Summary of the 2025 IPAC-RS Nasal Innovation Forum and Audience Feedback

In September 2025, the International Pharmaceutical Aerosol Consortium on Regulation & Science (IPAC-RS) held its first **Nasal Innovation Forum (NIF).** Over 140 individuals from more than 50 life-sciences companies and other organizations participated in the 1.5-day discussions. The Forum brought together leading voices from industry, academia, and regulatory agencies to explore the latest in nasal drug and biologics delivery. Most attendees hailed from the US, but some came from as far as Europe and Japan.

As can be seen from the program (see Table 1), a diverse mix of themes and perspectives addressed a wide range of topics, from device design, to manufacturing, quality, and regulatory considerations, to innovative trends, clinical and patient perspectives. Additionally, valuable networking and further learning took place during breaks and social events.

At the conclusion of the Forum, the audience was asked to provide feedback, which is summarized below.

Audience's View of Forum's Strengths

The IPAC-RS NIF Organizing Committee was delighted to learn that the 2025 Forum was rated highly. Every score was **7 or above (out of 10)**, and **100% of respondents** said they would attend future forums (see Table 2).

According to the responses, of particular value were:

- High-quality scientific talks;
- Relevant, forward-looking topics;
- A strong balance of discovery, CRO expertise, and device innovation;
- Opportunities to connect with peers across the nasal drug development ecosystem.

Overall Impressions and Trends

Participants shared suggestions across several key areas, including ways to enhance networking opportunities, improve session formats, and provide more interactive discussions. These ideas reflect a strong desire for deeper engagement and practical takeaways.

Attendees valued the scientific depth of the sessions — mechanistic insights, formulation considerations, analytical progress, and regulatory discussions. Many respondents expressed a desire for more integrated, practical guidance on converting their exploratory projects into viable products. Researchers at small and large companies as well as in academic institutions are increasingly seeking support on how to convert promising science into approvable, commercialized products for intranasal delivery.

Several delegates commented that they understand *what* needs to be measured or demonstrated scientifically, but want more structured clarity on:

- How to connect early scientific findings to device selection and engineering feasibility.
- How to translate early-stage experimental outputs into a regulatory submission strategy.
- How to anticipate the commercial pathway early enough so that device, formulation, and analytical decisions do not have to be reworked later.

This was summed up by the sentiment: **"We need help getting beyond Phase 1."** For many in the field, Phase 1 is now viewed as not just a scientific milestone, but a crucial checkpoint where device-formulation compatibility, regulatory precedent, manufacturing/scalability, quality considerations, and patient usability must all be considered and aligned.

Attendees further indicated that the community would benefit from:

- Clearer frameworks for bridging discovery-stage concepts to device architecture; Case studies showing successful transitions from first-in-human trials into pivotal programs;
- More dialogue between analytical scientists, device engineers, clinicians, and regulatory experts;
- Guidance on common pitfalls that delay Phase 2 entry—particularly around CMC expectations, human factors, and robustness of early device/formulation pairings.

Additional detailed feedback is provided in Table 3.

All this feedback will help shape future programming, with a stronger emphasis on the *end-to-end journey* from concept to clinic to commercialization. Delegates have signaled that the next frontier for this field is not more data in isolation, but greater integration — science placed in the context of real-world development and regulatory expectations.

Attendees' Preferences for the Next Forum's Dates and Location

The evaluation survey also solicited input about the audience preferences for the next NIF. Timing options included Spring and Fall of 2026 and 2027. Location options included Europe and the US East Coast, West Coast, and Southwest. A Fall 2026 session on the East Coast emerged as the top choice.

The insights gleaned from the NIF-2025 evaluation survey are being factored into the planning of the next event, to ensure NIF-2026 meets participants' expectations.

Concluding Remarks and Looking Ahead

NIF-2025 underscored a powerful theme: intranasal medical products are entering an era where **scientific depth, data integrity, and cross-disciplinary collaboration will determine success**. Opportunities in this field have never been greater. Join us, learn with us, and accelerate the availability of much-needed products to patients around the world.

Planning for the 2026 Nasal Innovation Forum has started. Stay tuned by bookmarking the IPAC-RS website, following IPAC-RS on LinkedIn, join the NIF Community, or best of all, have your company become an IPAC-RS member and help shaping the future!

For further inquiries, please contact info@ipacrs.org.

Table 1. NIF 2025 Sessions

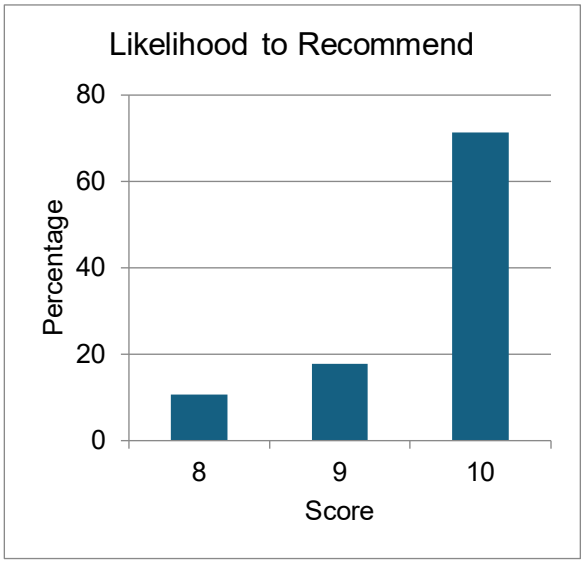
Session 1: Scientific Understanding Laleh Golshahi, VCU	
Intranasal Nanovaccines for Tuberculosis Prevention: Novel Strategies in Formulation and Delivery	Sara Maloney Norcross, RTI International
Brain Bound! Nose-to-Brain Delivery with In-situ Intranasal Gels	Vivek Gupta, St. John's University
Current and Future Nasal Pipeline: Benefits and Challenges in Drug Repurposing	Irene Rossi, Harro Höfliger

Session 2: Marrying Formulation and Device & the Role of Preclinical Models Sana Hosseini, Aptar Pharma	
Delivering for Patients: Navigating Nasal Routes for Optimal Impact	Reenal Gandhi, Aptar Pharma
How to Use Non-clinical Models in Intranasal Drug Development	Philip Kuehl, Lovelace Biomedical
Strategic Product Design for Liquid Nasal Formulations: A Target Profile Perspective	Lucas Silva, Nanopharm, An Aptar Pharma Company
A Novel Modified-Release Nasal Self-Nanoemulsifying Drug Delivery System (n-SNEDDS) for Enhanced Solubility, Retention, and Brain Targeting	Deb Das, Bayer Healthcare LLC
Intranasal Nose-to-Brain Delivery of ST266 Cell Secretome: From Non-Human Primate to Clinical Translation	Larry Brown, Noveome Biotherapeutics, Inc.
Developing Nasal Powder Products: Formulation, Delivery and Characterization	Alan Watts, Catalent Pharma Solutions
Nano-CNSTM: Patient-centric CNS Medicines	Kay Olmstead, Nano PharmaSolutions, Inc.
Development of a Loxapine Nasal Powder: Leveraging a 505(b)(2) Regulatory Pathway and PK Bridging to Enable At-Home Prevention of Acute Agitation	Paul Shields, Aptar Pharma
Panel Discussion: The Future of Nasal Drug Delivery: Trends and Innovations Moderator: Reenal Gandhi, Aptar Pharma; Panelists: Philip Kuehl, Lovelace Biomedical; Vivek Gupta, St. John's University; Robert McNeil, Renaissance Lakewood, LLC	

Session 3: Good Practices for Manufacturing and Commercialization Eric Uffman, Proveris Laboratories	
Sniffing Out the Standards: Making Sense of Evolving Nasal Spray Testing	Maria Smith, Proveris Laboratories
Commercializing Nasal Sprays: Overcoming Challenges in Manufacturing & Tech Transfer for Sterile and Non-Sterile Products	Mark Ignaczak, Catalent Pharma Solutions
Development and NDA Approval of STS101 (Dihydroergotamine Nasal Powder)	Robert Schultz, Satsuma Pharmaceuticals, Inc.
Recommendations for Demonstrating Bioequivalence of Complex Nasal Sprays: Scientific Thinking and Regulatory Research (Pre-recorded)	Susan Boc, US Food & Drug Administration

Session 4: Regulatory Perspective Julie Suman, Aptar Pharma	
Navigating Regulatory Bridging Strategies for Nasal Product Development	Rachel Ward, Kymanox
Post Approval Change Strategy	S. Prasad Peri, Eli Lilly and Company
Panel Discussion: Regulatory Roundtable Moderator: Julie Suman, Aptar Pharma; Panelists: Rachel Ward, Kymanox; Prasad Peri, Eli Lilly and Company; Bryan Newman, U.S. FDA	

Table 2. Responses to questions about overall satisfaction (Left panel) and Likelihood to recommend (Right panel). The scale of possible answers was from 1 (not satisfied or not likely to recommend) to 10 (completely satisfied and likely to recommend).



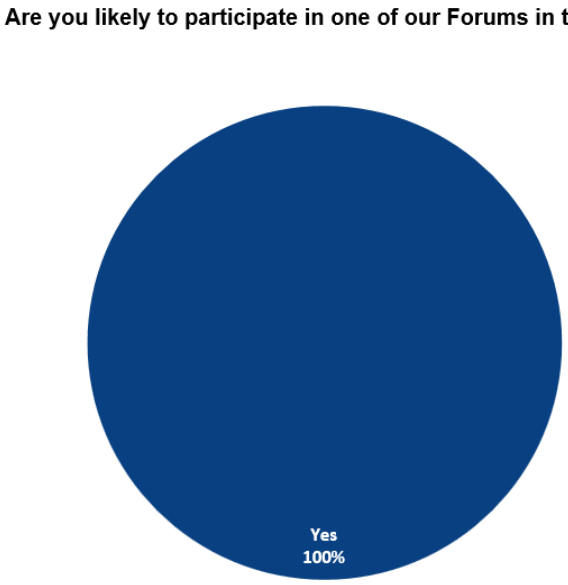


Table 3. Details of the Audience Feedback

Category	Post-Event Survey Data
Device Innovation & Design	• Many respondents noted the need for more content on nasal device design and innovation, including new non-standard devices and the science behind delivery of nasal and oral formulations. • Topics suggested include: technical details on industrial-scale production, device assembly, filling (liquid and powder), secondary packaging, and parameters affecting bioavailability.

Manufacturing, Quality & Regulatory Guidance	• There is strong interest in sessions covering manufacturing/quality perspectives, including:
	  ○ Complaint trending and improving products from VOC
	  ○ FDA 483 observations and resolutions
	  ○ Post-approval changes requiring clinical studies
	  ○ Cost considerations at various development stages (POC, Phase 1, Phase 3)
	  ○ Engagement with regulatory bodies and updates on draft guidance

Emerging Innovation & Entrepreneurship	• Attendees suggested including tracks dedicated to small organizations and emerging innovations, with short, focused presentations. • Guidance on funding sources, venture capital, and entrepreneurial pathways was requested.
Clinical & Patient Perspectives	• Participants recommended including patient advocacy groups (e.g., ALS, Parkinson's, Alzheimer's) to share perspectives on treatment needs. • Additional interest was expressed in N2B studies, bridging animal to human studies, and new protein therapeutic approaches.
Overall Forum Experience	• The mix of discovery-focused sessions, CRO expertise, and industry insights was appreciated. • Many suggested aligning sessions with ongoing work in the IPAC-RS nasal sub-team to create stronger connections between forum content and real-world applications.