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#RESEARCHNEVERSTOPS

FASTEST ROUTE TO THE CLINIC

For decades, the biotechnology industry has struggled to align complex drug research and development processes. Drug development is still long, expensive, and associated with high failure rates. INDiGO is Evotec's solution designed to de-risk and accelerate IND-enabling programs.

INDiGO, the market-leading integrated drug development solution, has 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 less than 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

- ADME, PK & DDI studies
- Bioanalysis
- Pathology
- Safety Assessment
- Formulation
- SEND

COMPOUNDS/THERAPIES

- Small molecules
- Monoclonal antibodies
- Peptides
- Oligonucleotides
- Gene therapies
- Cell therapies

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1. INDiGO: THE FASTEST PATH TO THE CLINIC

- Accelerated drug development through inter-disciplinary 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, cross-functional team with decades of drug development experience. All while increasing the probability of success and speed of your program.

Highlights

- 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
- 56 INDiGOs successfully completed in just the last 5 years
- 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 of the appropriate formulation for *in vivo* administrations
- SEND: generation of SEND datasets for all studies conducted using internal data capture systems

Experience to support the pre-clinical development of:

- Small molecules
- Monoclonal antibodies
- Peptides
- Oligonucleotides
- Gene therapies
- Cell therapies

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Learn more about our capabilities in detail:

Safety Assessment

We offer a full range of services from exploratory programmes to fully GLP-compliant toxicology studies with the aim to establish the toxicological profile of new compounds or to extend the known profiles of existing ones (new indications, new formulations, new routes of administration).

Highlights

- Fully integrated, science-driven development approach with pharmaceutical background
- State-of-the-art quality systems with impeccable regulatory inspection history
- 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
- Multiple modalities: NCE, NBE, gene therapy/ viral vectors, mAb, cell therapy

Pathology

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

Highlights

- 25+ years of experience with a broad skillset in discovery and clinical-enabling pathology
- GLP certified with highest quality standards and an impeccable regulatory inspection history
- Unparalleled flexibility with all capabilities in-house and under one roof
- DACVP/DECVP, MRCPATH, DECLAM, DECVCP qualified pathologists/clinical pathologists

Abuse Liability Assessment

Our team has 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.

Highlights

- 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

Bioanalysis

We have a 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.

Highlights

- 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

ADME

We apply rational, 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.

Our expertise is based on a thorough understanding of regulatory requirements and many years of hands-on experience (*in silico, in vitro* and *in vivo*) with a diverse range of molecules, both of chemical and biological origin, as well as many of the combinations/permutations in-between, against a vast array of clinical indications.

Highlights

- 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, specific study designs to advance understanding of drug disposition and fully meet regulatory requirements and timelines

Integrated Formulation Support

Our dedicated team of pre-clinical formulators is working in synergy with DMPK/toxicology experts to offer integrated formulation support into early tox phase and GLP IND-enabling studies.

Based on study design needs, the compound's physico-chemical properties, the dose-requirement and an in-depth understanding of complex bioavailability issues, our formulation experts use their knowledge to guide formulation development tailored to each animal species both for oral and parenteral compounds, even with challenging water-insoluble compounds with bioavailability issues. Thereby, it improves chances of selecting the best compound and 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.

Highlights

- 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.

Find out how Evotec INDiGO integrated solutions and our pre-clinical team can de-risk and accelerate your IND-enabling programs:
Please contact us at info@evotec.com or visit www.evotec.com