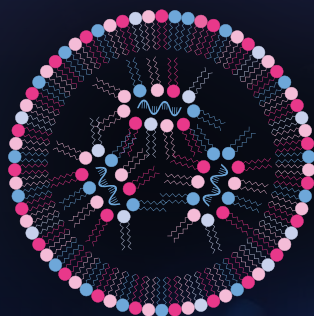


December 3, 2025 | Digital Event
8:30 - 17:00 EST

www.lnp-immunogenicity-toxicity-summit.com

REGISTER BY FRIDAY,
SEPTEMBER 12
& SAVE UP TO
\$520



4th Annual

LNP Immunogenicity & Toxicity Summit **DIGITAL**

Assessing LNP Immunogenicity & Toxicity to Effectively Monitor Clinical Safety & Ensure Regulatory Compliance for Novel Therapeutics & Vaccines

Expert Speakers Include:



Ka-Wai Wan
Senior Pharmaceutical
Assessor
Medicines & Healthcare
Products Regulatory
Agency



Zohreh Amoozgar
Principal Scientist &
Head of Lab
Sanofi



Joanna Grudzinska
Senior Lead – Drug
Metabolism &
Pharmacokinetics Project
Bayer



Shambhunath Choudhary
Pathology Therapeutic
Area & Vaccines Lead
Pfizer

■ An interactive and informative conference where people in the field share knowledge and challenges to be overcome ■

Johnson & Johnson

+1 617 455 4188 @ info@hansonwade.com

www.lnp-immunogenicity-toxicity-summit.com

[LNP Development](#)

hansonwade

WELCOME

EXPERT SPEAKERS

AGENDA

PARTNER WITH US

REGISTER YOUR PLACE

Welcome to the 4th LNP Immunogenicity & Toxicity Digital Summit

4th Annual LNP Immunogenicity & Toxicity Summit DIGITAL
December 3, 2025 | Digital Event

The recent success of lipid nanoparticle (LNP) safety has put the industry back in the spotlight. From personalized CRISPR treatments and **Capstan's** phase I trial initiation for autoimmune diseases, to **Verve's** recent clinical progress to lower cholesterol; these headlines have reignited the hope for LNPs to solve the biggest hurdles in drug delivery.

The **4th LNP Immunogenicity & Toxicity Summit** returns in December, as your **industry-dedicated virtual forum**, bringing you the key updates on pre-clinical and clinical safety assessments and assays to effectively measure and monitor LNP safety for gene and cell therapies and vaccine applications.

This year's exclusive one-day program will provide you with an deep-dive into scientific progress and technical insights into LNP mechanism of action, translational animal model approaches, and pharmacokinetic and dynamic studies to support the **prediction, dosing strategy**, and **improve clinical effectiveness** of pegylated and ionizable LNPs across all payloads.

Log on to the platform from the comfort of your home or office and connect with 80+ other LNP experts spanning non-clinical and clinical safety, from **immunology, toxicology, pharmacology**, and **bioanalytics** to learn, share, and network virtually to support the development of safer LNPs for patients faster.

“ A well-organized conference around the ‘hot’ topics for LNP immunogenicity and toxicity. The talks and discussions allowed for the audience to digest and think about the material in creative ways, and also to interact differently. Also, there were plenty of networking opportunities ”

Past Attendee, **Orna Therapeutics**

Key Benefits of Attending



Gain safety insights on immunogenicity and toxicity of lipid nanoparticles in gene therapies, vaccines, and mRNA, with real-world case studies from **Bayer, Pfizer, and Orna Therapeutics**



Explore next-generation LNPs with the latest data on degradable lipids, ligand-functionalized formulations, and extrahepatic delivery strategies that are helping to design safer, more effective therapeutics from **AstraZeneca**



Bridge preclinical to clinical success through practical guidance on translating animal model data, selecting biomarkers, and optimizing doses to reduce clinical risk, as well as **regulatory insights** from the **Medicines and Healthcare products Regulatory Agency**



Leverage cutting-edge tools as experts share how AI, predictive modeling, and integrated safety-immunogenicity assessments are transforming the way safer LNPs are developed with **Mana.Bio** and **Bayer**



Advance safer LNPs through in vitro immunology, by exploring how ligand-functionalized LNPs affect immune activation, complement responses, cytokines, and off-target effects to guide more precise therapies with **Genentech**

WELCOME

EXPERT SPEAKERS

AGENDA

PARTNER WITH US

REGISTER YOUR PLACE

Your Expert Speakers

4th Annual
**LNP Immunogenicity
& Toxicity Summit**
December 3, 2025 | Digital Event

WELCOME

EXPERT SPEAKERS

AGENDA

PARTNER WITH US

REGISTER YOUR PLACE



Ka-Wai Wan
Senior Pharmaceutical
Assessor
**Medicines & Healthcare
Products Regulatory
Agency (MHRA)**



Zohreh Amoozgar
Principal Scientist &
Head of Lab
Sanofi



Joanna Grudzinska
Senior Lead – Drug
Metabolism &
Pharmacokinetics Project
Bayer



**Shambhunath
Choudhary**
Pathology Therapeutic
Area & Vaccines Lead
Pfizer



Aparajita Dutta
Head of Toxicology
Orna Therapeutics



Momei Yao
Senior Scientist –
Immunologist
Orna Therapeutics



Soojin Kim
Senior Scientist
Genentech



Yogeve Debbie
Chief Executive officer &
Co-Founder
Mana.Bio



Eric Dane
Principal Scientist,
Advanced Drug Delivery,
Pharmaceutical Sciences,
R&D
AstraZeneca



Lily Li
Senior Director-Medical-
Accelerated R&D
Leadership Program
Eli Lilly



Haoyan Zhou
Director
Eli Lilly

“ This conference gave me great opportunities to learn wide range of knowledges and experiences of LNP immunogenicity. In addition, networking is valuable time for me to exchange thoughts among persons working same research area ”

Astellas Pharma

“ A rare opportunity to meet with experts and representatives from industry and academia, and discuss emerging issues and challenges in the field of LNP-based therapeutics ”

ReNAgade Therapeutics

Conference Agenda

Wednesday | December 3, 2025

* All timings shown in EST



08:30 Digital Networking Room Opens



Zohreh Amoozgar
Senior Principal
Scientist Lead
Sanofi

08:55 Chair's Opening Remarks

From Bench to Bedside: Immunogenicity Risk Assessment & Regulatory Considerations for LNP-Delivered Modalities



Ka-Wai Wan
Senior Pharmaceutical
Assessor
Medicines &
Healthcare products
Regulatory Agency

09:00 **Quality, Safety & Efficacy: Building a Phase-Appropriate Foundation for Regulatory Success in LNP Development**

- Understanding how quality, safety, and efficacy data requirements evolve from early clinical trials to marketing authorization, and why foundational thinking should start early for safety and approval
- Reframing regulatory frameworks as protective tools for both patients and developers, mitigating legal risk while guiding better science
- Identifying and addressing data gaps early on to ensure a comprehensive understanding of product behavior and de-risk development decisions to ensure smoother approval



Joanna Grudzinska-Goebel
Senior DMPK Project
Lead
Bayer

09:25 **Immunogenicity Risk Assessment of LNP-Delivered Nucleic Acid Modalities in Therapeutic Applications**

- Discussing how these therapies can trigger unwanted innate and adaptive immune responses, potentially impacting treatment efficacy and patient safety
- Describing strategies for product design adaptations during early development stages to minimize immunogenicity
- Outlining recommendations for defining an Immunogenicity Risk Assessment-based clinical testing strategy driven by immunogenicity consequences, including streamlined monitoring for minimal impact scenarios and comprehensive testing protocols when safety concerns are anticipated or arise



Joanna Grudzinska-Goebel
Senior DMPK Project
Lead
Bayer

09:50 **Q&A session**

Join our speakers for an interactive Q&A session, where they'll come together to answer your questions, share further insights, and expand on key themes from their presentations.



Ka-Wai Wan
Senior Pharmaceutical
Assessor
Medicines &
Healthcare products
Regulatory Agency



10:10 **Morning Break & Virtual Networking**

This session is the ideal opportunity to connect with many of the brightest minds working in the LNP around the world and establish meaningful business relationships, through randomly allocated, one-to-one meetings.

Accelerating the Development of Safer, Next-Generation Lipid Nanoparticles Through Artificial Intelligence & Preclinical Models



Yogev Debbie
Chief Executive officer
& Co-Founder
Mana.Bio

10:55 **Designing Safer LNPs With Machine Learning: Reducing Immunogenicity & Toxicity Through Predictive Modeling**

- Discussing how machine learning models are being trained to predict innate immune activation, cytokine profiles, and complement responses based on LNP composition to optimize lipid and ligand selection early in the design process
- Using algorithm-driven screening to identify novel lipid structures with minimal immune stimulation and improved biocompatibility
- Applying machine learning to triage formulations prior to *in vivo* testing, enabling earlier identification of low-risk candidates and safer design iterations



Conference Agenda

Wednesday | December 3, 2025

* All timings shown in EST

11:25 Bridging the Translational Gap in Extrapolating LNP Safety & Immunogenicity in Preclinical Models



Shambhunath Choudhary
Associate Research Fellow & Pathology Therapeutic Area Lead
Pfizer

- Exploring how rodents, non-human primates, and humans differ in complement activation, cytokine responses, and anti-PEG antibody formation to determine immunogenicity
- Discussing the limitations of rodent and monkey data in forecasting human immunogenicity and toxicity, with examples from mRNA vaccines and therapeutic LNP studies
- Exploring strategies for dose scaling, biomarker selection, and aligning immune endpoints across species to improve predictive accuracy and reduce clinical surprises



Yogev Debbie
Chief Executive officer & Co-Founder
Mana.Bio

11:50 Q&A session

Join our speakers for an interactive Q&A session, where they'll come together to answer your questions, share further insights, and expand on key themes from their presentations.



Shambhunath Choudhary
Associate Research Fellow & Pathology Therapeutic Area Lead
Pfizer



12:10 Lunch Break

Improving First-Generation LNPs & Advancing the Development of Safer Second-Generation Degradable LNPs



Aparajita Dutta
Head of Toxicology
Orna Therapeutics

13:10 Bridging Toxicology & Immunogenicity: An Integrated Approach to Advancing Safer Next-Generation LNP Therapeutics

- Outlining how Orna Therapeutic's LNP therapeutic programs focusing on linking safety assessment and immune response evaluation
- Exploring immunogenicity assessment strategies including anti-particle and anti-transgene assays, plus cytokine/chemokine biomarker analysis
- Advancing toxicology considerations for next-generation LNPs and how integrated safety-immunogenicity data informs safer design decisions



Momei Yao
Senior Scientist – Immunologist
Orna Therapeutics

13:50 Immunological Assessment in *in Vitro* Models for the Development of Safer LNPs



Soojin Kim
Senior Scientist
Genentech

- Exploring the safety implications of introducing targeting ligands into LNP systems, including antibodies and peptides as a fifth component beyond the traditional lipid architecture
- Discussing innate immune activation, complement responses, and cytokine profiles from ligand-functionalized LNPs
- Assessing potential off-target effects and unintended biodistribution caused by ligand incorporation to minimize systemic toxicity



Aparajita Dutta
Head of Toxicology
Orna Therapeutics

14:15 Q&A session

Join our speakers for an interactive Q&A session, where they'll come together to answer your questions, share further insights, and expand on key themes from their presentations.



Momei Yao
Senior Scientist – Immunologist
Orna Therapeutics



Soojin Kim
Senior Scientist
Genentech

Conference Agenda

Wednesday | December 3, 2025

* All timings shown in EST

4th Annual
**LNP Immunogenicity
& Toxicity Summit**
December 3, 2025 | Digital Event



14:30 Afternoon Break

Delivering Lipid Nanoparticles to Extrahepatic Tissues by Redesigning Formulations for Selective & Targeted Therapeutic Distribution



Eric Dane
Principal Scientist,
Advanced
Drug Delivery,
Pharmaceutical
Sciences, R&D
AstraZeneca

15:00 Overcoming Immunogenicity Challenges in Extrahepatic mRNA-LNP Delivery

- Discuss why efforts to go beyond the liver can heighten immune risk and how to design smarter LNPs that minimize it
- Review approaches to control innate immune responses when directing LNPs to organs like the heart, lung, or spleen
- Discover how administration methods and LNP composition influence immune profiles in non-hepatic targeting



Led By:
Zohreh Amoozgar
Senior Principal
Scientist Lead
Sanofi

15:25 Round Table Discussion: Navigating the Toxicity Landscape of Extrahepatic LNP Delivery

- Exploring how altered biodistribution of LNPs influences off-target accumulation and related toxicities in non-hepatic organs
- Discussing how targeting tissues outside the liver, such as lungs, spleen, or CNS introduces distinct toxicity profiles compared to hepatic delivery
- Highlighting the differences in innate immune activation and local cytokine responses when LNPs interact with immune cells or tissue-resident macrophages in extrahepatic tissues



Eric Dane
Principal Scientist,
Advanced
Drug Delivery,
Pharmaceutical
Sciences, R&D
AstraZeneca

16:00 Q&A session

Join our speakers for an interactive Q&A session, where they'll come together to answer your questions, share further insights, and expand on key themes from their presentations.



Zohreh Amoozgar
Senior Principal
Scientist Lead
Sanofi

Advancing Dose Optimization in LNP Therapeutics: Addressing Repeat Administration, Cumulative Toxicity & Maximum Tolerated Dose



Lily Li
Senior Director-
Medical-Accelerated
R&D Leadership
Program
Eli Lilly

16:20 Fireside Discussion: Overcoming Barriers in Repeat Dosing & Dose Escalation of LNP Therapeutics

- Exploring how PEGylation impacts repeat dosing, including the development of anti-PEG antibodies, their effect on clearance and efficacy, and strategies to optimize PEG amount, chain length, and alternatives to minimize immune responses
- Discussing non-clinical and clinical biomarkers that inform on cumulative toxicity, highlighting translational markers that correlate with human outcomes and guide safety margins, dose selection, escalation decisions, and long-term monitoring
- Reviewing strategies to safely increase overall dose in LNP therapeutics by mitigating key toxicities, modifying LNP composition or administration routes, and applying real-time assessment of immunogenicity and inflammation to balance efficacy with immunotoxicity management



Haoyan Zhou
Director
Eli Lilly



Zohreh Amoozgar
Senior Principal
Scientist/Lad Lead
Sanofi

16:55 Chair's Closing Remarks

17:00 End of the 4th LNP Immunogenicity & Toxicity Digital Summit

Partner With Us

Position Yourself in Front of the Pioneers Shaping Safer LNP Therapeutics Across the Value Chain

Providing you with global insights and connections from the comfort of your office, this is your opportunity to engage with senior stakeholders shaping LNP safety and efficacy, including the full form of **MHRA**, **Genentech**, and **Bayer**. This intimate digital setting has been designed for meaningful dialogue, practical conversations, and actionable takeaways with industry experts in need of your capabilities.

Partner With Us To:



Showcase Your Solutions Where They're Needed Most

Highlight your expertise in front of leading mRNA and nucleic acid therapy developers actively seeking partners to solve immunogenicity and toxicity challenges.



Form High-Value Partnerships

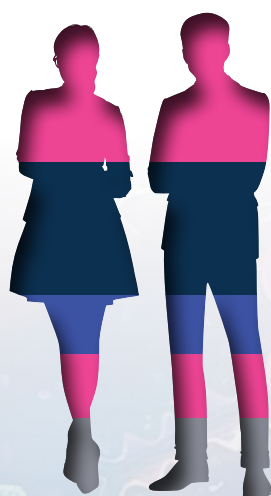
Connect with global decision-makers to build collaborations that accelerate innovation, streamline development, and bring successful LNP therapies to patients faster.



Stand Out as a Trusted Innovator

Differentiate your company as the go-to partner for advancing next-generation LNP therapies and securing future business opportunities.

Seniority of Attendees



C-Suite / Founders: 29%

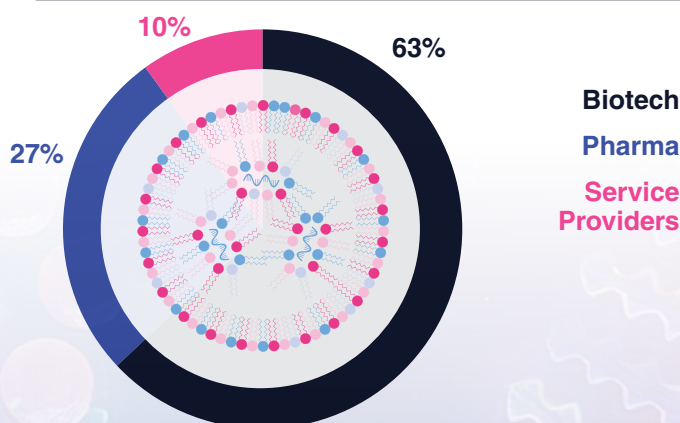
Vice President / Heads / Global Lead: 9%

Senior Director / Director: 27%

Senior Manager / Team Lead: 15%

Scientist / Researcher / Others: 20%

Type of Companies Attending



*Statistics taken from the 3rd LNP Immunogenicity & Toxicity Summit

Get Involved



Nicholas Ramovic
Partnerships Director
Tel: +1 617 455 4188
Email: sponsor@hansonwade.com

An Interactive Online Experience

The **4th LNP Immunogenicity & Toxicity Summit** is committed to delivering the high-quality insights and industry connections that our customers expect, in a format that is accessible from the comfort of your home or office.

We have created the virtual summit to satisfy the industry's need to share cutting-edge research, learn from your peers and engage in quality networking with a niche and highly selective audience to forge valuable collaborations.

To effectively facilitate this need to learn and connect, our custom-built virtual event platform will combine best-in-class platforms to deliver a seamless event experience. Accessing the platform is simple, you'll be provided with a unique link in the run up to the event that will take you directly to the online event space where you'll follow a few simple steps to set up your delegate profile and get started.

Key Features & Functionalities:

 Personalized Profile Create and personalize your profile, allowing you to connect with other event attendees, speakers, and sponsors. You'll be able to see who is attending, send messages and set up 1-to-1 meetings.	 Live Polls Contribute to sessions and have your insights heard through interactive polling features.	 Poster Session Area Explore cutting-edge research posters, where you'll be able to view the author's work, ask questions, and discuss the research with your peers.
 Search Functionality Search by keyword or filter by criteria to find relevant sessions, speakers, and attendees to maximize your event experience.	 1-2-1 Messaging Engage in direct conversations using our secure instant messaging feature, making connections and fostering collaborations with other attendees.	 Business Card Exchange Exchange your contact information with other delegates to build your professional network and extend collaborations beyond the event.

What You Can Expect from a Digital Event:

 Live Q&As with Speakers Ask your burning questions directly to our expert speakers in real-time, just as you would at a physical conference	 Audience Discussions Join smaller, informal group chats or video calls designed to spark crucial conversations around key challenges for the industry	 2+ Hours of Networking Facilitated and informal networking breaks will allow you to connect 1-2-1 with other attendees and kick start critical discussions	 Content Available Post-Event On conclusion of the event, presentations will be made available to attendees where possible
---	---	---	---

If you have any other questions about the platform, please **get in touch**

Ready to Register?

3 Easy Ways to Book



www.lnp-immunogenicity-toxicity-summit.com/take-part/register



Tel: UK: +44 (0)20 3141 8700 | US: +1 617 455 4188



Email: info@hansonwade.com



Advance Safety & Efficacy

Join the only summit dedicated to overcoming LNP immunogenicity and toxicity hurdles and gain the insights needed to design safer, more effective delivery systems for next-generation RNA, gene editing, and vaccine programs.



Stay Ahead of Regulatory & Clinical Shifts

Hear directly from the MHRA, Pfizer, Sanofi, Bayer, and leading biotech pioneers on evolving regulatory expectations, in vitro and in vivo models, and emerging strategies to de-risk LNP development.



Forge Strategic Collaborations

Engage with 80+ leaders in RNA delivery, toxicology, immunology, and formulation science to build partnerships that accelerate progress from preclinical research to clinical applications

Industry Pricing	Register & Pay by Friday, September 12	Final Price
Conference	\$979 (Save \$380)	\$1,359

Academic & Non-Profit Pricing	Register & Pay by Friday, September 12	Final Price
Conference	\$839 (Save \$520)	\$1,079

Solution Provider Pricing	Register & Pay by Friday, September 12	Final Price
Conference	\$1,539 (Save \$380)	\$1,919

Please visit the website for full pricing options or email info@hansonwade.com

*To qualify for the drug developer rate your company must have a public drug pipeline. Please visit the website for full pricing options or email info@hansonwade.com

**To qualify for the discounted rate you must be full time academic or researcher. Please visit the website for full pricing options or email info@hansonwade.com Do you work for a Not-for-Profit organization? Email us at info@hansonwade.com to inquire about attending

Team Discounts***

- 10% discount – 2 Attendees
- 15% discount – 3 Attendees
- 20% discount – 4+ Attendees

***Please note that discounts are only valid when two or more delegates from one company book and pay at the same time.

Discounts cannot be used in conjunction with any other offer or discount. Only one discount offer may be applied to the current pricing rate.

Contact: register@hansonwade.com

TERMS & CONDITIONS

Full payment is due on registration. Cancellation and Substitution Policy: Cancellations must be received in writing. If the cancellation is received more than 14 days before the conference attendees will receive a full credit to a future conference. Cancellations received 14 days or less (including the fourteenth day) prior to the conference will be liable for the full fee. A substitution from the same organization can be made at any time.

Changes to Conference & Agenda: Every reasonable effort will be made to adhere to the event programme as advertised. However, it may be necessary to alter the advertised content, speakers, date, timing, format and/or location of the event. We reserve the right to amend or cancel any event at any time. Hanson Wade is not responsible for any loss or damage or costs incurred as a result of substitution, alteration, postponement or cancellation of an event for any reason and including causes beyond its control including without limitation, acts of God, natural disasters, sabotage, accident, trade or industrial disputes, terrorism or hostilities.

Data Protection: The personal information shown and/or provided by you will be held in a database. It may be used to keep you up to date with developments in your industry. Sometimes your details may be obtained or made available to third parties for marketing purposes. If you do not wish your details to be used for this purpose, please write to: Hanson Wade Ltd, Eastcastle House, 27/28 Eastcastle Street, London, W1W 8DH, United Kingdom



+1 617 455 4188

@ info@hansonwade.com

www.lnp-immunogenicity-toxicity-summit.com

LNP Development



WELCOME

EXPERT SPEAKERS

AGENDA

PARTNER WITH US

REGISTER YOUR PLACE