



IPAC-RS Nasal Innovation Forum

Wednesday - Thursday, September 16- 17, 2026 *(In-Person Event)*

[Liberty House](#) - 76 Audrey Zapp Drive, Jersey City, NJ 07305 (See [website for Forum details](#))

Day 1 – Wednesday, September 16, 2026	
8:00 – 8:15 AM	Check In and Continental Breakfast
8:15 – 8:25 AM	Housekeeping and Rules of Engagement Mary Devlin Capizzi, Faegre Drinker, IPAC-RS Secretariat Welcome and Introduction David Wilcox, Catalent Pharma Solutions
8:25 – 9:00 AM	Patient Perspective Keynote Introduction Robin Boyd, Neurelis Inc., Director, Patient Advocacy and Strategic Alliances My Journey: Embracing Life with Epilepsy Danielle P., Neurelis Inc., Patient Ambassador Danielle is a strong advocate for herself and has a passion for making the world a better place for others with epilepsy. Danielle will talk about her journey with epilepsy and share a message of empowerment. Acute Repetitive Seizures: Addressing the Unmet Need Stuart Madden, Neurelis Inc., CSO
Session 1: Roadmap: From Discovery into the Clinic Moderator: Reenal Gandhi, Aptar Pharma	
9:00 – 9:20 AM	Engineering the Nasal Portal of Defense: Tuning Mucus Mechanics to Extend Antiviral Protein Residence Ashlee Brunaugh, University of Michigan Intranasal antiviral proteins could provide broad prophylactic protection, but rapid mucociliary clearance limits their local exposure window. We developed a mechanistic formulation framework linking polymer behavior, mucus viscoelasticity, ciliary function, and in vivo nasal retention. Across bench studies and a pilot mouse study, retention followed an operating-window response rather than increasing with polymer concentration, supporting strategies that slow clearance without eliminating functional mucociliary transport.
9:20 – 9:40 AM	Progress Towards A Nasal Klebsiella Pneumoniae Vaccine Elizabeth Norton, Tulane University I will discuss our progress towards developing a nasal Klebsiella pneumoniae vaccine. This includes the selection of protein antigens and adjuvants, evidence of strain coverage, vaccine efficacy and protective mechanisms. In addition I will discuss some of the feedback we have received from our pre-IND submission to the FDA and the resulting new data generated in response to nasal spray device selection and safety considerations.
9:40 – 10:05 AM	Key Considerations from Innovation to Clinic: Translating Nasal Formulation Development Strategy from Pre IND to CTM Paul Shields, Aptar Pharma This presentation follows the development of two representative nasal drug products, a preserved multidose liquid and a unit-dose powder, from initial product definition through manufacture of clinical trial materials. The discussion examines how the target product profile

	and critical quality attributes guide formulation, specification, analytical method, reference-standard, and manufacturing-process development. It then considers how technical batches and leading stability integrate these activities and support preparation for GMP clinical manufacture, long-term stability, and clinical-supply logistics. The presentation concludes by showing how the records, reports, and data generated during development provide the foundation for the quality sections of an IND or IMPD.
10:05 – 10:30 AM	Insights into Molecule Repurposing: A Framework for 505(b)(2) Nasal Drug Development Pathways Michael Lusty, Industry Consultant Drug repurposing can be an attractive strategy for accelerating pharmaceutical development. The 505(b)(2) pathway references existing knowledge of approved drugs for new formulations, routes of administration, or therapeutic indications. The nasal route is particularly well suited to this approach because it may offer opportunities to improve onset of action, patient convenience, systemic bioavailability, and direct nose-to-brain delivery while reducing development timelines and clinical risk. In practice, the application of the 505(b)(2) regulatory pathway for repurposed nasal drug products shows a wide divergence in the complexity of development pathways. Drawing on recent regulatory experience and selected case studies, the paper discusses an approach to characterizing and classifying the complexity of development based upon four simple pillars. Using these pillars a roadmap and model can be constructed and repurpose candidates may be ranked and benchmarked. Examples will be provided, along with an assessment of the models' accuracy.
10:30 – 11:00 AM	Coffee Break & Networking
Session 2: Device Selection Moderator: David Wilcox, Catalent Pharma Solutions	
11:00 – 11:20 AM	Insights into Intranasal Oligonucleotide Delivery: From Formulation and Process Design to Device Performance Sana Hosseini, Aptar Pharma & Silvia Matiz, Nanopharm, an Aptar Pharma company This work presents an integrated approach to evaluate the compatibility of diverse biologic modalities with Aptar Pharma's portfolio of nasal delivery devices. A model antisense oligonucleotide was selected as a nucleic acid therapeutic to investigate formulation and delivery challenges specific to this class. Several liquid and dry powder intranasal formulations were developed, employing tailored excipient systems and particle engineering approaches, alongside a robust and scalable manufacturing process to support device compatibility and performance testing. The evaluated device portfolio spans active and passive unit-dose powder delivery systems, multidose and unit-dose liquid platforms, preservative-free and advanced nose-to-brain delivery technologies, and transfer devices designed for intranasal vaccination.
11:20 – 11:40 AM	Supporting Device Selection: Anatomical Models in Intranasal Drug Delivery Laleh Golshahi, Virginia Commonwealth University Anatomically realistic nasal models, capturing total dose beyond the vestibule, let developers characterize delivery ranges for regional targeting, from dose adjustment in narrow-therapeutic-index drugs to olfactory-region access for high-MW biologics bypassing the blood-brain barrier via direct olfactory bulb pathways. This talk covers variability in olfactory bulb localization, surface coverage, and NALT (Nasal-Associated Lymphoid Tissue)-region dose relevant to immunomodulation, along with the need for models that better reflect dissolution and surface chemistry across solution, suspension, and powder formulations. It closes on a drug- and device-agnostic platform enabling data-driven device selection post-formulation, extensible from adult to pediatric combination products, and built on human-relevant anatomy and physiology rather than animal models.

11:40 AM – 12:00 PM	From Concept to Clinic: Developing a Patient-Centric and Versatile Intranasal Dry Powder Platform Alain Regard, Nemera and Maria Wilson, Therakind Limited DriDose® is a novel nasal dry powder delivery platform, originally developed by Therakind and now advanced by Nemera to industrialised manufacture. This presentation will trace how the technology evolved into a versatile platform, highlighting transformative design iterations and concepts explored throughout development. Particular emphasis will be placed on how user feedback was integrated to refine device performance, usability, and patient experience, ultimately shaping the final platform.
12:00 – 12:15 PM	Panel Discussion
12:15 – 1:30 PM	Lunch Break & Networking
Session 3: Manufacturing Best Practices Moderator: Irene Rossi, Harro Höfliger	
1:30 - 1:55 PM	From Concept to Commercialization: Strategic Decision Making for Prototyping, CMC, Device Development, and Clinical in Nasal Products Kiran Chaudhari, Hikma Pharmaceuticals Developing novel nasal drug products demands integrated decision making from concept stage in balancing scientific feasibility, regulatory framework, and commercial viability. Misalignment at any stage in formulation design, device selection, CMC strategy, or clinical planning often results in avoidable risks, extended timelines, and limited translation to late-stage development. This presentation will outline a strategic framework for advancing nasal products from concept to commercialization by focusing on pragmatic choices made early in development strategies.
1:55 – 2:20 PM	Manufacturing Nasal Powders: Key Spray Drying Process Considerations Molly Adam, Lonza This talk focuses on the design of spray drying processes for the manufacture of nasal dry powders, addressing the interplay between formulation and process variables. Key topics include solvent and solution considerations, atomization strategies, particle size control, and the thermodynamics governing droplet drying and particle formation. Particle engineering approaches will be discussed to enable powders with properties suited for efficient intranasal delivery.
2:20 – 2:45 PM	Filling and Assembly of Nasal Rescue Products Jonas Sävmarker, Orexo AB Rescue medications are life-saving treatments used in acute, life-threatening situations, including anaphylaxis, seizures, and opioid overdose, where rapid and effective drug delivery is essential for patient survival. Orexo's rescue medication portfolio includes several products, with Izipry (naloxone) the most advanced and OX640 (epinephrine) following closely behind. For nasal powder rescue products, the amorphOX platform offers a plug-and-play formulation and manufacturing approach designed to support stability and reliable performance under varied real-world conditions. This presentation gives a high-level overview of filling and assembly for rescue products, focusing on the critical manufacturing steps needed to meet a reliability target of 99.999% with 95% confidence. It also highlights the importance of quantified reliability targets, statistically justified performance demonstration, and testing under worst-case and real-world conditions.

Rapid Fire Device Showcase and Panel Discussion (7-minute presentations, followed by Q&A)

Moderator: Maria Smith, Proveris Laboratories

2:45 – 3:30 PM

- **Maximizing Olfactory Deposition With Non-invasive Nasal Delivery**

- **Alain Regard, Nemera**

Guided Stream Technology (GST) is a novel non-invasive nasal delivery platform designed to enhance olfactory targeting. In a purpose-built nasal cast, GST achieved up to 80% olfactory deposition with high reproducibility, while usability studies demonstrated robust and reliable targeting under clinically relevant conditions.

- **SMI Reimagined: Controlled Aerosol Clouds for Nasal Precision**

- **Frank Verhoeven, Resyca B.V.**

This presentation introduces a novel soft mist inhalation (SMI) approach that generates controlled aerosol clouds for precise nasal drug delivery. By controlling plume characteristics, it improves targeting within the nasal cavity and reduces variability versus conventional swirl-based nasal sprays. The product enables more efficient and reproducible delivery to local and systemic targets, such as into the olfactory region.

- **Device Technology Should Be Your First Decision, Not Your Last**

- **Selena Roberts and Manu Sharma, Rocket Science Health**

Rocket Science Health is developing a patient-first intranasal drug-delivery platform designed to achieve consistent, repeatable deposition in the olfactory region. The platform integrates human factors, an upper-nasal vantage point, and controlled fluidics to deliver a cohesive, low-force liquid stream. This presentation will highlight clinical and on-market device configurations, performance across a broad formulation-viscosity range, and targeted olfactory deposition demonstrated in nasal-cast and non-human primate studies.

- **Dianosic: Breaking Barriers with Next-Gen Intranasal, Long-Acting Resorbable Solid Dosage Forms for Respiratory and Brain Diseases**

- **Howard Levine, Cleveland Nasal Sinus & Sleep Center**

Dianosic intends to transform patients' lives through intranasal therapeutics for chronic diseases by providing a platform of long-acting, resorbable, intranasal solid-dosage forms that reduce the burden of daily medication and open new therapeutic pathways in respiratory and CNS diseases.

- **ICOone® Nasal: Inspiratory Flow-Driven Dry Powder Delivery to the Nose**

- **Måns Österberg Widerstrand, Iconovo AB**

ICOone® Nasal is a single-dose, inspiratory flow-driven device for intranasal delivery of dry powder formulations. The patient's own inspiratory flow aerosolizes and delivers the powder, combining simple operation with a compact, one-piece design. The platform supports a wide range of powder payloads and can be configured with two separate cavities, providing flexibility for combination products.

In addition, by tailoring the formulation and aerosol characteristics, ICOone® Nasal offers the potential to target different regions of the respiratory tract, from local deposition in specific areas of the nasal cavity to combined deposition in the nasal cavities and lungs through nasal inhalation.

The simple device architecture is designed for highly cost-efficient manufacturing and enables customization to specific product and formulation requirements at comparatively low cost. This presentation will introduce ICOone® Nasal and highlight how its high payload capacity, low manufacturing and customization costs, and patient-driven delivery can support the development of nasal dry powder products, including biologics and vaccines.

Q&A (10 min)

3:30 – 4:00 PM	Coffee Break & Networking
Investor Roundtable: Inside the VC Mindset Moderator: Ryan Kole, Beyond Barriers Therapeutics	
4:00 – 5:00 PM	Panelists: • Ronak Savla, Yale Ventures • Nil Gural, Polaris Partners Q&A
5:00 – 6:30 PM	Happy Hour & Networking

Day 2 – Thursday, September 17, 2026	
8:00 – 8:15 AM	Check In and Continental Breakfast
8:15 – 8:20 AM	Welcome and Introduction to Day 2 Philip Kuehl, Aptar Pharma
8:20 – 8:45 AM	A Nose for What's Next Justin Lygrisse, Kindeva
Session 4: Successful Case Studies Moderator: Philip Kuehl, Aptar Pharma	
8:45 – 9:00 AM	A Novel Drug Series Optimized to Address Cystic Fibrosis and Other CFTR Deficiency Diseases Such as Chronic Rhinosinusitis Eric Sorscher, Emory University Therapeutic enhancement of cystic fibrosis transmembrane conductance regulator (CFTR) activity has fundamentally altered the treatment landscape for cystic fibrosis (CF). Impaired CFTR function, however, is not limited to CF and has been implicated in several other airway disorders. Individuals who carry a single pathogenic CFTR allele and those who develop secondary reductions in CFTR activity appear to have an increased risk of chronic rhinosinusitis, suggesting that restoration of CFTR-mediated ion transport may offer clinical benefit in these populations. In this study, we report the development of a novel class of triazolo-thiadiazine derivatives designed for topical airway delivery and optimized to enhance the function of both wild-type and mutant CFTR. Considered alongside accumulating prior and emerging evidence, these findings support CFTR activation as a promising therapeutic approach for people with CF who are not adequately served by currently available modulators, while also highlighting potential applications in prevalent non-CF airway diseases such as chronic rhinosinusitis.

9:00 – 9:20 AM	INNA-051: Intranasal Host Defence Enhancer for Respiratory Viral Prophylaxis Christophe Demaison, ENA Respiratory Pty Ltd Respiratory viral infections remain a major driver of morbidity in at-risk populations, including the elderly, those with underlying medical conditions such as chronic lung disease, diabetes, kidney disease and cardiovascular disease, and individuals with occupational risk (e.g., first responders, military personnel and essential service workers). Yet current prevention strategies — pathogen-specific vaccines and direct-acting antivirals — offer only narrow, virus-specific protection. INNA-051 is a first-in-class, synthetic, pegylated TLR2/6 agonist designed to locally prime the nose's innate antiviral defences at the primary site of viral entry, offering virus-agnostic protection with minimal systemic exposure. Delivered as a once-weekly intranasal dry powder, INNA-051 boosts nasal innate host-defence pathways as a seasonal prophylactic that complements, rather than competes with, existing vaccines and antivirals. This presentation traces INNA-051's translation from an early liquid nasal spray to a stable dry-powder formulation delivered via the Aptar Unidose® (UDSp) single-dose nasal powder device. This dry-powder/device combination is now being evaluated in a Phase IIa seasonal prophylaxis study in adults aged 18–45 at risk of exposure through living or working in crowded environments, enrolled across the North American respiratory-virus season (up to 1,100 participants). Following a completed safety part (Part A; four-week course; n=200), the ongoing efficacy part (Part B; three-month course; n=900) evaluates the safety, tolerability and efficacy of INNA-051 in reducing the incidence, duration and severity of symptomatic infections caused by common respiratory viruses — including influenza, RSV, rhinovirus, human metapneumovirus and coronaviruses. Together, this journey — from early liquid formulation to a clinically validated dry-powder/device combination — offers a real-world case study in advancing a nasal immunomodulator through clinical proof of concept.
9:20– 9:40 AM	Engineering D-MAVs, Designable Multi-Antivirals, for Nasal Administration Michael Lipp, Decoy Therapeutics Inc.
9:40 – 10:00 AM	Breath-Propelled Intranasal Delivery of a Novel Neurosteroid James Kelly, Oragenics, Inc. The patented Oragenics intranasal delivery device provides therapeutic doses of spray-dried medication targeting brain-related conditions. The prescribed dose of medication is pre-loaded into a small, flexible, disposable device which has an oral end and a nasal end. Rather than inhaling or spraying the medication into the nose, the process of self-administered breath-propelled delivery into the nostril closes the nasopharynx (soft palate), trapping the powered preparation of medication deep within the nasal passages where it sticks to the moist mucosal lining and is rapidly absorbed by the local blood supply shared with the intracranial compartment and the brain. This method delivers small amounts of medication directly to the brain, thus producing maximum clinical benefit with minimal systemic side-effects.
10:00 – 10:20 AM	CYR-064: Developing the First Pharmaceutical Treatment for Persistent Smell and Taste Loss Rick Geoffrion, Cyrano Therapeutics, Inc.

10:20 – 10:40 AM	Pharmacokinetic Comparison of Intranasal Apomorphine Freebase and Subcutaneous Apomorphine Hydrochloride in Healthy Volunteers Kay Olmstead, TransformaBio, Inc. Apomorphine is an established rescue therapy for OFF episodes in Parkinson’s disease, but currently available subcutaneous formulations use the hydrochloride salt in an acidic solution and require injection. NT-301 is a novel intranasal dry-powder formulation of apomorphine freebase nanoparticles designed to enable rapid systemic absorption from a near-neutral formulation. This presentation will describe the development of NT-301 from formulation and device selection through first-in-human evaluation, with a focus on results from a randomized, two-period crossover Phase 1 study comparing the pharmacokinetics, safety, and tolerability of intranasal NT-301 with marketed subcutaneous apomorphine hydrochloride in healthy volunteers. The study demonstrated rapid absorption of intranasal apomorphine freebase, with a Tmax comparable to the subcutaneous reference product, supporting further dose optimization and clinical development of this needle-free approach for treatment of OFF episodes.
10:40 – 11:00 AM	Coffee Break & Networking (20 minutes)
Session 5: Regulatory Pathway Moderator: Julie Suman, Suman Pharma Solutions, LLC	
11:00 – 11:20 AM	Bridging the Gap: Turning Nasal Development Data into Regulatory Success Maria Smith, Proveris Laboratories Nasal drug delivery is expanding into new therapeutic areas, increasing the challenge of demonstrating consistent product and device performance. Regulatory expectations span FDA guidance, USP standards, product-specific guidances and evolving European requirements. The challenge is not simply knowing which tests to run, but what questions those tests answer. This presentation will translate current regulatory expectations into a practical, weight-of-evidence approach to nasal spray development and characterization. It will examine how measurements such as actuation, dose delivery, spray pattern, plume geometry, and droplet size distribution can be connected to understand product performance, identify sources of variability, and guide development decisions. Attendees will learn how to build robust characterization strategies, control critical sources of variability, and use data collectively rather than as isolated endpoints. The goal is not more testing. It is asking the right questions, generating the right evidence, and understanding what the product is actually doing.
11:20 – 11:35 AM	Environmental sustainability – EMA Perspective Claudia Vincenzi, European Medicines Agency (EMA)
11:35 – 11:55 AM	Lowering Regulatory Barriers to Adopting Sustainable Practices in Medicines and Medical Devices Steve Hoare, Medicines and Healthcare products Regulatory Agency (MHRA) Steve will give a flavour of the recent Agency approved variations with sustainability themes and the emerging policy themes to lower regulatory barriers to adopting sustainability in medical device and medicine design.
11:55 AM – 12:25 PM	Panel
12:25 PM	Closing Remarks

Nasal Innovation Forum Faculty

Molly Adam, M.S., Group Lead, Respiratory Delivery Engineering, Lonza
Ashlee Brunaugh, Ph.D., Pharm.D., Assistant Professor, Department of Pharmaceutical Sciences, University of Michigan College of Pharmacy
Kiran Chaudhari, Ph.D., Associate Director - R&D, Formulation Development, Hikma Pharmaceuticals
Christophe Demaison, Ph.D., CEO, ENA Respiratory Pty Ltd
Reenal Gandhi, Global Business Development Director, Aptar Pharma
Rick Geoffrion, President & CEO, Cyrano Therapeutics, Inc.
Laleh Golshahi, Ph.D., Associate Professor, Virginia Commonwealth University and Founder & CEO, 3DInhale
Nil Gural, Ph.D., Principal, Polaris Partners
Steve Hoare, Head of Standards and Regulatory Governance, Medicines and Healthcare products Regulatory Agency (MHRA)
Sana Hosseini, Ph.D., Principal Engineer, Aptar Pharma
James P. Kelly, M.D., Chief Medical Officer, Oragenics, Inc.
Ryan Kole, MBA, CEO of Beyond Barriers Therapeutics and Partner at VCapital
Philip Kuehl, Ph.D., Director of Science and Technology, Aptar Pharma
Howard L. Levine, MD, FACS, FARS, Director, Cleveland Nasal Sinus & Sleep Center
Michael M. Lipp, Ph.D., Chief Technology Officer, Decoy Therapeutics Inc.
Michael Lusty, Ph.D., Industry Consultant
Justin Lygrisse, Director, Research & Development, Kindeva
Silvia Matiz, MSc, Formulation Specialist, Nanopharm, an Aptar Pharma company
Elizabeth B. Norton, Ph.D., Associate Professor, Tulane University
Kay Olmstead, Ph.D., Chief Executive Officer, TransformaBio, Inc.
Måns Österberg Widerstrand, M.Sc., Director Business Development and Alliances, Iconovo AB
Danielle P., Neurelis Inc., Patient Ambassador
M. Alain Regard, MSc, Technology Product Manager, Nemera
Selena Roberts, B.Sc., PMP®, Medical Device Program Leader, Rocket Science Health
Irene Rossi, Ph.D., Respiratory Science Expert, Harro Höfliger
Ronak Savla, Ph.D., Pharm.D., MBA, Blavatnik Fellow, Yale Ventures
Jonas Sävmarker, Ph.D., R.Ph., Scientific Director, Orexo AB
Manu Sharma, Project Manager, Rocket Science Health
Paul Shields, Ph.D., Site Director, Aptar Pharma Services
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