



RSNN Regulatory Science Network Netherlands

Launch Special Interest Groups at RSNN

September 5th, 2022
RSNN Workshop 2022

Introduction of SIGs at RSNN

- Special Interest Group (SIG): community within a larger organization with a shared interest in advancing a specific area
- RSNN SIGs contribute to this by utilizing the established RSNN network and bundling fragmented expertise in the Netherlands and beyond
- With data-driven discussions, the SIGs bring together this expertise, identify knowledge gaps, and enable deeper insights that foster multi-stakeholder collaborations.



RSNN Regulatory Science Network Netherlands

Special Interest Groups Advanced Therapies

September 5th, 2022
RSNN Workshop 2022

SIG Advanced Therapies

- Dr. **Lourens Bloem**, Assistant Professor Clinical Therapeutics Division of Pharmacoepidemiology and Clinical Pharmacology; Utrecht University (**Co-Chair**)
- Dr. **Renske ten Ham**, Assistant Professor HTA Julius Center; University Medical Center Utrecht (**Co-Chair**)
- Members representing stakeholder groups: patients, industry, HTA, regulators, academia



SIG Advanced Therapies: Why?

- Advanced therapy medicinal products (ATMPs) are highly innovative
- Considerably different characteristics from small molecules or biologicals result in challenges for developers, regulators, HTA agencies
- Number of ATMPs stranded during (clinical) development expectedly considerable given contrast between high clinical activity and low number of products reaching patients
- Most ATMP developers are not companies but hospitals, academic facilities, and small and medium enterprises (SMEs)

SIG Advanced Therapies: Why?



REPORT OF THE RSNN EXPERT MEETING HOW TO BRING ADVANCED THERAPY MEDICINAL PRODUCTS FROM BENCH TO BEDSIDE: THE LOCAL HOSPITAL EXEMPTION PROCEDURE VERSUS EMAS' CENTRALISED AUTHORISATION

On 10 March 2021, an RSNN expert meeting was held to discuss 'The route for Advanced Therapy Medicinal Products from bench to bedside: the local hospital exemption procedure versus the EMA centralised authorisation'. Advanced Therapy Medicinal Products (ATMPs) form a new group of drugs including somatic cell therapy, gene therapy and tissue engineering. Although ATMPs have only found their way into the clinic in recent years, this innovative group of drugs is considered to hold great promise for a range of future treatments. As a rule, a European marketing authorisation granted by



Mission & Vision

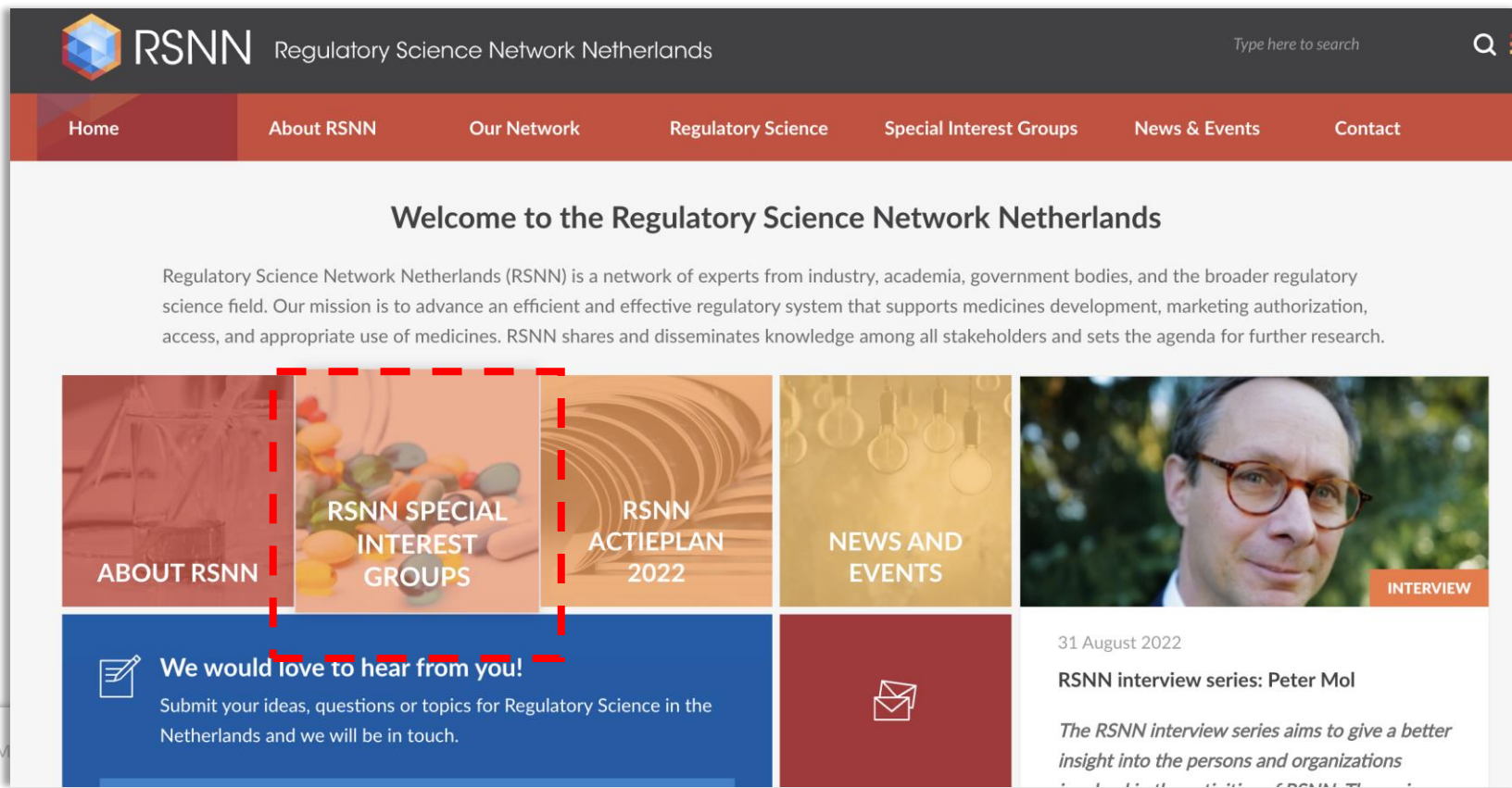
- Patient access to innovative, advanced therapies by addressing hurdles
- Aim: identify knowledge gaps and actions to address challenges perceived by stakeholders in ATMP development and assessment
- Address important questions related to ATMP development in a bottom-up fashion, by bringing together public and private parties
- Objectives met if these therapies have become an integral part of the drug development landscape

Activities & Deliverables

- Website is reference point for network, information & documentation
- Meet twice a year around a specific topic
- Discussions are data-driven, e.g., dossier and qualitative research
- Outcomes:
 - ▶ Research questions to address specific challenges
 - ▶ Actionable next steps for stakeholders

Research should inform next meetings


Activities & Deliverables




The image shows a screenshot of the RSNN website homepage. At the top, there is a dark grey header with the RSNN logo (a blue cube) and the text "RSNN Regulatory Science Network Netherlands". To the right of the header is a search bar with the placeholder text "Type here to search" and a magnifying glass icon. Below the header is a red navigation bar with the following menu items: "Home", "About RSNN", "Our Network", "Regulatory Science", "Special Interest Groups", "News & Events", and "Contact".

Welcome to the Regulatory Science Network Netherlands


Regulatory Science Network Netherlands (RSNN) is a network of experts from industry, academia, government bodies, and the broader regulatory science field. Our mission is to advance an efficient and effective regulatory system that supports medicines development, marketing authorization, access, and appropriate use of medicines. RSNN shares and disseminates knowledge among all stakeholders and sets the agenda for further research.




ABOUT RSNN




RSNN SPECIAL INTEREST GROUPS




RSNN ACTIEPLAN 2022




NEWS AND EVENTS



INTERVIEW



We would love to hear from you!
Submit your ideas, questions or topics for Regulatory Science in the Netherlands and we will be in touch.



31 August 2022

RSNN interview series: Peter Mol

The RSNN interview series aims to give a better insight into the persons and organizations involved in the activities of RSNN. The series





RSNN Regulatory Science Network Netherlands

Vereniging
Innovatieve
Geneesmiddelen

$\frac{c \ B \ G}{M \ E \ B}$



Holland
BIO



Universiteit Utrecht

lygature
pioneering medicine.
together.