NUVISAN
Pharma Services

The Best of CRO & CDMO

NUVISAN as CRO

Fully Integrated CRO

NUVISAN is a fully integrated Contract Research Organization and pharmaceutical service provider with an over 40 years track record of serving clients‘ needs in early and late clinical development.

We provide the complete spectrum of clinical pharmacology and exploratory studies. As a highly recognized service provider for international pharma and biopharma industries, we focus on early clinical drug development. We can offer 160 beds (intensive and overnight) on two sites.

Study Types

Our clinical services include the following study types, and can be performed in healthy volunteers and in special patient populations:

First in man SAD / MAD and integrated packages Studies with biologicals | Drug / Drug interaction studies | Bioavailability and Bioequivalence Studies Biosimilar studies | Studies on biomarkers, e.g. immunological parameters | Phase IIa, Proof of Concept studies special patient populations
Respiratory and rare diseases studies

NUVISAN as CDMO

Chemical Development
Bridging the Gap between CRO & CDMO

We support API Manufacture from Route Scouting up to Phase IIa. Our Infrastructure is optimized to support Process Development from mg to Kg Scale GMP Compliant | Tox & GMP Batches up to 5 Kg

Clinical Trial Supplies

Specialized in topical Formulations - We conduct all steps for Sourcing, Importation, Manufacturing, Labeling, Handling and Distribution of Clinical Supplies. We manufacture, fi ll and package for Development, Process Scale-up and Clinical Trials. We are empowered to guide the Client to the best strategic clinical Supplies Solution for the Clients Project while ensuring the Deadlines are met.

Formulation Development

Specialized in R&D of topical Formulations for pharmaceutical and OTC dermatological Treatments and complementary Consumer Products. We support your Formulation Conception and Creation From Preformulation to Formulation Selection and Transition into Scale-up, Clinical Development and QbD. Innovative Formulas are created with Pragmatism that facilitate Scale-up and Clinical Development

Headquarters Neu-Ulm

In-house CPU with 140 beds | Bioanalysis | Safety Lab | CTS | Pharmaceutical Testing

NUVISAN – The Best of CRO & CDMO

The increasing complexity in the early development phase led to an increasing market demand for sophisticated CRO/ CDMO partners.

Along the Value Chain

We recognized these trends early on and successfully positioned ourselves as Europe‘s only integrated full-service CRO provider. Along the value chain, we offer a comprehensive portfolio of solutions from early development, Phase I to Phase IIa. Or in other words: from the molecule to the patient.

Four Units – One Goal

With such a comprehensive portfolio, you benefi t from modular solutions of the highest quality that can be seamlessly combined. At NUVISAN, these integrated services include the following business areas: Pharmaceutical,
Clinical, Non Clinical and Analytical.

You Choose – We Deliver

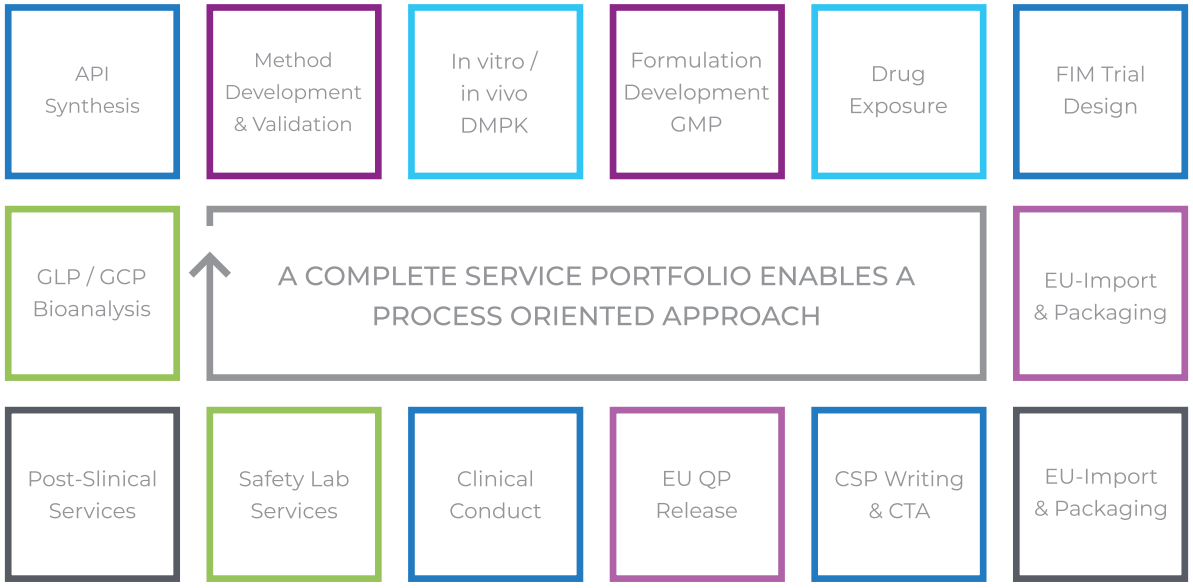
Depending on your specific requirements and standard processes, we work closely with you along the value chain and proactively keep the next steps in mind during the course of the project. Whereby you always decide which services you would like to use from us.

Site Waltrop

Pharmaceutical Analysis including large Molecules | TDS and other Polymer based Drug Delivery Formulations

The NUVISAN Concept

Connected services and support along the value chain from late research up to completions of early phase.



Site Sophia Antipolis

API Synthesis | Formulation Development | Manufacturing | Pharmaceutical Analysis | CTS & Bioanalysis

NUVISAN – Our Working Fields

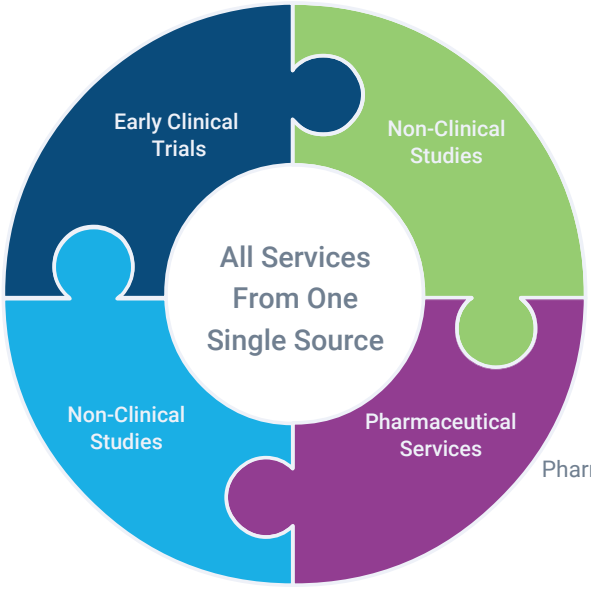
We are operating partner to the pharmaceutical industry, biotech companies, research institutes and universities.

Early Clinical Trials

In-house Clinical Pharmacology Unit
Clinical Development
Clinical & Medical Monitoring
Data Management & Biometrics

Non-Clinical Studies

DMPK: Discovery & Development
In vitro & in vivo
Radiosynthesis/Isotope Labeling
Metabolite Profiling and Identification
QWBA



Analytical Labs

Small and Large Molecule Bioanalysis
Immunogenicity Testing
Biomarker Analysis
TK Data Analysis
Clinical Safety Laboratory

Pharmaceutical Services

API Synthesis
Formulation Development
Pharmaceutical & Biopharmaceutical Testing
IMP Manufacturing
Clinical Trial Supply
QP Services

Site Grafing

In-vitro & In-vivo DMPK | Bioanalysis | Metabolite Profiling & Identification Radiosynthesis/ Isotope Labeling/ QWBA

Company Profile

Our history is a 40+ year success story

With over 40 years of experience, more than 400 employees and 5 sites, NUVISAN is a global specialist from drug synthesis to the clinical development of Phase I and II drugs and active ingredient development.

Our particular strength lies in our ability to form powerful teams from a top-class pool of experts that fit your specific needs. From drug synthesis to clinical testing in all GxP areas, we provide reliable support in drug development.

We can work as a contract research institute or as a contract manufacturer. To accelerate the development of customized service modules, we adapt our processes to your usual workflows.

Why choose NUVISAN

You benefit from a high degree of planning security and many valuable synergy effects in the development project. In this way you receive fast, reliable and comprehensive solutions.

Formulation Development

NUVISAN is GMP and GLP certified, GCP compliant and is tested by BfArM, EMA, FDA, ANVISA & AAALAC. We also support you in regulatory matters.

Flexibility

Multi-site capacity with alternatives and backup solutions.

NUVISAN
Pharma Services

Your Value is our Business.

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