Introduction
NUVISAN is a fully integrated CRO/CDMO
Offering all relevant GxP Services from Molecule Synthesis up to Completion of Clinical Trials in Phase II

Background
Capabilities are distributed over four Locations in Europe
Balanced Client Portfolio incl. Pharmaceutical and Biotech Companies, Academic Institutions & CROs

Staff
Headcount of ~420 highly educated Employees
40% academics and 38% of these with PhD level
A high Level of Employee Loyalty ensures Business Continuity during the Project and enables the Establishment of reliable long-term Relationships
Quality Metrics
>90% Percent Repeat Business per Year reflects our Client Satisfaction
High Quality was multiple Times confirmed by various Authority Inspections (e.g. BfArM, EMA, FDA, ANVISA)

Sponsor Audits
In 2019: 40
In 2018: 34
In 2017: 38

Business Units
Non-Clinical Studies
Clinical Trials
Pharmaceutical Services
Bioanalytical Labs
All Services From Along the Value Chain
One Single Source

Clinical Trials
In-house Clinical Pharmacology Unit
Clinical Development I + II
Clinical & Medical Monitoring
Data Management & Biometrics
Regulatory Affairs

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
API Manufacturing
Clinical Trial Supply
QP Services
### Drug Development Steps

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>GMP API Synthesis</td>
<td>GMP Method Development &amp; Validation &amp; Stability Testing</td>
</tr>
<tr>
<td>In Vitro / In Vivo DMPK (Toxicology)</td>
<td>Formulation Development &amp; Manufacturing</td>
</tr>
<tr>
<td>FIH Trial Design/Drug Exposition Calculation</td>
<td>FIM Trial Design/Drug Exposition Calculation FIH</td>
</tr>
<tr>
<td>GLP / GCP Bioanalysis</td>
<td>EU-Import &amp; Packaging &amp; Labeling/EU QP Release</td>
</tr>
<tr>
<td>Post-Clinical Service (Marketing Authorisation)</td>
<td>Medical Device &amp; Reg. Cosmetic</td>
</tr>
<tr>
<td>Safety Lab Services (Pharmacovigilance)</td>
<td>Clinical Conduct</td>
</tr>
<tr>
<td>Clinical Study Protocol Writing &amp; CTA Preparation</td>
<td>Regulatory Consulting</td>
</tr>
</tbody>
</table>

**A COMPLETE SERVICE PORTFOLIO ENABLES A PROCESS ORIENTED APPROACH**
Neu-Ulm (GER)
FTE: 244
In-house CPU with 140 beds
Bioanalysis, CTS, Pharmaceutical Testing, Safety Lab,

Waltrop (GER)
FTE: 26
Pharmaceutical Analysis incl. large Molecules, TDS and other Polymer based Drug Delivery Formulations

Grafing (GER)
FTE: 55
In-vitro & In-vivo DMPK, Bioanalysis, Metabolite Profiling and Identification, Radiosynthesis/ Isotope Labeling & QWBA

Sophia Antipolis (FRA)
FTE: 80
API Synthesis under GMP, Formulation Development, Manufacturing, Pharmaceutical Analysis, CTS & Bioanalysis

Gauting (GER)
FTE: 15
Phase I and Phase II CRO with focus on respiratory diseases
24 beds + 6 intensive monitoring beds
Clinical Services
NEU-ULM | GAUTING | SOUTH AMERICA

The modern Phase I/II Unit set-up in Neu-Ulm and Gauting near Munich
All Services from one single Source
Study Conduct

Staff
6 Physicians
6 Part Time Physicians
11 Study Coordinator
40 Part Time Staff
Network of Specialists

Facilities
~4,000 m²
140 Bed Capacity
Functional Rooms
Cantine (incl. Special Diets)
Laminar Flow

Services
4 Decades of Experience in PK/PD/BE Trials
Broad Experience with NCE, NBE and Biosimilars
Possibility for combined Study Designs e.g. SAD, MAD, FDI, DDI, Patient PK/PD

Recruitment
4 Recruiter
5 Call Center
All studies have been performed in the agreed timeframe
Currently two studies are part of a process with the European regulatory approval

### METRICS in CLINICAL TRIALS

<table>
<thead>
<tr>
<th>Sample Size</th>
<th>Biosimilar trials 2014-18</th>
<th>BA / BE / PD</th>
<th>FIH trials</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>290 subjects</td>
<td>48 subjects</td>
<td>260 subjects</td>
</tr>
<tr>
<td></td>
<td>180 subjects</td>
<td>56 subjects</td>
<td>3x64 subjects</td>
</tr>
<tr>
<td></td>
<td>150 subjects</td>
<td>178 subjects</td>
<td>100 subjects</td>
</tr>
<tr>
<td></td>
<td>100 subjects</td>
<td>172 subjects</td>
<td></td>
</tr>
<tr>
<td></td>
<td>100 subjects</td>
<td>96 subjects</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4 biosimilar trials ongoing</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### SAMPLE WORK UP
- ultra - centrifugation
- PBMC sampling
- cell-surface marker CD34+
- large quantities

### SPECIAL POPULATIONS & DEMANDING STUDY DESIGNS
- 60 subjects / 14 days treatment / 3 x 24 hrs infusions
- Recruitment of 20 diabetic patients for a POC trials
- Women’s health trials like tubal ligation or post-menopausal
- 54 Elderly Subjects in one trial

### ON-LINE ANALYSIS for therapeutic Proteins
- PK on-line measurement
- PD on-line measurement
- Safety parameter
<table>
<thead>
<tr>
<th>Substance Class</th>
<th>Theapeutic Area / Indication</th>
<th>Design</th>
<th>Admin. Route</th>
<th>Subjects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recombinant interferon</td>
<td>Hepatitis B/C</td>
<td>Comparative PK, sd</td>
<td>subcutaneous</td>
<td>24</td>
</tr>
<tr>
<td>Recombinant hGH</td>
<td>Growth hormone deficiency</td>
<td>Comparative PK, sd</td>
<td>subcutaneous</td>
<td>24</td>
</tr>
<tr>
<td>Enzyme preparation</td>
<td>FABRY disease</td>
<td>PK, sd</td>
<td>intravenous</td>
<td>42</td>
</tr>
<tr>
<td>Recombinant interferon</td>
<td>Hepatitis B/C</td>
<td>Comparative PK, sd</td>
<td>intravenous</td>
<td>28</td>
</tr>
<tr>
<td>Vasopressin analogue (protein)</td>
<td>Central diabetes insipidus, PNE, nocturia, Haemophilia A, von-Willebrand’s disease</td>
<td>PK, sd</td>
<td>intravenous</td>
<td>72</td>
</tr>
<tr>
<td>Vasopressin analogue (protein)</td>
<td>Central diabetes insipidus, PNE, nocturia, Haemophilia A, von-Willebrand’s disease</td>
<td>PK, sd</td>
<td>oral</td>
<td>28</td>
</tr>
<tr>
<td>Glucagon Like Protein-1</td>
<td>Diabetes type II</td>
<td>Comparative PK, sd</td>
<td>subcutaneous</td>
<td>22</td>
</tr>
<tr>
<td>Recombinant microbial lipase</td>
<td>Exocrine pancreas insufficiency</td>
<td>PK/PD, md</td>
<td>oral</td>
<td>36</td>
</tr>
<tr>
<td>Recombinant hGH</td>
<td>Growth hormone deficiency</td>
<td>PK, sd</td>
<td>subcutaneous</td>
<td>40</td>
</tr>
<tr>
<td>Flue H5N1 Vaccina</td>
<td>Bird flu vaccination</td>
<td>PD, md</td>
<td>intramuscular</td>
<td>32</td>
</tr>
<tr>
<td>Recombinant erythropoetin</td>
<td>Anemia</td>
<td>PK/PD, md</td>
<td>intravenous</td>
<td>279</td>
</tr>
<tr>
<td>Synthetic bile acid</td>
<td>Primary sclerosing cholangitis</td>
<td>PK/PD, md</td>
<td>oral</td>
<td>72</td>
</tr>
<tr>
<td>Recombinant met-G-CSF</td>
<td>Neutropenia</td>
<td>PK/PD, sd</td>
<td>Intravenous, subcutaneous</td>
<td>48</td>
</tr>
<tr>
<td>Recombinant met-G-CSF</td>
<td>Neutropenia</td>
<td>PK/PD, md</td>
<td>subcutaneous</td>
<td>56</td>
</tr>
<tr>
<td>Monoclonal antibody</td>
<td>anti-inflammatory drug</td>
<td>PK, sd</td>
<td>intravenous</td>
<td>48</td>
</tr>
<tr>
<td>Recombinant met-G-CSF</td>
<td>Neutropenia</td>
<td>PK/PD, sd</td>
<td>Intravenous, subcutaneous</td>
<td>48</td>
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<td>56</td>
</tr>
<tr>
<td>Recombinant met-G-CSF</td>
<td>Neutropenia</td>
<td>PK/PD, SD</td>
<td>subcutaneous</td>
<td>172</td>
</tr>
<tr>
<td>Glucagon Like Protein-1</td>
<td>Diabetes type II</td>
<td>PK/PD, SD</td>
<td>subcutaneous</td>
<td>48</td>
</tr>
<tr>
<td>Recombinant met-G-CSF</td>
<td>Neutropenia</td>
<td>Immunogenicity /PD, md</td>
<td>subcutaneous</td>
<td>96</td>
</tr>
</tbody>
</table>
CASE STUDY

Demonstration of Pharmacokinetic and Pharmacodynamic Equivalence in Healthy Volunteers for B12019, a New Proposed Pegfilgrastim Biosimilar
Karsten Roth, Barbara Gastl, Dirk Lehnick, Karin Jacob, and Ruediger Jankowsky
Blood 2016 128:5079;

DIA 28th Annual EuroMeeting 2016
Dr Karsten Roth, Director Clinical Operations of Cinfa Biotech GmbH, "Clinical Development Strategies for Biosimilars - A Mid-Size Pharma Perspective,“
<table>
<thead>
<tr>
<th>Group</th>
<th>Analytes / Marker</th>
<th>Est.</th>
<th>Qual.</th>
<th>Valid.</th>
<th>Methodology</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cytokines (multiplex)</strong></td>
<td>MSD V-Plex, 30-plex (full listing, see below)</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>MSD</td>
</tr>
<tr>
<td><strong>Other cytokines (single plex)</strong></td>
<td>G-CSF, Epo, IFN-a, TNFSF13, TNFSF13B, TGF-b, FGF-23</td>
<td>X</td>
<td>X</td>
<td></td>
<td>ELISA</td>
</tr>
<tr>
<td><strong>Other soluble biomarkers</strong></td>
<td>AKT, pAKT, PRAS40, pPRAS40, STAT5, Gd IgA1, TPA, Asparaginase, GLP-1, Insulin, Glucagon, Prolactin, Aldosterone, Renin, ADMA, PAI-1, Lepreprolin, P-Selectin, LTB4, TxB2, anti-Tetanus Ab, hGH, IGF-1, IGFBP-3, ACTH, OX40, OX40L</td>
<td>X</td>
<td>X</td>
<td></td>
<td>MSD/ELISA</td>
</tr>
<tr>
<td><strong>Cell-based biomarkers</strong></td>
<td>Cell proliferation, apoptosis induction, cell death (toxicity testing), reporter assays, ADCC assay, EliSpot assays</td>
<td>X</td>
<td>X</td>
<td></td>
<td>Luminescence / fluorescence reader</td>
</tr>
<tr>
<td><strong>Cell surface and intracellular marker</strong></td>
<td>CD3, CD4, CD8, CD14, CD19, CD25, CD34, CD45, CD56, CD69, FoxP3, TNF-α, IFN-γ, IL-2</td>
<td>X</td>
<td>X</td>
<td></td>
<td>Flow Cytometry</td>
</tr>
<tr>
<td><strong>Proliferation Assay</strong></td>
<td>CFSE</td>
<td>X</td>
<td></td>
<td></td>
<td>Flow Cytometry</td>
</tr>
</tbody>
</table>

Mesoscale V-Plex 30-plex: Eotaxin, Eotaxin-3, GM-CSF, IFN-γ, IL-10, IL-12/IL-23p40, IL-13, IL-15, IL-16, IL-17A, IL-1a, IL-1b, IL-2, IL-4, IL-5, IL-6, IL-7, IL-8, IP-10, MCP-1, MCP-4, MDC, MIP-1a, MIP-1b, TARC, TNF-α, TNF-β, VEGF-A, IL-8 (HA).
Project Management

Planning and Coordination of the Project

Main Contact for the Sponsor

Surveillance of the Project regarding Regulatory, Time and Quality

Staff

- 10 Project Manager with scientific Education
- 3 CTA
- 1 Regulatory Affairs Manager
- 2 Regulatory Start-up Coordinator

Medical Monitoring/Pharmacovigilance

Independent evaluation of Safety Aspects

Project Management

Regulatory Affairs

Preparation of Investigational Medicinal Product Dossier

Organisation of scientific advice meetings

Submission for Approval from Ethics Committee and Competent Authority
Safety Laboratory

**Staff**
- 24/7 Availability
- 3 Lab Technicians
- 2 Data Specialists
- 1 Support Staff

**Facilities**
- Lab Area of ~100 m²
- Roche Diagnostics Equipment

**Central Lab**
- Sample Logistics and Documentation
- Samples analyzed on the Day of Receipt
- Data Export in Client specific Formats

**In-House Trials**
- Door to Door with CPU
- Turnaround 4 to 6 Hours
- Continuous Safety Assessments
Backend Services

Biostatistics
1 Statistician (+ back-up Partners)
4 Data Programmer / 2 Data Analyst
Analysis of Study Data (SAS, WinNonlin) in ADaM Dataset Structure

Data Management
6 Data Manager / 2 Data Coordinator
Preparation of Paper CRF or eCRF according to CDASH
Setup and Validation of Database (Clintrial, Inform) / Data Cleaning
Data Provision in SDTM Data file structure

Medical Writing
3 Medical Writer (EMWA certified)
Preparation of Study Protocols, Investigator’s Brochure, and clinical Study Reports in eCTD Format for Submission for Registration

Monitoring
1 Lead CRA & 4 Monitors in Europe
1 Lead CRA & 4 Monitors in Lat. America
Bioanalysis

NEU-ULM | GRAFING | SOPHIA-ANTIPOLIS

Support Drug Metabolism, Non-clinical & Clinical Pharmacokinetics, Immunogenicity and Toxicokinetics throughout the R&D Value Chain
Analytics & Technology

LCMS Equipment
18 UPLC-MS Systems
All Assays on UPLC
Ion Mobility Capability
Automation (Hamilton Starlet)
All Sciex State-of-the-Art Instruments

Storage
5 Walk-in Freezers (-20°C)
23 Deep Freezers (-75°C)
1 Ultra-Deep Freezer (-150°C)
Dedicated Sample Management Team
24/7 Temperature Controlled (REES)

IMM Equipment
2 Tecan ELISA Readers
2 MSD QuickPlex 120
1 Singulex Erenna
1 Gyrolab xPlore
3 Flow Cytometry Analysers
Full Equipped Cell Culture Lab

Highlights
All bioanalytical Services under one Roof incl. Cell Culture
BSL 2 Lab available for Supporting infectious Diseases
Strong Regulatory Background with Industry-renowned Scientists
Key Capabilities

Assay Development
- ELISA
- MSD
- Gyrolab
- Singulex (ultrasensitive single cell analysis)
- Flow Cytometry
- Cell Preparations

Assay Validation
- FDA BMV 2018
- EMA BMV 2012
- ANVISA BMV
- ICHM10 BMV
- FDA (ADA) 2019
- EMA (ADA) 2018
- C-Path (Biomarker)

Sample Analytics
- Highest Flexibility
- Short Lead Times
- Biosimilars
Bioanalysis

Support Drug Metabolism and Non-Clinical Pharmacokinetics, Toxicology and Clinical Development

Our Mission:
Generate reliable PK/TK Data with fast Turnaround and highest Flexibility to maximize the Benefit for our Clients

New Assays are developed in short Periods of Time with applying fit-for-purpose Strategies depending on our Clients’ Needs

High Quality Development DMPK Studies in Compliance with strong Inter-connection with In-vivo DMPK to ensure successful fast PK Studies (Planning, Conduct, Reporting)

GLP accredited since 1994 and ANVISA accredited
Clinical Trial Supplies
NEU-ULM | SOPHIA ANTIPOLIS

GMP Manufacturing & Packaging Services built among 36 Years leading to strong Client Portfolio
Clinical Trial Supplies

**Services**
- Powders, Capsules, Over Encapsulation, Tablets Manufacturing
- Comparator Sourcing
- Global Distribution & Depot Management
- Label Design and Printing

**Capacities**
- 2.250 m² cGMP Facility
- 250 m² Manufacturing & Primary Packaging Area
- 1 Class A Clean Room
- 1,000 m² Secondary Packaging & Storage

**Team**
- 17 experienced Employees (FTE) supported by
  - 2 Qualified Persons
  - 3 Heads of Production
  - 4 Heads of Quality Control
  - 2 Responsible Persons GDP

**Highlights**
- Specific Design of Storage Area to handle Labelling of Biologicals with 3 walk-in refrigerators 2-8°C (135 m³)
- 2 walk-in freezers (63 m³)
- Handling of highly potent API up to OEB5
Clinical Trial Supplies

Rapid Entry into Phase 1 for FIM Trials

We conduct all steps for Sourcing, Importation, Manufacturing, Labeling, Handling and Distribution of Clinical Supplies

With Powder in the bottle the Sponsor could save up to 6 months Development Time

Just in time Labelling for immediate Service to our Clients

GMP Solutions for In-house Trials like aseptic Reconstitution

Expertise in Cold Chain Supplies for Biologics, Vaccines and other sensible Products
Formulation Science & Technology

SOPHIA ANTIPOLIS

Topical Formulation Innovation and strategic Life-cycle Management
Customized compositions to optimize Safety, Performance and Compliance
Formulation Science and Technology

Capacities
300 m² R&D State of the Art Laboratory
100g – 10Kg batch capacity
Handling of highly potent API up to HHB4 (OEL >1µg/m³)

Technology Development
Technology assessment
IP creation
Patent Strategy
Strategic Life-cycle Management

Preformulation
Solubility and compatibility profiling in single solvents and solvent blends
Accelerated Degradation: extreme pH, UV, Oxidation
Rational residual Composition
Design to optimize Solubility and optimize Skin Delivery

Formulation & Process
Excipient Selection & Function Justification
Prototyping to ensure optimized Formulation parameters:
Stability / API release & skin delivery /
Tolerance customized to disease /
Sensory Profile / Microstructure characterization
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

Compositions are customized to meet the specific Physicochemical Characteristics of each active and disease State / Skin Condition

Innovative Formulas are created with Pragmatism that facilitate Scale-up and Clinical Development

Solubility, Stability, Delivery, local Tolerance and cosmetic Elegance are optimized to maximize Safety, Compliance and Efficacy
Chemistry
SOPHIA ANTIPOLIS

Bridging the Gap between CRO’s & CMO’s
**Chemical Development**

**Capacities**
- 100 m² Non-GMP Facility with 40 L reactor Capacity for Development
- 200 m² GMP Facility with 266 L Reactor Capacity
- State of the Art Laboratory
- Handling of highly potent API up to HHB4 (OEL >1µg/m3)

**Impurities**
- Preparative HPLC /SFC systems
- High Resolution Mass Spectrometry Equipment and 400 MHz NMR for Identification and Characterization of Small Molecules

**Chemistry**
- API route Scouting & Process Research
- Process Development combined with GMP Manufacturing
- Custom Synthesis of advanced Intermediates
- Package ready to transfer to CMO

**Solid form characterization**
- Crystal 16, XRPD, DSC and Microscopic Observations
- For Polymorph screening, Salt Screening, Solubility Curves and Filtration Assessments
Chemical Development

Bridging the Gap between CRO & CMO

We support API Manufacture from Route Scouting up to Phase IIa

Infrastructure is optimized to support Process Development from mg to Kg Scale

GMP Compliant

Tox & GMP Batches Manufacture up to 10 Kg
Pharmaceutical Analytical Services
NEU-ULM | WALTROP | GRAFING | SOPHIA ANTIPOLIS

Overview of 36 Years of Experience in Analytical Testing
Pharmaceutical Analytical Services

**Capacities**
2,400 m² GMP facility, incl. 800 m² GMP Laboratory
State of the Art Laboratory & 20 High Performance Liquid Chromatography
80 very experienced Analysts
LIMS

**Method Development, Validation and Transfer**
Complex Matrixes
Design of Experiment
Compliant with ICH
Oral dosage forms with small Molecules and peptides

**Highlights**
Microbiological Testing
Microstructure Characterization
Semi-solid Expertise
GMP certified since 1989
Handling of highly potent API up to HHB5

**Quality Control**
Stability Management, ICH Guidelines Compliant
Challenge Test and Microbial Limit Tests
Packaging Safety and Performance
Cleaning Validation
Pharmaceutical Analytical Services

We support Method Development, Validation, Quality Control and Stability Studies

GMP Certification in Place

Drug Substances, Preclinical and Clinical Batches testing

Formulation Development and Manufacturing Support

Center of Excellence in Oral Drug Testing

Experience with Human medical Products and Veterinary drugs
Analytics & Technology

NUVISAN Waltrop is a Center for Antibody Analysis

Equipment
19 (Ultra) High Performance Liquid Chromatography Systems
Laboratory Information Management System (LIMS)

Storage
130 m³ Storage Capacity
Walk-in Climate Chambers, Fridges, Freezers
Storage from -80°C to +40°C
Duration between 1 Day and 6 Years

Highlights
1st European Provider for microHVLĐ under GMP
High Resolution Mass Spectrometry Equipment for Identification and Characterization of Small Molecules and Antibodies

Antibody-specific
4 UV Photometers for Protein Quantification
3 Capillary Electrophersis Systems
2 CAD Detectors for Polysorbate Quantification
2 ELISA Readers for Protein Interactions
1 Biosafety Cabinet
Isotope Chemistry
GRAFING

Synthesis of Radiolabeled and Stable Isotope Labeled NCEs
Isotope Chemistry

Capacities & Working Fields
- Headcount: 6 (60% Academics)
- Five State of the Art Labs (200 m²)
- Knowledge in isotope Chemistry from >50 Years Part of Big Pharma Company
- Isotopes: $^3$H, $^{14}$C, $^{177}$Lu, $^{32}$P
- Current License allows Handling of up to 88 GBq $^{14}$C and 141 GBq $^3$H

Radioactive Synthesis ($^{14}$C)
- Custom (multistep) radioactive Synthesis
- Isotopes: $^3$H, $^{14}$C
- Detailed Synthesis Report and comprehensive Certificates of Analysis:
  (H/UPLC), NMR, (radio-)TLC, LC-MS

Synthesis of Stable Labeled Compounds
- Isotopes: $^2$H, $^{13}$C, $^{15}$N, others…
  (e.g. bioanalytical Standards for Mass Spectrometry)
- CoA: Chemical (enantiomeric) Purity (HPLC/UPLC), NMR, TLC and critical Release Criteria, e.g. D0 contribution ≤ 0.5% (LC/MS)

Further Services
- Re-analysis and Re-purification of Test Items Stability Investigations
- Storage of (radio-)labeled Test Items worldwide Shipment of radioactive Compounds
- Formulation for In-vivo Studies
Isotope Chemistry

We support the Development Program of our Clients offering Synthesis of Stable Isotope Labeled NCEs as bioanalytical Standards for Mass Spectrometry and radioactive labeled NCEs ($^3$H, $^{14}$C) for e.g. DMPK Studies

Proposal of optimal Labeling Position

Permission to Work with Radioactivity is regularly adapted to the Needs of Client Projects (recently added $^{177}$Lu and $^{32}$P)

Store radioactive Samples (Sample HUB) before Routine Analysis ($^{14}$C, $^3$H, $^{32}$P and $^{177}$Lu)
Supporting Pharmaceutical Clients with DMPK Studies and scientific Consultancy along the entire R&D Value Chain
Biotransformation & In-vitro PK

Our Experts Guide Pharmaceutical Clients throughout all R&D Phases starting from Discovery into Clinical Development and Marketing Authorization

Our Mission:
Generate PK Data to enable the safe Administration of NCEs at the right Dose and regimen to maximize the Benefit for Patients

Standardized or tailor-made high quality DMPK Studies and complete Packages enabling IND/ IMPD, Start of FIM and/ or large Clinical Trials

Project Management and scientific Consultancy

All studies will be performed in compliance with FDA and EMA requirements as described in the respective guidelines
In-Vivo DMPK
GRAFING

Supporting In-vivo DMPK at all Stages and comprehensive Range of Species
In-vivo DMPK

**Capacities**
- Headcount: 14 (35% Academics)
- Mice, Rats, Dogs and Minipigs
- Pharmacokinetic studies for Discovery and Development Programs
- GLP and Non-GLP DMPK Studies
- Radiolabeled and ‘cold compound’ Studies

**Discovery**
- Fast turnover Discovery In-vivo Screening PK
- Blood Brain Barrier Assay
- Single, multiple and Cassette Dosing
- Micro-sampling
- Infusion Studies

**Development**
- Absorption, Metabolism, Excretion
- Quantitative Tissue Distribution
- Juvenile PK
- Lactation studies
- Placental Transfer
- Mechanistic Studies

**Quality**
- AAALAC Accreditation
- State of the Art Animal Welfare Standards
- Strong Focus on 3R Principles
- GLP Certified
In-vivo DMPK

We contribute to the Optimization of Compounds for Man by In-vivo DMPK Services in Discovery screening and preclinical Development

Full AAALAC Accreditation

Established Dog Training Programme

Fast Turnover: your timelines are our priority

Tailored Study Designs to meet Requirements of each individual Client
Thank you for your interest in our services!