RNA delivery LNP kit

Streamline payload screening

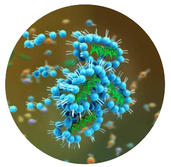
Drug delivery validation with scalable LNP technologies

cytiva

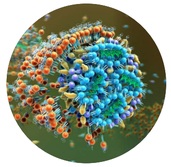
Accelerate RNA-LNP drug delivery validation

Lipid nanoparticle (LNP) carriers designed to deliver RNA are the most clinically validated drug delivery systems, protecting the nucleic acid from degradation and mediating a safe and efficient intracellular delivery. The RNA delivery LNP kit for the NanoAssemblr™ Ignite™ system and Ignite+™ system offers a pre-optimized ionizable lipid mix and prepared reagents to fast-track payload screening and RNA drug delivery validation, progressing lead candidates quickly through preclinical studies and accelerating clinical evaluation.

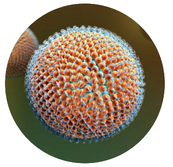
RNA-LNPs leverage endogenous cellular uptake mechanism



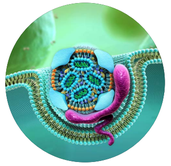
← Lipid nanoparticles contain ionizable lipids, which at low pH mediate efficient encapsulation of RNA.



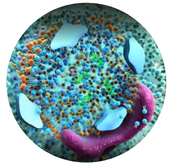
← Once formed, RNA-LNPs are neutral at physiological pH, eliminating a source of toxicity present in other RNA delivery methods.



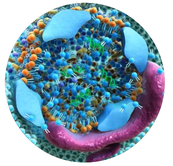
← The RNA-lipid core is surrounded by helper lipids, cholesterol, and stabilizers in the formed RNA-LNP.



← RNA-LNPs mimic low-density lipoproteins (LDL) and are then taken up through receptor-mediated endocytosis.



← Once in the endosome, ionizable lipids in the RNA-LNP respond to low pH and become cationic.



← The cationic ionizable lipids in the RNA-LNP interact with anionic lipids in the endosome and release the RNA into the cytoplasm.

Why use the RNA delivery LNP kit?

Easy to use

Confidently produce LNPs using prepared reagents and protocols, designed to validate RNA drug delivery quickly and easily without being an LNP formulation expert.

Streamline payload screening and optimization

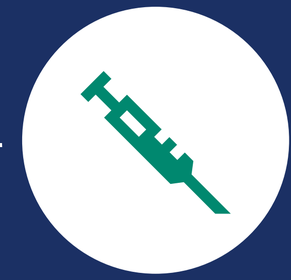
Benefit from pre-optimized ionizable lipid mix for RNA-LNP delivery, leveraging our demonstrated experience to decisively screen and fast-track lead candidates through preclinical stages.

High-quality and stability

Achieve robust LNP characterization, ensuring homogenous and reproducible nanoparticles with proven stability, providing protection against RNA degradation and long shelf-life.

Scalable LNP technologies

Advance with consistent LNP formulation on NanoAssemblr platforms using compositions that can be used to validate RNA drug delivery and include an ionizable lipid excipient that can be licensed for future clinical evaluation.



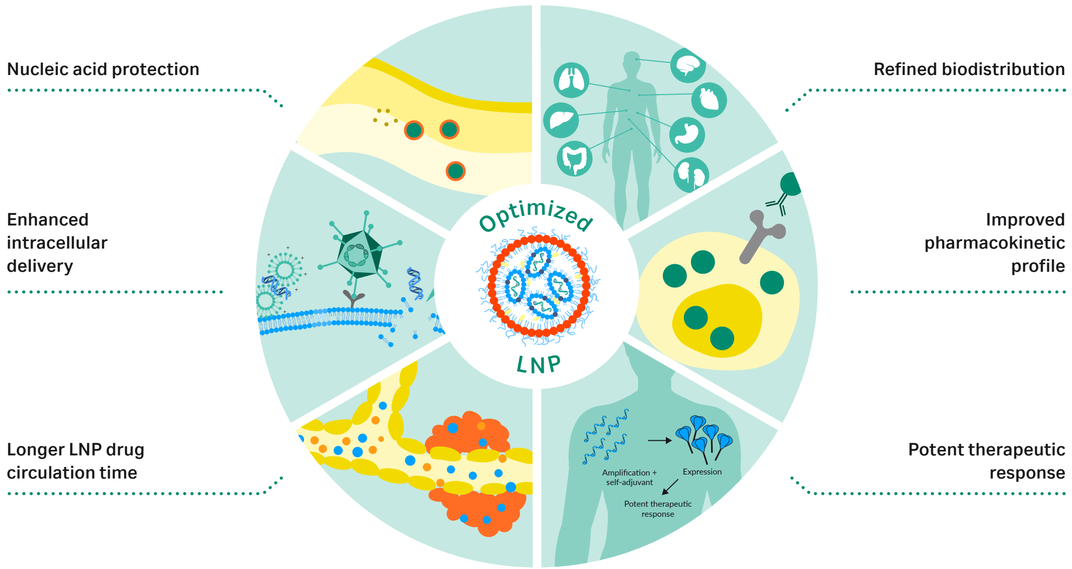
Proof of concept data for infectious disease vaccines

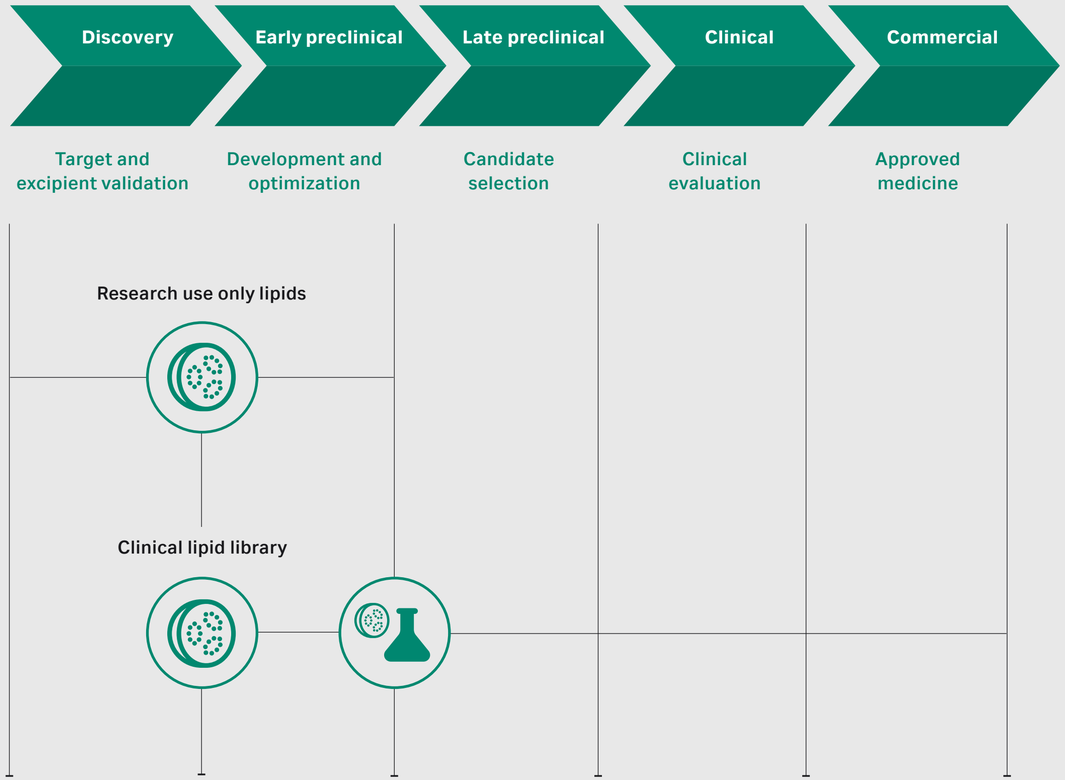
Access LNP potency data demonstrating *in vitro* protein expression and *in vivo* immunogenicity for RNA vaccine applications, accelerating vaccine development.

Lowering the lipid barrier for LNP-RNA drug delivery

Optimization of the chemical structure of the ionizable lipid, along with selecting the right stabilizer, cholesterol, helper lipid, and the ratio of each component leads to LNP formulations that allow for targeting novel applications and modalities. Choosing the right LNP formulation can significantly influence biodistribution, efficacy, and pharmacokinetic profile and enhance the overall drug's safety profile.

Developers can fast-track RNA-LNP development and streamline payload screening with the off-the-shelf Cytiva RNA delivery LNP kit, which includes ready-made compositions, buffers, and protocols, eliminating many of the laborious steps of early preclinical development. The kit, featuring the pre-optimized, scalable ionizable lipid mix, includes proof-of-concept data and protocols for RNA vaccine delivery, validated for reproducible, high-quality LNP production and stability for scalable LNP manufacturing, up to clinical and commercial production.





Transition to the clinic: scaling ionizable lipids and LNP technologies

Genomic medicine success starts at discovery. Screening and validating LNP formulations for RNA drug delivery at a small scale with nanotechnologies lowers the challenges and risk of producing consistent nanoparticles with large-scale manufacturing infrastructure for commercial production. The research-use-only Cytiva RNA delivery LNP kit offers LNP formulation with a scalable ionizable lipid ready to support the preclinical drug delivery validation and GMP clinical evaluation.

Streamline payload screening

The RNA delivery LNP kit offers easy screening of RNA payloads for physicochemical attributes and potency to fast-track lead candidate selection for RNA drug delivery.

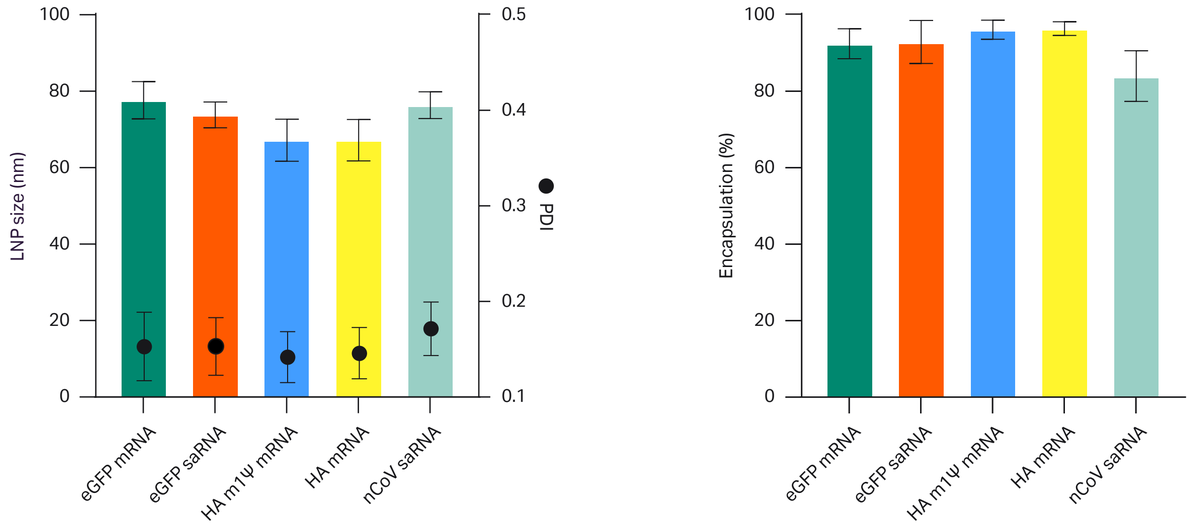


Fig 1. Graphs above show (left) the LNP size and polydispersity (PDI), and (right) the encapsulation efficiency of LNPs, prepared using the Cytiva RNA delivery LNP kit with both mRNA and self-amplifying RNA encoding for different antigens.

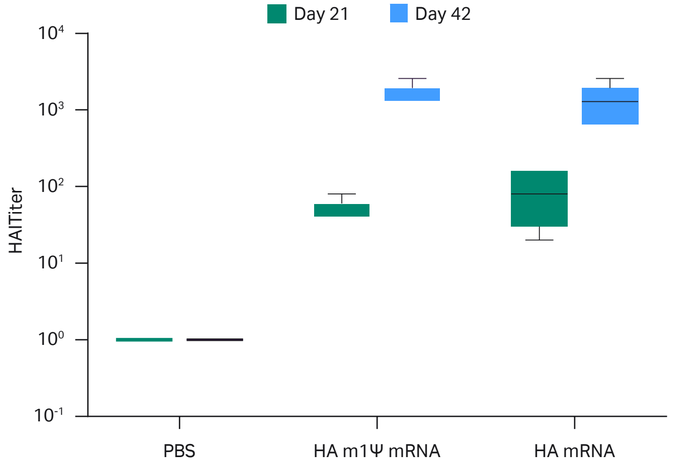


Fig 2. LNPs were prepared using the RNA delivery LNP kit and mRNA encoding for either haemagglutinin (HA) or a surface protein on the H1N1 virus. LNPs were used to immunize BALB/c mice with a primary and booster dose of 2 µg RNA on days 0 and 28 of the immunization schedule. The immunogenicity of LNPs is shown in the graph above, showing the HA inhibition titers using serum sampled on days 21 and 42.

Stable, high-quality RNA-LNP formulations

The RNA delivery LNP kit consistently produces quality LNPs that efficiently protect encapsulated nucleic acids, maintaining critical quality attributes (CQAs) and potency with long-term stability and storage capabilities.

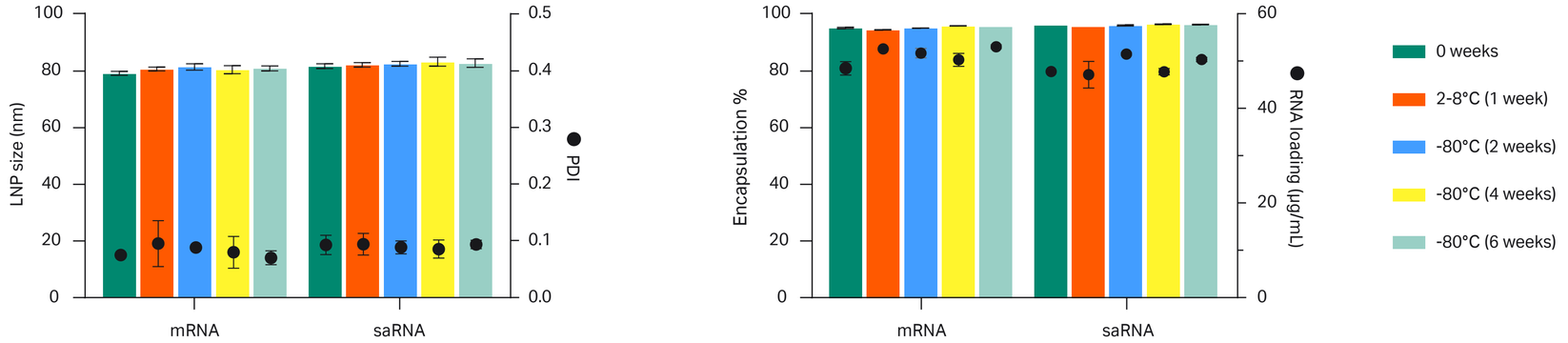


Fig 3. Top graphs show storage stability and CQA consistency of LNPs produced with the Cytiva RNA delivery LNP kit, prepared with cryopreservation buffer, over one week of storage under refrigerated conditions and six weeks of storage at -80°C.

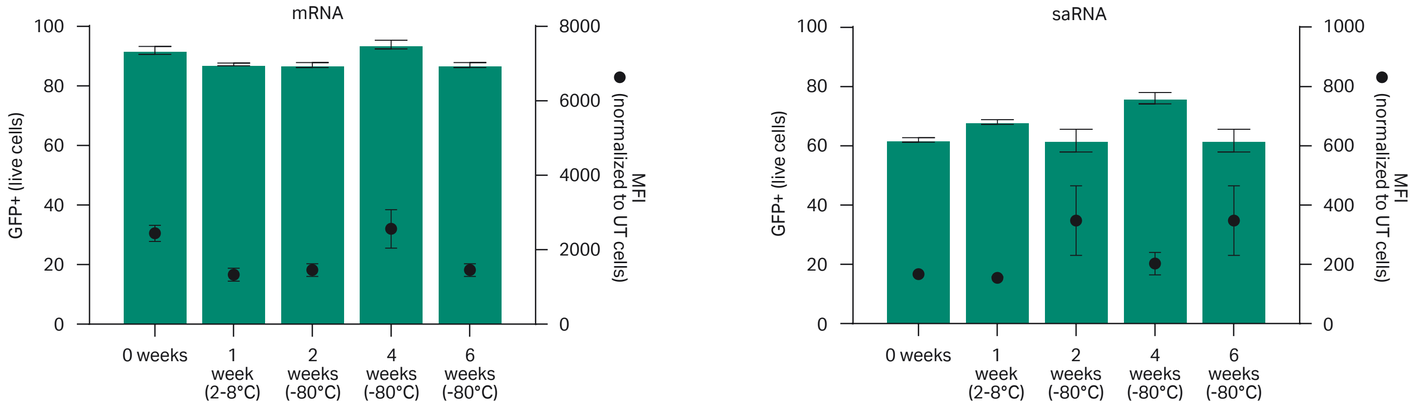


Fig 4. Lower graphs show the in vitro potency of LNPs encapsulating (left) eGFP mRNA or (right) eGFP saRNA in HEK-293 cells over one week of storage under refrigerated conditions and six weeks of storage at -80°C.

Scalable LNP technologies

Genomic medicine success starts at discovery. RNA drug delivery is validated with ionizable lipid compositions and LNP technologies at a small scale followed by LNP formulation using the NanoAssemblr NxGen™ platform for clinical evaluation and commercial production.

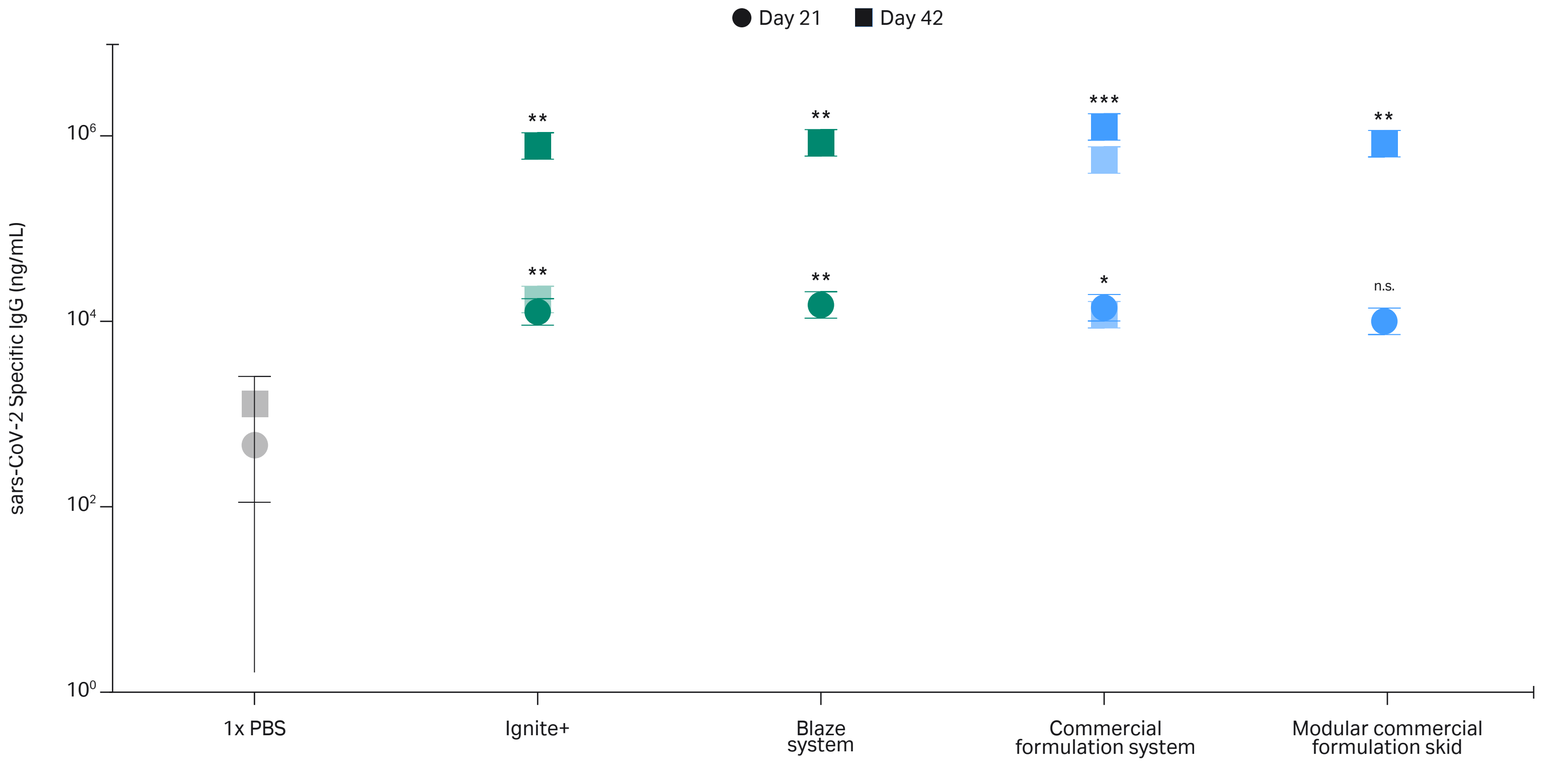


Fig 5. The graph (left) shows the immunogenicity of saRNA-LNPs prepared using NanoAssemblr NxGen technology at different scales, showing the SARS-CoV-2 spike protein specific IgG titers in serum of BALB/c mice treated with saRNA-LNPs formulated with the RNA delivery LNP kit.

Ordering information

RNA delivery LNP kit

	**RNA delivery LNP kit, 3 mL**	1002569	Lipid mix, 3 mL Formulation buffer, 6 mL Dilution buffer, 100 mL Cryopreservation buffer, 12 mL
	**RNA delivery LNP kit, 6 mL**	1002471	Lipid mix, 6 mL Formulation buffer, 6 mL Dilution buffer, 100 mL Cryopreservation buffer, 12 mL
	**NanoAssemblr Ignite system**	NIN0001	1 Instrument 2 Sample switch arms 2 Cartridge adapters
	**NxGen cartridges (up to 20 mL/min flow rates)**	NIN0061 NIN0062	100 pack 200 pack
	**NxGen cartridges (up to 20 mL/min flow rates)**	NIN0063 NIN0064	50 pack 100 pack
	**NanoAssemblr Ignite+ system**	1001413	1 Instrument 2 Sample switch arms 2 Cartridge adapters

About Cytiva

Cytiva offers a comprehensive suite of technology solutions including nucleic acid synthesis, LNP delivery systems, and an end-to-end manufacturing workflow for clinical and commercial nanomedicine production. Our support and offerings, designed for nanomedicine developers, provide the ability to scale up and scale out a range of facilities.

We are committed to a flexible, individualized approach with a global team of field application scientists and engineers to support your business. Collaborate with our BioPharma Services team and get started with a well-defined project plan, milestones, deliverables, and timeline customized to your needs and budget.

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Upstream processing

Downstream processing

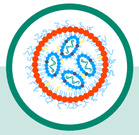
GenVoy-ILM™ delivery platform

NanoAssemblr™ instruments

ÄKTA™ systems

Supor® EKV filtration

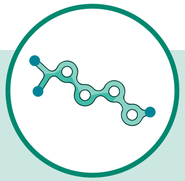
Microcel™



Lipid selection

Fit-for-purpose lipid formulation

DNA or RNA payload

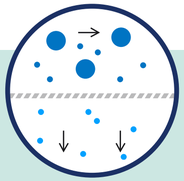


NxGen™ mixing

Self-assembly of nanoparticles with defined size and properties

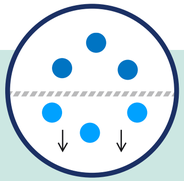
In-line dilution

Reduce proportion of solvent to stabilize nanoparticles



Tangential flow filtration (TFF)

Process nanoparticles into final drug product form



Sterile filtration

Sterilize drug product

Fill and finish

Sterilize drug product and vial

Drug product

Treat disease

aldevron

cytiva

IDT INTEGRATED DNA TECHNOLOGIES

SCIEX The Power of Precision

cytiva

Analytics

The RNA delivery LNP kits are for research use only. The composition includes an ionizable lipid excipient that can be licensed for future clinical evaluation.

cytiva.com

For local office contact information, visit cytiva.com/contact

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