NUVISAN

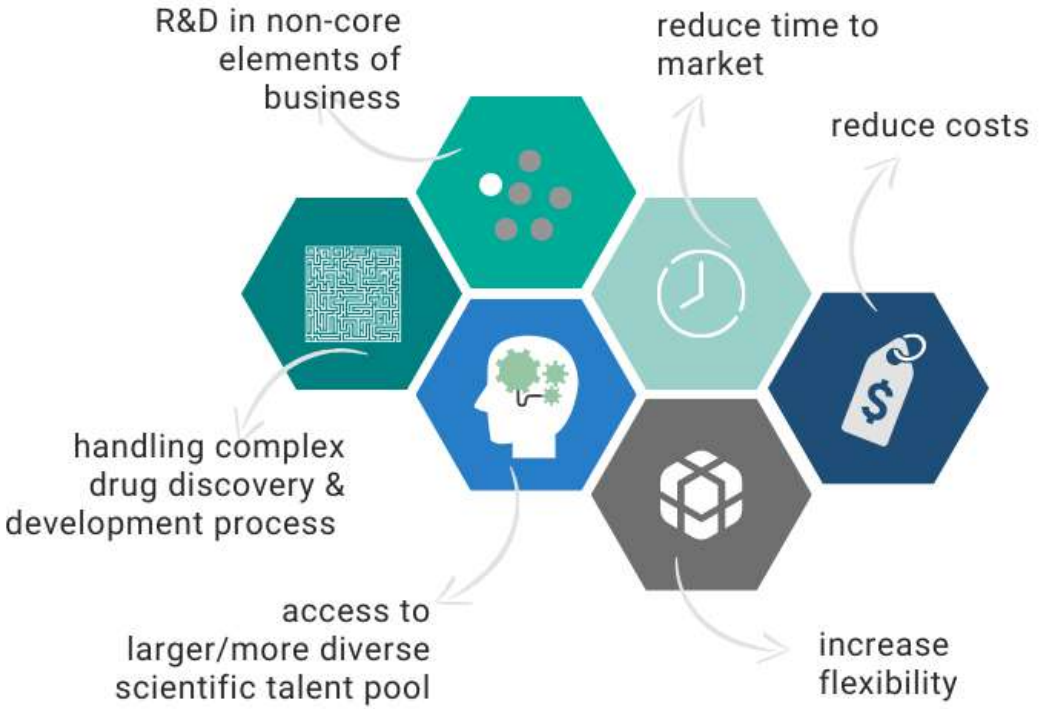
Today´s Agenda

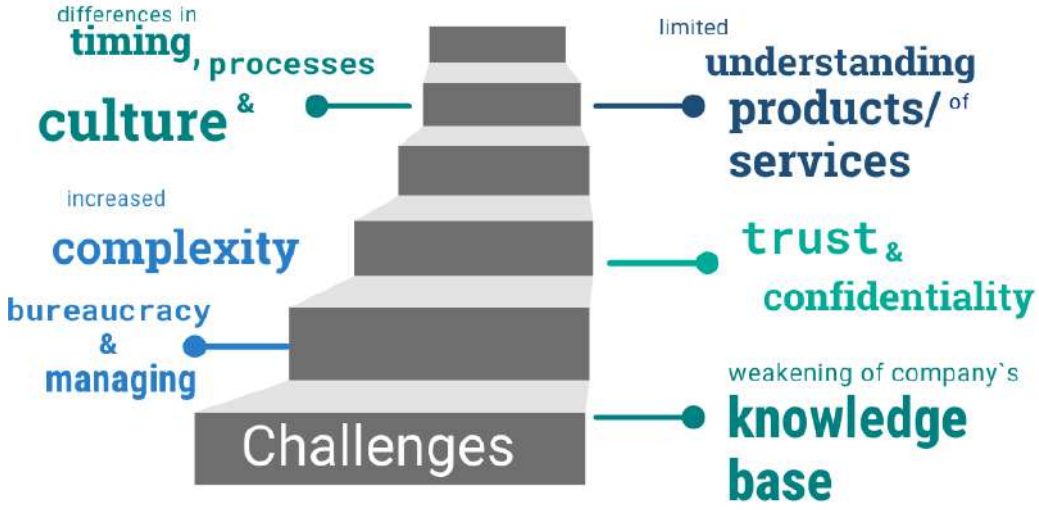
1. Drug Discovery & Development
2. About NUVISAN
3. Drug Discovery Solutions
4. Drug Development Solutions
5. Integrated Solutions

R&D Challenges

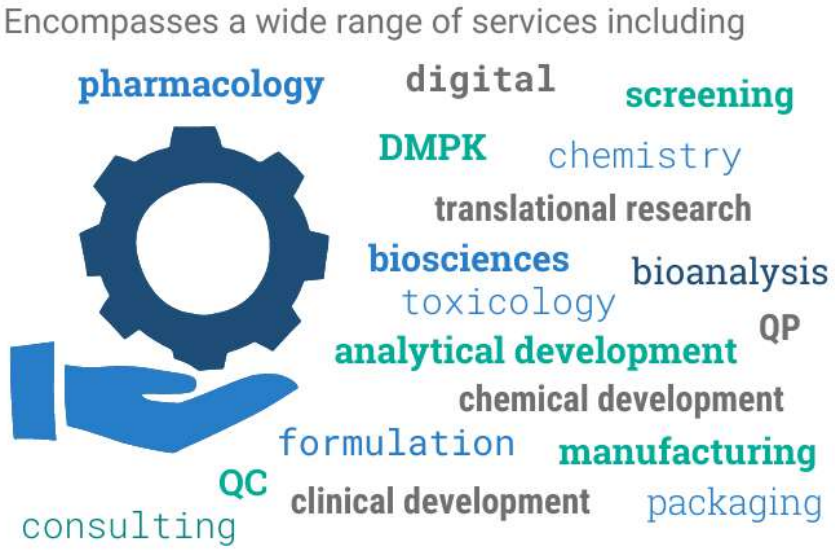
How to meet the growing demands of flexible and integrated drug discovery & development solutions

Outsourcing of Drug Discovery & Development
Opportunities & Challenges





Growing Demands on Outsourcing Settings
Integrated Solutions & One-stop Shop



Single Master Agreement
keeping minimum contractual burden

Flexibility of research
of outsourcing capabilities

1 project manager
for multidisciplinary operations

Deliverable: biological data
via compound handling & storage capabilities

NUVISAN
The Science CRO

Drug Discovery & Development
Meet Scientific Excellence

Focus on Science & Pharma Expertise

- Extensive industry experience (scientists, lab professionals & leadership team) thanks to integration of functional R&D teams from Pharma companies
- “Science first” & customer-centric focus paired with creative, flexible & solution-driven mindset to meet your individual needs
- Audits & inspections
  (clients & BfArM, EMA, FDA, ANVISA):

2017	2018	2019	2020	2021
38	34	40	29	36

Balanced Client Portfolio

- Clients & partners from Pharma industry, biotech / startup companies, venture capitals & non-profit organizations
- With a focus on transparent discussion, review & revision of project strategies, our industry-experienced scientists
  - Provide consulting - from idea to asset
  - Increase your project value
  - Optimize your portfolio with enabling solutions

Fully Integrated Solutions

From Target to Patient

- EU-based company with > 40 years of experience, short communication paths, quick turnaround & unified molecule and data handling standards

- One partner to move your assets with seamless transition of unique, high-quality, & tailored integrated solutions along R&D value chain

DRUG DISCOVERY

DRUG DEVELOPMENT

Target identification & validation | **Target-to-lead** | **Lead-to-candidate** | **Preclinical development** | **Phase I** | **Phase II** | **Phase III**

Discovery Pharmacology

Discovery Biosciences

Screening

Life Science Chemistry

Chemical Development

Translational Research

DMPK

Toxicology

Bioanalysis

Digital Life Sciences

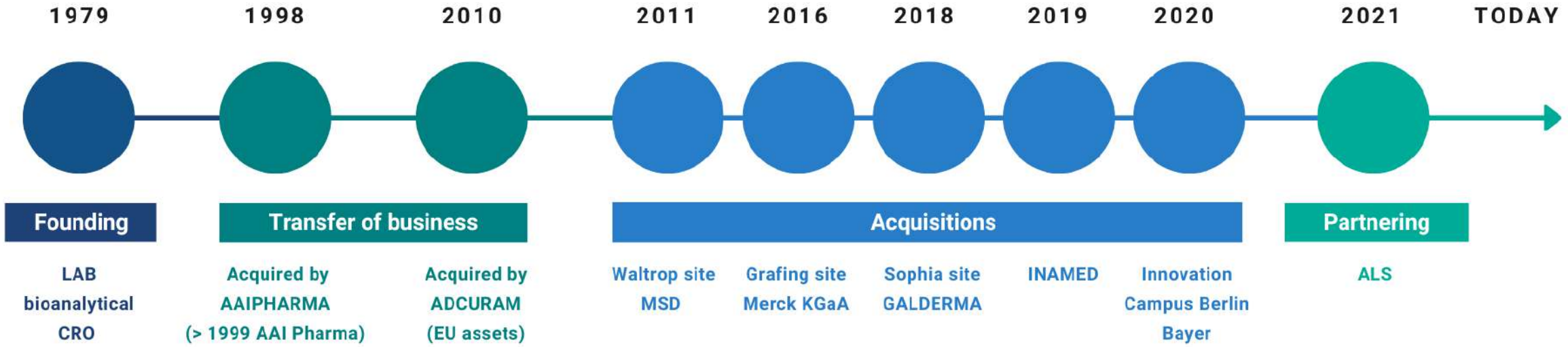
Formulation Development

Analytical Development & QC

Clinical Trial Supplies

Clinical Development

Our History



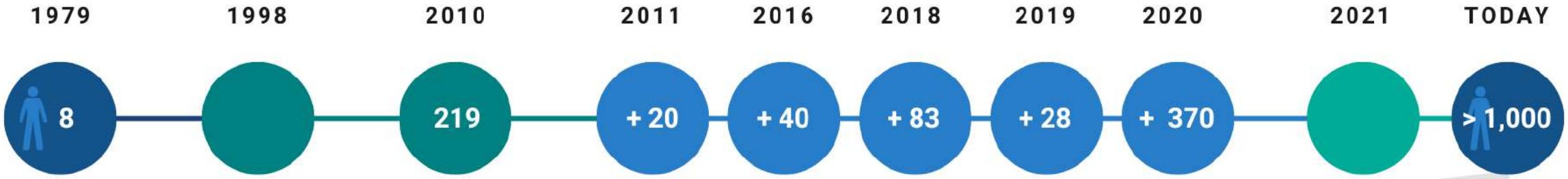
2014

Management buy-out

Name changed to

NUVISAN

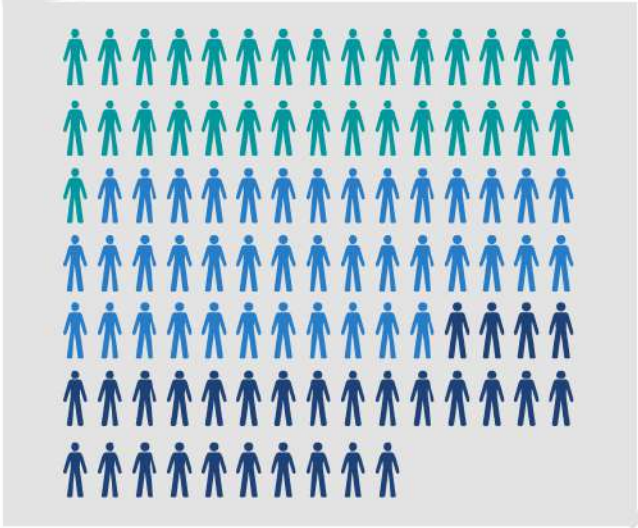
Our People



~ 31% scientists (69 % *Ph.D.*)

~ 40 % lab professionals

~ 29 % non-scientific staff



Our Sites in Europe & Beyond

Berlin (GER)

Neu-Ulm (GER)

Waltrop (GER)

Grafing (GER)

Gauting (GER)

Sophia (FRA)

Lima (PE)
Sao Paolo (BRA)
Buenos Aires (ARG)

Drug Discovery Hub — **Drug Development Hubs** — **Local Experts**

Drug Discovery

From Target to Lead

Our Drug Discovery Leadership Team

Charlotte Kopitz
Discovery Pharmacology
& Translational Research

Franz von Nussbaum
Life Science Chemistry
& Digital Life Sciences

Olaf Prien
DMPK
& Toxicology

Holger Steuber
Discovery Biosciences
& Screening

Discovery Pharmacology

Target Validation

***In vitro* Biology**

***In vivo* Pharmacology**

Functional Genomics

Therapeutic Areas

Discovery Pharmacology

Target Validation

- Bioinformatics *in silico* target analysis
- Indication space assessment, positioning & expansion
- Cell engineering tools
- CRISPR screening
- Target deconvolution
- Strategy development

Functional Genomics

- Next-generation & single-cell sequencing
- CRISPR / RNAi platform
- Expression analysis
- Bioinformatics services

In Vitro Biology

- Cellular assays & assay development
- Cell line generation
- iPSC platform
- *Ex vivo* assays
- Virus biology
- Flow cytometry, IHC & microscopy units

Therapeutic Areas

- Oncology
- Dermatology
- Inflammatory / autoimmune diseases
- Fibrotic diseases
- Contraception
- Women‘s health
- Neurology / pain
- Metabolic diseases / aging
- Cardiology / pulmonary diseases

In Vivo Pharmacology

- Efficacy & PD studies
- Disease models
- *Ex vivo* analysis
- Imaging capabilities
- Model development

Translational Research

Biomarkers

Biomarker Discovery

Biomarker Assay Development

Biomarker Technologies

Clinical Translation of Biomarkers

Translational Research

Biomarker Discovery

- Target / mode-of-action based or hypothesis free global biomarker discovery approaches
- Proof-of-concept studies *in vitro* & *in vivo*
- Demonstration of target engagement & pharmacodynamic effects
- Correlation of predictive biomarkers & response

Biomarker Technologies

- Next-generation & single-cell sequencing
- Immunohistochemistry
- *In situ* hybridization
- Flow cytometry & cytokine / chemokine platform
- Real-Time PCR / automated Western Blot
- *In vivo* imaging platform

Biomarker Assay Development

- Project tailored *in vitro & in vivo* models for PK / PD assessment
- Assays in target & surrogate tissue
- Assay optimization & fit-for-purpose validation
- Analysis of preclinical & clinical samples

Clinical Translation of Biomarkers

- Human tumor & normal tissue biobank
- Indication profiling to support Ph1 target patient population
- Reverse translation of biomarker read-outs from clinical trials

Discovery Biosciences

- Protein Sciences
- Assays
- High-Content Analysis
- Biophysics
- Mass Spectrometry
- Structural Biology

Discovery Biosciences

Protein Sciences

- Customized molecular biology service
- Multi-parallel expression optimization (*E.coli*, insect & mammalian cells)
- High quality protein production for assays, structural biology & biophysics
- Protein QC (MS, fSEC, aSEC, nDSF, DLS)
- Membrane protein platform

Assays

- Assay development incl. tool generation (stable cell lines)
- Biochemical, cellular & high content assays
- Binding & enzyme activity assays
- Adaptation to ultra high-throughput

High-Content Analysis

- Phenotypic & multiplexed HTS
- SMOL & CRISPR libraries
- Eukaryotic cells (animal, fungi, plant), bacteria & 2D and 3D cell systems
- Single time points & live-cell kinetics

Biophysics

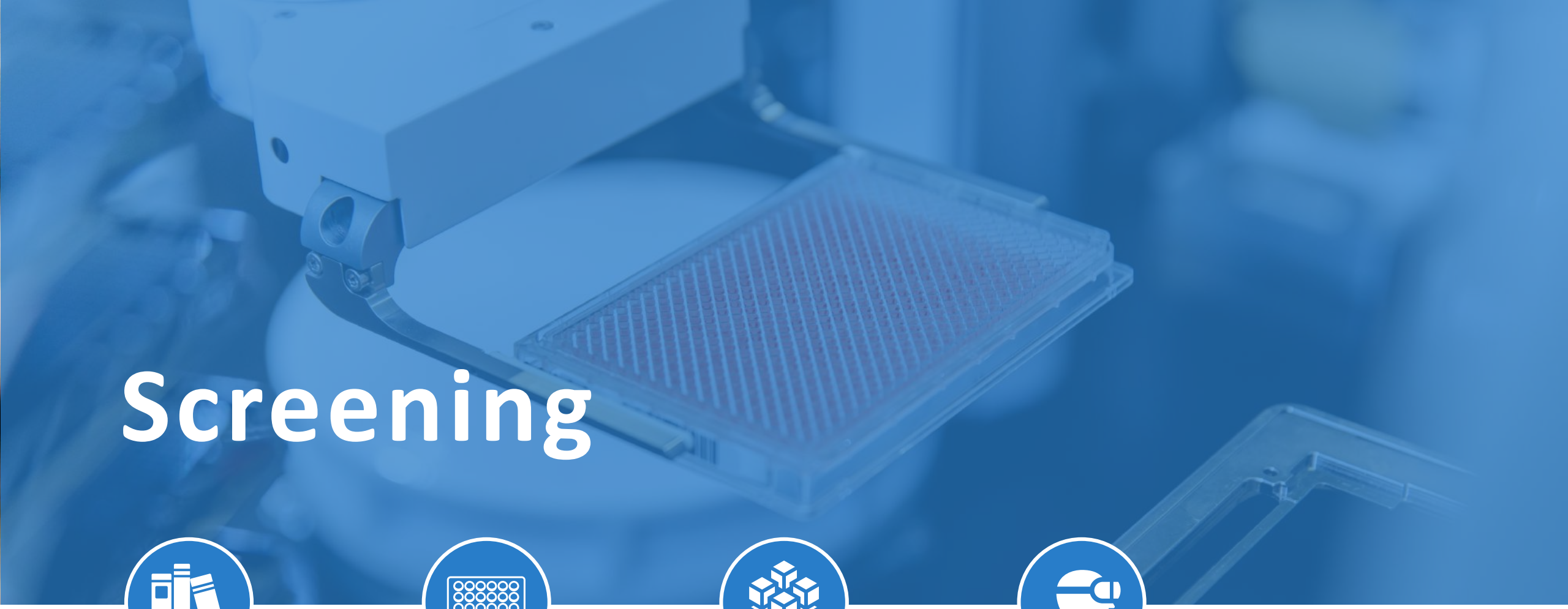
- Versatile platform: SPR, TSA, nDSF, NMR, ITC, DLS, MST
- Hit characterization, kinetic profiling & SAR support
- Mode-of-action & target engagement
- Biophysical fragment screening (SPR, TSA, NMR)

Mass Spectrometry

- High-throughput (HT) MS (RapidFire MS & MALDI-MS)
- Intact mass measurement
- Native mass spectrometry
- Targeted metabolomics
- Proteomics & peptide mapping

Structural Biology

- X-ray determination & analysis
- High-throughput platform for multi-target crystallization
- Cryo-EM, NMR
- HT Crystallography (HTX) for fragment screening
- Small molecule structure determination



Screening

- Libraries
- High-Throughput Screening
- Fragment Screening
- Virtual Screening

Screening

Libraries

- 3 million small molecule library (access to Pharma library)
- Different subsets & focused libraries (e.g. 290k / 820k / 2.4 million compounds)
- High chemical diversity, > 70 % proprietary

High-Throughput Screening

- Biochemical, biophysical, cellular with up to 300,000 tests / day
- Mass spectromety HTS (MALDI-HTOF, RapidFire)
- Best-in-class high content analysis (HCA) screening platform
- > 20 yrs of Pharma HTS experience (> 10 clinical cpds)
- State-of-the-art screening data management

Fragment Screening

- Biophysical screening (SPR, TSA, NMR) of customized library (~ 2k Ro3 fragments)
- X-ray screening of customized library (~ 900 fragments @500 mM DMSO)
- 1° screen / hit confirmation → hit validation → fragment-to-lead

Virtual Screening

- Internal library (3 million small molecules)
- External libraries (100k - > 1b)
- *In silico* virtual screening
- Target / ligand data mining
- Hit expansion

Life Science Chemistry

- Design & Synthesis
- Analytics & Purification
- Scale-up & Special Technologies
- Microbiological Chemistry
- Compound Logistics
- PhysChem

Life Science Chemistry

Design & Synthesis

- Decades of MedChem experience from hit assessment to clinical compound
- ID of new leads for challenging targets
- Multi-parameter optimization of molecules (hit-to-lead, lead-to-candidate)
- SMOLs, probes & new modalities (incl. PROTAC®s)

Purification & Analytics

- Separation technology platform (from < 1 mg up to 1 kg)
- Chiral separation incl. SFC
- NMR, MS & OPT expertise for structure services
- Ligand-protein interaction analysis via NMR & MS

Scale Up & Special Technologies

- Large-scale synthesis of API or intermediates incl. route optimization
- High pressure reactions, photochemistry, hydrogenation, carbonylation

Microbiological Chemistry

- Biotransformation & protein / plasmid production
- Integration in NUVISAN metabolite discovery platform
- Metabolite identification, screening, synthesis & characterization

Compound Logistics

- Collection, storage, plating & shipping of compounds
- Building block collection for fast synthetic diversity

PhysChem

- Solubility
- Lipophilicity
- Stability
- Crystallinity (XRPD) & pKa

Digital Life Sciences

Life Science Datasets

Molecular Modeling

Cheminformatics & Machine Learning

Omics Data Analysis & Bioinformatics

Digital Life Sciences

Life Science Datasets

- ~1b *in vitro* & *in vivo* data points connected to 3 million well-characterized compounds from > 1 decade of research
- HTS, physicochemical, biochemical, pharmacological, pharmacokinetic & toxicological data
- Digital technologies & data mining

Cheminformatics & Machine Learning

- Fingerprint, substructure & similarity search
- ML models for ADME end points
- QSAR predictions
- Clustering & SAR
- Chemical space analysis
- R-group decomposition & visualization, activity cliffs

Molecular Modeling

- Virtual screening
- Structure-based design
- Pharmacophore- & ligand shape-based screen
- Scaffold hopping
- Molecular docking
- Molecular dynamics & free energy calculation

Omics Data Analysis & Bioinformatics

- Interpretation of transcriptomics, genomics, epigenomics (single-cell & bulk next-generation sequencing) / spatial profiling / pooled, arrayed & single-cell CRISPR screens
- Microscopy image analysis at single-cell resolution
- *In silico* target & indication space evaluation
- Literature & database mining

DMPK

Discovery & Development

In Vitro PK & DDI

In Vivo DMPK

Biotransformation & MET ID

Consultancy Services

Isotope Chemistry

DMPK (Discovery & Development)

In Vitro PK & DDI

- *In vitro* ADMET assay panel for research (HT) & IND-enabling PK characterization
- *In vitro* HT assays with custom protocols
- Investigation of absorption, distribution, metabolism, excretion (ADME) with radio- / non-labeled material
- DDI profiling (victim & perpetrator) & assessment of transporter proteins & metabolizing enzymes

In Vivo DMPK

- PK in rodents, dogs & minipigs, single compound & cassette dosing, different admin routes
- Microsurgical rodent models e.g. cannulation of bile duct & portal vein, lymph sampling, femoralis admin
- Absorption, metabolism & excretion (mass balance studies incl. bile excretion & expired air)
- Quantitative tissue distribution incl. placental transfer
- According to GLP upon request

Biotransformation & MetID

- *In vitro* & *in vivo* metabolite profiling, quantification & structure elucidation in various matrices
- Analysis of clinical trial samples (metabolite "scouting", relative & absolute quantitation, profiling & metabolite ID in hADME)
- Mass spectrometry imaging

Consultancy Services

- DMPK consultancy through all R&D phases
- Human PK predictions & DDI evaluations
- Project management, DMPK representation
- Scientific writing (IND/IMPD, IB, briefing books, reports)

Isotope Chemistry

- ^{14}C radiosynthesis
- Synthesis of stable labeled compounds (^{2}H, ^{13}C, ^{15}N)
- Manufacturing & QC of radiolabeled APIs according to EU-GMP guidelines
- Reanalysis & repurification of APIs
- Dedicated storage for radioactive APIs (^{14}C & ^{3}H)

Best Practice in Animal Welfare

(Discovery & Development)

- We believe that humane care & use of animals is a key element of high-quality science
- Our high standards are confirmed by continuous positive feedback from client audits, authorities & full AAALAC accreditation at all sites working with animals
- In addition to complying with legal requirements, we strive to continuously improve our practices & husbandry conditions in the interest of animal welfare

Drug Development

From Preclinical Candidate to Patient

Our Drug Development Leadership Team

Martina Knoedler
DMPK

Jean-Guy Boiteau
Chemical Development

Achim Freisleben
Bioanalysis

Gareth Winckle
Formulation Development

Sandrine Antoniotti
Analytical Development & QC

Christin Erbach
Clinical Trial Supplies

Ralf Wulkow
Clinical Development

Toxicology

Discovery & Development

In vitro **Toxicology**

In Vivo **Toxicology**

Toxicologic Pathology

Clinical Pathology

Formulation

Toxicology (Discovery & Development)

In Vitro Toxicology

- Genotoxicity: Bacterial Reverse Mutation & Mammalian Cell / Erythrocyte Micronucleus Test, Mammalian Erythrocyte, Pig-a Gene Mutation & *In Vivo* Mammalian Alkaline Comet Assay
- Skin toxicity: Skin irritation (corrosion & sensitization) assays & NRU 3T3 phototoxicity test
- Cardiac safety (ion channel screenings)

In Vivo Toxicology

- Single-dose toxicity, dose range finder & toxicokinetics
- Pivotal repeated dose toxicity (4-, 13- & 26-week)
- *In vivo* genotoxicity
- Customized mechanistic toxicity
- Investigations: clinical observations, ophthalmology, sensory reactivity, functional observations & motor activity

Toxicologic Pathology

- Gross examination, histotechnique & histopathology assessment
- Molecular services incl. development of customized staining / biomarker assays
- Digital pathology platform
- Organ databank
- Peer review for external studies

Clinical Pathology

- Analysis of clinical chemistry, hemostasis, hematology & urine parameters
- Specific clinical biomarkers services, (e.g. insulin, thyroid hormones) from discovery & validation to robust assay development

Formulation

- Formulation stability, homogeneity & test substance concentration
- Development & validation of analytical methods

Bioanalysis

Discovery & Development

LC-MS Assays

Ligand-Binding Assays

Cell-based Assays

Bioanalysis (Discovery & Development)

LC-MS

- Method development & validation (> 100 assays / yr)
- Dedicated large molecule & new modality assay development team
- > 250 non-proprietary assays
- Experienced in VAMS, peptide analysis, PROTAC®s, chiral separations & ion mobility chromatography
- Support from discovery PK throughout non-clinical GLP & clinical development; all biological matrices

Cell-based Assays

- Support of cell-based assays & cell preparations (lysates & cryopreservation)
- Fully equipped cell culture laboratory
- State-of-the-art flow cytometry (BD FACSLyric)

Ligand-binding Assays

- Support of PK & immunogenicity studies (ADA & NAb), biomarkers & biosimilars
- Fully validated systems incl. MSD QuickPlex SQ 120, Gyrolab xPlore & xPand, Tecan M200 ELISA Reader
- Experience with various tissues (using Precellys tissue homogenizer)

- All assays validated according to applicable international guidelines
- Fully validated Watson LIMS incl. immunogenicity module covering validation studies as well
- GLP, ANVISA, S1 license (GMO), BSL2 certification (pathogenic / infectious samples)
- Co-location with Phase I clinic

Chemical Development

- Process Research & Development
- GMP Batch Manufacturing
- Solid Phase Investigations
- Impurities ID & Assessment

Chemical Development

Process Research & Development

- Fast, efficient route evaluation, selection & scale-up
- Co-localized process development & Kg batch manufacturing of preclinical & clinical supplies
- Production of 1 - 10 kg batches (intermediate / API) incl. impurity control for preclinical studies

GMP Batch Manufacturing

- Advancing of candidate from preclinical through phase I / IIa by scale-up in GMP Kilo Lab
- Starting material definition, analytical method validation & PGI assessments, informal & full ICH stability studies & CoA

Solid Phase Investigations

- Selection & control of API solid state
- Identification of new solid forms of small organic molecules (e.g. polymorphs, salts, co-crystals, or amorphous forms)
- Polymorph & salt screening, solubility curves, filtration assessments

Impurities ID & Assessment

- Isolation, identification, synthesis & assessment of unknown impurities (higher than ICH legislation, 0.1 %)
- Analysis of degradation pathways
- Identification of potential ingredient interactions for dossier examination by regulatory agencies

- GMP compliance
- Tox & GMP batches up to 10 kg
- HPAPI up to OEL 0.1 µg/m^3
- Prep-HPLC / SFC, high-res MS, 400 MHz NMR
- State-of-the-art laboratory

Formulation Development

Focus on Semi-Solids & Liquids

Consulting & Technology Development

Preformulation

Prototype Development

Formulation Selection & Preliminary Process

Formulation Development

Consulting & Technology Development

- Project evaluation, product development planning & troubleshooting
- Technology assessment
- IP creation & patent strategy
- Strategic life-cycle management

Prototype Development

- Target product profile & formulation strategy
- Excipient selection & function justification
- Prototyping for optimized formulation parameters
- Stability / API release & skin delivery / tolerance customized to disease / sensory assessment / microstructure characterization

Preformulation

- Solubility & compatibility profiling (single solvents & solvent blends)
- Assessment of key formulation parameters incl. pH, temperature & oxidation
- Rational residual composition design to optimize solubility & skin delivery

Formulation Selection & Preliminary Process

- Robust & de-risked formulation selection of lead & backup candidates & regulatory compliance, stability
- *In vitro* release & skin permeation testing (IVRT/ IVPT)
- *In vitro* (irritation, inflammation), & *in vivo* models, imaging (AP-MALDI-MS)*
- Preliminary assessment of critical process parameters to support scale up

- R&D of topical formulations for pharmaceutical & OTC dermatological treatments & complementary consumer products
- Conception & creation from TPP, preformulation to formulation selection & transition into scale-up, clinical development & QbD.
- 10 g – 10 kg capacity
- HPAPI up to OEL 0.1 µg/m3 (OEB5)
- Other delivery routes, incl. oral liquids (see slide 44)

*atmospheric pressure-Matrix-assisted laser desorption/ionization-mass spectrometry

Analytical Development & QC

Full Service

Method Development & Validation

Release & QC testing

Stability Testing

Analytical Development & QC

Full Service

- Specifications tailored to project stage
- Small & large molecules
- Dosage forms: solid, semi-solid, liquids
- Highly potent APIs up to HHB5 (OEL > 1 µg/m^3)
- GMP certified & FDA inspected

Method Development & Validation

- Analytical continuum DS/DP
- Forced degradation studies
- Container closure integrity testing (blue dye, headspace analysis, high voltage leakage detection)
- Break-loose / glide-force testing
- Rheology platform & *in vitro* release testing

Release & QC Testing

- QC testing of drug substances & products
- Support to preformulation, formulation & scale-up
- Cleaning validation methods
- Non-sterile microbial testing with preservative efficacy & microbial limit tests (USP & Eur Ph)
- In-house QP release

Stability Testing

- Stability chambers, climate cabinets & stand-alone stability storage
- Zone I to IV, ICH compliance
- 320 m^3 of storage with rooms from - 70 → + 60 °C
- Temperature, light & humidity controlled
- Cycling, photostability & transportation studies

Clinical Trial Supplies

Manufacturing

Packaging & Labeling

Logistics & Depot Solutions

Supporting Services

Clinical Trial Supplies

Manufacturing

- Solid oral forms, esp.:
  - Automatic capsule filling, incl. over-encapsulation
  - Tablet pressing (matching placebos)
- Creams, lotions, ointments & oral solutions
  - 10 & 50 kg tank with 5 kg / 25 kg melting vessel
- Handling of high potent APIs

Packaging & Labeling

- Primary packaging of non-sterile products
- Blistering (PVC / Alu, Alu / Alu, Aclar) & wallet packs
- Secondary packaging & labeling at:
  - Ambient / 2 - 8°C / - 20°C / on dry ice
- Blinding solutions for, e.g., PFS, inhalers, tubes
- Packaging of light-sensitive products

Logistics & Depot Solutions

- > 700 m^2 clean rooms for manufacturing & primary packaging
- 6 walk-in refrigerators & 2 walk-in freezers
- Global distribution
- Worldwide depot network
- Reconciliation & destruction

Supporting Services

- Import & QP services (incl. blood products & vaccines)
- Creation of randomization lists & emergency envelopes
- In-house label printing, all types of labels
- Comparator sourcing incl. decommissioning
- Handling of controlled substances

Clinical Development

Early Clinical Development

Phase II-III, Clinical Efficacy Trials

Clinical Trial Services

Clinical & Regulatory Consulting

Clinical Development

Early Clinical Development

- Clinical trials:
  - First-in-man (SAD/MAD)
  - Pharmacokinetic (incl. PK, BA / BE, DDI)
  - Special safety (e.g. TQT trials)
  - PK / PD
  - Proof-of-concept
  - First-to-patient (Phase Ib)
  - Exploratory in patients with PK / PD endpoints

Phase II-III, Clinical Efficacy Trials

- Phase II clinical trials with complex endpoints at few specialized sites
- Large-scale Phase II or III clinical trials in a multi-center setting
- Special expertise & track record in therapeutic area respiratory

Clinical Trial Services

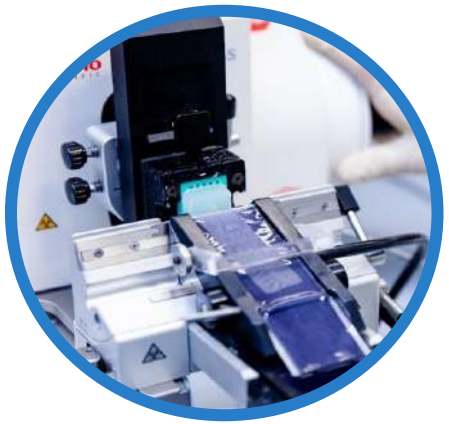
- Project management
- Clinical trial supply management
- Data management
- Medical writing
- Biostatistical & bioanalytical evaluation
- Regulatory support
- Clinical monitoring

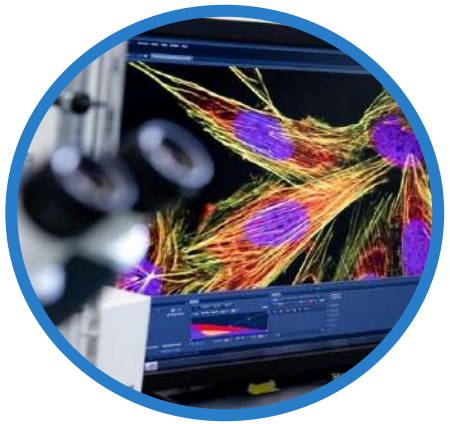
Clinical & Regulatory Consulting

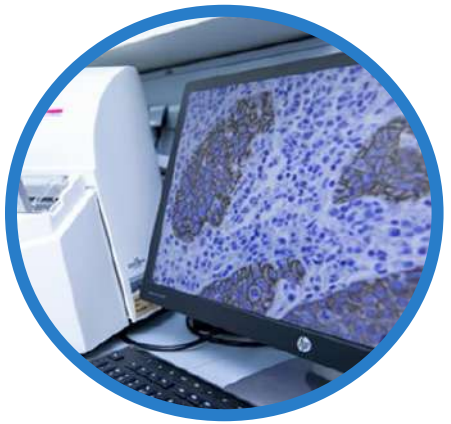
- Setup of clinical trial concepts & development plans
- Regulatory consulting
- Advice on clinical-pharmacological questions

Integrated Drug Discovery & Development Solutions

Integrated Therapeutic Solutions – Oncology







Solutions along the Value Chain

- Target Identification & validation
- *In vitro* biology & *in vivo* pharmacology
- Biomarker discovery
- Bioinformatics platform
- Preclinical & clinical sample analysis
- API manufacturing
- Clinical Phase I studies in healthy volunteers
- Clinical monitoring (Phase II-IV) studies

In Vitro Capabilities

- Functional genomics platform (CRISPR & viral expression systems)
- Gene expression platform (bulk & single-cell next-generation sequencing)
- Flow cytometry, IHC & microscopy units
- Cellular assays
- Mode-of-action exploration

In Vivo Capabilities

- Efficacy, PK/PD & biomarker studies
- *Ex vivo* analysis in tissues & tumors
- >100 xenogeneic & syngeneic tumor models
- Radiation & imaging capabilities
- Model development
- PK/PD modeling & human dose prediction
- Preclinical safety & toxicology
- AAALAC accredited *in vivo* facility

Integrated Therapeutic Solutions – Dermatology

Our Experts

- Multidisciplinary teams combining a unique blend of discovery, research, and development expertise in drug substance & drug product creation
- Decades of experience in identifying, developing & manufacturing drug substances, systemic candidates & topical products

How We can Support You

- Identification of optimal asset indication space
- Preclinical *in vitro & in vivo* efficacy models for various skin diseases, safety, PK & toxicology
- PKPD modelling & human dose prediction
- API, finished semi-solid & liquid product development incl. creams, gels, ointments & foams

Facilities & Equipment

- Established on former medium and big Pharma R&D sites incl. one that was the world's largest skin-focused R&D center
- Best-in-class equipment incl. liquid chromatographs (UPLC/HPLC), LC-MS/MS, Q-TOF, qNMR, Biolumix, LUMISizer, RapidOxy, AP/MALDI-MS

Integrated Solutions – Our PROTAC®s Platform

Target / POI Identification

Various indications
Unbiased target ID approaches
Target selection
ID of POI binder using uHTS, fragment / MS / biophysical / virtual screens

MedChem Design

Collection of building blocks for rapid PROTACS assembly, with focus on:

- Linkers
- POI & E3 ligase binders
- Property optimization

E3 Ligase Portfolio

Known E3 binders
Novel E3 ligases & binders:

- Focused / rational approach
- Comprehensive bioinformatics analysis / unbiased screen strategy

PROTACs Characterization Platform

Biochemical, biophysical & cellular mechanistic assays
Ubiquitylation assays
Proteomics
DMPK & bioanalysis
In vivo models

Contact Us

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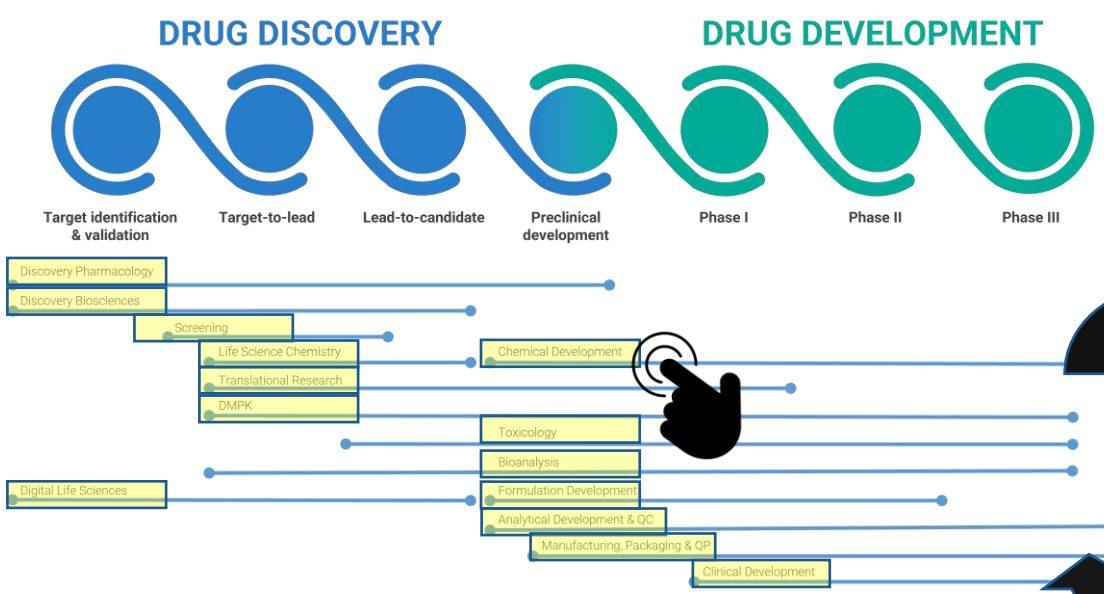
www.calendly.com/nuvisan

How to Use the Value Chain Hyperlinks



- Hidden behind the respective name of the solution lines in the value chain on slide #10 are invisible hyperlink boxes (exemplary shown in yellow here)
- ***When in presentation mode***, you can click on them and you automatically jump to the respective detailed solution line slide

- If you are on the detailed solution line slides and would like to go back to value chain, there is an invisible hyperlink box at the bottom of those slides (exemplary shown as a yellow box here)