INOVIGATE
achieving outcomes

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ATMP-NL Report

February 2026

Project Organisation and Approach

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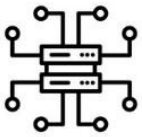
ATMP-NL: Project objective

Objective of the project
Developing an action plan and facilitating the implementation of the ATMP-NL hub.

Key Aspects:

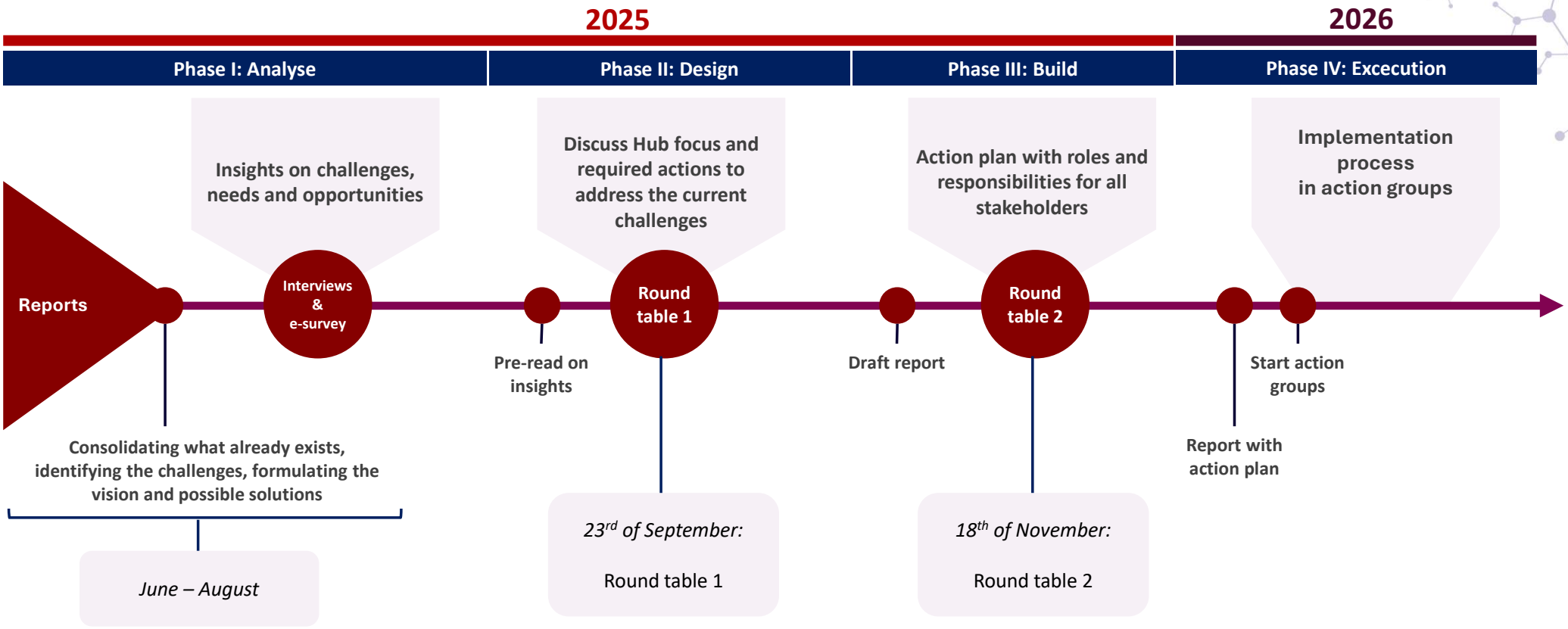


Sustainable and Well-Supported Hub
Organizational Structure: Governance, integration, and financing options (short- and long-term)
Structural Collaboration with relevant stakeholders (patient organizations, academic institutions, industry, and regulatory authorities)

Collaboration with National and International Networks
Strategy for integration with existing ecosystems
Strengthening synergies between relevant stakeholders

Priority Agenda
Defining a project agenda to address previously identified bottlenecks
Identifying responsible stakeholders for implementation

ATMP-NL: Approach



Phase I, Analysis
Current situation and challenges/bottlenecks of ATMP development in the Netherlands

Gathering insights on challenges, needs and opportunities

Desk research

Focusgroups

E-survey

International benchmark

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Gathering insights on challenges, needs and opportunities

Desk research

Performed a systematic review of available ATMP related reports, bottleneck analysis, recommendations, and stakeholder communications.

Including:

Gathering insights on challenges, needs and opportunities

Focusgroups

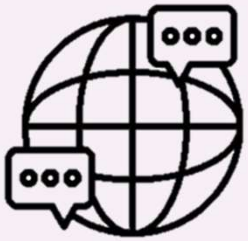
We organised 5 focus groups with representatives from:

- Patient representatives
- Patient foundations
- Authorities
- Payers
- Academia
- Research organisations
- Health care providers
- Pharmaceutical industry
- Industry associations
- (inter)national initiatives

E-survey

Send out an e-survey to 300+ stakeholders in the field

Gathering insights on challenges, needs and opportunities



International benchmark

Looked at (emerging) national ATMP networks across Europe and reflects on learnings and best practices.

Country	Name of network
United Kingdom	Cell and Gene Therapy Catapult (CGT Catapult)
	Advanced Therapy Treatment Centre network (ATTC network)
Ireland	CGT Forum
Sweden	ATMP Sweden
Italy	National Center for Gene Therapy and Drugs based on RNA Technology
Spain	The Spanish Network of Advanced Therapies (TERAV+)
Germany	GCT Germany
Denmark	ATMP Denmark
Norway	ATMP Norway

13 major challenges are currently impacting the Dutch ATMP landscape

Challenges identified by stakeholders in the ATMP development cycle

1. **Pricing/ funding hurdles**, incl. insufficient funding, small budgets to fund promising start-ups, inadequate pricing models, and limited pricing transparency and price management tools
2. Lack of capacity in materials, workforce and infrastructure combined with inefficient use of existing resources (initiatives, materials, developments) due to **lack of overview and coordination** (fragmentation)
3. **Insufficient adaptation of processes, systems, regulations** (manufacturing, market access, …etc.) **and reimbursement pathways** to the complex nature of ATMPs
4. **Lack of national and international harmonization over the entire value chain** of (manufacturing) procedures, regulations, data collection, reimbursement pathways of ATMP
5. **Limited interaction and knowledge sharing** between stakeholders across different stages of the ATMP value chain
6. **Fragmented knowledge and education** on ATMPs (by the broader public) and the requirements across the different steps of the ATMP value chain
7. **Complexity of both clinical trial design and execution** (e.g. difficult patient recruitment, interpretation of clinical endpoints, publication pressure, short shelf-life, …etc.)
8. **Contrast between a highly dynamic & rapidly evolving field and the long clinical trial timelines**, creating difficulties around selecting a single product for clinical testing
9. **Challenges in collaboration among different stakeholders** e.g. IP discussions, public vs private companies, national vs international, …etc.
10. Market access through hospital exemption and **differing interpretations of hospital exemption at state level leads to unfair competition**, unequal access for patients and fewer applications of market

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13 major challenges are currently impacting the Dutch ATMP landscape

Challenges identified by stakeholders in the ATMP development cycle

11 **Long and complex regulatory and reimbursement path**

12 Many stakeholders are making efforts to address key challenges in the ATMP field, However, **the fragmented value chain and initiatives** limits their impact.

13 **Political divergence and interest tensions** around hub

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ATMP-NL should address the following opportunities:

Opportunities

There is a strong **informal network** across all parties within the Dutch ATMP field that should be made **more structural** and **joint learning needs more moderation**

There are **a couple of policy initiatives at EU level that can be leveraged to NL** if concrete actions are taken and implemented

The presence of **EATRIS headquarters** in the Netherlands creates a strategic opportunity to strengthen collaboration and provides a direct link to the **EU network**

There is a clear opportunity to establish **joint projects** under **one umbrella**, **connecting** and amplifying the currently fragmented activities & stakeholders **across the value chain**

There is joint consensus that the traditional **development pathway** needs to change into one with an **end-to-end view**, based on a joint responsibility, a **viable businessmodel** to make it 'successful' for all

ATMP-NL should address the following challenges:

Challenges

The NL has a strong academic backbone, but **knowledge and network gaps** hinder development and translation into clinical and commercial success

Despite the strong concentration of companies, initiatives and research, **fragmentation**, **poor coordination** and **lack of focus** prevent NL from leading in ATMP

Existing **regulations** are overly complex, **not suited** for ATMPs and not harmonised. **National guidelines**, aligned with EU frameworks, are **missing**

A landscape map and overview, **structural mechanisms** and standardisation is missing **to retain and share knowledge**/technology once funding ends, leading to repeated efforts and lost learning

Reimbursement is uncertain and value **frameworks** and payment & budgeting **models are not suited** for ATMPs

A **unified voice from the field** to support informed decision-making at **policy level** is missing

The **Dutch investment landscape** with (inter)national public & private funding **is insufficient**. Individual interests are prioritised over collective efforts

ATMP-NL should address the following requirements:

Requirements

Provide end-to-end ATMP development **support**, incl. training, know-how and sharing of expertise

Drive a national ATMP plan aligned with all stakeholders and supported by the government including an adapted reimbursement solution

Connect all stakeholders and initiatives, innovation system with the healthcare system and forming a **SPOC**

Each stakeholder group should be a **full partner** in the Hub, with an active role beyond an ad hoc advisory role to create win-wins for all

Overarching coordinator for the NL ATMP-ecosystem to **facilitate collaboration** (on asset and overarching level) and build on stakeholders' strengths

Act as a unified voice that advocates for the NL ATMP ecosystem and is a trusted contact that knows the ecosystem

Be an **investment hub focused on** maximizing health benefits, with a structured process based on defined milestones and clear governance

The insights gathered from the e-survey supplement the interviews

Challenges

The majority of respondents experience **funding and reimbursement, regulatory and limited stakeholder interaction/networking** as the main challenges

Requirements

The Hub should **build on existing initiatives, with focus on reimbursement, regulatory, quality and production, and fostering collaboration** between national and international stakeholders

The Hub can truly **differentiate by including all stakeholders** (incl. public sector) and focusing on inclusivity and benefits for all

Operate as a not**-for-profit, prioritising health impact** and **inclusivity over economic** gain, and its legal structure must be tailored to support its mission and objectives

Potential pitfalls for the Hub are **lack of resources and funding**, **unbalanced stakeholder interests and groups**, **neglecting the international interests and fast evolution of the field**

Best practices and learnings from other ATMP initiatives across the EU

Key learning	Best practices
All networks fulfill multiple roles, however their approach differ mainly in their level of active contribution, ranging from support systems to more delivery-oriented models.	• ATMP Sweden: support-system • CGT Catapult delivery-oriented • TERAV & ATMP Norway: Education & training programs • ATMP Denmark: innovation through pilot projects • ATMP Norway, Italy's National centres: access to expertise/facilities
A broad representation of all stakeholders is needed, but regulators, patient organizations, and investors are currently underrepresented in most of the networks	• ATMP Sweden: participation of national regulator • GCT Germany
Long-term sustainable funding requires balanced models that ensure financial stability while maintaining inclusivity	• ATMP Sweden: inclusivity • CGT Catapult: stable multi-year funding
All networks struggle but recognize the need for cross-border collaboration to amplify the impact of national initiatives and align with EU	• TERAV: organised in six projects of which one is national and international relationships • Pan-EU efforts: EATRIS, join4ATMP

Key learning	Best practices
Reimbursement strategies, systematic collection of RWD and ethics remain insufficiently embedded in many network activities	• ATMP Denmark: collaborations in RWD collection • ATMP Sweden, TERAV+, ATMP Denmark, SITGEC: focus on ethics
Mapping and resource coordinating activities is seen as a key factor for long-term success	• CGT Catapult, CGT Ireland: mapping manufacturing facilities • ATMP Sweden, CGT catapult, CGT Ireland: strength mapping • CGT Germany, CGT Denmark: national & international mapping
Networks need neutral and transparent governance with clear mandates	• ATMP Sweden: maintains it neutrality, but lack of authority • CGT Catapult: supported by a clear governmental anchor
Networks with a broader scope tend to achieve greater impact, but their scope and focus must be clearly defined to ensure results	• Networks have broad focus (all types of diseases and all types of ATMPs) except ATMP Norway and Italy's National centre.

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Source: Article in preparation'Shaping national networks to expedite patient access to advanced therapy medicinal products in Europe', 2025, Lourens T. Bloem, Mike Broeders, Renske M.T. ten Ham, Francisco Hernandez, Joyce M. Hoek, Heather Main, Pauline Meij, Daniël O. Warmerdam, RSNN Advance Therapy SIG Steering Committee

Conclusions based on the insights:

Conclusion 1	Analysis based on the desk research, stakeholder interviews, e-survey and international benchmarking

The Netherlands has all the ingredients to become a hotspot in ATMP, but the challenges must be addressed now together with all stakeholders

- All the ingredients are there in NL to become a hotspot for ATMPs.
- There is currently a **momentum** where **willingness and opportunities are coming together**, but a coordinated approach is essential.
- **This requires concrete action now**, going beyond analyses and reports, to address the many challenges efficiently and effectively, **with all stakeholders on board.**

Conclusions based on the insights:

Conclusion 2	Analysis based on the desk research, stakeholder interviews, e-survey and international benchmarking

The innovation and healthcare value chains must be integrated in a well-functioning ecosystem to optimize the NL' potential in ATMP

- Developing ATMPs and bringing them to patients has specific challenges, but the solution can serve **as a model for other innovations.**
- The **challenges lie across the entire fragmented ATMP innovation and healthcare value chain**. Both must be **integrated into a single, cohesive value chain and ecosystem**, **focused on patient and societal needs and health objectives.**
- This will have a positive impact on the patient care and outcomes, and the country's economic development.
- RWD/E will support the integration of the innovation and healthcare value chains to benefits for all.

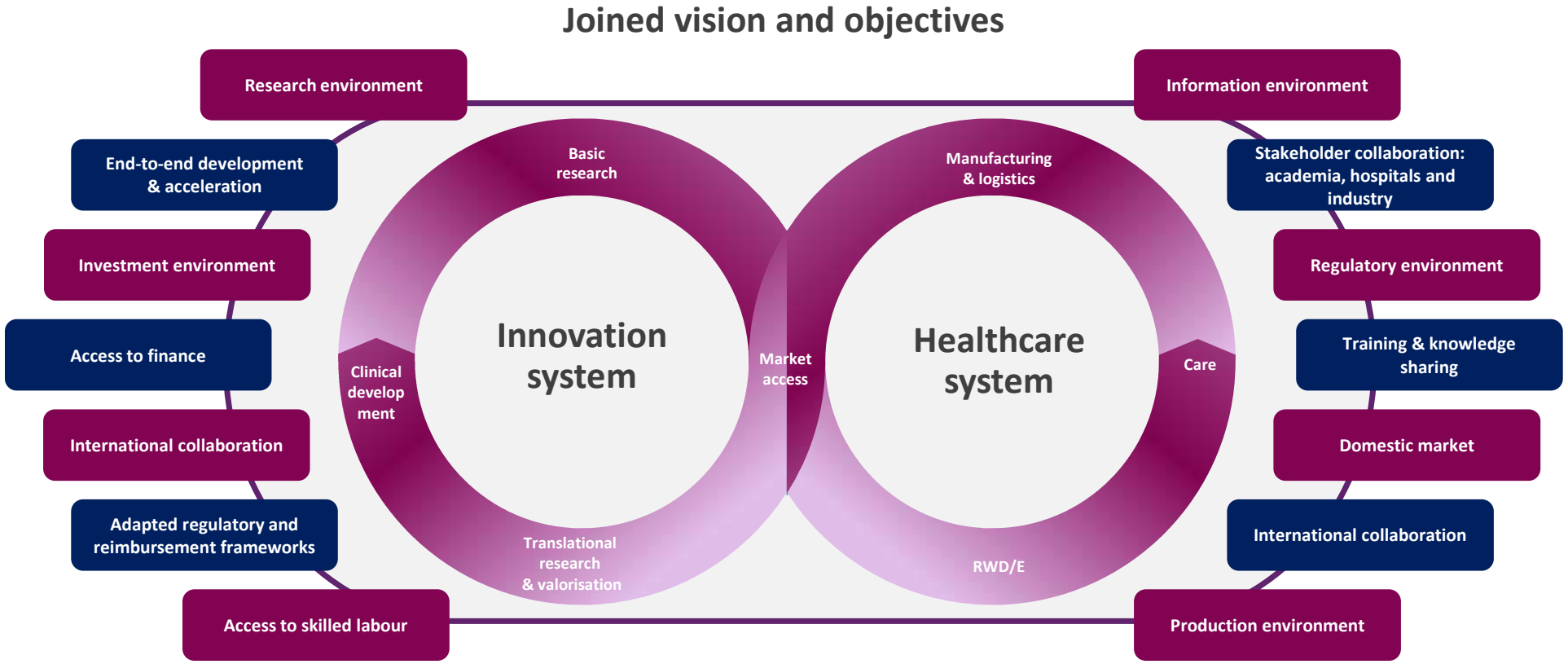
Conclusions based on the insights:

Conclusion 3	Analysis based on the desk research, stakeholder interviews, e-survey and international benchmarking

An integrated action plan and effective coordination of the implementation with all stakeholders is needed now to make it happen

- NL boasts a **unique and diverse ecosystem** with high-quality facilities and multidisciplinary expertise. However, its full potential is not being realized due to **numerous structural shortcomings.**
- Current initiatives offer valuable benefits, but a **comprehensive overall approach that integrates all aspects of the ATMP field** and **effectively coordinates its implementation** is lacking.
- NL must draw **inspiration from international best practices to distinguish itself.**
- A **concrete action plan involving all stakeholders** can make all the difference in expanding international cooperation.

Moving towards an integrated well-functioning ecosystem with effective coordination by all stakeholders



Phase II: Design
Detailed ATMP-NL vision, mission, objectives

First multi-stakeholder round table: ATMP-NL vision and roadmap to build a top performing Dutch ATMP ecosystem

Round table 1

23 September 2025

Build support for ATMP-NL hub concept and model

Purpose
Jointly shape the **vision and roadmap** for a strong Dutch ATMP ecosystem
Validate direction for a national **ATMP-NL Hub**

Participants
+50 multi-stakeholder representation across patient representatives, academia, healthcare, industry, regulators, and funders

Core topics discussed
Proposed **ATMP-NL Hub vision and objectives**
Draft **action plan** and **governance model**
Key challenges, opportunities, and system-level needs

Input used
Pre-read synthesising stakeholder insights, international benchmarks, and bottleneck analysis

Alignment achieved
Broad support for the **ATMP-NL Hub vision and objectives**

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Vision and mission statement of ATMP-NL

Why an ATMP-NL hub?

Everyone in society is confronted with illness sooner or later, ATMPs are a crucial part of the solution. The Netherlands already has strong foundations and the right ingredients to become an international leader and attract investment. By acting together, we can maximize the benefits for patients, society, and the economy. Today and for future innovations.

Vision

The national ATMP Hub aims to strengthen the Dutch ecosystem and prepare the healthcare system for the future, starting today. This ensures that patients gain faster, affordable, and sustainable access to ATMPs, contributing to broad societal value.

Mission

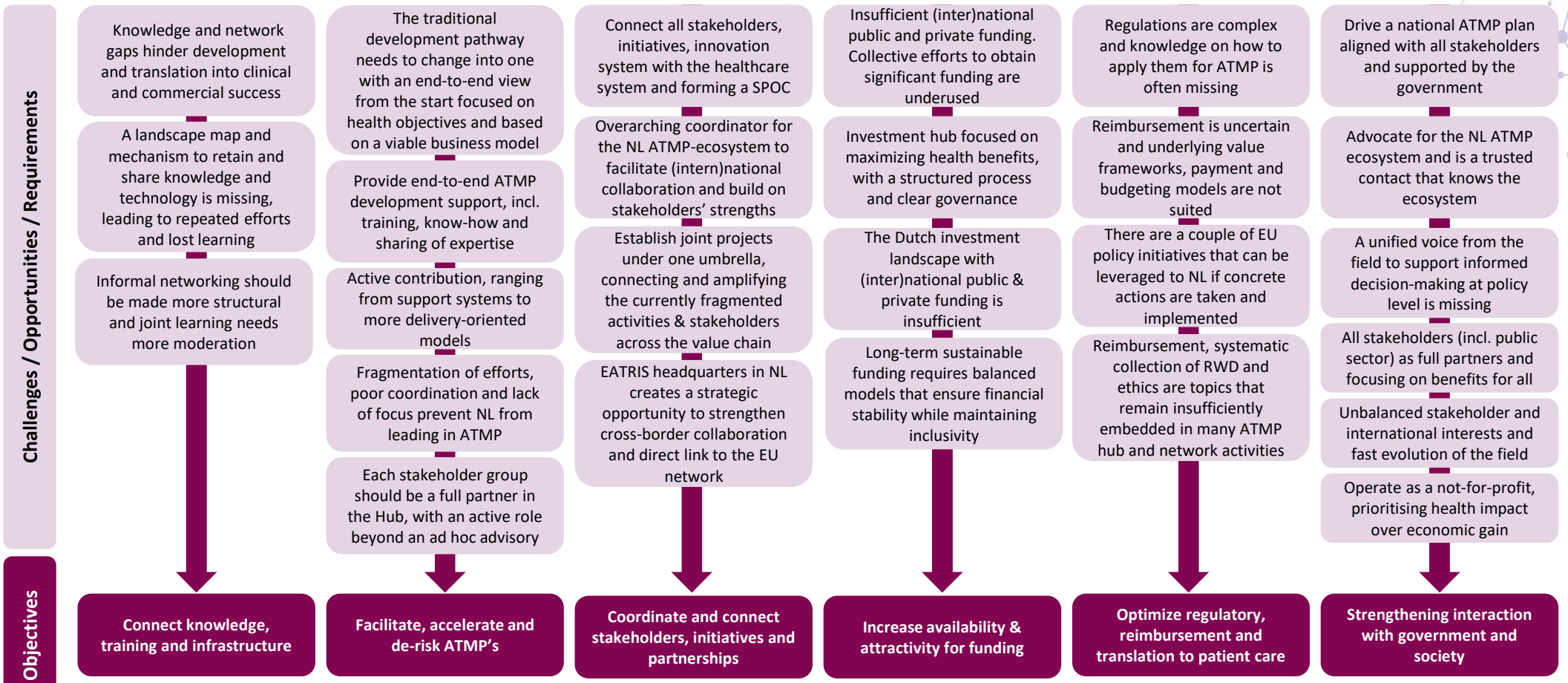
The national ATMP Hub is an **independent and connecting platform** that serves as the central nexus within the ATMP field. Together, as stakeholders, we accelerate the development and access to ATMPs through collaboration across the entire value chain, strategic use of resources, a focus on shared interests (common ground), and co-creation of practical solutions. In doing so, we contribute to national and European health objectives and policy frameworks.

ATMP definition according to EMA

According to the EMA definition, ATMPs can be classified into three main types:

- **Gene therapy** medicines: medicines containing genes that lead to a therapeutic, prophylactic or diagnostic effect. They work by inserting 'recombinant' genes, laboratory-created DNA combining material from different sources, into the body
- **Somatic-cell therapy** medicines: medicines containing cells or tissues that have been modified to alter their biological characteristics, or different intended essential functions in the body.
- **Tissue-engineered medicines**: medicines containing cells or tissues that have been modified for use in repairing, regenerating, or replacing human tissue

From challenges, opportunities and requirements to objectives



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From challenges, opportunities and requirements to objectives

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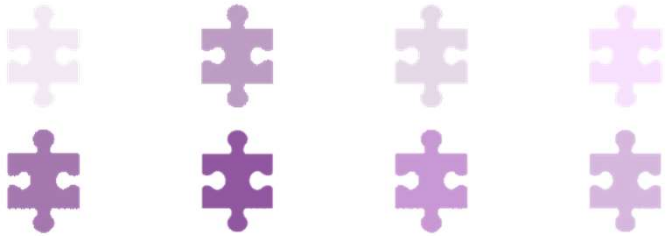
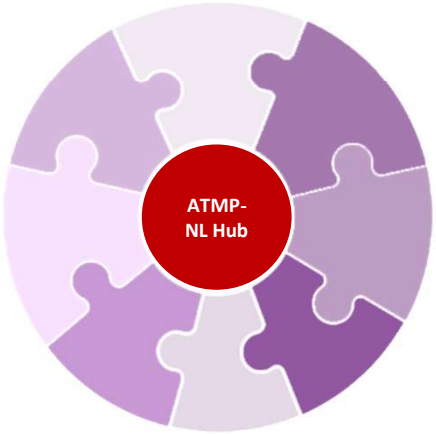
ATMP-NL as a connector for all stakeholders in the development chain

From a fragmented field…



Individualized stakeholders and initiatives

…to a connected and functioning ATMP field in the Netherlands



Connected ATMP field

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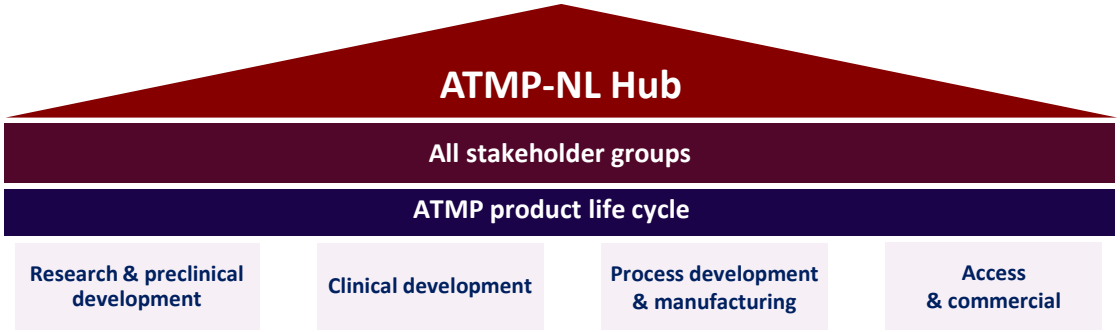
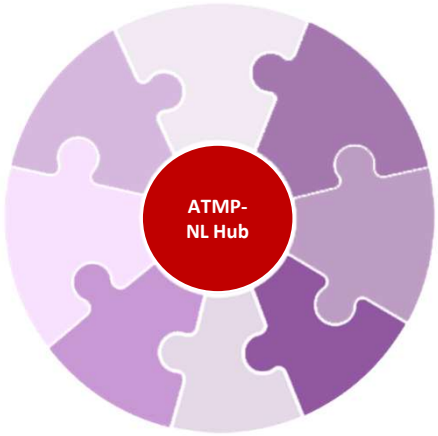
ATMP-NL as a connector for all stakeholders in the development chain



The ATMP-NL Hub as an independent and connecting and overarching platform across the entire ATMP value chain and its initiatives

The ATMP-NL Hub ensures representation of all stakeholder groups and their interests.



Connected ATMP field

The ATMP-NL Hub as a catalyst and central spil to:

- **Accelerate the development and access to ATMPs**
- **Facilitate collaboration and co-creating solutions** that **bridge current and future gaps/bottlenecks** in the ATMP-NL ecosystem **contributing to broad societal value**
- **Build** upon**, strengthen** and **connect existing initiatives and promote the sustainable and transparent use of resources**
- **Strengthen the Dutch ATMP ecosystem and embedding it within national and European policy frameworks**
- **Develop and implement a national ATMP strategy**

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ATMP-NL creates value across the ATMP ecosystem

	Added value and benefits per stakeholder group
Patients & patient organizations	• Accelerated **access to ATMPs in UMN areas (incl. in clinical trials)** • Involving patients as a **full valuable partner**
Government and payer	• Represents all stakeholders in the NL ecosystem, **simplifying collaboration and dialogue** with the field • Enabling **targeted policy and investment** • **Cross border / EU collaboration**
Academia & researchers	• **Central expert gateway** for ATMP and end-to-end development advice - **Knowledge centralisation and sharing** • **Optimal** use and overview of **resources, infrastructure and capabilities** • **National guidelines** on interpretation for regulation and required evidence for reimbursement
Healthcare providers	• **Access to innovative treatments** and enhanced **outcome predictability** • Accessibility to **national training centres/program** to upskill
Companies	• Attractive market with **equal level playing field between hospital (HE) and pharma** for ATMP production • **Efficient and attractive market access** • **Attractive clinical trial environment**

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Phase III: Build action plan and approach in action groups

Second ATMP-NL Round Table: From vision to implementation

Round table 2

18 November

Support for the implementation roadmap, incl. roles & responsibilities

Purpose
Move from shared vision and conceptual alignment to practical implementation
Jointly develop a concrete implementation roadmap for ATMP-NL

Participants
+50 multi-stakeholder representation across patient representatives, academia, healthcare, industry, regulators, and funders

Core topics discussed
Define **action areas,** identify **priorities** for the short, medium and longer term
Clarify **roles, responsibilities and (co-)leadership**

Input used
Agreed ATMP-NL vision and objectives (Round Table I)
Pre-read outlining draft action areas, timelines and dependencies

Alignment achieved
Implementation roadmap with key actions and milestones, ownership and coordination.
Identification of **'low-hanging fruit'** (short-term, visible actions) and actions requiring broader collaboration or longer-term investment

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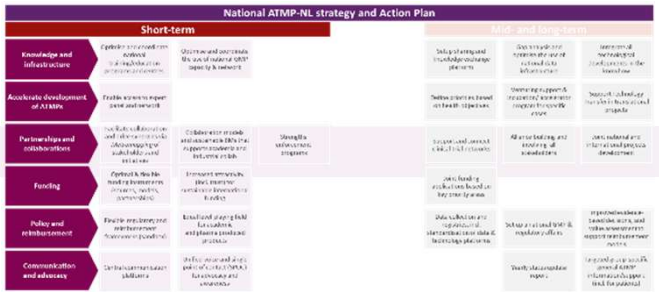
Operationalising through a parallel approach: start-up of the Hub vehicle and multi-stakeholder action groups

Based on the challenges, opportunities, requirements & needs we can start building the Hub



Start-up

Operationalisation

Hub building

Start-up of the Hub vehicle: Based on defined legal structure, governance & organisational model, PMO for action groups, partnering model

AMTP-NL Hub is fully operational, supported by all stakeholder groups with 6 key functions, well defined roles & responsibilities and sustainable funding model

Implementation

Action plan in 6 multi-stakeholder action groups

To continue to support the execution of the **ATMP National Strategy**

Max. 1 year

Engage stakeholders through dialogue to collect input

… and move to fast parallel start-up and multi-stakeholder action

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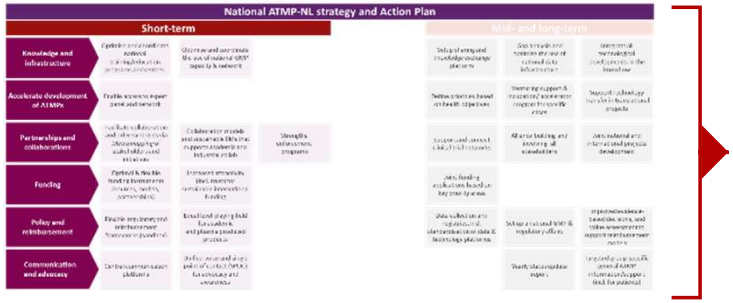
Six multi-stakeholder action groups supported by a PMO and a multi-stakeholder board



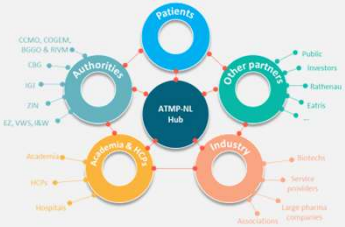
Chairman

- Aligning bottom-up efforts with top-down initiatives
- Bridge-builder
- Transparency enabler
- Trust builder
- Reporter

\+

Multi-stakeholder board

- Oversee and monitor strategic direction and objectives of the ATMP-NL Hub
- Represent the interests of all stakeholder groups
- Ambassadors for ATMP-NL Hub



Action groups

To implement the action plan and put it in practice, **6 action groups have to be set up:**

1. **Knowledge and infrastructure**
2. **Accelerate development of ATMPs**
3. **Partnerships and collaborations**
4. **Funding**
5. **Policy and reimbursement**
6. **Communication and advocacy**

- All stakeholders should volunteer to (co-)lead or contribute.
- Per action group, **action charters** will have to be developed
- The **action groups work on their objectives**

Program Management Office (PMO)

- **Guidance, coordination and reporting of the different action groups**
- **Performance tracker**
- **Process enabler**

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Funding, governance and operational set-up of a multi-stakeholder board

7 **Working group to set-up the ATMP-NL Hub vehicle**

- **Short-term funding to fund the first year** to support action group coordination and PMO, etc.:
  - Funding for PMO
  - In kind contribution for action group participators
  - Start-up funding sources (to cover the start-up costs)
  - Mid-term funding sources (>1 yr)
- Further development of **multi-stakeholder board composition** and set-up
- Appointment of **chairman**
- Define **optimal legal structure** and set-up
- **Detail processes**

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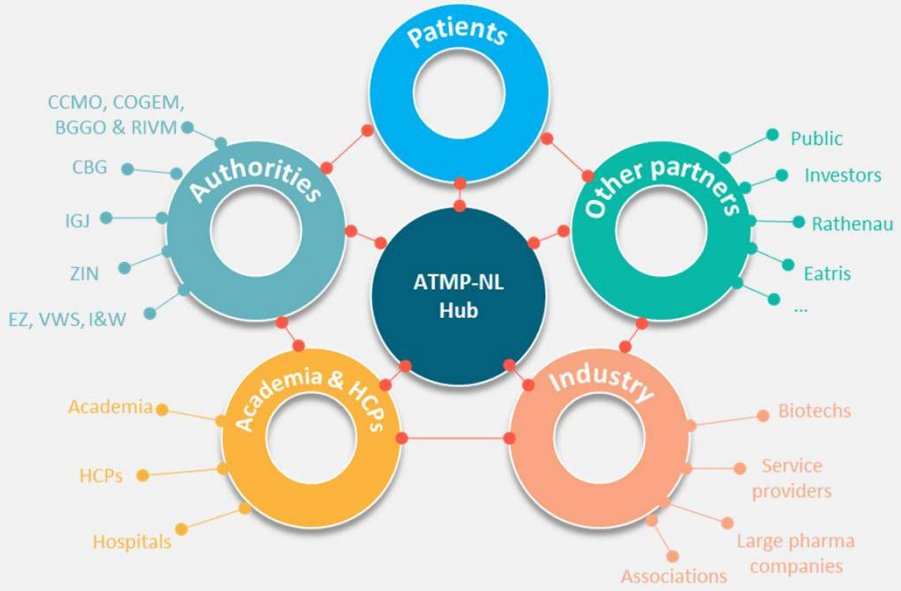
A multi-stakeholder board to balance between interests of all stakeholders

ATMP-NL Multi-stakeholder Board governance model



Board composed of representatives of each of the stakeholder groups

- **Members selected for their knowledge and excellence in the field.** These board members have to be **outstanding, very experienced and highly networked individuals in the field of ATMP.**
- To keep independence and balance the interests.

ATMP-NL Implementation & Governance Structure

Governance instruments

ATMP-NL Hub Multi-stakeholder board

- With balanced representation of all stakeholder groups, by individuals with actual decision-making authority (to realise the ambition of the ATMP-NL Hub and increase its effectiveness).
- Chaired by a neutral chair (TBD)
- Goal: to maintain an overview of the strategy, objectives and direction of implementation
- Quarterly (virtual) meeting

Action groups

- Team of experts and stakeholders working on the actions, who are well connected with their community to ensure representation of the entire field
- Based on an action charter for each action group
- Led by an action group lead and co-lead
- Goal: Detailed solutions for implementation
- A minimum of 4 to 6 thoroughly prepared meeting during first year and annually

Operational steerco

- Consists of the action group leads.
- Objective: Discuss action status and interdependencies between the action groups, to avoid overlaps and gaps
- Monthly (virtual) meeting.

Project coordination and support / PMO

- Coordination of actions and action groups with implementation measures and activities
- Support for the action groups
- Organisation of consultations
- Progress reporting

Principles for a Sustainable ATMP-NL Funding Mix

Start-up funding

Funding: **Public funding and contribution in kind** will dominate

Budget estimate:
- 200k - 250k for PMO (based on similar approach in BE)
- In kind contribution for action group participators

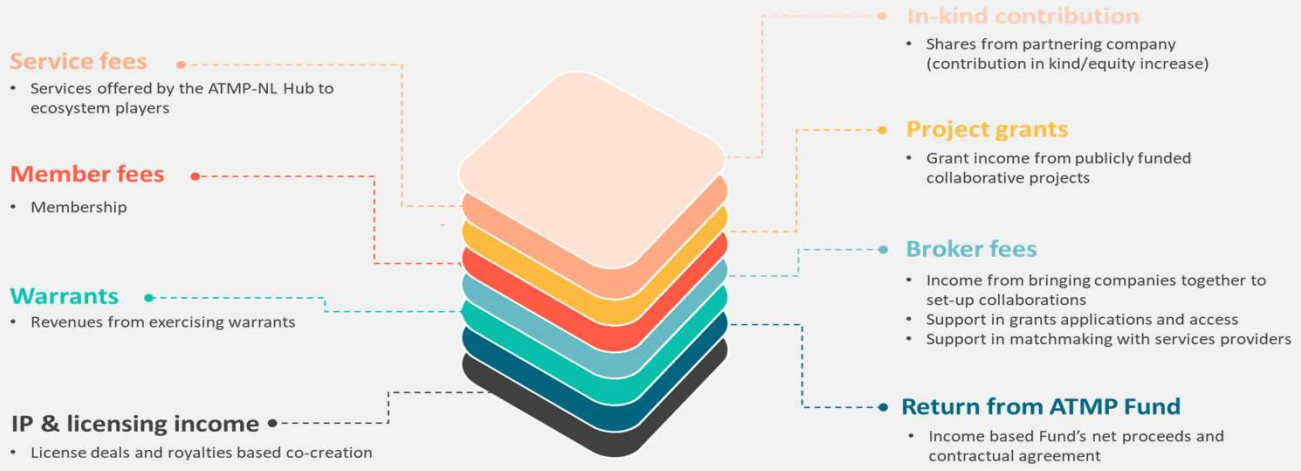
Funding sources: TBD

Later

Funding: **mixed fee model**

Long-term sustainable funding strategy

During the later impact phases different financing mechanisms can be set up tailored to each service line with the participation. **Key principle:** inclusivity is at the core of the Hub, and access to the hub should not be based on financial contribution alone, but should also reward contribution in expertise, know-how, etc.



Action group priorities as defined by the stakeholders

National ATMP-NL strategy and action plan

	Short term			Mid- and long-term		
Knowledge and infrastructure	Optimise and coordinate national training/education programs and centres	Optimise and coordinate the use of national GMP capacity & network		Setup sharing and knowledge exchange platform	Gap analysis and optimise the use of national data infrastructure	Integrate all technological developments in the knowhow
Accelerate development of ATMPs	Enable access to expert panel and network			Define priorities based on health objectives	Venturing support & incubation/ accelerator program for specific cases	Support Technology Transfer in translational projects
Partnerships and collaborations	Facilitate collaboration and drive synergies via *Metromapping* of stakeholders and initiatives	Collaboration models and sustainable BMs that supports academia and industrial collab	Strengths enforcement programs	Support and connect clinical trial networks	Alliance building and involving all stakeholders	Joint national and international projects development
Funding	Optimal & flexible funding instruments (sources, models, partnerships)	Increased attractivity (incl. trust) for sustainable international funding		Joint funding applications based on key priority areas		
Policy and reimbursement	Flexible regulatory and reimbursement frameworks (sandbox)	Equal level playing field for academic and pharma produced products		Data collection and registries, incl. standardisation of data & technology platforms	Set up a national GMP & regulatory affairs	Improved evidence-based decisions, and value assessment to support reimbursement models
Communication and advocacy	Central communication platforms	Unified voice and single point of contact (SPOC) for advocacy and awareness			Yearly status update report	Targeted group-specific general ATMP information/support (incl. for patients)

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The prioritised action plan is detailed in action charters

National ATMP-NL strategy and action plan

Short term

Knowledge and infrastructure	Optimise and coordinate national training/education programs and centres	Optimise and coordinate the use of national GMP capacity & network	
Accelerate development of ATMPs	Enable access to expert panel and network		
Partnerships and collaborations	Facilitate collaboration and drive synergies via *Metromapping* of stakeholders and initiatives	Collaboration models and sustainable BMs that supports academia and industrial collab	Strengths enforcement programs
Funding	Optimal & flexible funding instruments (sources, models, partnerships)	Increased attractivity (incl. trust) for sustainable international funding	
Policy and reimbursement	Flexible regulatory and reimbursement frameworks (sandbox)	Equal level playing field for academic and pharma produced products	
Communication and advocacy	Central communication platforms	Unified voice and single point of contact (SPOC) for advocacy and awareness	

1 Knowledge and infrastructure

Optimise and coordinate national training/education programs and centres and align

Optimise and coordinate the use of national GMP capacity & network

1.1 Optimise and coordinate training and education

Scope:
- Map the nationally available knowledge, existing training programmes, and skills-development initiatives across academia, hospitals, and industry.
- Conduct a gap analysis to identify unmet training and education needs across the ATMP value chain (discovery, manufacturing, clinical, regulatory, market access).
- Define quality criteria and standards for ATMP-related education and training programmes (learning outcomes, GxP compliance, trainer qualifications, assessment methods).
- Develop ATMP-specific educational content and curricula aligned with these quality criteria and addressing identified gaps, including modular e-learning and hands-on training.
- Develop a plan for optimal use of current national and international training and education.

Deliverables / KPIs:
- National training landscape map
- Gap analysis report
- Quality criteria framework
- ATMP curriculum
- Plan for national & international training integration

Ongoing initiatives include:
- Pharma-NL
- EATRIS
- Cunuluz
- Beethoven project
- CHDR
- Health-RI
- Biotech Booster

Critical interdependencies with other action groups:
- Link to action group 3: The tools and collaboration models will serve as input for action group 1 whenever

1.2 Optimise and coordinate GMP infrastructure

Scope:
- Map the national GMP infrastructure and facilities across academia, hospitals, and industry, including capacity, certifications (GMP/GxP), and capabilities for ATMP manufacturing.
- Conduct a gap analysis to identify bottlenecks in GMP capacity, equipment, and qualified professionals,...etc.
- Develop a national coordination framework for GMP facilities to ensure maximum efficiency and avoiding duplication of investments
- Create a sustainability and governance model for long-term GMP infrastructure management and future growth, including funding and compliance monitoring.
- Establish international collaborations with GMP centres of excellence to leverage global expertise and facilitate cross-border manufacturing

Deliverables / KPIs:
- National GMP facility/capacity map
- GMP gap analysis report
- Optimisation plan for national GMP use
- Established international connections

Ongoing initiatives include:
- Pharma-NL
- EATRIS
- National institute for bioprocessing research and training
- RARE-NL
- Parma-NL
- Health-RI
- Cunuluz
- Beethoven project
- Venture Challenges
- Joint4ATMP
- ATMP biotech campus
- National growth fund initiatives
- Biotech Booster
- CHDR

Critical interdependencies with other action groups:
- Link to action group 3: The tools and collaboration models will serve as input for action group 1 whenever collaborations are required to optimise GMP infrastructure

FAST

Detailed action charters

Detailed action charters

1 Knowledge and infrastructure

Optimise and coordinate national training/education programs and centres and align

Optimise and coordinate the use of national GMP capacity & network

Detailed action charters

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Deliverables / KPIs:
- National training landscape map
- Gap analysis report
- Quality criteria framework
- ATMP curriculum
- Plan for national & international training integration

Examples of ongoing initiatives:
- PharmaNL
- EATRIS
- National institute for bioprocessing research and training
- RARE-NL
- DARE-NL
- Health-RI
- Cunuluz
- Venture Challenges
- Joint4ATMP
- ATMP biotech campus
- National growth fund projects
- Biotech Booster

Critical interdependencies with other action groups*:*
- Link to action group 3: the tools and collaboration models will serve as input for action group 1 whenever collaborations are required to optimise national and international training.

Detailed action charters

1.2 Optimise and coordinate GMP infrastructure

Scope:
- Map the national GMP infrastructure and facilities across academia, hospitals, and industry, including capacity, certifications (GMP/GxP), and capabilities for ATMP manufacturing.
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Deliverables / KPIs:
- National GMP facility/capacity map
- GMP gap analysis report
- Optimisation plan for national GMP use
- Established international connections

Examples of ongoing initiatives:
- EATRIS
- Cunuluz
- Joint4ATMP
- ATMP biotech campus
- Biotech Booster
- RegMed XB
- iCAT
- NecstGen
- DARE-NL
- Oncode Accelerator
- NXTGEN Hightech

Critical interdependencies with other action groups*:*
- Link to action group 3: the tools and collaboration models will serve as input for action group 1 whenever collaborations are required to optimise GMP infrastructure

Detailed action charters

2 Accelerate development of ATMPs

Enable access to expert panel and network

Detailed action charters

2.1 Expert panel and network

Scope:
- Develop a multidisciplinary expert network including representatives from all relevant stakeholder groups across the ATMP value chain
- Design a governance framework to enable the formation of ad-hoc expert panels for specific topics, urgent decision-making needs (e.g. evidence generation for reimbursement, due diligence activities to guide investments,…)
- Ensure sustainability and governance for the expert network, including funding, membership criteria, and performance monitoring
- Develop protocol for easy and timely engagement with the expert network to accelerate ATMP development (e.g., manufacturing, regulatory, reimbursement, evidence generation)
- Develop standardised tools and protocols (e.g., templates, checklists) to enable evidence-based decisions throughout ATMP development, anticipating regulatory, clinical, and market access needs, based on input from action group 5

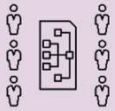
Deliverables / KPIs:
- Established multidisciplinary expert network
- Governance framework for ad-hoc panels
- Sustainability & governance model for expert network
- Clear protocol for access to expert advice
- Expertise centre for reimbursement & evidence
- Standardised tools & protocols to support the development

Examples of ongoing initiatives:
- RSNN
- DARE-NL
- RARE-NL
- RegMex XB
- EATRIS
- Cure4life
- UMCNL
- AGORA

Critical interdependencies with other action groups*:*
- Link to action 4.1: the expertise centre/panel of action 2.1 can be used by funders and investors to guide investment decisions
- Link to action group 5: the expertise centre/panel of action 2.1 can be used to guide on regulatory frameworks and market authorisation routes

Detailed action charters

3 Partnerships and collaborations



Facilitate collaboration and drive synergies via *Metromapping* of stakeholders and initiatives

Collaboration models and sustainable BMs that supports academia and industrial collab

Strengths enforcement Programs

Detailed action charters

3.1 Facilitate collaborations and drive synergies

Scope:
- Set up and maintain an up-to-date metromapping overview of stakeholders, initiatives, and resources to stimulate collaboration and synergies in ATMP development.
- Act as a single point of contact (SPOC) for national and international partnerships through physical and virtual platforms
- Facilitate international connections and collaborations to leverage global expertise and accelerate ATMP development.
- Develop governance structures and coordination tools to enable transparent, efficient collaboration and decision-making.
- Monitor and guide partnerships to ensure they deliver measurable outcomes and avoid duplication

Deliverables / KPIs:
- Comprehensive metromapping overview
- Established SPOC for ATMP collaborations
- National and international collaboration framework
- Coordination tools to facilitate collaboration
- Monitoring & reporting system to ensure transparent and efficient collaborations

Examples of ongoing initiatives:
- Cure4life
- RegMed XB
- ERDERA national mirror group
- EATRIS

Critical interdependencies with other action groups*:*

Detailed action charters

3.2 Collaboration models and sustainable BMs between academia and industry

Scope:
- Identify and document collaboration models specifically for academia-industry partnerships tailored to ATMP development
- Develop business model framework
- Provide guidance and criteria for selecting appropriate collaboration and business models based on project type and stage.
- Co-create and pilot business and pricing models that reflect ATMP-specific characteristics (e.g., high upfront cost, long-term benefit), ensuring integration with reimbursement and investment models, based on input from action group 5
- Ensure alignment with national (based on national strategy determined in acton 6.2) and EU objectives..

Deliverables / KPIs:
- Collaboration model modalities complemented with guidance & selection criteria
- Business model framework
- Pricing and business model pilots
- Plan for integration with reimbursement & investment models

Examples of ongoing initiatives:
- RARE-NL
- Biotech Booster
- Oncode Accelerator
- Cure4life
- National vision biotechnology
- RegMed XB
- ERDERA national mirror group
- EATRIS
- J&JInnovative Medicine partnerships

Critical interdependencies with other action groups
- Link to action 5.1: Dependency on reimbursement and investment models, as these are essential to ensuring long-term viability.
- Link to action 6.2: The national strategy from action 6.2 is required as input to ensure alignment of collab and BMs with national objectives

Detailed action charters

3.3 Strengths enforcement programs

Scope:
- Develop targeted strength enforcement programs to highlight and leverage national capabilities in ATMP development
- Define and implement a standardised protocol to monitor strength-enforcement programs, track their impact, and update them regularly based on performance data and evolving national priorities.
- Establish strategic connections with national and international lobbying bodies (e.g., NFIA, RVO, foreign affairs) and provide accurate, up-to-date information on the strengths and qualities of the Dutch ATMP landscape
- Position the Netherlands as a competitive ATMP hub by showcasing key strengths (e.g., GMP capacity, clinical trial expertise, regulatory know-how)
- Establish strategic connections with national and international lobbying bodies to influence policy and attract investments

Deliverables / KPIs:
- Established strength enforcement program
- Monitoring & impact dashboard for the strength enforcement programs
- Targeted ATMP landscape information
- Established national & international lobby connections

Examples of ongoing initiatives:
- National vision biotechnology

Critical interdependencies with other action groups
- Link to action 3.1: The tools and collaboration models will serve as input for action 3.2, as these tools will be required to establish both national and international lobbying connections

Detailed action charters

4 Funding

Optimal & flexible funding instruments

Increased attractivity (incl. trust) for sustainable international funding

Detailed action charters

4.1 Optimal & flexible funding instruments

Scope:
- Explore and facilitate collaborations between stakeholders to optimise the use of existing financial resources and unlock new financing instruments.
- Investigate EU funding opportunities and develop and pilot a plan for integration of EU funding instruments that offer flexibility and can mitigate identified gaps
- Develop practical tools and guidance to help stakeholders efficiently navigate funding opportunities.
- Stimulate and educate funders and investors regarding long-term financing requirements across all ATMP development phases

Deliverables / KPIs:
- Plan for partnerships that optimise financial resources and unlock new financing instruments
- Optimise EU Instrument mapping & integration
- Tools to guide stakeholders through funding landscape

Examples of ongoing initiatives:
- Thematische Technologie Transfer (TTT) programs
- RegMed XB
- Biotech Booster
- Consultancies
- AFM telethon (FR)
- Fondazione Telethon (IT)
- Strategy of national growth fund projects (broader than ATMP)
- IPCEI
- EIC transition (EIC-NL)

Critical interdependencies with other action groups*:*
- Link to action 2.1: the expert panel/centre established by Action Group 2 can guide stakeholders and support decision-making on funding opportunities and investments
- Link to action 3.1: the SPOC and frameworks of action 3.1 can be used form the collaborations that optimise the financial resources or unlock financing instruments

Detailed action charters

4.2 Attractivity of ATMP-NL for international funding

Scope:
- Create a strategy for attracting international funding, including positioning ATMP-NL as an innovation hub and building trust with global investors
- Summarise the key requirements for international attractiveness for funding, to be used as input for action group 5 on reimbursement and investment models and action group 1 on required skillset
- Engage stakeholders through targeted workshops with funders, government, and international networks (e.g., EATRIS, EIC) to raise awareness and secure commitment to these success requirements
- Establish EIC-NL as a national coordination point for EIC-related funding and partnerships

Deliverables / KPIs:
- Strategy for attracting international funding incl. key success requirements and roles and responsibilities of other action groups
- Established Dutch EIC-NL coordination point

Examples of ongoing initiatives:
- Strategy of national growth fund projects (broader than ATMP)
- IPCEI
- EIC transition
- HORIZON

Critical interdependencies with other action groups
- Link to action 1.1: key requirement for skills and high-quality training to be international attractive is input for action 1.1
- Link to action 5.1: key requirement for access and reimbursement to be international attractive is input for action group 5

Detailed action charters

5 Policy and reimbursement

Flexible regulatory and reimbursement frameworks (sandbox)

Equal level playing field for academic and pharma produced products

Detailed action charters

5.1 Flexible regulatory and reimbursement

Scope:
- Evaluate current regulatory rules and reimbursement frameworks and usage for ATMPs and identify constraints, pain points and opportunities for flexibility
- Pilot alternative use of current regulatory and reimbursement frameworks (national and EU) that can accelerate and improve ATMP development and approval
- Design and pilot new flexible regulatory and reimbursement frameworks to fill the gaps, aligned with ATMP-specific characteristics, to enable controlled innovation and adaptive pathways (e.g., sandbox models)
- Engage stakeholders (regulators, payers, industry, hospitals) to validate frameworks and ensure practical implementation

Deliverables / KPIs:
- Comprehensive evaluation and gap analysis of the current regulatory and reimbursement frameworks for ATMPs.
- Established pilots for flexible regulatory & reimbursement models
- Multi-stakeholder workshops

Examples of ongoing initiatives:
- RSNN SIG ATMP
- CORE-ATMP
- Oncode Accelerator
- DARE-NL
- Bureau for Genetically Modified Organisms
- Toekomstbestendig stelsel geneesmiddelen
- RARE-NL
- Cure4life
- AGORA
- ODAP
- Innovative Health Initiative
- Instituut voor verantwoord medicijngebruik
- Pilots conducted by ministry of economic affairs

Critical interdependencies with other action groups*:*
- Link to action 4.2: the access and reimbursement requirements defined in Action 4.2 must be considered when evaluating and developing regulatory and reimbursement frameworks
- Link to action 2.1: the expertise centre/panel of action 2.1 can be used to guide on market authorisation routes

Detailed action charters

5.2 Equal level playing field

Scope:
- Bring relevant stakeholders together to clarify the meaning of an 'equal level playing field', define which domains are included, and identify the bottlenecks experienced by different stakeholders and their underlying reasons
- Benchmark regulatory practices with other sectors and countries to extract best practices
- Define/develop different marketing authorisation routes, complemented by guidelines on when specific routes apply.
- Leverage the national expert network (action group 2) to advise stakeholders on selecting the most appropriate authorization pathway
- Establish a fair competitive environment for academic and pharma ATMP production through concrete agreements

Deliverables / KPIs:
- Comparative analysis with best practices of ATMP regulations in other countries and relevant sectors
- Established agreements between academia and pharma for ATMP production with clear guidelines incl. different market authorisation routes
- Monitoring system for compliance and adoption

Examples of ongoing initiatives:
- RSNN SIG ATMP
- Oncode Accelerator
- Toekomstbestendig stelsel geneesmiddelen
- Cure4life
- AGORA
- ODAP
- Innovative Health Initiative

Critical interdependencies with other action groups
- Link to action 2.1: the expertise centre/panel of action 2.1 can be used to guide on market authorisation routes

Detailed action charters

6 Communication and advocacy

Central communication platforms

Unified voice and single point of contact (SPOC) for advocacy and awareness

Detailed action charters

6.1 Unified voice and SPOC

Scope:
- Conduct horizon scanning to identify and prioritise common interests and challenges in the ATMP landscape
- Develop a widely supported national strategy that aligns stakeholders around shared priorities/objectives
- Act as a unified voice for policymakers, the public, and national/international stakeholders to communicate the national vision and common interests
- Act as SPOC for policymakers, society, national and international stakeholders
- Create a positive public and stakeholder perception of ATMPs through targeted advocacy and awareness campaigns.

Deliverables / KPIs:
- National ATMP strategy
- Established SPOC
- Recognised and trusted unified voice/SPOC for government, policymakers and the public
- Advocacy and awareness plan

Examples of ongoing initiatives:
- DARE-NL
- CURE4life
- Samenwerkende Gezondheidsfondsen
- HollandBio
- RegMed XB
- NACCG (community genetics)
- VIG
- NVGCT
- AGORA
- Health-RI
- RSNN SIG ATMP
- Alliance for Regenerative Medicine
- Joint4ATMP
- EATRIS
- RVO
- Helpdesk Regeneratieve Geneeskunde (UMCU)
- German national ATMP strategy
- ATMP-Sweden
- Danish ATMP strategy

Critical interdependencies with other action groups
- Link to action 3.2: the national strategy from action 6.2 is required as input to ensure alignment of collab and BMs with national objectives

Detailed action charters

6.2 Central communication platform

Scope:
- Set up a central communication platform accessible to all stakeholders, including the wider public.
- Stimulate information sharing and interaction between all stakeholders to enhance transparency and collaboration

Deliverables / KPIs:
- Launched central communication platform
- Strategy to ensure active participation and uptake of the platform to Increase communication between stakeholders

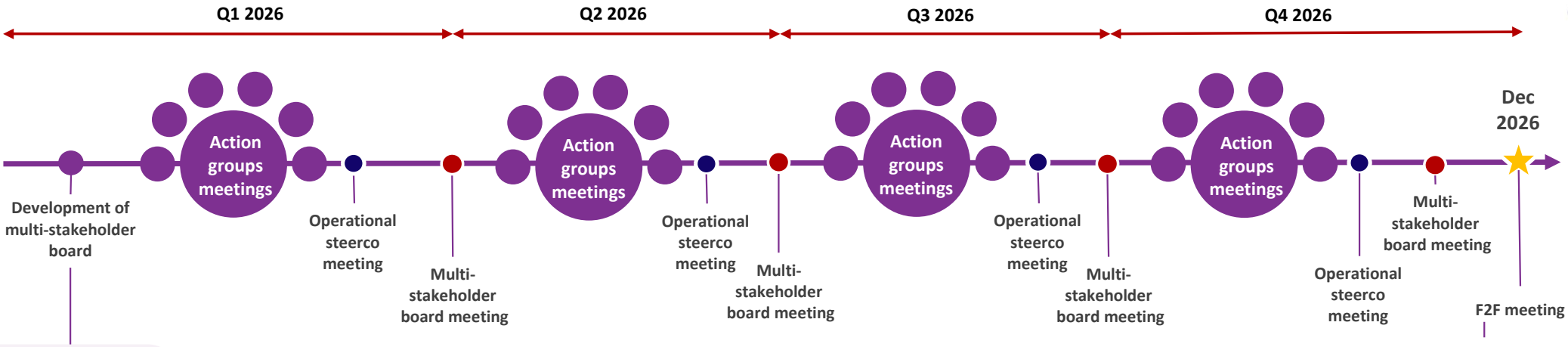
Examples of ongoing initiatives:
- DARE-NL
- CURE4life
- Samenwerkende Gezondheidsfondsen
- HollandBio
- RegMed XB
- NACCG (community genetics)
- VIG
- NVGCT
- AGORA
- Health-RI
- RSNN SIG ATMP
- Alliance for Regenerative Medicine
- Joint4ATMP
- EATRIS
- Helpdesk Regeneratieve Geneeskunde (UMCU)

Critical interdependencies with other action groups:

Phase IV: Excecution
Launch and implementation of ATMP-NL

The retro planning for the implementation of the ATMP-NL Hub action plan

The following meeting calendar will be followed to ensure timely execution of the deliverables in 2026:



Working group 7 meeting to decide on the composition of the multi stakeholder board

- In parallel **hold 4-6 action group meetings per action group in y1** on the prioritised actions, involving all relevant stakeholders
- **Quarterly operational steerco** meeting to align between action group leads
- **First multi-stakeholder board meeting** to validate the action charters and implementation approach
- **Quarterly multi-stakeholder board meeting** to maintain an overview of the strategy, objectives and direction of implementation

Event to update ATMP stakeholders on the status of the action groups

ATMP-NL

HUB FOR ADVANCED THERAPY MEDICINAL PRODUCTS

www.ATMP-NL.nl is now live

Participants include			
Amsterdam UMC	iCAT	Nierstichting Nederland	Rom Utrecht Region
AstraZeneca	Inspectie Gezondheidszorg en Jeugd (IGJ)	NKI -AVL	Sanquin
Biotech Booster	Involv	Novartis	Spierfonds
Bristol Myers Squibb	Johnson & Johnson	NVHP	Spierziekten Nederland
Centrale Commissie Mensgebonden Onderzoek (CCMO)	Kidnie	Oncode Accelerator	Stichting Lygature
College ter Beoordeling van Geneesmiddelen (CBG)	KuiperCompagnons	Orchard Therapeutics	UMC Utrecht
Cure4life	KWF	Patiëntenvereniging voor Stofwisselingsziekten	UMCNL
DARE-NL	Leijnse Artz	Prinses Beatrix Spierfonds	Uniqure
Diabetes Fonds	LentiCure	Prinses Máxima Centrum	Universiteit Utrecht
EATRIS	Leiden University Medical Center	Radboudumc	Vereniging Innovatieve Geneesmiddelen
Erasmus MC	Maastricht University	RARE-NL	Vos de Boer & Partners
Galapagos	Medace	RegMed XB	VSOP- Patientenkoepel voor zeldzame aandoeningen
Gilead | Kite	Ministerie van Economische Zaken	ReumaNederland	ZonMw
Hartstichting	Ministerie van Volksgezondheid, Welzijn en Sport	Rijksdienst voor Ondernemend Nederland (RVO)	Zorginstituut Nederland
Hematon	NecstGen	RIVM (BGGO)	Zorgverzekeraars Nederland
hollandbio	NFK	Roche	