Shaping the potential of a Dutch ATMP network

Report of the RSNN SIG Advanced Therapies and FAST workshop on 11 June 2024

Colophon

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Executive summary

On 11 June 2024, a multistakeholder workshop was organised by the Regulatory Science Network Netherlands (RSNN) special interest group (SIG) Advanced Therapies and Centre for Future Affordable Sustainable Therapy Development (FAST). The aim of the meeting was to investigate the need for a national ATMP network in the Netherlands, including objectives, activities, relevant stakeholders, and governance. This hypothetical network was given the working title 'ATMP-NL'.

Participants of the multistakeholder workshop expressed a clear need for a national ATMP network. Such a network should facilitate sustainable patient access to ATMPs by addressing fragmentation of the Dutch ATMP field, specifically through 1) maintaining an overview of existing initiatives and information, 2) acting as a knowledge-exchange platform that connects stakeholders, and 3) facilitating collaboration on specific topics. Importantly, alignment with existing ATMP-related initiatives in the Netherlands should be carefully considered to avoid overlap and ambiguity of roles and responsibilities. In addition, a national network should represent the Dutch ATMP field internationally and facilitate international collaboration with, for example, similar initiatives outside the Netherlands. Participants stressed the importance of having all stakeholders involved in such a network, establishing trust between stakeholders, and creating a safe environment to share knowledge and experience.

Based on the learnings from the workshop, the following recommendations concerning the establishment of a national ATMP network (i.e., an 'ATMP-NL') were formulated:

- ✓ Create a working group with a broad stakeholder representation, at least in line with the representation during the workshop, to establish the mission, vision, and governance of the network. These discussions should consider the learnings described in this report, to avoid duplication of efforts. Importantly, the working group should *also* include representatives of the existing ATMP-related initiatives including, but not necessarily limited to, DARE-NL; the National Growth Fund initiatives Biotech Booster, Oncode Accelerator, and RegMed XB; the Patient Platform Gene and Cell Therapy; and the RSNN SIG Advanced Therapies. A neutral party in the Dutch life sciences landscape should lead this effort (e.g., FAST).
- ✓ Create an agenda for the network based on input from the Dutch ATMP field.
- ✓ Involve EATRIS and funders such as the Association of Collaborating Health Foundations ('Vereniging Samenwerkende Gezondheidsfondsen' [SGF]), Health~Holland, NWO, the Netherlands Enterprise Agency (RVO), and ZonMw, to highlight opportunities for funding that can further strengthen the Dutch ATMP field.
- ✓ Launch the Dutch ATMP network at a national multistakeholder meeting that is focused on getting to know all network partners and stakeholders.
- ✓ Liaise with related international initiatives to seek collaboration and avoid duplication of efforts. Examples of such international initiatives are ATMP Engage (United Kingdom), ATMP Sweden, at.las (Belgium), Cell and Gene Therapy Catapult (United Kingdom), EuroGCT (Europe-wide), JOIN4ATMP. Alignment is essential given the broader European and international context of ATMP development, regulation, and use, including important developments such as the revision of the European pharmaceutical legislation and the new regulations on health technology assessment (HTA) and substances of human origin (SoHO).

Executive summary in Dutch

Op 11 juni 2024 werd een multi-stakeholderbijeenkomst georganiseerd door de Regulatory Science Network Netherlands (RSNN) special interest group (SIG) Advanced Therapies en het Centre for Future Affordable Sustainable Therapy Development (FAST). Het doel van de bijeenkomst was om de behoefte aan een nationaal ATMP-netwerk in Nederland te onderzoeken, inclusief doelstellingen, activiteiten, relevante belanghebbenden en governance. Dit hypothetische netwerk kreeg de werktitel 'ATMP-NL'.

Deelnemers aan de multi-stakeholderworkshop gaven duidelijk aan dat er behoefte is aan een nationaal ATMP-netwerk. Een dergelijk netwerk zou duurzame toegang van patiënten tot ATMP's moeten faciliteren door de versnippering van het Nederlandse ATMP-veld aan te pakken. Dit kan gedaan worden door 1) een overzicht te onderhouden van bestaande initiatieven en informatie, 2) te fungeren als een kennisuitwisselingsplatform dat belanghebbenden verbindt, en 3) samenwerking te faciliteren rond specifieke onderwerpen. Het is belangrijk dat rollen en verantwoordelijkheden zorgvuldig worden afgestemd op bestaande ATMP-gerelateerde initiatieven in Nederland om overlap en onduidelijkheid te voorkomen. Bovendien zou een nationaal netwerk het Nederlandse ATMP-veld internationaal moeten vertegenwoordigen en internationale samenwerking moeten faciliteren, bijvoorbeeld met vergelijkbare initiatieven in het buitenland. Deelnemers benadrukten het belang van betrokkenheid van alle belanghebbenden bij een dergelijk netwerk, het opbouwen van vertrouwen tussen belanghebbenden en het creëren van een veilige omgeving om kennis en ervaring te delen.

Op basis van de uitkomsten van de workshop zijn de volgende aanbevelingen ten behoeve van de oprichting van een nationaal ATMP-netwerk ('ATMP-NL') geformuleerd:

- ✓ Creëer een werkgroep met een brede vertegenwoordiging van belanghebbenden, ten minste in lijn met de vertegenwoordiging tijdens de workshop, om de missie, visie en governance van het netwerk vast te stellen. Deze discussies zouden moeten voortborduren op de in dit rapport beschreven lessen zodat dubbel werk wordt voorkomen. Het is belangrijk dat in de werkgroep óók de bestaande ATMP-gerelateerde initiatieven vertegenwoordigd zijn, waaronder – maar niet noodzakelijk beperkt tot – DARE-NL; de Nationale Groeifondsinitiatieven Biotech Booster, Oncode Accelerator en RegMed XB; het Patiëntenplatform Gen- en Celtherapie; en de RSNN SIG Advanced Therapies. Een neutrale partij in het Nederlandse life sciences landschap zou deze werkgroep moeten coördineren, bijvoorbeeld FAST.
- ✓ Stel een agenda op voor het netwerk op basis van input uit het Nederlandse ATMP-veld.
- ✓ Betrek EATRIS en financiers zoals de Vereniging Samenwerkende Gezondheidsfondsen (SGF), Health~Holland, NWO, de Rijksdienst voor Ondernemend Nederland (RVO) en ZonMw om financieringsmogelijkheden voor de versterking van het nationale ATMP-veld te belichten.
- ✓ Lanceer het ATMP-netwerk tijdens een nationale multi-stakeholderbijeenkomst waar netwerkpartners en belanghebbenden elkaar kunnen leren kennen.
- ✓ Onderhoud contact met gerelateerde internationale initiatieven ten behoeve van samenwerking en het voorkomen van dubbel werk. Voorbeelden van dergelijke initiatieven zijn ATMP Engage (Verenigd Koninkrijk), ATMP Sweden, at.las (België), Cell and Gene Therapy Catapult (Verenigd Koninkrijk), EuroGCT (Europa-breed) en JOIN4ATMP. Onderlinge afstemming is essentieel gezien de bredere Europese en internationale context van de ontwikkeling, de regelgeving en het gebruik van ATMP's. Belangrijke ontwikkelingen daarin zijn onder andere de herziening van de Europese farmaceutische wetgeving en de nieuwe wetgeving over *health technology assessment* (HTA) en *substances of human origin* (SoHO).

Background

Advanced therapy medicinal products (ATMPs), encompassing cell therapies, gene therapies, and tissue engineered products, have great potential to treat and potentially cure diseases with unmet medical needs.[1] However, despite the rapidly advancing developments in the field and the potentially transformative nature of ATMPs, the process to patient access is challenging.[2-11]

ATMPs comprise living cells or genetic material that are intended to provide long-lasting or curative effects and require unique methods of manufacturing and/or administration. These features necessitate dedicated efforts to generate evidence of quality, safety, efficacy, and effectiveness for ATMPs to become and remain authorised. In addition, at the time of initial authorisation, limited long-term follow-up typically leaves high uncertainty about treatment effects that requires further evidence. Combined with the often high prices of ATMPs, this yields significant challenges for the current healthcare system, with low affordability and thus accessibility of these promising therapies. In addition, while the landscape of stakeholders involved in development, assessment, and use of ATMPs is highly diverse, it is also often described as highly fragmented, which further contributes to the challenge of making ATMPs available, affordable, and accessible.[2-10]

In 2023, a report commissioned by the Dutch funding organisation ZonMw provided a comprehensive overview of the Dutch ATMP landscape, the stakeholders that are involved in the development, assessment, and use of ATMPs in the Netherlands, and the hurdles they perceive.[12] In addition, the report provided recommendations to overcome or mitigate these hurdles, including a comprehensive overview of ongoing initiatives addressing specific hurdles. One recommendation pertained to the fragmented Dutch ATMP field and yet unaddressed hurdles, advising to investigate a national ATMP network that can play a central role in the dissemination of knowledge and expertise, facilitate interaction between stakeholders, and stimulate collaboration. By strengthening the position of the Dutch ATMP field nationally and internationally, such a network may contribute to timely patient access to new ATMPs.

To follow-up on this recommendation, the Regulatory Science Network Netherlands (RSNN) special interest group (SIG) Advanced Therapies and the Centre for Future Affordable Sustainable Therapy Development (FAST) organised a multistakeholder workshop in Utrecht, the Netherlands, on 11 June 2024. The aim of this workshop was to investigate the need for a national ATMP network in the Netherlands, including objectives, activities, relevant stakeholders, and governance. The hypothetical network was given the working title 'ATMP-NL'.

The RSNN SIG Advanced Therapies[i] aims to facilitate knowledge development and knowledge sharing about ATMPs and their regulation. To achieve this aim, the SIG draws on the trusted position, experience, and network of RSNN as an independent broker within the Dutch regulatory and policy field. The ATMP-specific focus allows the SIG to not only identify knowledge gaps but also formulate and facilitate actions to address perceived challenges in a unique multistakeholder setting.

FAST[ii] is a coordinating centre of expertise that provides support to therapy developers and solutions for bottlenecks in therapy development, based on research and practical testing and pioneering with case studies. FAST's goal is to make innovation and affordability go hand in hand for patient-centred therapy development.

[i] www.rsnn.nl/rsnn-special-interest-group-advanced-therapies
[ii] www.fast.nl/en/home/

Pre-workshop survey

A pre-workshop survey was sent to all registrants to gather input about the need for and the objectives of a potential national ATMP network. Based on the responses (*N* = 30), six topics were selected for the breakout sessions during the workshop: (pre-)clinical research; clinical practice and post-marketing; regulatory; pricing and reimbursement; patient engagement; and manufacturing and quality.

Workshop programme

The multistakeholder workshop was attended by approximately 80 participants, including patient representatives, healthcare professionals, academic developers, representatives from large and smaller pharmaceutical companies, representatives from contract development and manufacturing organisations, clinical trial regulators, medicine regulators, payers, representatives from other governmental organisations, consultants, funders, lawyers, other academic researchers, and representatives from other not-for-profit organisations.

After a general introduction, participants of the meeting were divided into six breakout groups. Each group consisted of about ten participants with diverse backgrounds to ensure broad representation of stakeholders and perspectives. The six groups each focused on one of the topics derived from the pre-workshop survey: (pre-)clinical research; clinical practice and post-marketing; regulatory; pricing and reimbursement; patient engagement; and manufacturing and quality. Each breakout group had approximately 45 minutes to discuss their topic. To guide the conversation, discussion leaders were provided with structured questions in advance. These questions concerned the scope and objectives of a national ATMP network, relevant stakeholders, impactful activities for the ATMP community, and how to align the network with existing initiatives.

The remainder of the report describes the learnings from the workshop and next steps. Quotes of participants are provided throughout the report to illustrate the discussions.

General conclusions multistakeholder meeting

The need for a national network: addressing fragmentation and lack of harmonisation

All six breakout groups indicated that the Dutch ATMP field around ATMPs in the Netherlands is scattered. There are multiple networks in the Netherlands that work on similar topics and goals; however, a clear overview of these networks, who is involved, and what they are specifically working on, is lacking. Stakeholders identified this organisational fragmentation as a hurdle. Moreover, participants discussed that they experience a lack of harmonisation regarding specific ATMP-related procedures, systems, and infrastructures. For example, the breakout group that focused on clinical and post-marketing activities mentioned the multitude of existing registries to collect data on the effects of therapies, each requiring time and financial investments.

This organisational fragmentation and lack of harmonisation leads to several issues. First, a multitude of scattered initiatives creates barriers regarding **stakeholder involvement** in each initiative. Experts are spread thin over multiple initiatives and need to be selective regarding their involvement. Therefore, it is challenging to bring all relevant stakeholders together while collaboration and involvement of all stakeholders is seen as essential for the success of these initiatives.

"There is no lack of knowledge, there is no lack of personnel. I think what is lacking is optimal interaction."

"We should not reinvent the wheel."

Second, the fragmentation leads to an **inefficient use of resources**, because stakeholders are unaware or poorly informed about ongoing activities and may not learn from other stakeholders' successes or failures. Stakeholders in multiple breakout groups highlighted that sharing experiences will increase efficiency. They found this important for multiple reasons. Stakeholders who rely on public resources mentioned that they have a societal obligation to make efficient use of these resources. Stakeholders from industry mentioned that efficient use of financial resources is important to remain competitive internationally.

The majority of the workshop participants agreed that there is a need for a Dutch ATMP network. Several breakout groups discussed that such a network can reduce the experienced fragmentation and address the lack of harmonisation. Stakeholders agreed that there is no need for an initiative that is similar to existing initiatives. (For an overview of existing initiatives, see ref.[12]) Instead, a new, national ATMP network should take on an overarching, connecting, and strengthening role. Some groups discussed whether an existing initiative should be expanded or whether multiple initiatives could be merged into a single larger initiative. For instance, DARE-NL, which connects academic stakeholders focussed on cancer-specific ATMPs, could be expanded to cover industry stakeholders and non-oncology ATMPs as well. However, expanding or merging initiatives was seen as challenging. Different initiatives may have their own vision and mission. Pushing one initiative forward or merging them may alienate others or create an atmosphere of competition instead of collaboration. Overall, the general consensus of the meeting was that there is a need for an independent and overarching network, which can serve to connect or coordinate existing initiatives.

Objectives and activities: mapping, connecting, and collaborating

Participants envisioned that an overarching ATMP network could have several purposes: 1) maintaining an overview of existing initiatives and information, 2) acting as a knowledge-exchange platform that connects stakeholders, and 3) facilitate collaboration between stakeholders on specific topics.

1. Maintaining an overview of existing initiatives and information

As explained before, stakeholders experience organisational fragmentation, which can be reduced by creating a **central point of information** about current initiatives and their participants. An overarching ATMP network could periodically perform a mapping exercise to create an up-to-date overview of what knowledge, experience and expertise exists in each network or initiative. Creating such an overview will help stakeholders in identifying experts to consult related to specific questions, to increase cooperation and lead to a more efficient use of resources. For example, one breakout group discussed that creating an overview of the current landscape of patient engagement in the Netherlands will help to use patient expertise more effectively.

"It's really important to have an overview of what is going on, what all the initiatives are, but also what is going on within the initiatives."

In addition to creating an overview of the different initiatives (including stakeholders), another need highlighted by participants was creating an overview of existing knowledge and guidance about processes and requirements. Existing initiatives often focus on a particular disease area or stakeholder (e.g., academia or industry). However, they may develop more general knowledge or

"We need a point where all the information can be found, like presentations that are given, but also roadmaps that have been made, etc., etc…"

guidance, which can be relevant for other initiatives or stakeholders as well. An example relates to guidance. Multiple stakeholders agreed that it is important to involve clinical trial ethics review boards, regulators, HTA organisations and payers early-on in the development process of new therapies. The entire ATMP community could benefit from sharing general insights developed through such interactions. For example, high-level learnings about reoccurring requirements or best practices could be distilled from scientific advice given to ATMP developers by regulatory authorities.

Creating an overview of existing knowledge on specific topics will help to identify gaps where knowledge or skills should still be developed. For instance, one breakout group discussed that while there are many ATMP initiatives in the Netherlands, these initiatives only cover pricing and reimbursement to a limited extent. Identifying knowledge gaps can be a first step to connect stakeholders and to facilitate collaboration on a specific topic, which are the other potential goals of a national ATMP network that were mentioned by participants.

2. Connecting stakeholders

As discussed above, it is important to learn from each other's successes and failures and to not reinvent the wheel. Participants discussed that a national network would help to achieve this by connecting people and by providing a **knowledge-exchange platform**.

"What we would like to get is to tap into the knowledge of the crowd. (…) That is the power of the network. If you try to formalize everything (…) then nothing happens, right?"

Multiple breakout groups discussed that it is important to exchange knowledge, have discussions, and ask questions or input about specific issues related to ATMPs. While people can seek formal advice or guidance (e.g., scientific advice procedures of regulators), a need was expressed to exchange knowledge more informally in a way that is "hands-on", "practical", or "action driven". Stakeholders would like to be able to approach experts with specific issues to find solutions and ask for feedback. For instance, one breakout group discussed the idea to pitch your project to a group of experts as a sort of "living business case", which can help to identify potential pitfalls in the project. Thus, stakeholders would value an informal exchange of information, instead of (or in addition to) relying on formal procedures. This is especially seen as valuable, since the development and implementation of ATMPs still includes many uncertainties that are not captured by formal guidance. A national ATMP network could facilitate this kind of informal and early interaction between stakeholders, for instance through the creation of a platform for knowledge exchange and by organising a yearly meeting.

Platform for discussion and questions (e.g., a forum, blog, or database)

Facilitating informal contact between stakeholders could be achieved through a platform that is open, available to all stakeholders (also ones outside of the current networks), and that has a low barrier for participation. Suggestions of what such a platform could look like ranged from a blog or forum to something like LinkedIn or a database with e-mail addresses that one can use to reach out to experts. A disadvantage of this approach, which was mentioned by some, is that the answers to these questions will only be available to some people within the network. Moreover,

private consultation may create a higher barrier for participation, since stakeholders may be approached with the same question multiple times, which is more burdensome than answering a question once on a public forum. Therefore, an open platform was suggested. Another advantage of an open platform would be that it is accessible to people who are not yet connected to the existing Dutch ATMP initiatives. On the other hand, a public discussion platform may lead to reluctance with some stakeholders to participate (e.g., due to sharing of sensitive information or conflicting interests).

"I know a lot about regulatory affairs. Would I be willing to give a presentation somewhere in a hospital to how do we build the dossier? I would love it. (…) So those things. (…) A general framework, expertise. (…) I think that's where industry could definitely help academia."

Yearly meeting

Besides creating a platform that facilitates connection between stakeholders, several people suggested that it would be helpful to organise a yearly meeting to exchange information. As mentioned before, participants felt like the number of meetings that are organised by different ATMP initiatives is quite overwhelming. Nevertheless, they expressed an interest in attending a yearly meeting of an overarching initiative. A yearly meeting can be used to showcase what people from the separate initiatives have been working on. Participants mentioned that such a meeting should be used to share success stories, best practices, problems they encountered, and solutions to these problems. Such a meeting can also be used to facilitate a brainstorming session where experts from diverse backgrounds can share their perspective on a particular issue.

3. Facilitating collaboration

In addition to creating a knowledge exchange platform, participants discussed that a national ATMP network should facilitate collaboration of experts from diverse backgrounds to combat some of the uncertainties associated with developing ATMPs and providing access to them.

"The aim of the meeting is to come up with a specific proposal. (…) Because otherwise you run the risk (…) of a continuous circle of talking and talking (…) I think there are a lot of people in the field (…) looking for specific answers."

Participants mentioned that an ATMP network could **organise problem solving sessions**, where experts work on a specific issue with the goal of reaching consensus and harmonisation on how to tackle the issue. As explained before, an overarching ATMP network should be action-oriented. Bringing people together to work on solutions would be one way to achieve this. Examples of topics that such problem-solving sessions could focus on are data collection or clinical trial endpoints. The problem-solving sessions that were suggested by the participants could take place during specialised smaller meetings in addition to a large overarching yearly meeting.

Stakeholders also proposed that a national network should serve the ATMP community by **creating educational material**, through setting up training programmes, for example. Other suggestions were the development of checklists to consider during ATMP development, such as an overview of costs involved, and an overview of guidelines and rules that apply to specific development pathways. For some topics, participants expressed a need to develop knowledge on the process of ATMP development and the factors that have an influence on it. For example, the breakout group on pricing and reimbursement discussed the need for an analysis of characteristics of academic and industry ATMP development pathways and the impact of these characteristics on decision-making by healthcare authorities later on.

Finally, several stakeholders suggested that a national network should take the lead in **setting up pilots or experiments** to generate and investigate alternative approaches to ATMP development and access (i.e., 'sandboxes'). The network could bring all stakeholders together and be a breeding ground for new ways of thinking and working. Participants expressed an interest in investigating and experimenting with novel approaches regarding patient engagement, stakeholder collaboration, and pricing and reimbursement.

"There is a standard of doing things. (...) But (...) maybe this platform can also generate different ideas of how to do it (...) a bit differently."

Success criteria: involvement, trust, low threshold for participation and shared goals

In general, participants were enthusiastic about connecting with each other and sharing experiences. However, they also mentioned some hurdles that could impede success. Following these discussions, recommendations were made of what is needed to make such an overarching ATMP network successful.

Every stakeholder needs to be involved and committed

In several breakout sessions, participants discussed the importance of the **involvement of all stakeholders** to bring the ATMP field forward. Participants expressed the need for expert advice and input from academia, industry, government, regulators, payers, patients, and healthcare professionals. They stressed that different stakeholders have unique contributions that could be valuable for everyone in the network. Moreover, involving all stakeholders can help to create a room for open constructive dialogue and mutual understanding. Thus, bringing all stakeholders together is seen as a prerequisite for success of a national ATMP network.

"It's quite challenging to get everyone together, and even more so on the long term. With commitment. That's really difficult, but if it succeeds, it's truly wonderful."

However, participants mentioned that it may be difficult to have all important stakeholders present at meetings. Moreover, even when everyone can be brought together, not everyone may be able to **contribute at the same level** to the network. For example, stakeholders may not be able to share product-specific knowledge or experience due to confidentiality issues. In contrast, sharing more high-level knowledge and experience about, for example, procedures, processes, and requirements may be possible and highly valuable. Additionally, participants in several groups discussed the tension that can exist between the perspectives and interests of private developers, academic developers, and regulators. Specifically, differences between academic and private drug developers were mentioned multiple times. Because both stakeholders are involved in the development of new drugs, they could be seen as each other's competition. Being (perceived as) competitors can make stakeholders hesitant in sharing information and collaborating.

Participants discussed what would be needed to overcome these hurdles towards stakeholder contribution and commitment. They discussed the importance of **establishing trust** between stakeholders and **creating a safe environment** to share knowledge and experiences. Therefore, a national ATMP network should preferably be set up by a neutral party that can act as a bridge between several stakeholders to address issues of confidentiality and sharing.

In addition, participants discussed that it must be clear to stakeholders why participating in an overarching ATMP network would be beneficial to them. One way to achieve this would be by focusing on **shared interests and goals**, which can also help to create an atmosphere of collaboration instead of competition. For instance, the group on pricing and reimbursement suggested that all stakeholders could benefit from collaborating on data collection. In a similar vein, participants discussed that another solution to overcome the hesitance towards sharing and collaborating could be to focus on overarching, instead of specific, issues. For instance, stakeholders could share insights about processes or requirements without sharing sensitive product-related information.

"So, we have to really search for the common goals and then maybe define the things that you find difficult to share, which we can share only within [specific smaller] groups."

Finally, participants discussed several existing initiatives that have successfully brought together various stakeholders and created an environment in which people were willing to share. The DARE-NL initiative was mentioned as an example of an initiative that created an open atmosphere in which a lot of information is shared, although currently this initiative is focused on oncology and not-for-profit stakeholders and excludes industry. When setting up a national ATMP network, lessons should be learned from how current initiatives have encouraged knowledge sharing and the hurdles that they have overcome.

The bigger picture: international collaboration

"The Belgians (…) bring everyone to the table. There isn't a single party you can think of that wasn't involved. It's very challenging, but they keep moving steadily forward (…). They keep understanding and talking to each other. I think it's valuable to take note of (…) the hurdles they have already overcome."

Like learning from existing Dutch initiatives, participants in all breakout groups mentioned the importance of looking at, connecting to, and **learning from international ATMP initiatives**. As explained before, participants found it important to make efficient use of resources and to not reinvent the wheel. When talking about what a national overarching ATMP network could look like, they therefore referred to existing networks in other countries, such as ATMP Engage (United Kingdom), ATMP Sweden, at.las (Belgium), Cell and Gene Therapy Catapult (United Kingdom), EuroGCT (Europe-wide). Similarly, participants mentioned that it would be useful to learn from the experience of these networks in addressing hurdles for patient access to ATMPs.

Additionally, multiple participants stressed that it is important that an overarching Dutch ATMP network creates international connections to strengthen and **represent the Dutch ATMP community**, while preserving national interests. Connecting to the international community may help to increase the Dutch stakeholders' awareness of international developments and requirements regarding regulation and patient access. In addition, an overarching Dutch ATMP network can represent the wants and needs of the Dutch ATMP community internationally, for instance towards regulatory bodies. Moreover, it may help in facilitating international collaboration.

"I think there is a lot of willingness also to collaborate more on the European level. So having a network. (…) That would be a way to also connect on the European level. Also more in a structured way."

Conclusion and next steps

In conclusion, participants of the multistakeholder workshop expressed **a clear need for a national ATMP network** in the Netherlands. Such a network should facilitate sustainable patient access to ATMPs by addressing fragmentation of the Dutch ATMP field, fulfilling at least the following three roles:

1) Maintaining an overview of existing initiatives and information.
2) Acting as a knowledge-exchange platform that connects stakeholders.
3) Facilitating collaboration between stakeholders on specific topics.

Importantly, alignment with existing ATMP-related initiatives in the Netherlands should be carefully considered to avoid overlap and ambiguity of roles and responsibilities. In addition, a national network should represent the Dutch ATMP field internationally and facilitate international collaboration with, for example, similar initiatives outside the Netherlands.

Based on the learnings from the workshop, the following recommendations concerning the establishment of a national ATMP network (i.e., an 'ATMP-NL') were formulated:

- ✓ Create a working group with a broad stakeholder representation, at least in line with the representation during the workshop, to establish the mission, vision, and governance of the network. These discussions should consider the learnings described in this report, to avoid duplication of efforts. Importantly, the working group should *also* include representatives of the existing ATMP-related initiatives including, but not necessarily limited to, DARE-NL; the National Growth Fund initiatives Biotech Booster, Oncode Accelerator, and RegMed XB; the Patient Platform Gene and Cell Therapy; and the RSNN SIG Advanced Therapies. A neutral party in the Dutch life sciences landscape should lead this effort (e.g., FAST).
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