Berlin Center for Gene and Cell Therapies

OSLO CANCER CLUSTER

Bridging the Gaps: Unlocking the Future of Advanced Therapies in Europe via Novel Alliances

Whitepaper building on the Roundtable at the Nordic Embassies in Berlin, Oct 17th, 2025

Now or Never: Europe Must Rethink Approach to ATMPs

Europe has everything it needs to become a world leader in the development of advanced therapy medicinal products, except for the right mindset.

Europeans like Ehrlich, Pasteur and Curie paved the way for humanity's understanding of the human body and the advent of modern medicine, and in the years since, Europe's biotechnology sector has grown to become incredibly valuable to the region. Building on this rich legacy, Europe continues to hold vast potential for groundbreaking medical innovation, capable of delivering immense economic and social value through the development of advanced therapies.

Those therapies, also called ATMPs - Advanced Therapy Medicinal Products - are a class of therapeutics including gene therapies, cell therapies, and engineered tissues that offer potential cures to currently incurable diseases.

The outstanding potential of novel biotechnological modalities was clearly outlined in EuropaBio's 2025 report, titled "Measuring the Economic Footprint of the Biotechnology Industry in the European Union", which stated that in 2022, Gross Value Added (GVA) from biotechnology activities was €38.1bn. And its growth rate – 5.3% – was double that of the whole EU economy.

But Europe's biotechnology industry is confronted by several urgent and potentially deterministic challenges. To remain competitive, it must grapple with and become expert at the development of ATMPs.

Crucially, without adequate investment in the necessary infrastructure to support the development of ATMPs, a mindset shift coupled with a novel and joint strategy in how ambitious biotechnology projects are approached, Europe risks pioneering breakthroughs that ultimately fail to benefit its own citizens, thereby sacrificing both technical sovereignty and economic value.

Moreover, looking at this problem from a strategic resilience perspective, it is clear that Europe is increasingly threatened by developments outside of its borders.

Recent policy decisions by the US are already stimulating some European and global pharma companies to re-prioritise American investment, and looking east to China, the country's detail-opaque yet visibly rapid development of its biotechnology infrastructure underlines the need for immediate investments into European competitiveness.

> *"In Europe, we must strike the right balance in terms of how fast we develop ATMPs. We certainly want to catch up to the United States, while also closely following the development of a regulatory structure in China in terms of how they approve novel therapies."*
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> **KNUT STEFFENSEN**, DIRECTOR OF THE KAROLINSKA ATMP CENTER

This whitepaper, built from a roundtable discussion which occurred between 20 leading European experts in the ATMP space, including individuals from industry, academia, investment and policy will acknowledge the core challenges companies, academics and regions face bringing medical advances to market, while also presenting potential solutions and novel approaches to collaboration.

The report's body will comprise four sections, or calls to action:

- The first will lay arguments for the creation of 'lighthouse hubs' in Europe – specialised clusters where particular sub-disciplines in the ATMP field are pedestaled.
- The second will delve into issues facing the financing of ambitious projects, and propose hybrid solutions which blend both public and private money.
- The third will discuss the manufacturing infrastructure needed for Europe to compete in the ATMP field, and make recommendations for improvements and lessons we can take from elsewhere.
- The fourth will be a conclusion – a final call to action.

Seeing Shore With Lighthouse Hubs

Throughout Europe, each country and typically several regions in each country feature one or more locations that claim themselves to be 'hubs' for the research, development and manufacture of ATMPs.

Principally, this leads to duplication of effort – and expense – throughout Europe. No one location can be an expert at all subtypes of ATMPs, and all the crucial steps along the value chain.

Fixing this is straightforward. Europe needs to designate locations as 'lighthouse hubs' - standout locations with true expertise in a therapeutic subtype. As these hubs, or clusters of companies and academic institutions collaborate, broader impact will be felt due to them bringing in exciting projects, additional expertise, talent and new partners through network effects.

Using the lighthouse analogy, their expertise, or 'light' will make its way to distant shores – only through collaboration can Europe compete globally in the ATMP space. Light will also be shed on and attract the surrounding regional actors, thus further increasing critical mass and value creation.

It is crucial to establish and strategically develop lighthouse hubs building on the availability of both academic and industrial expertise in development, translation, scaling and commercialisation in the selected region; the manufacturing steps and regulatory requirements required to make an ATMP are all too rarely considered prior to approval and therefore are prone to issues when it comes to scalability, leading to early design failures and dooming projects on a cost-efficacy basis.

> *"It comes down to critical mass. You need academics, startups and larger companies working closely enough in an ecosystem to spark exchange, innovation and commercial development. In the US, strong financial incentives helped build such hubs. Europe could do the same, there are quite a few promising hubs. But the essential point is this: while these EU hubs will naturally compete, they must also collaborate if they want to reach global scale and catch up with China and the US."*
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> **TOBIAS HELMSTORF**, PROJECT LEAD BERLIN CENTER FOR GENE AND CELL THERAPIES, BAYER

Via lighthouse hubs attracting and connecting all necessary ecosystem components – companies including big pharma, well-versed CDMOs, early-stage biotechnology companies, academic centres, university hospitals, patient representatives, tech transfer and regulatory experts, service providers, regional, national and European-level funding agencies and private investors – Europe can generate more dynamic and flexible partnerships along the value chain. In doing so, Europe will 'front load' its early-stage ATMP projects with the various competences, insights and contacts needed for value-based healthcare and commercial success. As a result, potential failure points for any novel therapy like product-market fit, clinical strategy, commercial and manufacturing viability can be addressed earlier, thereby lowering costs, increasing speed and raising the chances of success.

> *"Hubs should compete, but should also ensure they make use of synergies between themselves so that duplication is mitigated. If this is done, hubs will become competitive at a global level, ensuring a degree of 'stickiness' which will prevent them from leaving to the US."*
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> **TOM SOLOWAY**, CHIEF EXECUTIVE OFFICER, T-KNIFE THERAPEUTICS

Changes to scientific grant processes at a European level could also serve as an earlier intervention preventing the failure of ATMP projects. By ensuring that each grant is assessed on end production viability – and not the science alone – only more scalable ATMPs will progress out of initial research stages, allowing lighthouse hubs to self-propagate over time.

By condensing talent in such a way, Europe will foster more impactful collaboration between industry and academia. Boston is a prime example of a location where talent revolves between companies and academic centers, fostering continuous growth.

> *"Boston wasn't created to be a hub – it was incentivised to be one. Look at the Research Triangle park in North Carolina – great tax incentives. They didn't spend a lot of money – and they didn't bring in much direct tax - but they created lots of jobs. Europe has a cautious approach which spreads gains across member states at the cost of some competition. This needs to change."*
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> **TOM SOLOWAY**, CHIEF EXECUTIVE OFFICER, T-KNIFE THERAPEUTICS

Seeing Shore With Lighthouse Hubs

Europe needs its own version of a "Boston" style concept, which in Europe's case could be a federated set of connected lighthouse hubs jointly having the critical mass and fostering a healthy competition while at the same time drive to collaborate and exploit synergies.

Furthermore, it should be noted that Europe is excellent in basic research on ATMPs, but translation and, in particular, monetisation of ATMPs takes place outside Europe. More than 90 % of all clinical cell/gene therapy studies are conducted in the United States and China, and less than 10 % in Europe.

We call on readers to pay attention to (i) Germany's National Strategy for Gene- and Cell-based Therapies (2024),) and (ii) DARE NL as the national strategy in Netherlands, which are good examples of national-level policy that aims to address these issues. Germany's NSGCT specifies that hubs should be created and "selected according to specifically defined topics and expertise," not political or personal desire, in order to reduce duplication and create a spirit of collective efficiency. Such a model can inspire a transnational European approach, driven by a coalition of like-minded countries creating a role model which can inspire others to join.

> *"Ensuring sufficient manufacturing capacity for the production of cell and gene therapies and their critical raw materials is highly relevant to Europe's technological sovereignty. In order to take all necessary aspects of value chain into account, the expansion of the relevant infrastructure should be coordinated across national borders and agreed between the various stakeholders in large networks and industry-academy partnerships. In the future we might have to address around 1.000-fold more patients suffering from various diseases, which requires interdisciplinarity between medicine, biotechnology and engineering sciences for AI-based, modular, automated process lines with industry 4.0."*
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> **ULRIKE KOEHL**, DIRECTOR FRAUNHOFER INSTITUTE FOR CELL THERAPY AND IMMUNOLOGY (IZI) AND DIRECTOR, INSTITUTE OF CLINICAL IMMUNOLOGY, UNIVERSITY AND UNIVERSITY HOSPITAL LEIPZIG

Financing Ambitious Projects

The economics of ATMPs are not kind. The costs associated with bringing one to market are broadly similar to other classes of drugs – around a billion euros – and the high post-approval production costs combined with (typically) small patient groups make it incredibly difficult to turn a profit.

The result is that most ATMPs on the market cost hundreds of thousands of euros – sometimes even over a million euros – per patient; Europe currently lacks the reimbursement models which reflect on the long-term health-economic impact of potentially curative therapies. Ultimately patients lose out.

This uncertain economics also impact the funding of research in this area. Currently, there is an inability and risk adversity from private-money backed European funds to invest in and back emerging ATMP companies along the development path – and one (not the only one) important reason is the commercial success in Europe. This aversion is valid: ATMP projects are still struggling to demonstrate sustainable business models due to issues with scalability, indication size and mismatch with current reimbursement models.

> *"The traditional, transactional way of suppliers working with customers is going away... we see a lot more strategic interaction with our customers. I'm in a role where I work on innovative projects – and all of these projects are about accelerating the processes, improving productivity and quality. We see this more and more - especially in the ATMP world - where the product is the process. Codeveloping with proximity to partners is really important."*
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> **FRAUKE GRAALFS**, DIRECTOR, ENTERPRISE SCIENCE AND INNOVATION, GLOBAL CORPORATE ACCOUNTS

But public money can afford to be much more patient and operate at greater scale.

Mario Draghi's 2024 report urged Europe to boost investment in resilience infrastructure, noting that trillions sit idle in bank accounts. The UK's 2025 Mansion House Accord will direct 10% of pension fund investments - about £50 billion - into start-ups, infrastructure, and private equity. Sweden has already achieved strong results by aligning pensions with government support for early-stage ventures like biotech.

Europe could follow these examples to unlock vast investment potentiall.

> *"Public-private partnerships don't always have to come with money – they can come with competence. Private partners are willing to spend time mentoring academic projects. We should rethink about how to better use crucial expertise and learning from pharma and biotechs, who did it, failed, tried again, or pivoted to "frontload" early-stage projects with expertise and expert contacts."*
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> **JUTTA HEIX**, HEAD OF INTERNATIONAL AFFAIRS AT OSLO CANCER CLUSTER

Another bold step being made is the European Competitiveness Fund. Aimed at supporting developments crucial to Europe's defence and resilience, the ECF will have a budget of €409bn between 2028 and 2034.

Proponents of the ECF are hoping to take this a step further with a proposed "European Future Fund," (EFF).

While the EFF is still just an idea, the majority of its backers believe that it should be structured like any other ambitious project – as a collaboration between public and private funds. Private equity and venture capital groups bring a wealth of experience regarding the commercial potential for new therapeutics – by working with these groups Europe can not only learn from their profit-driven mandate but also reduce the competition between public and private-funded projects.

Growth Fund Germany is one example of such a model achieving success. Operating as a fund of funds, the Super Fund, relies on investors to choose the right companies, clusters and solutions to complex problems.

Regardless, raw cash alone is not enough to encourage companies to build infrastructure, base talent and develop a therapeutic in any one region – companies need incentives both physical and financial.

> *"The idea of the Super Fund came from Germany's Future Fund, which is a fund of funds. That is a model which I would support – we as investors have experience choosing the right companies, the right clusters and the right solutions to problems."*
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> **KARL NAEGLER**, PARTNER, SOFINNOVA PARTNERS

And while Europe has generous rebates for biotech R&D, the region needs to be bolder. Rewarding private enterprise for staying in Europe, developing in Europe, hiring in Europe, **and ultimately selling a therapeutic from Europe** needs to be normalised.

Europe should learn from the North Carolinian research triangle. Upfront investment from the US government was not insignificant – yet was also not vast. Instead, generous tax incentives brought in companies, bringing in the wealth of employment and discoveries observed today.

EU Biotech Growth and Innovation Fund (EBGIF)

Imagine a European Fund where public and private money unite to secure the future in biotech.

The €20 billion fund, combining €15 billion in public capital and €5 billion from private investors, can provide long-term capital to back high-risk, high-impact ventures that strengthen Europe's health innovation.

Using a blended finance model, public funds act as a risk anchor to attract institutional and pension investors, targeting €200 billion by 2030. The fund should focus on early-stage investment to nurture true innovation by dedicating 30-40 % of the fund to seed and Series A financing to enable the creation of 1,000 + new biotech startups across Europe. To grow fast or fail fast, the fund should also offer integrated support (grants and mentorship) to bridge the "valley of death" between academic research and market entry. It should also provide late-stage growth financing, support, and regulatory fast-track guidance. Here it needs to concentrate resources on high-potential companies to build a "Biotech Power Portfolio" of 50-100 global champions.

Manufacturing Miracles

Production of ATMPs is complex and costly, especially for therapies taking autologous approaches due to the logical complexities associated. New approaches to ATMP manufacture are clearly needed lest we continue depriving patients of potential cures.

Throughout Europe, companies already make use of various "Industry 4.0" technologies – the region's globally-recognised excellence in engineering and process automation regularly contributes to significant developments in industries like aerospace, petrochemical and automotive.

But thus far, applications of Industry 4.0 in GMP manufacture – which is required for all ATMPs – is limited. Chapter 4 on Documentation, Annex 11 on Computerized Systems of the EU Good Manufacturing Practice (GMP) guidelines specifically bans the use of 'self-learning' artificial intelligence algorithms, instead only permitting static, or deterministic, models in GMP settings.

Meanwhile, in the US, we are now starting to see the first Industry 4.0 factories being used for pharmaceutical processes – nearly closed-loop systems that turn inputs into outputs with only minimal human involvement.

Importantly, these factories can 'learn' from external sources, allowing them to increase, decrease or otherwise alter production for maximum efficiency.

Europe has all the talent which it needs already – the challenge is just about how to cross-apply this talent to the GMP manufacturing sector, and prove it is safe for patients.

There are already advanced technologies being used in ATMP manufacture:

- **Platformed processes relying on closed and automated systems – which negate the need for mistake-prone human involvement**
- **Single use systems, which in ATMP manufacture helps ensure sterility and allow for faster throughput**
- **Real-time QC – the ability to monitor a product's quality as it is made – is used in many of Europe's heavy industries**

It must be emphasised that automated, modular processes with industry 4.0 need interdisciplinary knowledge which combines biotechnology, automation, production and sensor technology as well as artificial intelligence. Addressing this major challenge will allow Europe to target hundred or thousand-fold more patients, while simultaneously vastly reducing the associated costs.

> *"We have very good regulatory agencies in Europe with high technical competence. I still wonder whether the balance between innovation and risk acceptance has been shifted too much towards a zero-risk approach even for patients with life-threatening conditions that have run out of options? Early in my career we spent the majority of our time focused on what we considered to be appropriate to maintain a positive benefit risk balance and spent only a minority of our time addressing additional questions by agencies and IRBs. Today, we find ourselves in situations where the fraction of time and resources spent on documenting, validating, and addressing remote or theoretical risk is increasing year by year, with sometimes only minimal incremental benefit for safety or product quality. I personally believe, we need a mindset shift where we are open to revisit our balance between innovation vs safety & quality and rigorously apply a combination of scientific rigor and common sense."*
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> **CEDRIK BRITTEN**, CHIEF MEDICAL OFFICER, IMMATICS

But we also need to adopt new ATMP technologies. Research into higher yield and non-viral vector technologies are enabling researchers to craft new types of therapy. Allogenic, or off-the-shelf approaches offer one-size-fits-all treatments, significantly reducing many of the complexities typically associated with ATMPs.

Strategic collaborations with CDMOs – who arguably appreciate more than anyone that in the ATMP world, the product is truly the process – could be the key to early-stage ATMP projects, which are today primarily found in academic centres, to seize the technologies of tomorrow, opening a new paradigm for how complex therapeutics are made. Example: Evotec Bridges Model and co-creation early in the R&D process.

Summing It Up

Europe has the foundations to catch up with the US and China in advanced therapy development: scientific pedigree, talent and physical infrastructure, academic centres of excellence, global pharma, CDMOs, and biotech companies as well as a wealth of experience from other industries for cross-fertilisation. Importantly, it also has the capital to invest.

What is missing is the necessary mindset coupled with a new joint strategy. Europe needs to embrace public-private partnerships as drivers of true innovation and must work harder to exploit the synergies available to reduce duplication. It also needs to look at how it balances innovation and regulation to take a more pragmatic approach to bold ideas which enable bold changes. However, it will require a major, coordinated effort. There is a lot at stake.

Every European actor involved in the biotechnology industry – organisation or individual - needs to consider how their actions drive the industry forward. By rethinking how **you** approach complex research and manufacturing tasks, and by taking a more collaborative approach, **you** can help secure Europe's competitiveness, resilience and a brighter future for patients in Europe around the world.

The time to rethink and act is now.

This Whitepaper builds on the Roundtable titled **Bridging the Gaps: Unlocking the Future of Advanced Therapies in Europe via novel alliances**, Oct 17th, 2025, at the Nordic Embassies in Berlin gathering:

- Lorenz Mayr, Mayr BioMed Consulting, Basel & Hevolution Foundation, Boston (Moderator)
- Hildegard Bentele, Member of the EU Parliament
- Christopher Baum, Chief Translational Research Officer of Charité - Universitätsmedizin Berlin and Chair of the BIH Board of Directors, Berlin Institute of Health at Charité (BIH); Speaker of the German National Strategy for CGT
- Marion Hitchcock, Managing Director Gene & Cell Therapies Incubator Berlin and R&D Strategy & Portfolio Manager, Bayer AG
- Stefan Fricke, Head of Department at Fraunhofer Institute for Cell Therapy and Immunology, Leipzig and Institute for Clinical Immunology and Cell Therapeutics, Otto von Guericke University Magdeburg
- Ulrike Koehl, Director Fraunhofer Institute for Cell Therapy and Immunology (IZI) and Director, Institute of Clinical Immunology, University and University Hospital Leipzig
- Anna Pasetto, Director of the Center for Advanced Cell Therapy (ACT), Oslo University Hospital
- Jim Lund, Chief Business Development Officer at CCRM Nordic
- Knut Steffensen, Director Karolinska ATMP Center, Stockholm
- Christian X. Andersson, Director Sahlgrenska ATMP Center, Gothenburg
- Cedrik Britten, Chief Medical Officer, Immatics
- Tom Soloway, Chief Executive Officer, T-Knife Therapeutics
- Luise Weigand, Chief Scientific Officer. Zelluna Immunotherapy
- Karl Naegler, Partner, Sofinnova Partners
- Frauke Graalfs, Director Enterprise Science and Innovation, Thermo Fisher Scientific
- Michael Kahnert, Manager Governmental Affairs, Miltenyi Biotec
- Andreas Scheel, EVP, Head of Cell Therapy, Evotec
- Elisabetta Zanon, Former Director of EU Public Affairs and Advocacy at the Alliance for Regenerative Medicine

This Roundtable & Whitepaper has been initiated and implemented by:

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