

DRUG DEVELOPMENT
Clinical services



Clinical phase 1-2 trial expertise

For over 40 years, our CRO has worked closely with pharmaceutical and biotechnology clients to support customised clinical solutions. Our experts provide solutions that meet international standards and deliver relevant strategic insights.

Nuvisan offers clients a unique and authentic full-scope service from consultancy to phase 2, including clinical pharmacology unit (CPU) and/or external site trials, clinical back-end support teams, and comprehensive solutions in laboratory and clinical trial supplies.



Nuvisan has conducted over 360 early-phase trials since the year 2000 for small molecules, biologics and other innovative therapies, primarily at our CPU in Neu-Ulm, Germany, for trials in healthy volunteers, and special or patient populations.

We have extensive experience in early-phase clinical trials, specialising in **first-in-human, pharmacokinetic, pharmacodynamic, proof-of-concept, and regulatory studies.**

Services include our CPU, consulting, regulatory, medical writing, project management, feasibility and external site selection, clinical and medical monitoring, data management, biostatistics, and pharmacovigilance.

Our clinical teams are co-located with our clinical safety, bioanalysis, and immunology laboratories, and our clinical trial supply facilities, enabling close collaboration on your trial.

Unique and comprehensive early-phase solutions



CLINICAL PHARMACOLOGY

Our CPU has conducted early-phase trials in healthy volunteers, special populations, and patients for over 40 years. Some of our highlights include:

- Highly experienced in-house medical and clinical staff, 40 high-monitoring beds and 60 overnight beds, and fully automated clinic (using the ClinSpark® platform)
- Expertise with the complete spectrum of early exploratory and regulatory clinical trials
- Trial-specific feasibility processes, in collaboration with clients and external parties to help ensure successful outcomes.



SAMPLE ANALYSES AND IMP MANAGEMENT

Our CPU is co-located with our expert laboratories in clinical safety, bioanalysis, and immunology, and our GMP accredited pharmacy, helping ensure seamless and timely conduct of early-phase trials.

- Clinical safety lab using CE-certified tests and sample barcoding for reliable and accurate safety data
- GLP accredited facilities enabling precise results for bioanalysis, and safety and PD biomarkers
- Clinical trial supply facilities offering the necessary preparation and handling of clinical trial materials and medications.



Operational excellence: from trial start-up to close-out



CLINICAL OPERATIONS

With extensive knowledge of project management, clinical monitoring and submission of clinical trials in the European Union, we are committed to delivering impactful results and transforming clinical research into practical outcomes, through:

- Streamlined study setup with advanced processes and solid regulatory know-how
- Project managers integrating seamlessly with your team, tracking milestones and finances, while our independent monitoring team ensures rigorous site management
- A team of highly qualified medical writers supporting flexible trial design conception and all your regulatory documentation requirements.



MULTICENTRE PHASE 1-2 TRIALS

We deliver comprehensive product development services for multicentre phase 1-2 clinical research across various therapeutic areas, aiming to achieve proof-of-concept (PoC) in patients as early as possible, enabled by:

- A detailed understanding of the research landscape in Germany and neighbouring countries
- Continuous collection of valuable feasibility insights to help ensure well-informed decisions throughout your trials
- A profound understanding of critical success factors, such as communication, site selection, training, and risk-based monitoring.

From data collection to informed decision-making



DRUG SAFETY

Nuvisan helps ensure compliance with GCP guidelines and country-specific regulations by continuously evaluating and reporting safety concerns during early clinical trials.

Our dedicated efforts help sponsors enhance risk-benefit assessments at every stage of early drug development, including:

- Principal investigator oversight to ensure safety and participants' well-being during clinical trial conduct
- Medical monitoring activities such as review and evaluation of trial-related safety data
- Trial-related pharmacovigilance support.



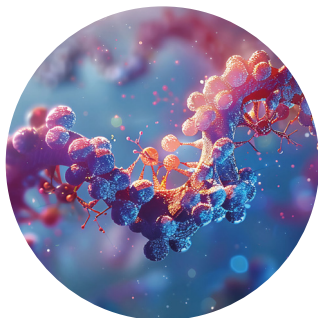
DATA MANAGEMENT AND BIOSTATISTICS

With extensive experience in clinical data management, biostatistics, and pharmacokinetics across various development phases and indications, we excel in delivering results.

Our team of highly qualified professionals adheres to industry best practices, helping you meet key trial milestones from initial planning to final study analysis, through:

- Clinical trials that are scientifically sound and compliant with data standards (CDISC)
- Dedication and flexibility to minimise impact on timelines
- Quality and on-time clinical study deliverables.

FOLLOW US



THE SCIENCE CRO

YOUR PARTNER OF
CHOICE IN BRINGING
THERAPEUTICS TO LIFE

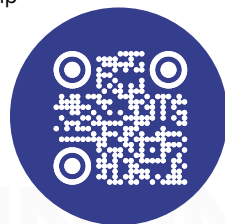
Nuvisan is a full-service contract research organisation (CRO) and development and manufacturing organisation (CDMO) with state-of-the-art laboratories in Germany and France.

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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