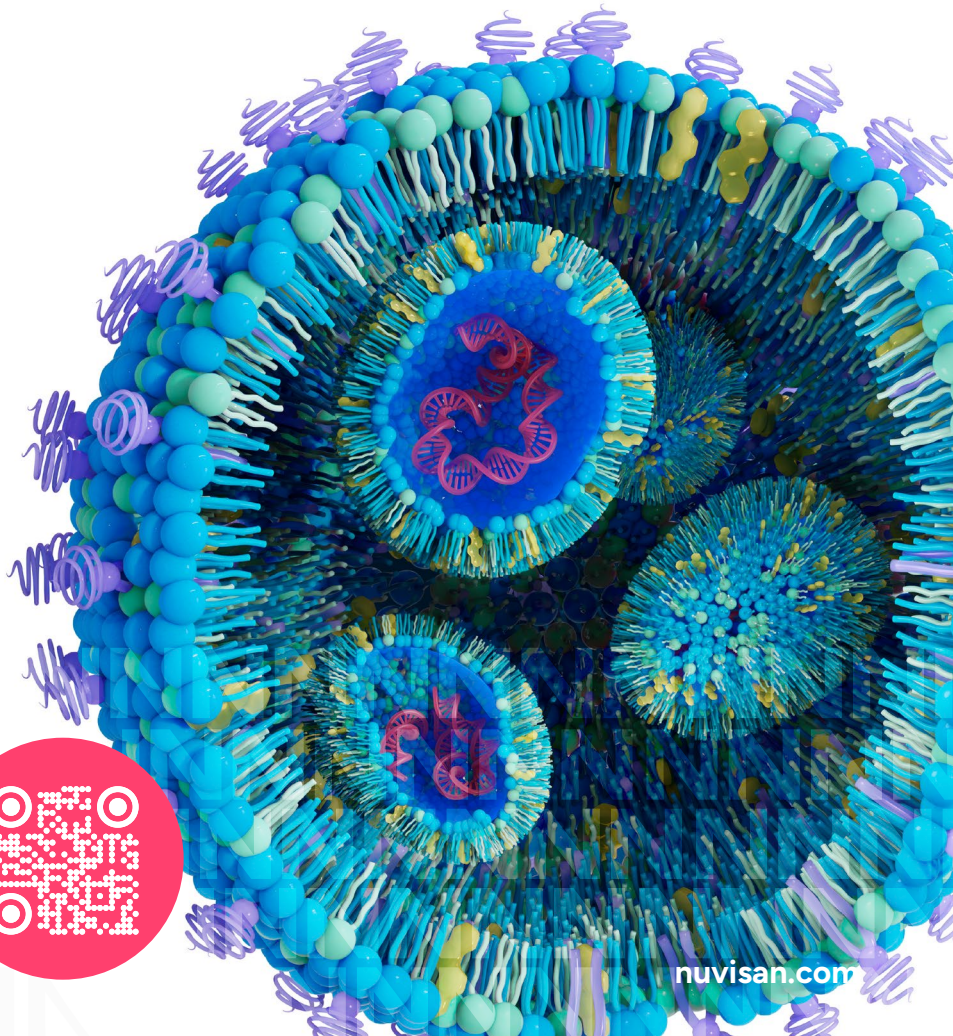
NUVISAN
The Science CRO

DRUG DISCOVERY

LNP and nucleic acid therapeutics services



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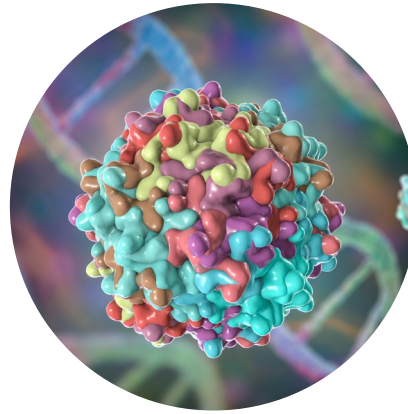
Advancing nucleic acid therapies

Accelerate the development of next-generation nucleic acid therapeutics with our gene delivery and LNP characterisation services. Generate valuable data to inform smarter decisions, with end-to-end support from analytical characterisation to in vitro and in vivo testing. We support rapid discovery and development of new therapies across vaccines, oncology, rare genetic diseases and beyond.

- **Manufacturing and quality control analysis** of LNP formulations
- **In vitro studies** to characterise LNP delivery mechanisms
- **In vivo DMPK profiling** to assess pharmacokinetics and dynamics
- **Lipid and excipient bioanalytics**, including metabolite identification and quantification
- **In vivo assessments** of biodistribution and tissue-targeting efficiency
- **Molecular and cellular analysis services** for efficacy determination
- **Comprehensive evaluation** of tolerability, safety and immune response profiles.



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Manufacturing of LNP formulations and quality control

LNP MANUFACTURING AND RADIOLABELLING

We offer flexibly scalable LNP manufacturing using advanced microfluidic mixing technique to produce high-quality unlabelled and [^{14}C]/[^{3}H]-radiolabelled LNP formulations.

- **LNP formulation:** production of LNPs using state-of-the-art microfluidic systems for precise and reproducible particle generation
- **Radiolabel incorporation:** radiosynthesis of [^{14}C]- or [^{3}H]-labelled lipid components for distribution studies
- **Radiolabelled compound certification:** verification of identity, chemical and radiochemical purity and specific activity
- **Radiochemical stability:** assessment of radiolabelled compound stability and determination of shelf life.

LNP FORMULATION CHARACTERISATION

Benefit from our comprehensive services to evaluate **LNP quality, lipid composition and payload integrity**.

- **Stability studies:** assessment of LNP stability under various conditions to achieve formulation robustness
- **Particle size and polydispersity:** measurement by dynamic light scattering (DLS) for uniformity and quality control
- **Lipid content composition:** characterisation, purity determination and quantification of of lipid components by (U)HPLC-CAD
- **RNA encapsulation and structure:** evaluation of RNA encapsulation efficiency and structural integrity using methods such as RiboGreen® assay, Cryo-EM and (U)HPLC-UV.

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Integrated LNP analysis across in vitro, PK and metabolism studies

IN VITRO LNP CHARACTERISATION

Our comprehensive **cellular analysis services**, utilising high-content imaging, support you in evaluating LNP performance in cell lines and iPSC-derived organoids.

- **Cellular uptake and delivery analysis:** characterise LNP uptake, endosomal escape and intracellular delivery using high-content imaging (HCA) in cell lines and iPSC-derived organoids
- **Transfection efficiency assessment:** quantify mRNA delivery and expression across a range of in vitro models
- **Cytotoxicity evaluation:** assess LNP-induced cellular toxicity with standardised cell line assays.

PHARMACOKINETIC AND METABOLISM STUDIES

Gain a clearer understanding of LNP delivery, clearance and metabolism by leveraging our comprehensive preclinical assessment services. Quantify the distribution and elimination of radiolabelled lipid components (total radioactivity).

- **Quantitative whole-body autoradiography (QWBA):** visualise LNP distribution in rodent models
- **In vivo pharmacokinetic (PK) studies:** evaluate LNP circulation, uptake and clearance profiles in rodents
- **Absorption, metabolism and excretion (AME) studies:** characterise LNP biotransformation and elimination pathways
- **Metabolite identification and quantification:** in-house analysis to detect, identify and measure metabolites with precision.

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Holistic LNP assessment: from delivery to mechanistic readouts

IN VIVO LNP EVALUATION

Drive your LNP and nucleic acid therapeutic programs forward with high-resolution imaging and trusted in vivo models in our AAALAC certified facility.

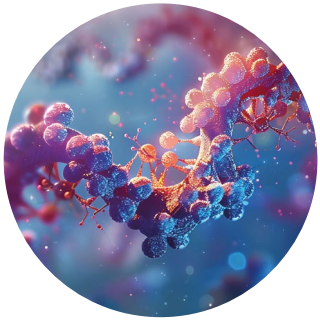
- **Biodistribution studies:** visualise and quantify RNA delivery in real time using bioluminescence (BLI) or fluorescence (FLI) imaging, or multiplexed amplicon sequencing in rodent models
- **Efficacy and pharmacodynamic studies:** demonstrate therapeutic performance and biological activity in a range of rodent models, including tumor-bearing animals
- **Vaccination studies:** evaluate immune responses in vivo, supported by ex vivo analyses such as IgG titers and ELISPOT assays
- **Gene therapy studies:** leverage advanced reporter models (including tdTomato mice) to assess gene expression, targeting efficiency and delivery success.

MOLECULAR AND CELLULAR ANALYSIS SERVICES

Our comprehensive analytical capabilities help reveal valuable insights into the biodistribution, expression and systemic impact of your LNP-mRNA therapeutics.

- **LNP-mRNA expression analysis:** quantify mRNA levels in tissues and organs using qPCR or RNA in situ hybridisation (RNAscope)
- **LNP-protein expression analysis:** measure protein expression (including luciferase) in tissues and organs via flow cytometry, ELISA or immunohistochemistry (IHC)
- **Single-cell sequencing:** identify cell subtype-specific RNA delivery and expression profiles within target organs
- **Systemic tolerability biomarkers:** evaluate cytokine induction, liver enzyme levels (ALT/AST) and complement activation in rodent plasma samples.

FOLLOW US



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YOUR PARTNER OF CHOICE IN BRINGING THERAPEUTICS TO LIFE

Nuvisan is a full-service contract research organisation (CRO) and development and manufacturing organisation (CDMO) with state-of-the-art laboratories in Germany and France.

Our pharmaceutical, biotechnology, venture capital and non-profit clients partner with us because our high-quality end-to-end solutions and scientific expertise enable us to streamline and accelerate drug discovery and development – from ensuring target understanding to helping bring therapeutics to life.

Founded over 40 years ago by a team of pharma industry innovators, Nuvisan has established a reputation for expertise and professionalism.

Our team leaders have extensive experience in the biopharma industry, and our unique centres of excellence – for drug discovery in Berlin, formulation and GMP manufacturing in Sophia Antipolis, and our bioanalysis hub in Neu-Ulm – enable our experienced scientists to help guide and advance projects.

We know how to discover, develop and bring the next generation of medicines to market. At the same time, we are committed to flexibility, transparency and collaboration in our approach, working closely with you to adapt to your individual needs, minimise risks and help deliver your project.

Contact us

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