharmaceutical companies, such as Takeda Pharmaceutical Company and Novo Nordisk A/S, have exited the field and venture investors who funded the first wave now hesitate to re-engage as they do not see sufficient potential for return on investment.

RM investment is unlikely to increase until a critical mass of credible, manufacturable, and commercially viable products succeeds and ascertains a perception of platform potential vs a "one-off". We refer to this inflection point as a trigger moment.

Our analysis identified a handful of assets in the current industry pipeline that may catalyse such a shift. Closely watched programmes include Bluerock's bemdaneprocel for Parkinson's Disease[8], Vertex's stem-cell-derived islet therapy[9,10], together

with Sana's hypoimmune approach[11,12], and Neurona's drug candidate in temporal lobe epilepsy[13,14]. Those programmes have sufficient clinical and commercial potential for delivering trigger moments. Neurona Therapeutics is in the process of being acquired by UCB (announced April 2026) for USD 650 million in cash with up to USD 500 million in future milestones, underscoring conviction in RM's commercial potential.

To achieve a trigger moment, the RM field should focus its actions and funding on broadening the pipeline of assets that combine the potential of offering significant patient benefit in areas of high unmet medical need with business cases that are attractive to investors and have platform potential. To understand the specific activities required in Europe to achieve a trigger moment within RM, we analysed the European RM landscape and global RM leaders.

Textbox 2

A TRIGGER MOMENT REQUIRES THREE ELEMENTS[15]:

1. Transformational target product profiles. Products that deliver impactful clinical outcomes in high-unmet-need indications (not incremental improvements). Typically, eligible for breakthrough therapy designation (BTD by FDA), PRIority MEdicines (PRIME by European Medicines Agency (EMA)) or SAKIGAKE (Japan) designations.

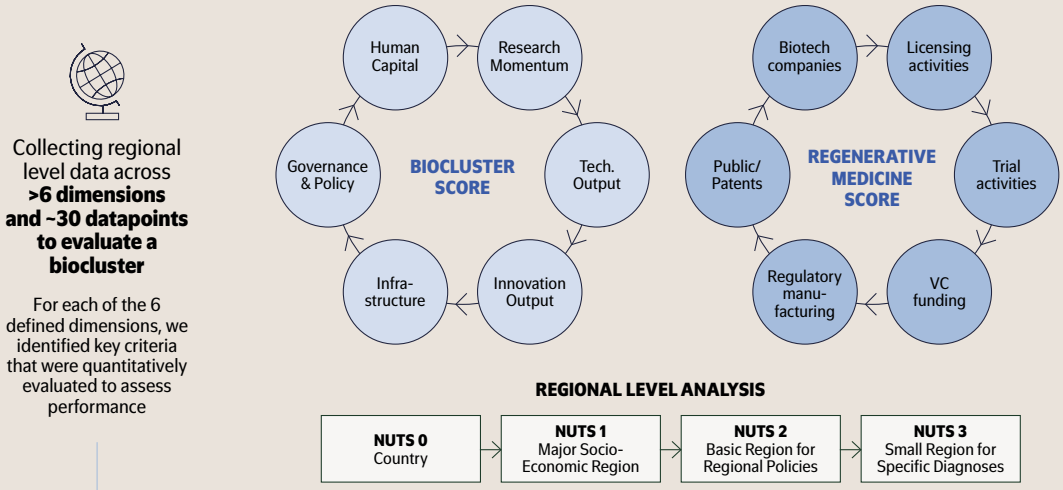
2. Commercial viability. Clear value propositions with pricing that supports positive margins, or platform potential that justifies investment despite initial challenges. Potential to unlock large markets (in the range of billions of euros).

3. Scalable execution strategies. Manufacturing processes that can be scaled to reach thousands of patients. Regulatory pathways that are understood, and well-functioning supply chains that span geographies.

When these conditions align, confidence is restored. Investment flows back. Pipelines accelerate. The ecosystem becomes self-sustaining and an "abundance wave" is triggered (a pivotal trigger sets in motion a flywheel of reinforcing independent enablers) (Figure 2).

FIGURE 2

Methodological framework for quantitative mapping of European regenerative medicine bioclusters



Regional-level data were collected across more than six core dimensions and approximately 30 quantitative indicators to evaluate biocluster strength and regenerative medicine activity. Data were aggregated from ~20 public and proprietary sources, including commercial databases and European statistical repositories. Each European NUTS 1-3 region (~1,500 regions) was geographically mapped and scored to generate (i) an overall biocluster performance score and (ii) a regenerative medicine-specific activity score, incorporating metrics such as research momentum, human capital, governance and policy, infrastructure, innovation output, patents, clinical trial activity, licensing, manufacturing readiness, and venture funding. The resulting dataset enables systematic comparison across European regions, identifying ~1,300 broader biotech regions, ~350 established bioclusters, ~300 regenerative medicine-active regions, and ~75 concentrated regenerative medicine bioclusters.

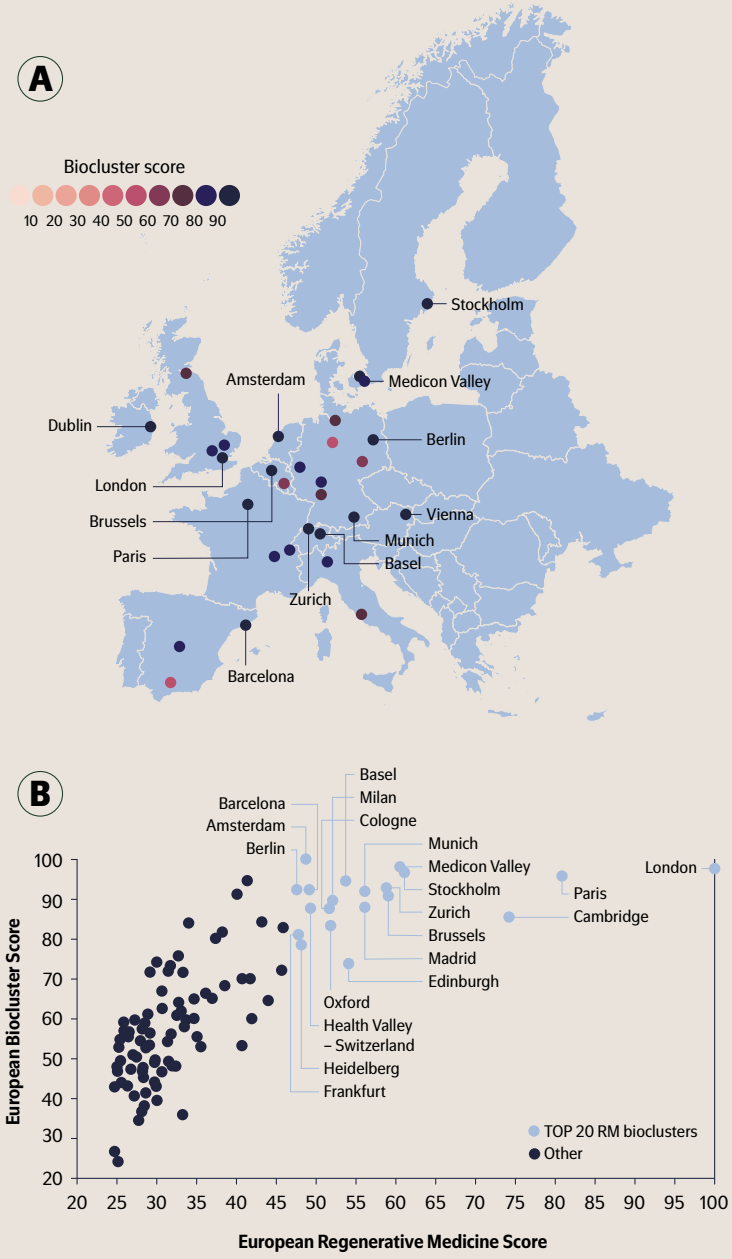
European biocluster status quo

Evidence from European clusters

In a first-of-its kind study, we scored ~1,500 European regions and evaluated them using ca. 30 quantitative metrics against six key biocluster dimensions (Figure 2). Each dimension consisted of several data points (Figure 2), including academic strength, biopharma company presence, venture capital activity, incubator presence, large pharmaceutical companies' presence and deals, clinical trial infrastructure, governance and policy indicators, and patents. We utilised more than 20 different public and proprietary sources (Figure 2) to collect data across the last decade to understand the historical performance of European clusters. The data allowed us to generate a 'European Biocluster Score' which we used for European biocluster ranking, and a technology-specific 'European Regenerative Medicine Score'. All clusters were ranked on a relative, 1-100 scale based on these two scores (100 indicating leadership and not perfection).

In terms of overall performance, high-ranking bioclusters include Amsterdam (including Leiden), Basel, London (and Cambridge), Medicon Valley (Copenhagen and southern Sweden), Stockholm, Paris, and Vienna, indicating these as the leading areas of biopharma innovation across Europe (Figure 3). These biocluster regions have strong research institutions,

FIGURE 3
Cross-comparison of European biocluster performance and regenerative medicine specialisation



A quantitative benchmarking framework was used to position European regions (EU27, United Kingdom, Switzerland, Norway) across two normalised composite indices (1–100 scale): overall European Biocluster Score and European Regenerative Medicine (RM) Score. This framework enables objective identification of European regenerative medicine hotspots and supports strategic prioritisation of high-performing nodes.

A The geographic map (top, prepared with Datawrapper) visualises the top-ranking bioclusters, illustrating the spatial concentration of excellence. Historical performance rankings are based on longitudinal data (2015–2025), with each top cluster manually reviewed to reflect functional metropolitan areas. Regions with Biocluster score >90 are named.

B The scatter plot (bottom) positions the top 100 European regions with measurable regenerative medicine activity, highlighting the top 20 RM-focused bioclusters relative to broader excellence hubs. The analysis identifies leading clusters that combine strong general biocluster performance with high regenerative medicine intensity.

a solid presence of diverse large pharmaceutical and biotech companies, and established clinical excellence centres. 20 of the 35 strongest European clusters (overall score >70) achieved RM scores above 45 (highest relative distribution score was 100 for London) (Figure 3). Examples of these clusters with stronger RM scores include London, Paris, Cambridge, Stockholm, Medicon Valley, Brussels, and Zurich.

We next performed in-depth assessments of high-ranking clusters to evaluate the current RM pipeline breadth and maturity, as well as strength of the cluster and operations. Our analysis evaluated public government support and infrastructure across these clusters – we covered dedicated stem cell research centres, government support for RM organisations, regulatory support, and good manufacturing practice (GMP) infrastructure availability. To specifically assess the RM innovation, we mapped the funding dynamics (such as volume and recency of funding), as well as pipeline activity. The pipeline assessment was completed by technology (embryonic stem cells, iPSCs, and others) and we assessed the technology maturity, clinical trial activity, mapped the key indications being pursued, and looked at how focused cluster pipelines were on high unmet need indications and how likely a 'trigger moment' could emerge from these pipelines. Finally, we examined how 'tied-in' the RM companies were to their local ecosystem; for this purpose, we looked for pipeline assets and companies that were spun-out from local universities, and local venture capital (VC) with ATMP investment.

Europe has academic excellence that needs translation power

European universities produce leading RM research, with high-impact publications and training of world-class scientists, as reflected in our analysis. However, our analysis also confirmed Europe's persistent lag in translating high-quality research into competitive startups and biotech companies. Across European clusters, the current clinical RM pipeline remains small, concentrated in early phases, and lacks flagship projects with high investment.

We identified around 30 active industry-sponsored clinical phase 2 programmes across Europe, alongside a handful of late-stage candidates (examples include Boost Pharma[16] and Novadip[17]). At cluster level, research programmes typically translate into one or two RM drug candidates entering the clinic every couple of years. Even the front-running RM clusters (London/Cambridge, Paris, Stockholm, Medicon Valley) lack the critical mass required to deliver repeated successes in RM. Based on historical likelihood of approval rates for cell therapies (<14%[18]), at least seven clinical programmes are needed to yield a single approval. Alofisel demonstrated Europe's ability to develop and commercialise RMs end-to-end, culminating in its 2018 approval and the €520 million acquisition of TiGenix by Takeda Pharmaceutical Company. However, failure of a confirmatory study led to its withdrawal from the European market in 2024[19,20].

Only a few companies have managed to raise significant funding since then, e.g. €50 million by SmartCella (Stockholm) in 2024[21,22] and €75 million series B from Resolution Therapeutics (London, Edinburgh) in 2024[23]. Even so, SmartCella announced the closing down of their RM business unit in March 2026.

Clusters with strong ATMP infrastructure often focus on chimeric antigen receptor T-cell (CAR-T) therapies or adeno-associated virus (AAV) gene therapy products, rather than RM [pluripotent and multipotent stem cell therapies and tissue engineering–based solutions, text box 1]. Barcelona has excellent ATMP facilities and developed the first academic CAR-T cell therapy authorised under hospital exemption in 2021[24], but the cluster has minimal RM substrate[25]. The same observation can be made for London's Cell and Gene Therapy (CGT) Catapult activities[26].

Across Europe, substantial public funding has been mobilised to support early RM research and the academia-to-startup transition. Such initiatives include the ATMP-PIT in Belgium (€81 million)[27], Germany's National Strategy for Gene- and Cell-based Therapies (€48 million until end of 2026)[28], Sweden's innovation agency in the process of establishing a coordinating body for Sweden's ATMP activities[29], France's Biotherapies and

Bioproduction strategy (funded through France 2030 initiative)[30], and the UK's National Cell and Gene Therapy Vision coordinated through the CGT Catapult in London[31].

However, the European experts we interviewed consistently identified funding scarcity as a central barrier to RM, driven by manufacturing uncertainty, high cost of goods, and weak business cases with limited exit potential. While funding gaps exist across the value chain, early translation and expertise in drug development and spin-out creation are major bottlenecks. Late-stage funding is also an issue, but less mentioned due to the small number of clinical phase 3 programmes in Europe.

Experts broadly agree that a clear "trigger moment" is critical to restore investor confidence but were less optimistic that the current European pipeline is sufficient to deliver it. Most experts supported concentrating efforts in selected high-potential hubs (77% of responders) rather than a dispersed European approach (23% of responders) that would risk spreading resources too thinly for any real impact.

Experts converged on several priorities: a single end-to-end support structure spanning manufacturing, regulatory navigation, and early commercial assessment; stronger professional project evaluation; and better use of existing regulatory pathways. On talent, recommendations aligned closely with the Draghi Report: attracting global scientific expertise; improving academia-industry mobility; and building skills in biotech, AI, and advanced manufacturing as foundations for Europe's long-term competitiveness.

Lessons from global clusters

Benchmarking against global clusters

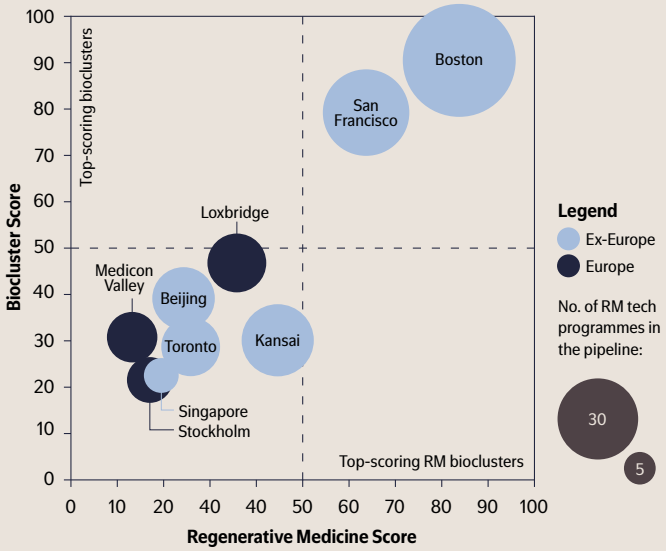
Valuable lessons may be learned from globally leading regions in the RM field, warranting an analysis of strategies on how to build and sustain strong RM pipelines.

Based on expert input and current RM pipeline activity we selected six non-European bioclusters for comparison (Osaka-Kyoto-Kobe (Kansai) cluster, Toronto, Beijing, Singapore, Boston, and San Francisco). We performed a similar data-driven scoring as for the European bioclusters, looking at overall global cluster performance and RM performance, before comparing them to selected top-performing European bioclusters: LOX-BRIDGE (fusion of Cambridge, Oxford and London due to regional proximity), Medicon Valley, and Stockholm (Figure 4). Cluster comparison was also visualised across key value-creation metrics, including biotech companies, VC funding, clinical trial activity, and research output (Figure 5).

US clusters set the global benchmark

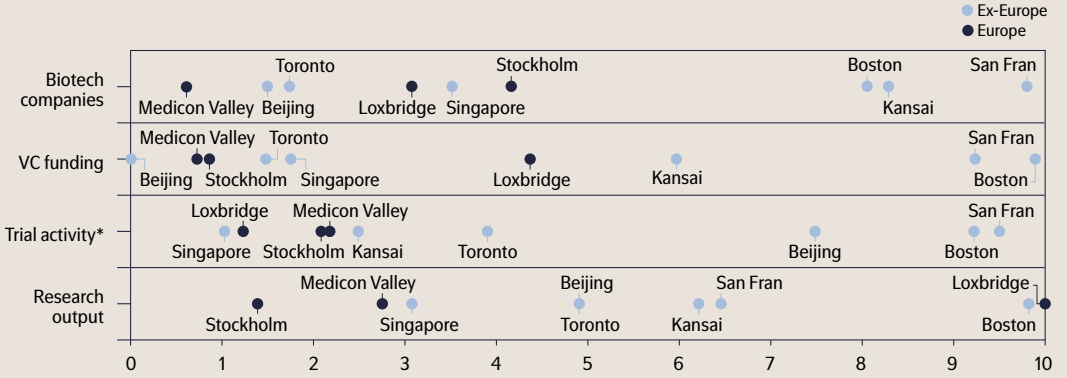
Boston and the San Francisco Bay Area dominate the global biotechnology sector and rank highest in RM innovation, consistent with expert feedback (Figure 5). Physical proximity of universities, VC firms (e.g., Flagship pioneering, F-Prime),

FIGURE 4
Comparative positioning of leading European and global regenerative medicine bioclusters



Top-performing European regenerative medicine clusters are benchmarked against leading global hubs using two normalised composite indices: overall Biocluster Score (y-axis) and Regenerative Medicine (RM) Score (x-axis). Bubble size represents the number of regenerative medicine technology programmes currently in the development pipeline within each cluster. Data reflect 2025 cluster performance; cross-regional comparisons were conducted using harmonised but non-identical datasets due to differences in regional data granularity.

FIGURE 5
Relative performance of leading regenerative medicine clusters across key value-creation metrics



Leading European and ex-European regenerative medicine bioclusters are compared across four normalised performance dimensions (non-exhaustive list of used scores for international benchmarking): (i) number of biotech companies, (ii) venture capital funding, (iii) clinical trial activity, and (iv) research output. Scores are scaled relative within the selected peer group (low to high) and reflect 2025 status quo performance. Financial data from databases: GlobalData & Dealroom. Research Output considers number of unique PMIDs for regenerative medicine related publications (as defined by Catenion). *Defined more broadly as any cell therapy trials within the region in the past 10 years

"Any time you have a network of universities that's a hotbed for innovation, you see companies springing up in those areas where the talent has been trained. [...] what makes San Francisco so unique [...] is that you have a lot of money here from tech, you have a lot of venture capital here, which makes it a really fruitful area to start companies and push them forward."

Co-founder of a San Francisco Bay Area-based biotech

biotech incubators, and industry is frequently referred to as the "secret ingredient" behind Boston's success, but the San Francisco Bay Area also demonstrates that strong pipelines and sustained investment activity can be achieved in more geographically distributed clusters.

A few important learnings emerge from our data-driven approach to compare the top three selected European RM bioclusters with the most notable examples of RM-focused or government-designed hubs from across the world (Kansai, Toronto, Beijing, Singapore, Boston, and San Francisco). First, the US clusters are clearly ahead compared with the rest of the world both based on the biocluster score and RM score (Figure 4). Second, LOXBRIDGE is the runner-up on biocluster score within broader Europe (Figure 3), but falls short on RM focus compared to Kansai, San Francisco, and Boston, despite the CGT Catapult. LOXBRIDGE emerges as a clear leader in research output, even outperforming Boston on this metric (Figure 5), yet this strength is not matched by VC funding or the volume of biotech companies. This gap reinforces the conclusion that Europe's challenge is less about scientific excellence and more about translation into companies and clinical programmes.

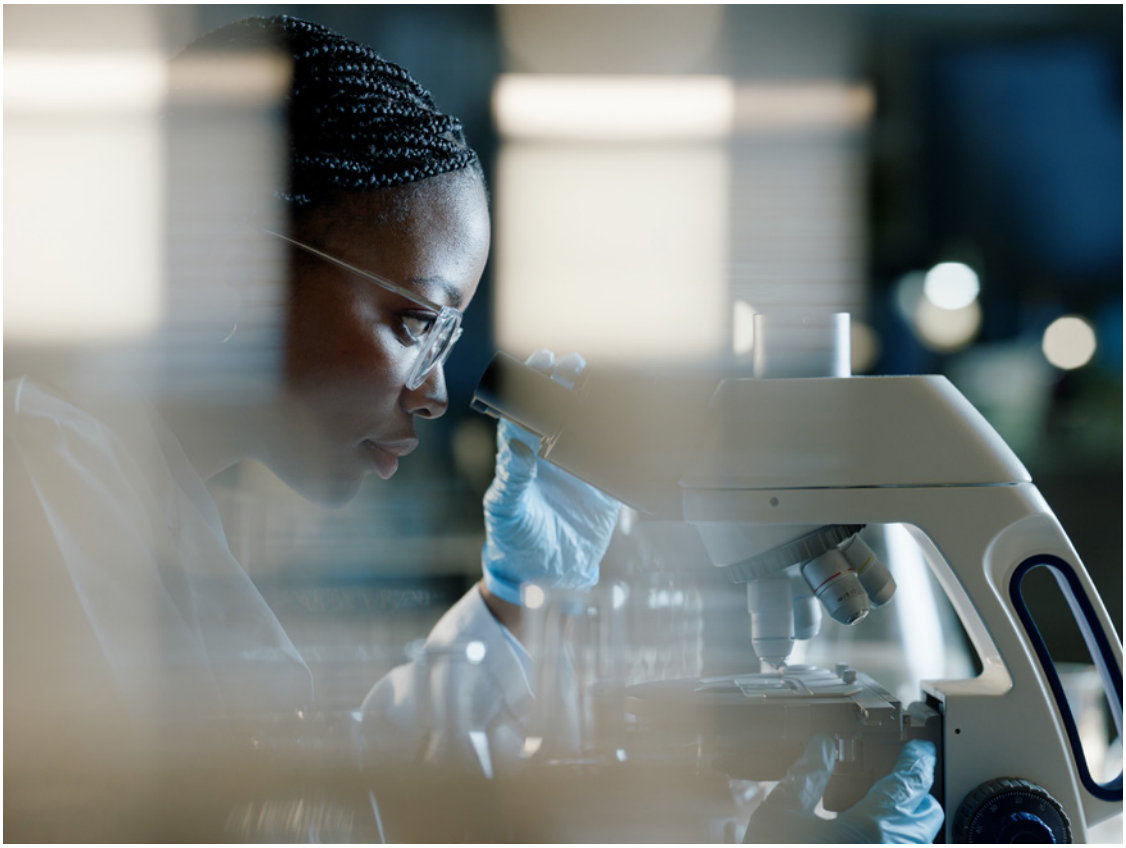
Japan's Kansai region: iPSC promise, limited validation

The Kansai region in Japan ranked second on the biotech company creation metric (Figure 5). Universities offer strong incentives for spin-outs, and local pharma investors recognise the potential of Nobel Laureate Yamanaka's research on induced pluripotent stem cell (iPSC) technology. This has resulted in a relatively high volume of biotech companies and VC funding.

At the national level, Japan's regulatory framework, with the possibility for early conditional approval (SAKIGAKE), appears to have accelerated clinical activity and company creation. Recent examples include Cuorips' cardiomyocyte patch Ri-HEART and Sumitomo Pharma's dopaminergic neural progenitor cell therapy AMCHEPRY[32]. Consistent with this, Kansai has a higher proportion of clinical stage companies than some other clusters (50% of cluster companies are at clinical stage, N=6/12).

There is also a notable shift to iPSC-based tech in the Kansai cluster, as around 67% of pipeline programmes are based on iPSC technologies versus less than 50% in European clusters (data not shown). However, to date there have been no commercial successes, and the regulatory initiatives have not translated into large-scale global partnerships; one of the few global collaborations between HeartSeed and Novo Nordisk A/S was recently discontinued due to strategic changes.

Overall, Japan's conditional approval pathway has helped solve the speed of regulatory approval but not the clinical validation. Conditional approvals have been granted based on safety and presumed benefit, but trials were underpowered to show real efficacy (Heartsheet and Collategene got withdrawn[33]). Strong randomised control clinical trial data is required to validate hypotheses, also in other geographies. Publicly funded initiatives such as the Toronto's Centre for Commercialization of Regenerative Medicine (CCRM), California's Alpha Clinics, or Nakanoshima Qross and Y-FIT (Yanai iPSC manufacturing facility) can support early-stage RM projects through translation and scale-up but do not guarantee attraction of investors and the pharmaceutical industry.



California and Boston: Lessons on strategic thinking

In addition to the "spillover" effect where the successful environment of a strong biocluster positively impacts the ecosystem overall, dedicated initiatives and incubation models have also played an important role in advancing RM and fostering innovation overall. We analysed two examples to derive lessons for the design of the RM ecosystem in Europe: the San Francisco-based California Institute for Regenerative Medicine (CIRM) and the Wyss Institute in Boston.

Matching the funding power of a large pharma company, CIRM has invested a staggering USD 8 billion since 2004 to build the local RM ecosystem, supporting translation including clinical

proof-of-concept programmes. This funding resulted in dozens of startups, enabled over 110 clinical trials, and strengthened clinical infrastructure, including the Alpha Clinic network and academic GMP facilities.

However, the programme has so far not resulted in an approved RM therapy nor a trigger moment. The possible reasons for this can provide valuable lessons for establishing the European RM ecosystem. For instance, early funding was distributed broadly across technologies and indications, thus prioritising ecosystem building over strategic pipeline building and establishing critical mass. CIRM's next funding phase has a more disciplined capital allocation through stronger project prioritisation, clearer therapeutic focus, and an emphasis on high-impact areas such as neurology – all this in the effort to advance 15-20 therapies to late-stage trials and 4-7 rare disease projects to BLA (Biologics License Application)[34]. We can reduce the risk of similarly expensive experiments within Europe by applying comparable strategic discipline from the outset.

In our systematic study, a big weakness of European models is the singular focus on academic excellence often at the expense of other equally critical dimensions. Upfront decisions around the choice of indication, intellectual property (IP) considerations, manufacturability, regulatory strategy, and clinical value are all important to consider in order to increase the likelihood that academic breakthroughs can reach as many patients as possible. Generating investor returns matters but will ultimately be a by-product of the broader mission: bringing therapies to patients.

The Wyss Institute for Biologically Inspired Engineering in Boston is a great example of combining academic excellence with commercial execution. Established through philanthropic funding from Swiss Medical Device entrepreneur Hansjörg Wyss (>USD 750 million)[35], the institute integrates scientific research with translational and venture-building capabilities.

Since 2009, Wyss has generated over 50 spin-outs raising over USD 4 billion, supported by around 12 annual validation projects that represent the final step before company formation. Dedicated IP, venture, and translational teams, together with

"Nowadays everything has changed, because the VCs have gotten so conservative and there's no doubt they want to see more data before deciding. [...] The business side is as important as doing a clinical study. That's why I think Europe doesn't get it."

Senior leader of the Wyss Institute

early manufacturability assessment and clear go/no-go gates, help bridge academic science and commercialisation, including in RM-adjacent technologies such as advanced biologics and organ-on-chip systems[36]. RM in Europe will require environments similar to the Wyss to increase the likelihood of a trigger moment.

Public vs private capital dynamics in Europe and USA

Finally, both public and private funding are critical at different stages of ecosystem building. In the initial phase, public funding can outpace private sector contributions. However, in a thriving ecosystem, private investment outpaces public investment. Cambridge, Boston secured USD 7.2 billion of VC funding and USD 3.1 billion from National Institutes of Health (NIH) in 2024[37]. Our analysis highlights the VC funding imbalance between the USA and the rest of the world (Figure 5)[2] which strongly impacts the ability in Europe to invest into early-stage companies. After the 2020–2021 biotech peak, in 2023 the USA saw at least 3-fold higher investment compared to Europe[38]. US biotech VC leadership is driven primarily by pension-fund capital, IPO (initial public offering) liquidity, and capital recycling from repeated biotech exits. Access to pension-fund capital would also be necessary in Europe, however the current RM field may not be able to compete with other, more attractive (as judged by pharma and investors) technologies and assets.

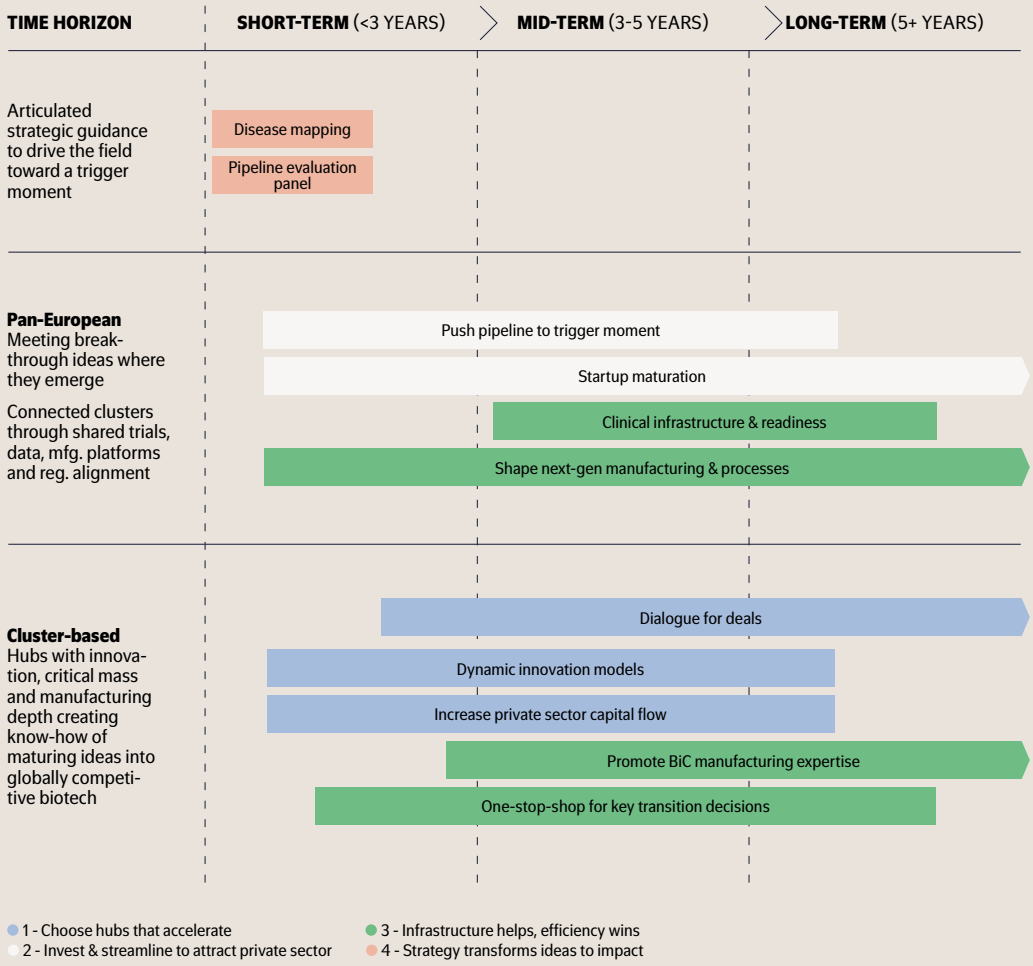
The European strategy

Our analysis highlights that the European RM clinical pipeline and the funding raised to push programmes forward remains limited. More RM therapy programmes with the right focus on delivering breakthroughs for patients in commercially viable indications are required. Given the cost and probability of success in drug development and the lack of approvals resulting even from multibillion dollar initiatives like the CIRM, the pipeline needs to be carefully shaped and based on strong foundational pillars. The overall strategy and operating model of European RM need an overhaul for private investors to become sufficiently attracted. At the core of a credible European strategy lies a disciplined approach to capital allocation that combines lessons from past failures and successes.

Shifting from projects to systems

The success rate for R&D programmes (in general) from clinical phase 1 to approval is frequently cited around 6–10%[39]. The risk-adjusted cost of drug development is in the multibillion-dollar range. This cost does not account for breakthrough potential and commercial success[40]. Making sure that enough blockbuster potential programmes will make it is key for a trigger moment, and this can best be achieved through proven

FIGURE 6
Coordinated pan-European and cluster-level roadmap to accelerate regenerative medicine excellence



A phased action framework outlines short-term (<3 years), mid-term (3–5 years), and long-term (5+ years) priorities to drive Europe toward a regenerative medicine trigger moment. Activities are structured across four strategic pillars: (1) selecting and empowering high-potential hubs, (2) mobilising and streamlining private-sector investment, (3) strengthening infrastructure and operational efficiency, and (4) embedding strategic coordination to translate ideas into impact. The activities are consolidated into three tracks – strategic and geographically agnostic work; pan-European geographically broad activities; and cluster-focused & geographically concentrated work. (BiC = Best in class)

techniques that have worked well for numerous biopharma companies addressing similar issues of having to revamp R&D productivity: a professional approach to project and portfolio prioritisation.

While net present value calculations are out of scope due to the number of unknowns, discussing target product profiles, market size and potential peak sales are valid questions that should be addressed upfront. The selected RM development programmes then need to be supported by situating them in a small number of clusters with critical mass in drug-development expertise, entrepreneurial capability, and a close-knit knowledge-sharing ecosystem.

The four strategic pillars

Finally, we combined our analyses of European bioclusters, global bioclusters, and expert interviews to define a strategic roadmap for Europe. Four strategic pillars emerged, and eleven activities anchored to these pillars will help guide the building of a self-sustaining European RM ecosystem (Figure 6). Aligning with the EU Commission Strategy for European Life Sciences to position Europe as the world's most attractive place for life sciences by 2030[41], the activities range from short term (<3 years) to mid-term (3–5 years) and long-term (5+ years). Importantly, these strategic pillars may serve as a blueprint for ecosystem building in general, independent of modality.

Pillar 1: Choose hubs that accelerate

Overall, activities within RM should concentrate on a limited number of European bioclusters, rather than dispersing resources too thinly. Even in the USA, an analysis of VC investment shows that the San Francisco Bay Area and Cambridge, Boston are key areas for investment and accounted for 50% of all US life sciences investment in 2024[42].

Our analysis shows that the RM pipeline in Europe is limited, creating a risk of clusters duplicating and underutilising infra-

structure. To realistically close the gap, a solid foundation in RM capabilities and supportive infrastructure is first required. A strong overall biocluster environment will enable trickle-down effects in a tightly connected ecosystem of academia, clinics, industry, and investors, reinforced by supportive policy frameworks. The focus on strong bioclusters is echoed in the 2026 EU Horizon call to establish a European network of centres of excellence for ATMPs[43], where a network of bioclusters is envisioned as a step towards positioning Europe as a leader in the ATMP sector.

Within the selected focus RM bioclusters, efforts should target current critical bottlenecks, notably in GMP/chemistry, manufacturing, and controls (CMC) capacity, clinical trial infrastructure, regulatory expertise, and business development networks. Integration must be prioritised on every scale: not just at the cluster level, but also within research organisations, to create a microcosmos that integrates top science with entrepreneurship, IP strategy, and drug-development thinking, inspired by the Wyss Institute operating model.

Specific activities to tackle current bottlenecks include: dialogue for deals (integration between private investors and RM companies/startups to facilitate regular engagement); dynamic innovation models (increased support for preclinical development of academic and non-academic translational RM projects, in order to deepen the pool of early pipeline opportunities); and increased private sector capital flow (facilitating structural changes to overcome constraints restricting capital flow in Europe).

Pillar 2: Invest and streamline to attract the private sector

RM's complexity and long development timelines mean public or philanthropic capital will be required to help bridge programmes to clinical proof of concept. Most private investors will only engage once assets are sufficiently de-risked. Thus, a suggested activity to help bridge this gap is creation of CIRM-inspired funding opportunities where public and private funders interact to push selected pipeline projects from proof of concept to potential trigger moment (push pipeline to trigger moment).

To attract private capital, RM programmes should embed strategic and business development thinking from the outset. Before advancing, RM development programmes should articulate clear value propositions, including: what unmet need is addressed; expected manufacturing costs; payer and reimbursement feasibility; size of the business case; platform potential; and what follow-on indications can be unlocked. These questions should shape research direction early rather than being deferred until clinical development starts, and could be facilitated by structures such as the one-stop shop described below. Similarly, dedicated investment for RM startup maturation within an environment where strategic thinking is embedded from the start should be a prioritised activity.

Regulatory and pricing complexity pose another significant barrier to investor appetite in RM. European regulatory agencies respond constructively when engaged early, but fragmentation across member states creates inefficiency and uncertainty. Coordinated alignment, through practical examples, shared learning networks, and early consultation, could reduce uncertainty for developers and investors.

Pillar 3: Infrastructure helps, efficiency wins

Clusters should provide clinical infrastructure and readiness, through specific CMC expertise. By providing direct access to key competences and leading-edge facilities and avoiding the need for companies to build from scratch, pathways are provided to reduce the cost of goods sold.

The feedback from experts, from pharma to VC funds and large initiatives, clearly stated that platform-level advances in manufacturing are essential to lower the entry barrier for new companies in the field. Next-generation technologies, such as scalable iPSC differentiation platforms, predictive quality assays, and automated cell processing, require pre-competitive investment but will provide a sustainable pathway for generating new, competitive products. Thus, a key activity within this pillar is to shape next-generation manufacturing and processes by solving bottlenecks and to promote best in class manufacturing expertise.

To help project developers navigate process optimisation, GMP scale-up, regulatory consultations, health technology assessments, and partnership discussions, another key activity would be to establish one-stop shops for key transition decisions. These could be dedicated hubs of expertise offering project guidance through advisory panels.

Pillar 4: Strategy transforms ideas to impact

European organisations should utilise disease mapping to develop disease roadmaps to identify therapeutic areas in which RM can deliver transformative outcomes with attractive business cases. Orienting research and funding toward areas with clear potential for impact will increase the likelihood of breakthroughs and private investment.

Pipeline evaluation panels, that approach every potential project like a pharmaceutical company due diligence process, are needed to take research over the finish line: investors are more likely to select projects that have a clear value proposition and de-risking strategy.

Finally, positioning RM around topics that resonate can help attract investors. One example is longevity, where Retro Bio is planning to raise USD 1 billion with a pipeline including iPSCs[44], and where a recent Oppenheimer report[45] on the field emphasised its investment appeal. An interesting aspect of the topic of healthy lifespan or longevity is that it attracts many non-traditional biotech investors from Silicon Valley (cf. investments of Sam Altman and others), thus unlocking an additional source of capital.

The path forward

Together, the actions across the four pillars amount to a single strategic bet: that Europe can produce the clinical and commercial trigger moments that the RM field needs to attract sustained private investment. Delivering the trigger moment requires coordination within selected clusters and pan-European collaborations to leverage key skills (Figure 6). While our analysis is focused on RM specifically rather than ATMPs more generally, the overarching principles and the strategic roadmap are likely similar.

- In the short term, articulated strategic guidance through disease mapping and formation of pipeline evaluation panels will be critical to provide guidance to direct academic research and identify opportunities that have the highest potential to become a trigger moment.

- In the long term, continued activities at the European and cluster level will help accelerate RM toward a successful proof of concept with transformative clinical potential, coupled to a large market and broad platform potential across indications.
- Funding opportunities must meet existing breakthrough ideas where they emerge through clinical funding and start-up maturation activities.

- Connecting RM clusters through shared trial infrastructure, data exchange, manufacturing platforms, and regulatory alignment would further increase Europe's attractiveness to domestic and foreign investors.

- Supporting selected hubs with high levels of innovation, critical mass, and manufacturing depth through deals dialogue, dynamic innovation models, and increased manufacturing and translational know-how, will help translate scientific excellence more efficiently into commercially attractive therapeutics.

- Until private sector confidence is restored, public-private partnerships must provide strategically oriented funding to ensure that promising scientific discoveries can progress through clinical validation and reach a broad patient population across indications, from ultra-rare to common.

The promise to patients is profound: conditions currently without disease-modifying options, from degenerative disorders to organ failure, could be transformed. Europe has the science; we now encourage European actors to coordinate efforts with the focus to build a competitive pipeline by concentrating on a few world-class hubs and investing accordingly.

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