NUVISAN

CLINICAL PHASE I

Early Clinical Trials

Clinical Services at NUVISAN

Site Neu Ulm | Site Gauting

State-of-the-art Phase I Unit for complex and large scale clinical trials in Neu-Ulm. Broad experience with special patient populations in Gauting.

Clinical Services at a glance

Excellence Center for the Pharmaceutical Industry

Site History

Located at headquarter of the company

One of the first Early Phase CROs in Europe (1979)

Results

Average of 40 - 50 projects per annum

90% Repeat Business

Equipment

Full service from consulting to reporting

Data management

Statistic & Monitoring

Bedside monitoring software

Clients

Partner for entire pharmaceutical Industry from small Biotech to global player

STUDY CONDUCT
NEU-ULM

Staff

6 Physicians

6 Part Time Physicians

11 Study Coordinators

50 - 60 Part Time Staff

Network of Specialists

Facilities

~4.000 m^2

80 Overnight beds, 40 Intensive Care

Functional Rooms

Cantine (incl. Special Diets)

Laminar Flow

Recruitment

4 Recruiters

5 Call Center

Services

4 Decades of Experience in PK/PD Trials

Broad Experience with NCE, NBE & Biosimilars

Possibility for combined Study Designs e.g. SAD, MAD, FDI, DDI, Patient PK/PD

EARLY CLINICAL TRIALS
NEU-ULM

Background

Four decades of experience in PK/PD trials

Broad experience with NCE, NBE & biosimilars

Possibility for mixed protocols by combining designs e.g. SAD, MAD, FDI, DDI, Patient PK/PD

Expertise in online PBMC processing

Large Capabilities

CPU is distributed over two levels to enable separation of trial activities

Bioanalytic & Safety Lab in-house

In-house infrastructure

In-house pharmacy with full service capabilities

Safety lab, small & large molecule bioanalysis and biomarker lab

Project Management, Clinical & medical monitoring, CDM, Biometrics & Medical Writing, DSMB management, Drug Safety

Staff Expertise

Specialists are part of the medical team to support your trial with their expertise

Our team consist of emergency specialists, board certified physicians in internal medicine, cardiology, gynecology, ophthalmology, neurology & anesthesia

STUDY CONDUCT
GAUTING

Clinical Unit Staff

5 Physicians

Incl. Clinical Pharmacologist & one experienced Emergency Physician

Study Nurses & Project Managers

Network of external Specialists

Facilities

~1.200 m^2

24 Overnight beds, 6 beds on Intensive Care Unit

Dedicated lab areas for the processing of blood samples & biomarkers

Located on the site of a special clinic

Clinical Operations Department

Able to organize multi-center (large-scale) trials in outpatients

5 Project Managers, 2 CTAs

Network of cooperation partners

Network of freelance CRAs who act as filed-based clinical monitors in multi-center trials

Services

More than two decades of experience in early & late-stage clinical development

Broad experience with PoC trials & special patient populations (focus on therapeutic area respiratory)

Focus on special studies

EARLY CLINICAL TRIALS
GAUTING

Early-phase clinical trials & specialized clinical trials

First-in-Man clinical studies with due consideration of safety & early biomarkers

PoC studies with complex endpoints Studies with medicinal products (e.g., feasibility, performance, handling)

All kind of Efficacy / Safety / BE / PK / PD Trials

Clinical Phase IIa, II, III, IV Trials

Multicenter clinical trials in target patient populations

Writing of study protocol, Recruitment of sites, Setup of clinical trial infrastructure, Monitoring, Project Management, Organization of Investigator Meetings, Study Conduct, Data Management, Evaluation & Reporting

Consulting / Drug Safety Management / Medical Monitoring

Capabilities

24 Beds, additional 6 beds with Intensive Monitoring Capabilities

State-of-the-art labs for e.g. sample preparation

More than 270 projects performed

>25 years of experience of key personnel

FACILITIES

Lab Area of ~100 m^2

Roche Diagnostics Equipment

CENTRAL LAB

Sample Logistics & Documentation

Samples analyzed on the Day of Receipt

Data Export in Client specific Formats

STAFF

24/7 Availability

3 Lab Technicians

2 Data Specialists

1 Support Staff

IN-HOUSE TRIALS

Door to Door with CPU

Turnaround 4 to 6 Hours

Continuous Safety Assessments

PROJECT MANAGEMENT

Planning & Coordination of the Project

Main Contact for the Sponsor

Surveillance of the Project regarding Regulatory, Time & Quality

STAFF

10 Project Managers with scientific Education

3 CTAs

1 Regulatory Affairs Manager

2 Regulatory Start-up Coordinators

REGULATORY AFFAIRS

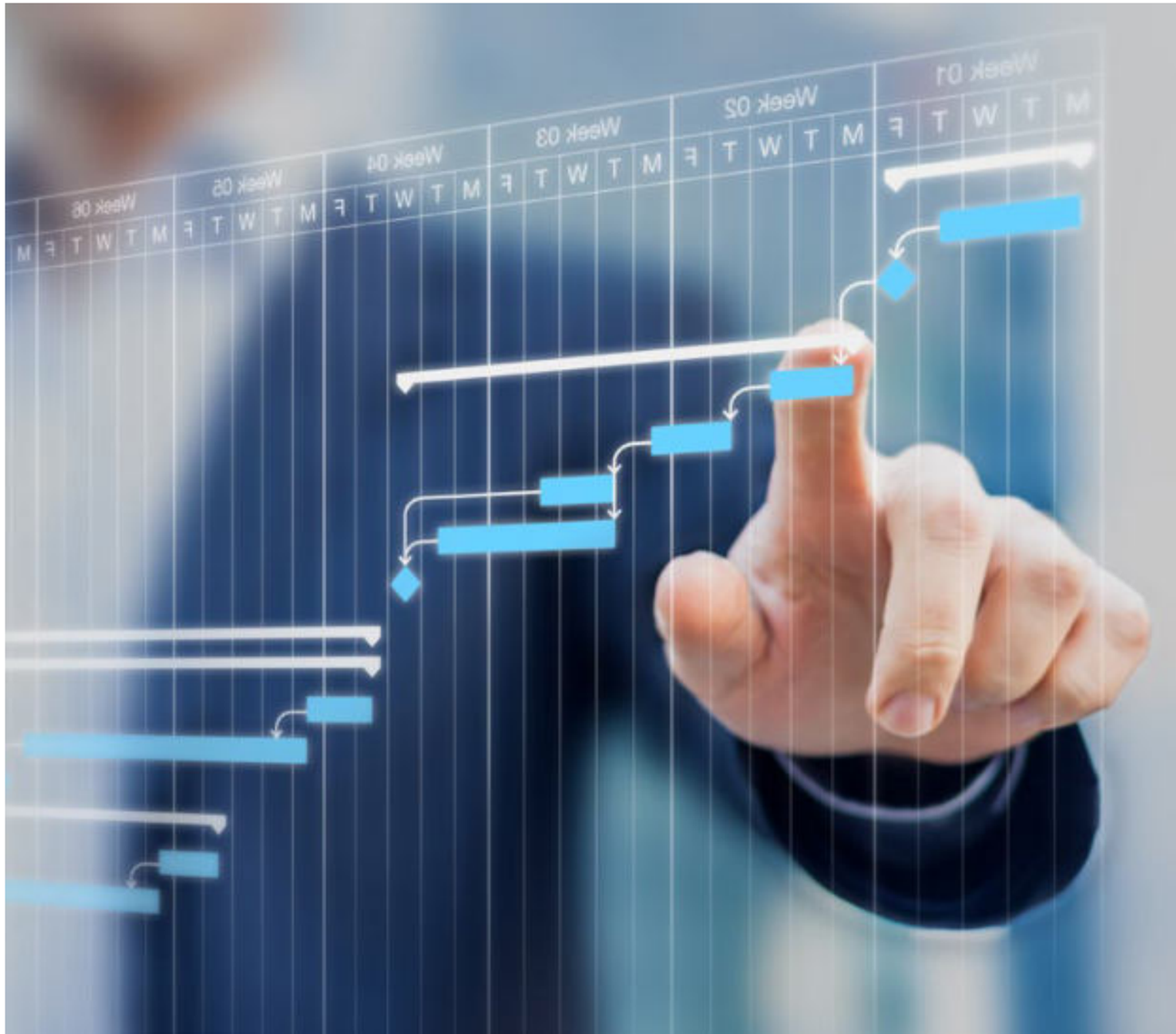
Preparation of Investigational Medicinal Product Dossier

Organisation of scientific advice eetings

Submission for Approval from Ethics Committee & Competent Authority

MEDICAL MONITORING / PHARMACOVIGILANCE

Independent evaluation of Safety Aspects



BIOSTATISTICS

1 Statistician

4 Data Programmers / 2 Data Analysts

Analysis of Study Data

(SAS, WinNonlin) in ADaM Dataset Structure

MONITORING

1 Lead CRA & 4 Monitors in Europe

1 Lead CRA & 4 Monitors in Lat. America

DATA MANAGEMENT

6 Data Managers / 2 Data Coordinators

Preparation of Paper CRF or eCRF according to CDASH

Setup & Validation of Database (Clintrial, Inform) / Data Cleaning

Data Provision in SDTM Data file structure

MEDICAL WRITING

3 Medical Writers (EMWA certified)

Preparation of Study Protocols, Investigator's Brochure, & clinical Study Reports in eCTD

Format for Submission for Registration

NUVISAN

YOUR SCIENTIFIC CRO PARTNER

NUVISAN is a fully integrated CRO/CDMO offering all solutions from drug discovery to Proof of Concept in patients including: target identification, high throughput screening, compound profiling, pre-clinical DMPK, toxicology, API synthesis, formulation development, pharmaceutical analysis, and clinical trials in healthy volunteers and patient populations.

With capabilities distributed over 5 locations in Europe and with more than 40 years of experience, we deliver high-quality solutions certified by various accreditations and inspections (e.g. BfArM, EMA, FDA, ANVISA, ANSES, AAALAC, GLP, GMP).

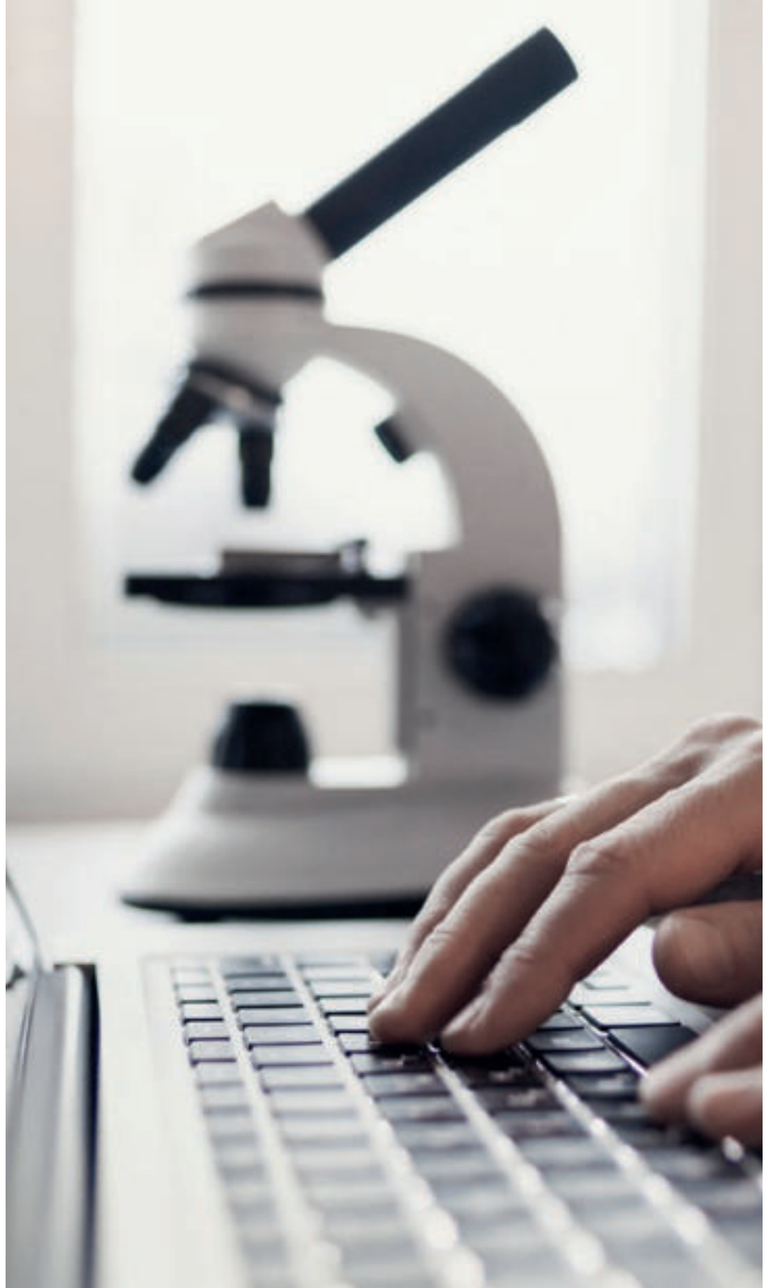
40

A trusted scientific partner
With a 40-year track record of customer satisfaction

A wide range of expertise
A unique, comprehensive and integrated offer from target identification to clinical trials

A data-focused expert
Our top priority is to ensure accurate, reliable, and consistent data quality

A flexible service provider
Fast turnaround ability and strong responsiveness to change



Enquire now

Whether you need support in specific areas only, or need a more comprehensive offer, NUVISAN can tailor a solution to fit your specific requirements.

Any questions or need further information?

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