RSNN

RSNN Annual Report 2025

January 2026

Introduction

The year 2025 marked a milestone for RSNN, celebrating its 10th anniversary. Throughout this jubilee year, dedicated efforts were made to strengthen the visibility and recognition of RSNN, both within the existing network and beyond. These activities highlighted the value, impact, and growing role of RSNN, laying a solid foundation for continued collaboration and future development.

Governance & partnerships

At the beginning of 2025, the RSNN welcomed Rick Vreman (Roche) as a new industry co-chair, after the departure of Sjaak Bot (JNJ). The RSNN Advisory Board also welcomed several new members: Patricia Otto-Terlouw (CBG-MEB) succeeding Aimad Torqui, Gideon van den Kieboom (Bayer) succeeding Huib Scheijbeler, Tinka Hogeling (Gilead) succeeding Marjon Troost, Eugenie van Lieshout (JNJ) succeeding Just Weemers, Mike Broeders (FAST) succeeding Marlous Kooijman, Michael Boele-Hensbroek succeeding Joop van Gerven (CCMO), Layla Fitoury (Sanofi) and Carolien van de Wal (MSD). Larissa De Lannoy (patient representative) left the Advisory board.

In 2025, Roche, MSD, and Sanofi were welcomed as financial partners of the RSNN. The financial governance remained unchanged, with equal overall financial contributions from the public and private partners and in-kind contribution from academia.

Activities

Annual workshop

The RSNN's 2025 annual workshop (November 18th, 2025) focused on Single Arm Trials (SATs) and we explored the promises, challenges, and impact across the pharmaceutical value chain. The session brought together a broad range of perspectives on Single Arm Trials, spanning methodological, clinical, regulatory, HTA, and patient viewpoints. Speakers discussed how surrogate endpoints, real-world data, and innovative approaches such as external or synthetic control arms can help contextualize SAT results, while also stressing the methodological uncertainties these approaches introduce. At the end of the meeting, an overview was presented of RSNN activities carried out over the past ten years, and key pioneers of RSNN were recognized and honored for their contributions over the last decade.

Expert meetings

In 2025, RSNN hosted three expert meetings. The first expert meeting, titled “Klinisch onderzoeksklimaat in Nederland: Reflectie en vooruitblik op het Nationaal Actieplan Klinisch Onderzoek”, took place on March 12, 2025. During this meeting, a group of 26 experts from a broad range of stakeholder groups came together to reflect on the National Action Plan for Clinical Research. The discussion focused on lessons learned since its introduction, current challenges in the Dutch clinical research landscape, and priorities for the future. The expert input provided valuable reflections on the implementation and impact of the Action Plan and informed ongoing dialogue on strengthening the clinical research climate in the Netherlands.

The second expert meeting was held online on September 11, 2025, and focused on the potential of the European Platform for Neurodegenerative Diseases (EPND) to support biomarker discovery and validation. The meeting brought together 31 participants from 9 different European countries, reflecting a wide range of expertise and perspectives. Discussions explored how EPND data and infrastructure could be leveraged to advance regulatory science, including opportunities and challenges related to data reuse, harmonisation, and biomarker qualification.

The third expert meeting was organised in collaboration with the Special Interest Group ATMPs and is described in more detail below.

The reports that resulted from the expert meetings can be found here.

Special Interest Group ATMPs

On July 15, 2025, the RSNN Special Interest Group (SIG) ATMPs organised an expert meeting focused on *in vivo* gene editing. The meeting consisted of a multidisciplinary panel of 32 experts to assess the current European regulatory framework for therapeutic *in vivo* gene editing, with particular attention to challenges in the transition from non-clinical to clinical development. Discussions centered on identifying regulatory gaps and developing concrete recommendations to support ongoing updates of regulatory guidance, including revisions of the *guidance on genome editing* led by the Committee for Advanced Therapies (CAT) at the European Medicines Agency (EMA). The meeting aimed to promote regulatory innovation while upholding high standards of safety and quality, ultimately supporting timely patient access to these novel therapies.

The report was shared with the CAT, and its findings were taken forward into the CAT workshop on gene editing held on September 16, 2025.

Masterclass

On December 9th, RSNN hosted its first masterclass entitled *Bridging Innovation and Regulation: The NAM's Challenge* - together with the Centre for Future, Affordable, and Sustainable Therapy development (FAST) at the Brightland Campus in Maastricht. The Masterclass was organized as an outreach activity to new audiences to give participants a clear understanding of the regulatory frameworks governing drug development in the Netherlands (and Europe), using new approach methodologies (NAMs) as a central use case. It aimed to equip (academic) researchers and start-ups with practical insight into how regulatory authorities assess and apply requirements for NAMs across clinical trials, approval, and post-marketing phases.

FIGON Dutch Medicines Summer Afternoon

During Leiden Bioscience Week in Leiden, several speakers from the RSNN network contributed to the FIGON Dutch Medicines Summer Afternoon. The session opened with an introduction to RSNN by Yvette Schipper (Lygature). This was followed by a presentation from Stan van Belkum (CCMO), who discussed the clinical research climate in the Netherlands and highlighted how an expert meeting with RSNN contributed to the development of the National Action Plan for Clinical Research. The session concluded with Francisco Hernandez (AstraZeneca, Chair of the RSNN Advisory Board), who introduced the RSNN Special Interest Group on ATMPs and explained how the 2024 meeting, which was organised together with FAST, laid the foundation for the ATMP-NL network.

FIGON Dutch Medicines Days

Parallel session

On October 8 and 9, 2025, FIGON organised the yearly Dutch Medicines Days, which were this year hosted in Leiden. On October 9, RSNN hosted a parallel session on patient access to unregistered medicines, with a focus on the regulatory and practical aspects of Compassionate Use Programs (CUPs) in the Netherlands and Europe. Chaired by Marjon Pasmooij (CBG-MEB; Utrecht University), the session brought together perspectives from regulatory authorities, academia, industry, and patient organizations to examine current early access pathways and policy developments.

The discussion highlighted the role of CUPs in bridging the gap between regulatory approval and national reimbursement, while also addressing challenges such as regulatory uncertainty, fragmentation across Europe, and declining use of these programs. Speakers emphasized the need for greater harmonization, transparency, and continuity of care to ensure equitable and timely access to innovative therapies for patients with unmet medical needs.

Plenary session

At the close of October 9, a closing panel discussion titled “Shaping the Future of Regulatory Science: Learnings from a Decade of the Regulatory Science Network Netherlands and the Launch of the European Platform” reflected on past achievements and future directions in regulatory science. The panel was led by Sjaak Bot (Lygature) and brought together key perspectives from European and national regulatory science leadership, highlighting the importance of sustained collaboration between regulators, academia, and other stakeholders.

The panel featured Ralf Herold (European Medicines Agency), Marjon Pasmooij (CBG-MEB; Utrecht University), and Sjaak Bot. Marjon Pasmooij introduced the RSNN, after which Ralf Herold presented the EMA/HMA European Platform for Regulatory Science Research, launched in March 2025, outlining its ambition to strengthen alignment and impact of regulatory science initiatives across Europe.

Highlights of 2025

New industry co-chair: Rick Vreman

As of 2025, Rick Vreman (Roche) has been welcomed as co-chair of the RSNN. He is succeeding Sjaak Bot (JNJ) as the representative of the industry stakeholder group following his retirement last year.

RSNN annual workshop 2025: *celebrating 10 years of RSNN*

The Annual RSNN workshop was organised on 18 November 2025. Contributions highlighted both the opportunities of SATs, particularly in rare diseases and areas of high unmet medical need, and the challenges. Key pioneers of RSNN were recognized and honored for their contributions.

RSNN Expert meetings 2025

Three expert meetings were held in 2025: “Klinisch onderzoeksklimaat in Nederland: Reflectie en vooruitblik op het Nationaal Actieplan Klinisch Onderzoek”, “RSNN Expert meeting ‘Potential of the European Platform for Neurodegenerative Diseases (EPND) to aid biomarker discovery and validation”, and “in vivo gene editing: regulatory framework in development”.

Plenary session FIGON DMD 2025

RSNN featured in the closing panel discussion of FIGON DMD 2025 titled “Shaping the Future of Regulatory Science: Learnings from a Decade of the Regulatory Science Network Netherlands and the Launch of the European Platform”. During the session Marjon Pasmooij and Ralf Herold, under guidance of Sjaak Bot, reflected on past achievements and future directions in regulatory science.

Status deliverables 2025

For 2024-2026 focus points for RSNN activities have been identified. To measure the impact of our actions, these focus points have been put into deliverables and formalized in the RSNN Long-term plan 2024-2026. In the paragraphs below, an overview of the status of the corresponding deliverables is provided.

Table 1. *Overview of actions and deliverables for 2025, and their status.*
☑*=status complete;* ☐*=status partially complete or in progress;* ☒*=status incomplete.*

Goals & deliverables 2025		
Goal	**Deliverable**	**Status**
1. Define regulatory science agenda	Identify opportunities RSNN role	☒ No concrete actions were taken
	Track the initiation of regulatory science research questions.	☑ The RSNN has focussed during the last years on specific regulatory science topics. This agenda has been continued.
2. Expand visibility and network	Send out 2 RSNN newsletters	☑ In 2025 RSNN newsletter has been sent in July 2025 (summer version) and December 2025 (winter version)
	Increase the # members with 10%	☐ As of January 2025, 634 members are listed for the RSNN newsletter, compared to 608 members in January 2024.
	Increase the # of followers on LinkedIn with 10%	☑ As of January 2026, RSNN has 1215 followers on LinkedIn, compared to 997 in January 2025
	Regular posting of updates via the different channels.	☑ RSNN posts regular updates on LinkedIn of its own events, or events held by partners within the network
	Increase shared communication with partners	☑ Regularly contacted communication colleagues of partners to contribute to and to share RSNN news(letters) and events.
	Organize 2 interviews	☑ Two interviews were held in 2025. One with Rick Vreman in July 2025 and one with four RSNN pioneers in December 2025.
3. Build on support "Translating Science to Practice"	Setting up a sustainable multistakeholder service model (e.g. service desk/roundtable)	☒ No concrete actions were taken regarding a multistakeholder service model due to budget limitations
	Continuous alignment FAST	☑ RSNN regularly stays in contact with FAST to align on topics such as ATMP-NL
4. Catalyze research activities	Facilitate student projects at the partners (UMCG, UU, CBG)	☐ The Annual meeting 2025 and the expertmeeting "Potential of the European Platform for Neurodegenerative Diseases (EPND) to aid biomarker discovery and validation" resulted in a written report led by a PhD-student.
	Bringing together regulatory science-PhD students in the Netherlands	☒ The number of regulatory science-PhD students in the Netherlands has been shown to be difficult to track given the large regulatory science-field. It could be considered to strengthen the connection with the regulatory science PIs to create a sort of hub-and-node system.
	Set up master program Regulatory Science	☒ No concrete actions were taken regarding a master program due to shifted priorities
	Identify new partners	☑ Roche, MSD, and Sanofi have been welcomed as new funding partners

5. Expand and strengthen public-private partnerships	Organize SIG ATMP meetings (2x / year)	☐ A SIG ATMP expert meeting was held on 15 July
6. Sustainable funding	Identify new funding partners	☑ Roche, MSD, and Sanofi have been welcomed as new funding partners
	Contracting for a minimum period of 3 years	☑ New funding agreements have been arranged for a three-years period where possible.

Impact

	Process indicators	Outcome indicators	
☑	• **Steering- and Advisory Board meetings (10x per year)**	• **2 follow-up activities** were identified with partners that build on the outcomes of RSNN activities.	☑
☑	• **Annual Workshop**	• **1 research project** was initiated aimed at addressing knowledge gaps identified by RSNN.	☑
☑	• **3 expert meetings**	• **2 outcomes of RSNN expert meetings** were discussed with policymakers (EC / Ministry of Health, Welfare and Sport) to assess feasibility and/or implementation.	☐
☑	• **DIA Europe**		
☑	• **FIGON DMD**		
☒	• **2 public consultations for policy documents**	• **1 scientific publication** in a peer-reviewed journal resulted from RSNN activities.	☒

In 2025, RSNN organized ten Steering group meetings, of which two were combined with the Advisory board (March and September). The Annual workshop, three expert meetings, a plenary session and a parallel session during the FIGON DMD were organized. In May 2024 an abstract to the DIA was submitted on “Multistakeholder Collaboration to Drive Regulatory Science in Europe” and was accepted in 2024 to be held as a session in March 2025.

The expert meeting “Klinisch onderzoeksklimaat in Nederland: Reflectie en vooruitblik op het Nationaal Actieplan Klinisch Onderzoek” was attended by the Ministry of Health, Welfare and Sport (VWS). VWS emphasized that clinical research in the Netherlands is under pressure and that it is crucial for all stakeholders to take joint action to keep the Netherlands attractive as a research country. VWS is working together with the Ministry of Economic Affairs (EZ) to promote a healthy investment and innovation climate. The strategic business plan of the CCMO and NVMETC to reform the assessment landscape in the Netherlands is welcomed by VWS as valuable input for policy development.

The expertmeeting “*in vivo* gene editing: regulatory framework in development” was organised by the SIG ATMPs and attended by a representative of the EMA CAT. The report was shared with the CAT, and its findings were taken forward into the CAT workshop on gene editing held on September 16, 2025.