European Alliance for Transformative Therapies

Event Report

TRANSFORM
MEP Interest Group
2025 Event

Igniting Innovation
The Future of the EU ATMP Ecosystem

November 2025 – European Parliament

1. Introduction

On 20 November 2025, the European Alliance for Transformative Therapies (TRANSFORM) convened the TRANSFORM MEP Interest Group Event, **"Igniting Innovation: The Future of the EU ATMP Ecosystem"**, at the European Parliament in Brussels.

This high-level gathering brought together Members of the European Parliament, patient advocates, medical experts, industry leaders and policymakers to address one of the most dynamic frontiers in healthcare: Advanced Therapy Medicinal Products (ATMPs).

Against the backdrop of pivotal EU legislative developments, including the Pharma Package trilogues, the Life Sciences Strategy and the forthcoming Biotech Acts, the event provided a unique platform to reflect on Europe's leadership in medical innovation and to chart a course for a future-proof, patient-centred ATMP ecosystem.

Conference speakers. Photos by ImagoSkills. (2025)

Executive Summary

The conference highlighted both the transformative potential of ATMPs and the significant challenges that remain for Europe, echoing with the Policy Asks of TRANSFORM launched in the European Parliament in June 2022. Participants also took stock of **TRANSFORM's latest report** on realising the value and supporting the uptake of ATMPs in the EU.

Simplifying the regulatory framework was identified as essential to accelerate innovation, and there are high expectations for upcoming legislation, such as the EU Biotech Act and revisions to the Clinical Trials Regulation, to address these challenges and strengthen Europe's leadership in ATMPs. Participants highlighted the potential of ATMPs to act as a strategic engine for biotech innovation in Europe, stressing the need to translate scientific excellence into tangible health and societal benefits. Key issues include fragmentation between Member States and the urgent need for greater collaboration to ensure timely and equitable patient access. Funding gaps and the necessity of sustainable investment were emphasized, alongside the central role of patients, who must be actively involved throughout research, development, and regulatory processes. The exchanges also brought forward the persistent barriers that hinder the development, manufacturing and equitable uptake of ATMPs across Member States, reinforcing the need for coordinated action.

Finally, by reframing access to ATMPs as a long-term investment for patients, healthcare systems and society, the event emphasised the broad value these therapies offer from immediate health outcomes to wider societal and economic gains, and the policy solutions required to unlock their full potential.

Main topics

Discussions were structured around three core themes:

1. **Unlocking the Future: Accelerating the Journey from Lab to Patients** — exploring the role of EU policy in supporting innovation, overcoming regulatory and investment barriers and ensuring that Europe remains at the forefront of ATMP development.
2. **The Potential of ATMPs and Hurdles for Patient Access** — featuring patient testimonials and examining the real-world challenges of timely diagnosis, reimbursement and infrastructure needed for equitable access.
3. **Learning from Each Other: Supporting the Uptake of ATMPs in the EU** — focusing on best practices for cross-border collaboration, innovative payment models and the importance of involving patients in trial design and value assessment.

Participants

The event was hosted by

Kristian Vigenin, MEP (S&D, Bulgaria) – European Parliament

Nikos Papandreou, MEP (S&D, Greece) – European Parliament

And moderated by **Jacki Davis**

Kristian Vigenin. Photo by ImagoSkills. (2025)

The featured speakers were:

- **Kristian Vigenin**
  MEP (S&D, Bulgaria) – European Parliament
- **Sakis Arnaoutoglou**
  MEP (S&D, Greece) – European Parliament
- **Olivia Romero Lux**
  CEO – European Haemophilia Consortium
- **Androula Eleftheriou**
  Executive Director – Thalassaemia International Federation
- **Dimitrios Athanasiou**
  Board Member – World Duchenne Organisation / Rare Diseases Greece
- **Prof. Axel Schambach**
  Vice-President – European Society of Gene and Cell Therapy
- **Céline Pouppez**
  Expert – Belgian Health Care Knowledge Centre
- **Erwan Gicquel**
  Government Affairs lead Europe – Miltenyi Biomedicine GmbH
- **John Coughlan**
  Director International Government Policy and Affairs – Regeneron
- **Victor Maertens**
  Government Affairs Director – EUCOPE

1. Opening remarks

Kristian Vigenin, MEP (S&D, Bulgaria) – European Parliament

MEP Vigenin opened the conference by explaining that ATMPs are no longer abstract concepts but rapidly becoming real transformative and life changing options for patients. He added that as Europe has a strong research base, it is well positioned to lead in this field. MEP Vigenin highlighted that this potential depends on sustained political commitment and a future-proof regulatory framework.

Sakis Arnaoutoglou, MEP (S&D, Greece) – European Parliament

MEP Arnaoutoglou first emphasised that ATMPs mark a major shift in modern medicine and are a key opportunity for Europe to lead globally in biomedical innovation.

He noted that this potential can only be realised if major challenges are addressed:

- Uneven patient access across Member States
- Divergent health technology assessments and reimbursement processes
- High upfront costs
- Fragmented data systems
- Limited infrastructure and workforce capacity
- Insufficient EU-based manufacturing

He called for a close collaboration across policymakers, authorities, industry, clinicians, researchers and patients to tackle these issues.

Victor Maertens, Government Affairs Director – EUCOPE

During his opening intervention on behalf of the TRANSFORM Steering Group, Victor Maertens stressed the strategic role that ATMPs play in the EU's health competitiveness, echoing the priorities set out in the Draghi report and pointing to a broader political momentum for innovation at EU level. He emphasised that scientific progress has delivered transformative therapies, and that upcoming policy initiatives – such as the EU Biotech Act – must now build policy frameworks that recognise and match this level of innovation. He added that realising the full value of ATMPs requires treating them as long-term investments for patients and health systems at large, and ensuring that all stakeholders in shaping future policies – an area where TRANSFORM can offer substantial expertise.

Victor Maertens. Photo by ImagoSkills. (2025)

2. Panel discussions: ATMPs – the EU's Engine for Biotech Innovation

Panel 1: Unlocking the Future: Accelerating the Journey from Lab to Patients

Discussion Session – Key Takeaways

Funding

- Early investment in ATMPs reduces long-term costs.
- Public-private partnerships have been successful in advancing science.
- Incentives are needed for companies to maintain manufacturing sites in Europe.

- External capital and new, flexible funding models are critical for product development and competitiveness.

Public money should attract private investment, especially for start-ups and scale-ups, and encourage coordination, such as joint procurement.

Fragmentation

- Reimbursement and pricing rules vary widely, creating unequal access to high-cost therapies.
- Greater coordination among Member States is needed on clinical trials, HTA, and broader policy development.

Simplification

- Regulatory and procedural conditions should be more flexible to accelerate innovation.

Patients

- Patients must be actively involved in processes like clinical trial design and value assessment.
- All efforts should ultimately benefit patients and improve outcomes.

Policy and Investment

- Policy priorities and investments must be coherent to support innovation effectively.

Collaboration

- Value-based models, alliances, and commercial exploration benefit both patients and the scientific community.

Olivia Romero Lux, CEO – European Haemophilia Consortium

Olivia Romero Lux provided an insightful patient perspective during her intervention, stressing the need for timely diagnosis and swift access to advanced therapies. Additionally, she underscored that meaningful patient involvement is essential at every stage of the innovation and access pathway, and called for a renewed prioritisation of the patient voice in shaping the future of ATMPs.

Olivia Romero &Victor Maertens. Photos by ImagoSkills. (2025)

Prof. Axel Schambach, Vice-President – European Society of Gene and Cell Therapy

Prof. Schambach first underlined that Europe is falling behind the US and China in translating ATMP innovation into patient solutions. Second, he noted that the EU regulatory pathway has become increasingly complex and slow and delay access to therapies. Finally, he called for the simplification of the regulatory framework, noting that with more than 50,000 patients already treated with cell and gene therapies, there is now substantial real-world evidence to support streamlining. He added that adopting a more risk-based approach, especially for patients with very poor prognoses, could also be a part of the solution.

Kristian Vigenin, MEP (S&D, Bulgaria) – European Parliament

MEP Vigenin outlined two main challenges for ATMPs in the EU:

- Persistent fragmentation: Each Member State operates its own separate healthcare system, leading to significant delays and unequal access to ATMPs across the Union.
- Funding constraints: Limited resources continue to restrict the timely uptake, delivery, and wider implementation of these advanced therapies.

Counterbalancing these challenges, he then talked about Europe's strengths in health policy, including healthcare becoming a major priority in the current parliamentary mandate, the establishment of the full Committee on Public Health (the SANT Committee), and the growing use of AI to improve the efficiency of research and development.

He also expressed his aim to simplify procedures and noted that the Clinical Trials Regulation needed to be made more flexible and workable for ATMP development. Finally, he mentioned that future budgets would better reflect patient needs and stressed that improved collaboration among Member States was essential to address fragmentation and accelerate patient access to ATMPs.

Erwan Gicquel, Government Affairs lead Europe – Miltenyi Biomedicine GmbH

Erwan Gicquel outlined three challenges for ATMPs in the EU:

- Weak translation to market: The transition from early research to commercialisation is insufficient in Europe.
- Complex regulatory framework: Current regulations are cumbersome and need simplification and streamlining.
- Funding gaps: Insufficient resources continue to hinder the development, uptake and implementation of ATMPs.

He concluded that Europe's competitiveness and autonomy in biotech are crucial and that upcoming policy initiatives, including the Biotech Act and revisions to the Clinical Trials Regulation, will be crucial for ATMPs.

Video panel: The potential of ATMPs and hurdles for patient access – Patient testimonial

Androula Eleftheriou, Executive Director – Thalassaemia International Federation

In a video message, Androula Eleftheriou shared the patient perspective, emphasising that the EU must maintain its focus on innovation and competitiveness to ensure transformative therapies reach patients in a timely and equitable manner.

She expressed TIF's support for initiatives aimed at building a more effective investment ecosystem for ATMPs, including:

- Integrating ATMP resources into the next Multiannual Financial Framework (MFF) and Horizon Europe (FP10) programs.
- Streamlining regulatory and clinical trial pathways.
- Harmonising overlapping legislations, including those soon to be integrated into national frameworks, with first assessments expected in 2029.
- Reducing duplication and administrative burden.
- Promoting early dialogue and patient involvement in trial design and value assessment.
- Increasing fairness and transparency in regulatory and Health Technology Assessment (HTA) discussions.
- Implementing the HTA Regulation, joint scientific assessments, and networks to support evaluation and real-world evidence adoption.
- Allowing greater flexibility in defining unmet medical needs, considering social integration and quality of life.
- Leveraging European Reference Networks and revisiting the Cross-Border Healthcare Directive to standardise and streamline both national and cross-border access pathways for ATMPs.

She concluded on an optimistic note, expressing hope that newly authorised gene therapies will be implemented more effectively, bringing improved and more equitable outcomes to patients across Europe.

Panel 2: Learning from Each Other: Supporting the Uptake of ATMPs in the EU

Discussion Session – Key Takeaways

Collaboration

- Many Member States have innovative models in place and should learn from one another.
- Eliminating internal barriers and ensuring consistent interpretation of regulations are essential.
- Centers of excellence and cross-border healthcare initiatives could help, especially for rare diseases, by facilitating access and sharing expertise.

Funding

- Pricing models, agreements, and financial mechanisms must be updated to facilitate access, especially for rare and medium-prevalence diseases.
- Europe needs robust R&D funding and greater expertise among funders.
- Public funding processes are cumbersome and should focus on reducing barriers.
- Innovative payment models, fair pricing, and mechanisms such as basket purchases are needed.

Patients

- Europe lacks a system to link R&D portfolios with patient needs.
- Patient organisations are struggling or closing due to lack of funding.

Key Next Steps

- Focus on the implementation of the Clinical Trials Regulation (CTR) and the Biotech Act.
- Develop a European research infrastructure that manages therapy portfolios and connects them to patient needs.
- Measure impact and strengthen political advocacy, as technical solutions alone are insufficient.
- Continue advocating for and promoting practical models to improve patient access.

Dimitrios Athanasiou, Board Member – World Duchenne Organisation/ Rare Diseases Greece

Dimitrios Athanasiou highlighted the urgent need to address extreme fragmentation in Europe's ATMP ecosystem and called for a clear plan to improve coordination. He further noted that the current economic model is not viable for broad patient access, despite many ATMPs being in the pipeline. While patient involvement in regulatory processes is improving, he finally stressed that planning and execution still lag, limiting the system's sustainability and effectiveness.

Céline Pouppez, Expert – Belgian Health Care Knowledge Centre

Céline Pouppez highlighted funding challenges, noting that academia struggles to support R&D up to the late stages, creating gaps that hinder the ATMP development pathway. She also explained that Europe could learn from academic initiatives in other (several) countries but currently lacks the infrastructures to consistently deliver public funding while managing therapy portfolios and connect them to the patient and society needs. While good practices exist, she stressed the need for greater cross-border collaboration and new models, like partnerships between academia, public funders, charities and industry, possibly using socially responsible licensing conditions, in particular to support rare disease therapies. In this regard, she emphasized that expertise in intellectual property and commercial strategy is also essential among public funders to ensure sustainable development and successful access of these therapies to the patients.

John Coughlan, Director International Government Policy and Affairs – Regeneron

John Coughlan outlined key challenges for ATMPs in Europe, noting an implementation gap between the intent of policy and its real world impact, including:

- A declining share of ATMP clinical trials being conducted in Europe.
- Regulatory implementation challenges, in addition to the regulations themselves, are a primary barrier.
- Slowed clinical trial processes due to implementation difficulties, including the In-Vitro Diagnostic Regulation.
- A real risk that Europe may become less attractive for R&D in the near future, if disclosure timelines for clinical trial data under the European Health Data Space do not align with current practice.

3. Conclusion

Jacki Davis

Jacki Davis closed the conference by highlighting that ATMPs offer transformative opportunities for Europe, while acknowledging ongoing challenges in access, manufacturing capacity, regulatory processes, and integration into national health systems. She emphasised that Europe can lead globally only through collective action, with the upcoming Biotech Act playing a crucial role in reducing fragmentation and accelerating development. She also noted that patient testimonies reinforced the fact that innovation is a lifeline, and affirmed that the SANT Committee will continue to champion policies aimed at strengthening Europe's biotech ecosystem and improving patient access in 2026 and beyond.

Conference Room, Kristian Vigenin & Networking session.
Photos by ImagoSkills & TRANSFORM. (2025)

About the European Alliance for Transformative Therapies (TRANSFORM)

The European Alliance for Transformative Therapies (TRANSFORM) is a multi-stakeholder alliance that connects Members of the European Parliament (MEPs) and policymakers with patient groups, medical experts and associations, scientists, researchers, industry actors, networks and other relevant stakeholders. TRANSFORM aims to foster effective dialogue and provide evidence-based policy recommendations to enable safe and timely patient access to cell and gene therapies, whilst ensuring the sustainability of healthcare systems.
TRANSFORM members include:

CCI Europe – Childhood Cancer International Europe
EAHAD – European Association for Haemophilia and Allied Disorders
EAHP – European Association of Hospital Pharmacists
EFNA – European Federation of Neurological Associations
ESGCT – European Society of Gene and Cell Therapy
EUCOPE and its members: BioMarin, Bristol Myers Squibb, CSL Behring, Kite – a Gilead company, Medac, Miltenyi Biomedicine, Orchard Therapeutics, PTC Therapeutics, Regeneron, Santen and Vertex.
EHC – European Haemophilia Consortium
EPTRI – European Paediatric Translational Research Infrastructure
EURORDIS – Rare Diseases Europe
GBS-CIDP Foundation
IPOPI – International Patient Organisation for Primary Immunodeficiencies
Lymphoma Coalition
reNEW Consortium Stem Cell Medicine
RI – Retina International
SIOP Europe – the European Society for Paediatric Oncology
TIF – Thalassaemia International Federation
WDO – World Duchenne Organization

The European Medicines Agency (EMA), the European Haematology Association (EHA) and the European Cancer Organisation (ECO) are Observers.

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