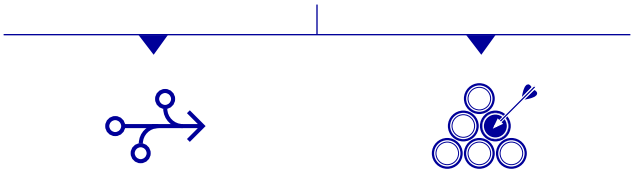
evotec

#RESEARCHNEVERSTOPS

Fastest Route To The Clinic

- **INDiGO** is Evotec's solution designed to de-risk and accelerate IND-enabling programs, with a proven track record in dramatically reducing time and costs during the IND-enabling phase of development (by more than 50%), while ensuring excellent quality and scientific integrity.
- Typically, drug candidates can be advanced from candidate selection to IND-submission in 48–52 weeks.
- Our experienced team not only executes R&D projects, but also proactively contributes to your scientific strategy.
- Clients can either opt for the full INDiGO platform or selected preclinical development and CMC components.

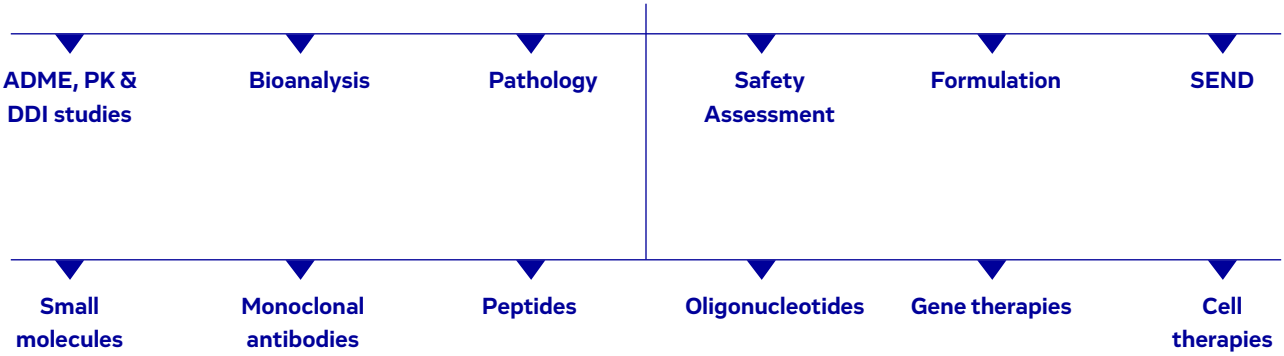
INDiGO Integrated Solutions



INDiGO

INDiGO- ***Select***

Integrated Pre-Clinical Development



1. INDiGO: The fastest path to the clinic

- Accelerated drug development through interdisciplinary integration and expert coordination of all drug development activities under one roof
- Industry-leading timeline from candidate nomination to regulatory submission
- Management by experienced, dedicated project managers and drug development professionals
- Seamless knowledge transfer across disciplines, maximising quality of overall development package
- Custom-designed, flexible development plans allow for real-time adjustments and maximum efficiency
- Superior project governance, performance review and issue escalation management

INDiGO offers a two-tiered approach to the clinic:

- **INDiGO-*Select*:** For a single or a short list of candidates, this integrated package will fully de-risk your molecule before investing millions and months in clinical-enabling studies. In addition, this package will enhance the quality, speed of delivery, and probability of success for your clinical candidate.
- **INDiGO:** Once your clinical candidate is selected, this fully integrated clinical-enabling package focuses on interdisciplinary coordination of all aspects of drug development, conducted and managed by a single Evotec team at a single Evotec site.

Our approach is designed to eliminate the inherent inefficiency of the traditional multiple-vendor approach by consolidating development to a single, crossfunctional team with decades of drug development experience. All while increasing the probability of success and speed of your program.

- More than 40 different functions across multiple disciplines
- Managed on an operational level by more than 100 experienced drug development professionals
- Industry leading timelines and excellent track record of on-time delivery
- 48 INDiGOs successfully completed
- High rate of client retention after first successful INDiGO programme

2. Integrated Pre-Clinical Development

We can perform the full spectrum of pre-clinical studies, with the assurance of accurate and balanced assessments even when meeting the tightest deadlines.

All components are an important part of our INDiGO fully integrated programs.

Capabilities and services

- ADME, PK and DDI studies
- Bioanalysis
- Pathology
- Safety Assessment
- Formulation: identification and preparation
- SEND: internal data capture systems
- Experience with all modalities (NCE, mAbs, peptides, RNA, cell and gene therapy)
- State-of-the-art quality systems with impeccable regulatory inspection history

Safety Assessment

Full range of services from exploratory programmes to GLP-compliant toxicology studies with the aim to establish the toxicological profile of new products

- Fully integrated, science-driven development approach
- Diverse, dynamic team of expert scientists capable of handling projects of any complexity
- Tailored studies and programmes based on specific client needs
- Solutions-based approach to problem solving
- Fully accredited AAALAC facilities

ADME

Tailored solutions using state-of-the-art technology to optimise and 'de-risk' potential lead candidates and to guide the selection of the most relevant pre-clinical tox species. We offer definitive radio-metabolism packages and Human Radiolabelled Studies (HRS) support.

Expertise based on a thorough understanding of regulatory requirements and many years of hands-on experience on a diverse range of molecules.

- Wealth of technical expertise and decades of experience
- Helped lift the FDA clinical hold of projects with suspected metabolite-based toxicity through the design and implementation of integrated approaches for profiling, isolation and structural identification studies across species and test systems
- Huge experience with tailored,study designs to advance understanding of drug disposition and fully meet regulatory requirements

Pathology

Our Pathology Unit is dedicated to toxicological pathology for drug development in multiple species, but it also supports investigative studies to target attrition issues, validation and characterisation of animal models, as well as identification and validation of biomarkers.

- 25+ years of experience with a broad skillset in discovery and clinical-enabling pathology
- Unparalleled flexibility with all capabilities in-house and under one roof
- DACVP/DECVP, MRCPATH, DECLAM, DECVCP qualified pathologists/clinical pathologists

Bioanalysis

Breadth of experience in regulated bioanalysis for small molecules and bio-therapeutics of any size: peptides, recombinant proteins, monoclonal antibodies, oligonucleotides, as well as anti-drug antibodies, vaccines, cell therapies and gene therapies, both for non-clinical and clinical sample analysis.

Full capabilities for clinical pathology in support of preclinical studies. Bioanalytical validations are performed according to EMA/FDA guidelines and the analyses are performed in compliance with GLP or GCP regulations.

- Rapid turnaround enabling "go/no-go" decisions faster
- Team with extensive knowledge of animal haematology, coagulation, clinical biochemistry and urinalysis
- All relevant mass spectrometry, ligand binding assay, and clinical pathology platforms in-house
- Dedicated sample management team

Integrated Formulation Support

A team of pre-clinical formulators working in synergy with DMPK/toxicology experts to offer integrated formulation support to preliminary or GLP toxicology studies.

Our formulation experts use their knowledge and experience to guide formulation development tailored to each animal species both for oral and parenteral compounds, even with challenging water-insoluble compounds with complex bioavailability issues. This improves the chances of selecting the best formulation for FIM studies and enables reduction of the number of animal studies. Knowledge gathered during this early formulation stage can later be used as a starting point for clinical formulation development.

- Designated team responsible for entire process from preclinical to clinical formulation
- *In silico*, *in vitro* and *in vivo* models
- Comprehensive, integrated capabilities with proven expertise in solutions, suspensions, amorphous solid dispersions, lipid-based systems etc.

Abuse Liability Assessment

More than 25 years of experience in preclinical models of drug dependence and abuse liability in the pharmaceutical industry environment.

We can ensure GLP compliance in accordance with the most recent guidelines for neuroscience drug development. Our studies can be integrated within a multidisciplinary full-scope clinical-enabling program with chemistry, pharmacology, DMPK, safety assessment, regulatory and clinical support.
To allow for proper risk mitigation, abuse liability should be incorporated early in development and begin at the candidate selection stage to avoid potential issues during early clinical trials.

- Consulting on abuse liability strategy including 8-factor analysis
- Broad range of behavioural studies including: drug discrimination; self-administration; withdrawal, conditioned place preference
- Integration of behavioural assessment with DMPK assessment to establish PK/PD relationship

Contact our experts to find out how Evotec INDiGO integrated solutions and our pre-clinical team can de-risk and accelerate your IND-enabling programs.