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Building an Ecosystem for Development and Commercialization of ATMPs in Skåne

INTRODUCTION AND PURPOSE

This report has been produced by Regional Development, Region Skåne in collaboration with SmiLe Venture Hub as a part of the ERUF-financed project "Kommersialisering av Advanced Therapy Medicinal Products (ATMP) i södra Sverige - en förstudie" with project ID 20363781. The aim was to demonstrate how an ecosystem for the commercialization of Advanced Therapy Medicinal Products (ATMPs) can be established in Skåne. The report can serve as a foundation for regional efforts and for defining its profile for national and international collaborations.

ATMP = Advanced Therapy Medicinal Products, are treatments based on genes, cells, or tissues developed through cultivation and manipulation. According to the European Medicines Agency (EMA), ATMPs are categorized into somatic cell therapies, gene therapies, tissue-engineered products, and combination products containing advanced therapies.

EXECUTIVE SUMMARY

ATMPs have the potential to be disease-modifying or curative therapies, and the global market is growing rapidly. However, their development and commercialization are complex. Skåne has the opportunity to build a strong ATMP ecosystem, supported by Lund University's research base, but its output of commercial projects has been limited. This report highlights key actions needed for an efficient support structure for ATMP commercialization in Skåne:

- Embed commercialization experts (IP, regulatory, market access) in research environments like LU-ATMP though expert innovation support from LU Innovation
- Develop mandatory commercialization training for researchers, focusing on IP, regulatory pathways, and strategies.
- Specialize business coaching for ATMP startups at Smile Venture Hub, bringing in experts for IP, regulatory, and market access support. Expand networks of specialized advisors for ATMP startups.
- Offer workshops on ATMP-specific regulatory pathways and market access planning, including health economics and pricing models.
- Improve collaboration between LU-ATMP, LU Innovation, and SmiLe Venture Hub for more effective commercialization.
- Facilitate ongoing engagement between researchers and industry players.
- SmiLe to launch an ATMP bootcamp with industry partners to address challenges like IP, scaling, and market access.
- Maximize the use of LU-ATMP's pre-GMP facilities and expand as needed.
- Engage national and international investors to increase funding for ATMPs.
- Improve access to public funding sources, like Vinnova, for early-stage projects.

1.Introduction

ATMPs are defined as advanced therapeutics based on cells, tissues or genes and have been shown to have potential as disease-modifying or even curative treatments. Twenty years ago interest in ATMPs was primarily academic, and it was challenging to secure investments for commercialization as these therapies were considered too risky for investments from the pharmaceutical industry and investors due to an immature market and unexplored risks. Over the years, investment opportunities have improved through market maturation as more and more ATMPs have been approved, with healthcare systems beginning to develop. Concurrently, many countries have made governmental or regional investments in cities with strong ATMP-related research to enable the commercialization of these products.

The development and commercialization of ATMPs present a unique set of challenges due to the complex nature of these therapies. Unlike traditional pharmaceuticals, ATMPs often involve personalized medicine approaches, high production costs, and intricate regulatory pathways. The commercialization of ATMPs requires a well-developed ecosystem that can mitigate risks and lower the threshold for market entry.

Sweden has a strong ATMP-related research base, but the output in terms of incorporated projects and commercial product development has been limited. A report from MSC (2020) has shown that Sweden emerges as a top 3 EU country based on the number of ATMP relevant researchers and ATMP companies, with the Skåne region identified as one of Swedens strongholds.

Indeed, Skåne has significant potential to establish a strong and sustainable ecosystem for ATMP commercialization through regional and national initiatives. This report summarizes how an ecosystem for commercialization should be built based on other ecosystems for ATMP commercialization and applies this framework to regional actors to demonstrate how a commercialization ecosystem in Skåne could be developed to operate regionally or nationally.

2. Unique Market Requirements for ATMPs

2.1 A New Market with Different Dynamics

The market potential for ATMPs is substantial, with the ability to disrupt existing treatment paradigms for various diseases. However, the path to market for ATMPs differs significantly from traditional pharmaceuticals. To date, 76 ATMPs have been approved globally and the vast majority of therse ATMPs are originated from so-called emerging biopharma companies (small or midsized biopharma companies). Indeed, in the last five years, 79 % of ATMP launches were originated by emerging biopharmas, compared to 56 % for other novel pharmaceuticals. Nearly half of these ATMPs are then acquired and launched by a larger pharma company, but these efforts have often failed to account for the unique economic and logistical challenges associated with these therapies (IQVIA, 2024).

Investor interest in cell and gene therapies has led to increased funding and deal activity in the sector. In 2023, venture capital funding reached $3.4 billion, with 406 new industry-sponsored clinical trials starting that year, marking a 46 % increase compared to a decade ago. Indeed, cell and gene therapies now represent a larger share of life sciences deals. Emerging biopharma companies, often spun off from academic research, are key players in this space.

Global initiatives have been established to advance cell and gene therapy research, with industry-sponsored trials tripling in the past decade. Non-industry trials, led by academic researchers or

government agencies, only grew by 5 %, driven mainly by CAR T-cell therapy research. Oncology remains the primary focus, though this varies by therapy type. Emerging biopharma companies lead early-stage research, while large pharma firms concentrate on gene therapies and later-stage trials.

The average ex-manufacturer price for CAR T-cell therapies exceeds $350,000, while gene therapies cost around $1.8 million, raising budget concerns for payers. Traditional health economics therefore need to be reassessed because ATMPs do not fit into the conventional assessment model. These treatments are expensive, but they also address the root causes of diseases and thus often offer a cure. The lack of data is a limitation that challenges the market adoption of ATMPs. Clinical studies on ATMPs may involve a small number of patients, use surrogate endpoints (biomarkers that are believed to correlate with clinical effect/safety), or have other designs that result in market approval. This often does not meet the health economic assessment requirements for the quantity and quality of generated data.

Business models and distribution chains for ATMPs also require adaptation. Unlike mass-produced pharmaceuticals, ATMPs have short shelf lives and require administration by specialized healthcare professionals. The distribution chain must therefore be closely integrated with healthcare systems, and reimbursement models need to be re-evaluated. Indeed, public reimbursement for these therapies varies across major markets, with some payers imposing additional restrictions beyond product labels, potentially limiting access for patients. To manage the high costs, payers and manufacturers are increasingly using innovative payment models, with outcomes-based agreements being the most common.

2.1.1. Limited transition of ATMP projects from academy to commercial development

The number of ATMP publications across Europe has steadily grown since 2009, peaking in 2021 with 5,064 publications. In 2023, Sweden had the highest publication productivity, with 20.5 publications per capita. Despite this, only 4 new SME ATMP developers have been founded in Sweden since 2018, adding to a total of 25 ATMP SMEs (ATMP Sweden, 2024). Thus, there is a clear need to facilitate the transition from promising academic ATMP projects into commercial ATMP projects developed by startups.

2.2 Established Ecosystems for ATMP Commercialization

To address the unique needs of ATMP development and commercialization, several specialized ecosystems have emerged globally. These ecosystems are typically supported by national or regional funding to promote commercialization, providing expertise and risk-mitigation strategies for both business and project development. Three notable examples are:

- California Institute for Regenerative Medicine (CIRM, USA)
- Centre for Commercialization of Regenerative Medicine (CCRM, Canada)
- Cell and Gene Therapy Catapult (CGT Catapult, UK)

Each of these ecosystems has developed its own approach to overcoming the challenges associated with ATMP commercialization.

2.2.1 California Institute for Regenerative Medicine (CIRM), USA

Founded in 2004, CIRM is the oldest of the three ecosystems and is focused on making ATMP treatments accessible to the public. Funded by the state of California with over $3 billion, CIRM supports projects across five key areas: Discovery, Translational, Clinical, Education, and Infrastructure. CIRM operates as a fund, supporting projects that strengthen the ecosystem.

The operational support for projects is provided by the IQVIA Cell and Gene Therapy Center (CAGT Center), a collaborative effort with several partners. The CAGT Center offers services in seven core areas, including technology transfer, process scaling, regulatory strategy, and health economics, among others. CIRM also invests in supportive infrastructure, such as biobanks and specialized clinics for ATMP treatments.

CIRM's initiatives have attracted over $24 billion in external investments and led to the formation of over 50 new companies, highlighting the effectiveness of its ecosystem in fostering ATMP commercialization.

2.2.2 Centre for Commercialization of Regenerative Medicine (CCRM), Canada

Established in 2011, CCRM operates on a consortium model involving academia, industry, and investors. The ecosystem is structured around intellectual property (IP) management, where CCRM assesses and de-risks academic projects to make them attractive for industry and investment partners.

CCRM’s model includes six working groups that handle different aspects of commercialization, from IP management to GMP manufacturing. While CCRM is less transparent about its project handling compared to CIRM, it has successfully supported projects that have attracted over 770 million CAD in investments and led to the creation of 11 companies, some of which have international origins.

2.2.3 Cell and Gene Therapy Catapult (CGT Catapult), UK

Launched in 2012, CGT Catapult addresses the need for risk mitigation to attract investors in cell and gene therapy projects. CGT Catapult provides flexible support across six areas, including industrialization, manufacturing, regulatory support, and health economics. Unlike CIRM and CCRM, CGT Catapult does not fund projects directly but supports grant applications and coordinates investor networks.

In 2023/2024, CGT Catapult’s efforts have helped 79 companies that have secured £656 million in investment. The ecosystem is designed to enhance the cell and gene therapy industry in the UK by providing knowledge and expertise rather than creating dependence on the ecosystem itself.

2.3.4 Summary of Ecosystem Development

These ecosystems were initially funded by regional or state resources, making them independent of industry influence. Each started with an accelerator function, followed by the development of process development units and GMP facilities. This systematic approach reflects the support needed by projects over time to reach commercialization.

Central to all these ecosystems is risk mitigation, focusing on ensuring market approval with a robust market access strategy. They emphasize proactive planning and offer flexible services based on the specific needs of the projects.

The strategic activities observed in these ecosystems can be summarized into eight key areas:

- **Project and Business Development**
  Dual-focused teams handle both business and project development, integrating expertise in process development, regulatory requirements, market understanding, and clinical competence to effectively mitigate commercialization risks. Business support regarding financial strategy and industry partnering is generally missing, however.
- **Regulatory Analysis and Market Approval**
  Emphasis is placed on the Chemistry, Manufacturing, and Controls (CMC) aspect of regulatory documentation. Other regulatory activities include orphan drug applications, ATMP classification, GAP analyses, clinical trial preparations, and market approval applications.
- **Health Economics and Market Access**
  Developing a clear understanding of the health economic landscape and reimbursement strategies is crucial, with continuous interaction with healthcare providers.
- **Technology Transfer and Process Development**
  Supporting the scaling up of manufacturing processes to meet regulatory standards and creating cost-effective production methods.
- **GMP Manufacturing**
  Establishing facilities that can produce clinical trial materials and support commercial production, adhering to Good Manufacturing Practices (GMP).
- **Clinical Trial Support**
  Providing CRO-like services in collaboration with national healthcare networks, ensuring efficient trial management and regulatory compliance.
- **Intellectual Property Management**
  Flexible IP management strategies are critical to ensure that projects are not hindered by IP disputes and can move forward smoothly.
- **Talent Development and Training**
  Developing a skilled workforce through educational programs and partnerships with academic institutions to support the growing needs of the ATMP industry.

To summarize, the commercialization of ATMPs requires a robust ecosystem that addresses the unique challenges of these therapies. The models provided by CIRM, CCRM, and CGT Catapult offer valuable lessons in risk mitigation, regulatory support, and infrastructure development. By integrating healthcare systems, focusing on economic and logistical considerations, and building comprehensive support structures, these ecosystems have successfully lowered the commercialization barriers for ATMPs. However, support in helping startups with financial strategy and future industry partnerships are generally missing. Future efforts in this field should continue to build on these strategies and broaden the scope regarding business development support, ensuring that ATMPs can reach their full market potential and provide life-changing treatments to patients.

3. Skåne's Ecosystem for the Commercialization of ATMPs

Skåne is developing a robust ecosystem for the commercialization of ATMPs, encompassing various sectors including academia, SMEs, tailored business support, technology and process developers, GMP manufacturers, and healthcare.

3.1 Academia Academic institutions in Skåne, notably Lund University (LU), Lund Stem Cell Center (SCC), Wallenberg Centre for Molecular Medicine (WCMM), Wallenberg Neuroscience Center (WNC), and Centre for Precision Medicine play a pivotal role. They contribute through cutting-edge research, talent development, and infrastructure for ATMP-related studies. Indeed, in 2023 Lund University established a university-wide development center for advanced therapies, LU-ATMP. This initiative is a concerted effort to move medical research with the potential for groundbreaking therapies closer to reaching patient groups for whom traditional medications are insufficient. However, LU-ATMP lack business support structures and there's a need for more specialized commercialization training and easier pathways for turning research into market-ready products. Establishing a dedicated ATMP-focused master's program could enhance regional and international development. Furthermore, tailored business support is needed for researchers in transitioning to commercial projects in a company setting and fostering industrial collaborations.

3.2 Business support structures in Skåne, such as LU Innovation and SmiLe Venture Hub provide crucial support for commercialization processes. They help startups with business development, financial strategy, and infrastructure. LU Innovation is Lund University's innovation and commercialization hub, supporting researchers and students in applying their research to real-world use. Its services are free and available to all faculties and disciplines across the university. **LUI has previously supported startups in the ATMP field but has not had a specific focus on this area. Thus, there is a need in LUI to recruit expert knowledge in ATMP to work closely with reseachers in the field to further promote** commercialization of ATMPs. SmiLe Venture Hub helps entrepreneurs and early-stage companies develop and commercialize new ideas in life science. SmiLe has developed effective processes for providing business support to Life Science startups within its incubator program and already has experience supporting companies that develop ATMPs or technology platforms for ATMP development such as Xintela, Asgard Therapeutics, rAAVen Therapeutics and Cellevate. Companies that in the last years have raised more than 500 million SEK in venture capital and secured strategic partnerships with industry leaders. The concept is based on assigning each incubator company a dedicated business coach who proactively supports the company with strategic-level business development. Early validation from investors and potential industry partners regarding the commercial strategy of the incubator company is a crucial part of this concept. **However, SmiLe recognizes a need to expand its network of experts in the above-mentioned areas critical to the successful development of ATMPs (IP, regulatory, market access, etc.) and, to some extent, to broaden its network of investors and pharmaceutical companies with a clear commercial focus on ATMPs., a support structure tailored for startups developing ATMPs is needed to enhance project flow and address specific challenges related to these therapies.**

3.3 SMEs Small and medium-sized enterprises (SMEs) in Skåne are actively involved in developing and commercializing ATMPs or ATMP platform technologies. Examples include companies like Asgard Therapeutuics, Xintela, and rAAVen Therapeutics, among others. Importantly, some of Skånes ATMP

biotechs, such as Magle Biopharma (previously Amniotics) and Xintela, have also built own GMP facilities for production of ATMPs for clinical studies and offer external ATMP developers CDMO services for GMP manufacturing.

3.4 Technology and Process Developers Technology and process development are critical for the successful translation of ATMPs from research to market. SmiLe Venture Hub has built 12 state-of-the-art lab core facilities to support early technology and drug development. Moreover, work is underway to establish a pre-GMP facility at the Lund Stem Cell Center, which will be essential for early-stage process development, where flexibility is highest. By incorporating vital regulatory knowledge along with industry-standard manufacturing equipment and quality control instruments, this facility aims to produce processes that can better meet the requirements of later development stages. The pre-GMP facility will be accessible to both academic researchers and biotech developers. Additionally, this pre-GMP space will support cost-effective development of manufacturing processes, relieving demand on the limited GMP-certified space within the ATMP Center. It also provides an environment for operator training in GMP manufacturing and the testing of batch records and SOPs.

3.5 GMP Manufacturers GMP manufacturing capabilities are vital for producing clinical trial materials. As mentioned above, two of Skånes biotech companies, Amniotics and Xintela, have built their own GMP facilities for production of ATMPs. Amniotics was recently acquired by Magle Group and offer CDMO services for ATMP GMP production. Xintela has buit its GMP facility at the Smile Venture Hub facilities and offers contract manufacturing of ATMPs. In addition, there are other CDMOs in Sweden and the Nordics with varying levels of specialization in ATMPs. Assessing the capabilities, availability, and cost-effectiveness of these CDMOs is essential. Enhancing GMP facilities in Skåne would prevent potential bottlenecks and support continuous project flow.

3.6 Healthcare Region Skåne has established an ATMP Center at SUS for the clinical development of new ATMPs and advanced therapy treatments. The purpose of the center is to create the necessary expertise and infrastructure for companies and academic groups to conduct high-quality clinical research, facilitate the development of new ATMPs, and streamline processes for the quicker and simpler implementation of advanced medicinal therapies in healthcare. The ATMP Center is responsible for coordinating clinical trials, providing support for the clinical development and testing of ATMPs, and assisting with the implementation of market-approved ATMPs. Facilities for the development and handling of advanced medicinal products according to European pharmaceutical manufacturing regulations are currently under construction. With over 20 years of collaboration with LU, this center will contribute significantly to both national and international ATMP initiatives.

4. Insights from researchers, investors and industry

To further investigate how business support could be tailored for commercialization ATMPs, Smile Venture Hub conducted a study financed by Tillväxtverket together with Region Skåne where important stakeholders were interviewed to increase knowledge of the specific needs researchers and startups have regarding business support for ATMP development. The different stakeholders interviewed were: researchers, big pharma, investors (VC/CVC), and biotechs.

4.1 Researchers: Researchers from Lund's Stem Cell Center highlighted shortcomings in early commercialization support for ATMP development at Lund University. They noted that researchers often lack understanding of patentability and need assistance with intellectual property issues. Many use materials in their research that are not suitable for commercial use, emphasizing the need for early guidance to avoid IP challenges. A significant knowledge gap exists regarding the commercialization process. Accessible support within the organization is crucial to help researchers translate basic research into practical applications. They also identified the need for support in securing semi-academic funding, such as from Vinnova.

4.2 Big Pharma: Three major pharmaceutical companies—AbbVie, Bayer, and Bristol-Myers Squibb—discussed their experiences with ATMPs, focusing on safety, treatment effectiveness, and cost-effectiveness. A primary challenge with ATMPs is their high manufacturing costs, which require strong clinical efficacy data to ensure cost-effectiveness. The selection of indications is crucial, as treatments must meet significant medical needs and provide clear benefits over the standard of care. Potentially curative treatments are more likely to attract patient use. Successful development and commercialization of ATMPs hinge on two key areas: regulatory strategy and market access. Startups must understand regulatory requirements and opportunities in major markets like the USA and Europe, utilizing pathways that streamline approval processes. Additionally, they need to tackle market access challenges early, which includes identifying the innovation's value through feedback, generating supportive clinical and economic data, and comprehending pricing and reimbursement models for ATMPs.

4.3 Investors: Two types of investors—Sound BioVentures (VC) and Boehringer Ingelheim Venture Fund (CVC)—were interviewed about cell and gene therapies, key areas in ATMPs. For cell therapies, investors noted that a major challenge is that intellectual property (IP) often protects the manufacturing process instead of the product, making it less attractive. Startups should focus on creating strong IP and developing a clear commercial pathway aligned with pharmaceutical collaboration models. High manufacturing costs hinder profitability, particularly for autologous therapies, which are costly and hard to scale. Unmodified cells are less appealing due to weak IP and unclear mechanisms of action. However, cell therapies combined with gene editing are promising for treating genetic diseases. The trend is moving toward allogeneic therapies, which modify donated cells for broader use, offering scalability advantages. The gene therapy area is generally seen as more attractive because it is product-focused. There is increasing interest in gene therapies targeting larger patient populations, in contrast to many approved products that focus on ultra-rare diseases, which are expensive and commercially challenging. Safety data is vital, as understanding of gene therapies lags behind other modalities like small molecules. A strategic approach is to first target a rare (but not ultra-rare) disease for proof of concept, then expand to more commercially viable indications.

4.4 Biotechs: One of the biggest challenges for startups is the difficulty in securing funding for development of ATMPs. Given the high development costs, it is even more crucial for ATMP companies to obtain early validation from potential partners regarding the data packages to understand what must be demonstrated to enable a partnership with a commercial entity. In Sweden, there are few companies working in gene therapy; many initiatives within ATMPs are focused on cell therapy development with an emphasis on research and development. There is limited innovation support directed towards gene therapy.

CONCLUSION

The key to advancing cell and gene therapy in Skåne lies in fostering a highly integrated ecosystem where LU-ATMP, LU Innovation, SmiLe Venture Hub, Region Skåne, investors and industry players collaborate effectively. Addressing the challenges of business models through innovative financing, risk-sharing, and flexible IP management will be crucial in taking this field to the next level.

Given the detailed input from the project, it's clear that while the fundamental approach remains sound, several specific gaps and needs have emerged that require a refined strategy. Here's an updated view of what needs to be done:

1. Strengthen Early Commercialization Support

- **Embedded Commercialization Experts:** Establish a more robust integration of commercialization experts (IP, regulatory, market access) within research environments like LU-ATMP. The previous approach of embedding LUI personnel with specific knowledge and experience from various fields within the academic units (e.g., oncology, CNS, diabetes) should be expanded to include the ATMP area, ensuring that researchers get early, tailored support for transition of academic projects into startups for commercial development.
- **Commercialization Training:** Develop mandatory training programs for researchers on IP management, regulatory pathways, and commercialization strategies, integrated into the research process early on. This will address the identified knowledge gaps around patenting and commercialization.

2. Focused Business Development Support for ATMPs

- **ATMP-Specific Business Coaching:** The existing model at SmiLe Venture Hub, where each startup gets a dedicated business coach that provides support to the startups at strategic level, could be specialized further for ATMP companies. Coaches with deep expertise in ATMP commercialization should be recruited or trained to provide strategic support on IP, regulatory strategy, and market access.
- **Extended Networks:** Expand the network of experts available to startups to include more specialized advisors in key areas like IP (especially for cell therapy), manufacturing, and market access. This addresses the noted gaps in expertise required for successful ATMP development and commercialization.

3. Enhanced Regulatory and Market Access Strategy

- **Regulatory Pathways Education:** Develop workshops or education programs focused on educating startups about the specific regulatory pathways available for ATMPs. This could be part of an ATMP bootcamp being developed in collaboration with a leading industry player.
- **Market Access Planning:** Ensure that startups understand the importance of early market access planning, including health economics and pricing models for ATMPs. This should be integrated into the business development curriculum and supported by expert consultations.

4. Strengthening Collaboration Between Stakeholders

- **Efficient processes:** Strengthen collaboration between LU-ATMP, LU Innovation and Smile Venture Hub to more efficiently transfer academic projects into commercial development within a startup setting.

- **Proactive Industry Engagement:** Facilitate closer, ongoing engagement between researchers, industry players, and the innovation ecosystem. This could include regular joint workshops, seminars, and collaborative research projects focused on ATMP development.

5. Bootcamp and Specialized Programs

- **ATMP Bootcamp:** SmiLe Venture Hub to launch an ATMP bootcamp with a focus on critical challenges identified (e.g., IP issues in cell therapy, scaling challenges, market access strategies) in collaboration with industry partners. This program should include real-world case studies, hands-on workshops, and direct feedback from industry veterans and investors.
- **Funding and Partnerships:** Secure additional funding and partnerships to support the bootcamp and similar initiatives. Engaging with global leaders (e.g., CIRM, CCRM) for insights and collaboration could help in refining these programs.

6. Leveraging Existing Infrastructure

- **Pre-GMP Facilities:** Utilize the existing pre-GMP facilities at LU-ATMP effectively by ensuring that they are accessible to startups needing process development support. Consider expanding these facilities or creating specialized cell labs as demand grows.
- **Collaboration with Science Parks:** Strengthen the partnership with Medicon Village Science Park and other local hubs to ensure seamless access to specialized labs, facilities, and commercialization support.

7. Addressing Financial strategy

- **Investor Engagement:** Given the challenges in securing funding for ATMPs, especially in Sweden, there's a need for targeted engagement with both national and international investors. The goal should be to increase their understanding and interest in ATMPs, focusing on the commercial potential of scalable and innovative therapies.
- **Public Funding and Soft Money:** Increase awareness and accessibility to public funding sources like Vinnova, especially for early-stage projects, ensuring that researchers can secure the necessary seed funding to move from research to commercialization.

8. Global Benchmarking and Continuous Learning

- **Learn from International Best Practices:** Continuously benchmark against leading international centers like CIRM, CCRM, and CGT Catapult, adapting their successful strategies while addressing identified gaps, such as business development support.
- **Feedback Loops:** Establish regular feedback mechanisms where startups, researchers, and industry players can provide input on the effectiveness of support systems, ensuring continuous improvement and adaptation to evolving needs.

The additional insights reinforce the need for a more specialized, integrated, and proactive approach to support the commercialization of ATMPs. By addressing the specific gaps in early commercialization support, regulatory strategy, and market access, and by enhancing collaboration and investor engagement, the ecosystem can more effectively drive the development and successful commercialization of cell and gene therapies.