

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



For decades, the biotechnology industry has struggled to align complex functions towards a singular goal of getting to the clinic. The process is long, expensive, resource straining, and bursting with risk.

We believe the road to the clinic is difficult enough without the inefficiencies of traditional drug development, so we are offering a better option. With our acquisition of Aptuit in 2017, Evotec is now the only organisation with the capability to successfully deliver fully-integrated drug discovery and development programs.

We offer 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 intensely on interdisciplinary coordination of all aspects of drug development, conducted and managed *by a single Evotec team, and at a single Evotec site.*

In bringing your candidate through IND filing “under one roof“, we will 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 and speed of success of your program.

CHEMISTRY & PHARMACEUTICAL PROPERTIES

- ▶ Evaluation of synthetic route/safety and scalability, analytical methods, physical form of solid (salts, polymorphism), physical & light stability
- ▶ Early pre-formulation and bio enhancement investigations

DRUG METABOLISM & PHARMACOKINETICS ASSESSMENT

In vitro and *in vivo* ADME characterisation, including

- ▶ cross-species behaviour and prediction to human PK and expected effective dose(s)
- ▶ non-rodent species selection

PHARMACOKINETIC – PHARMACODYNAMIC RELATIONSHIP

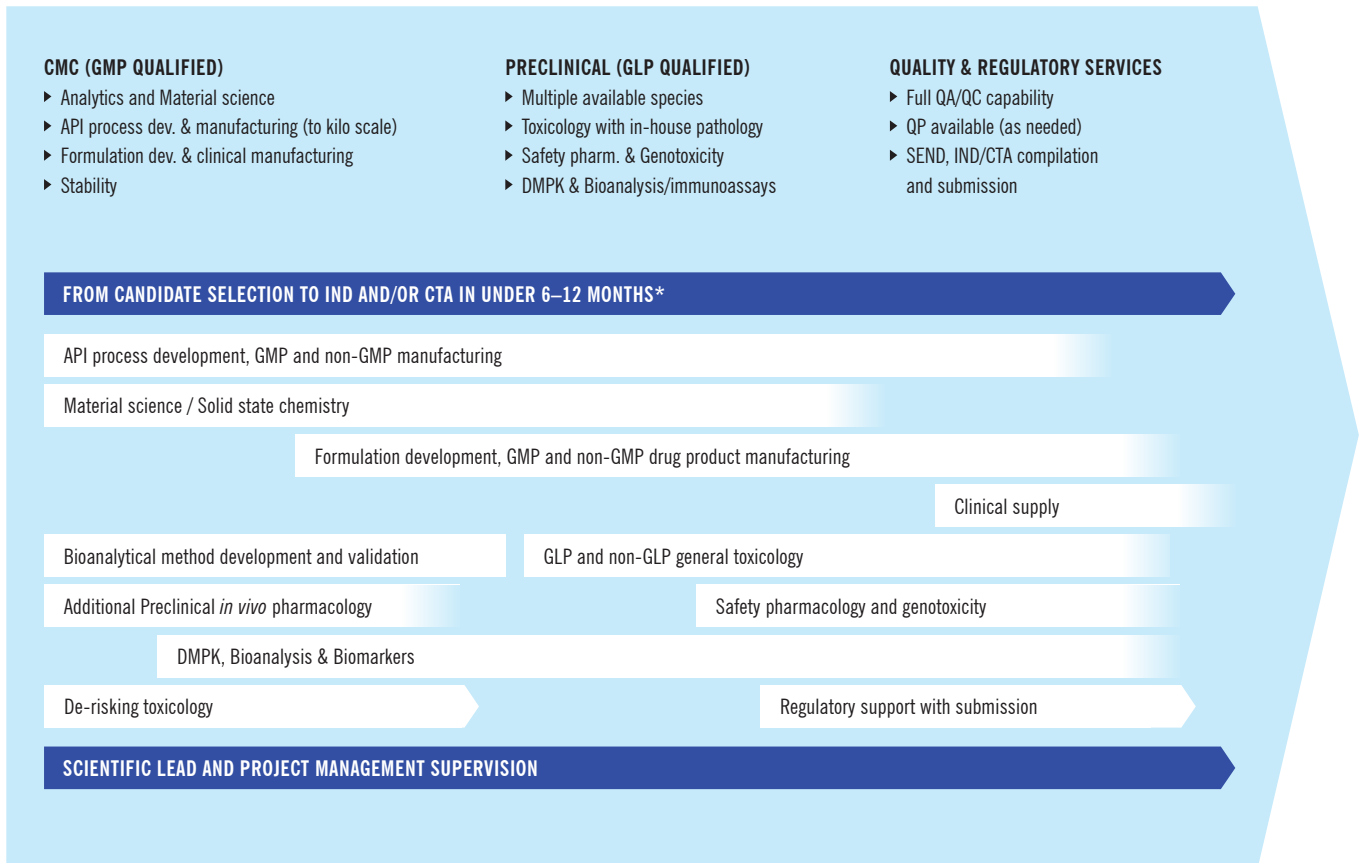
- ▶ Detailed examination of PK:PD relationship is required to refine dose response and predicted human dose

PRELIMINARY SAFETY ASSESSMENT

- ▶ *In vitro* safety package and non-GLP *in vivo* safety evaluation to determine safety risks, on-target and off-target pharmacology

INTEGRATED VIEW ON

- ▶ Selection of best compound(s)
- ▶ Current level of development readiness of key compounds
- ▶ Work package recommended to identify single compound which has best characteristics for further development



*Note: timeline to regulatory submission is dependent upon several factors and will be determined based upon your candidate's profile

ATTRIBUTES

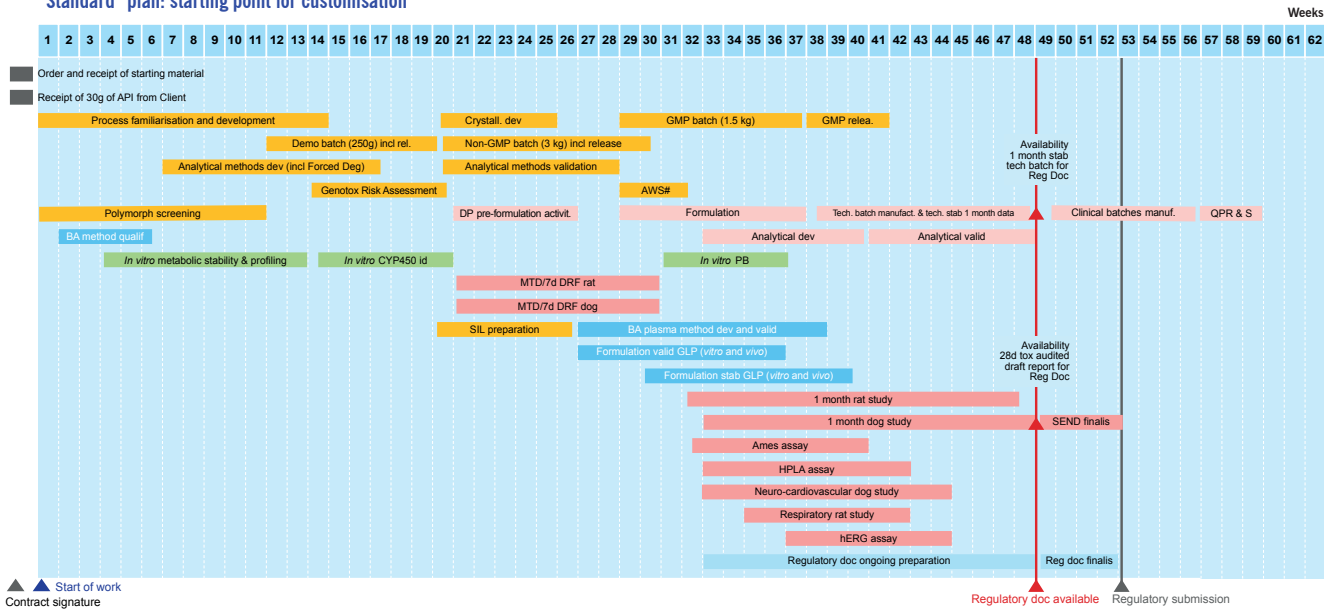
- ▶ **Integrated science “under one roof”**
 - Reduced tech transfer time and cost
 - Flexibility and efficiency
- ▶ **Aggressive timelines with track record of delivery**
 - Drug development experts with pharma background
 - True extension of Partner’s organisation
 - Leads to higher quality scientific solution
- ▶ **Professional alliance and project managers**
- ▶ **Top GxP standards for quality**

HIGHLIGHTS

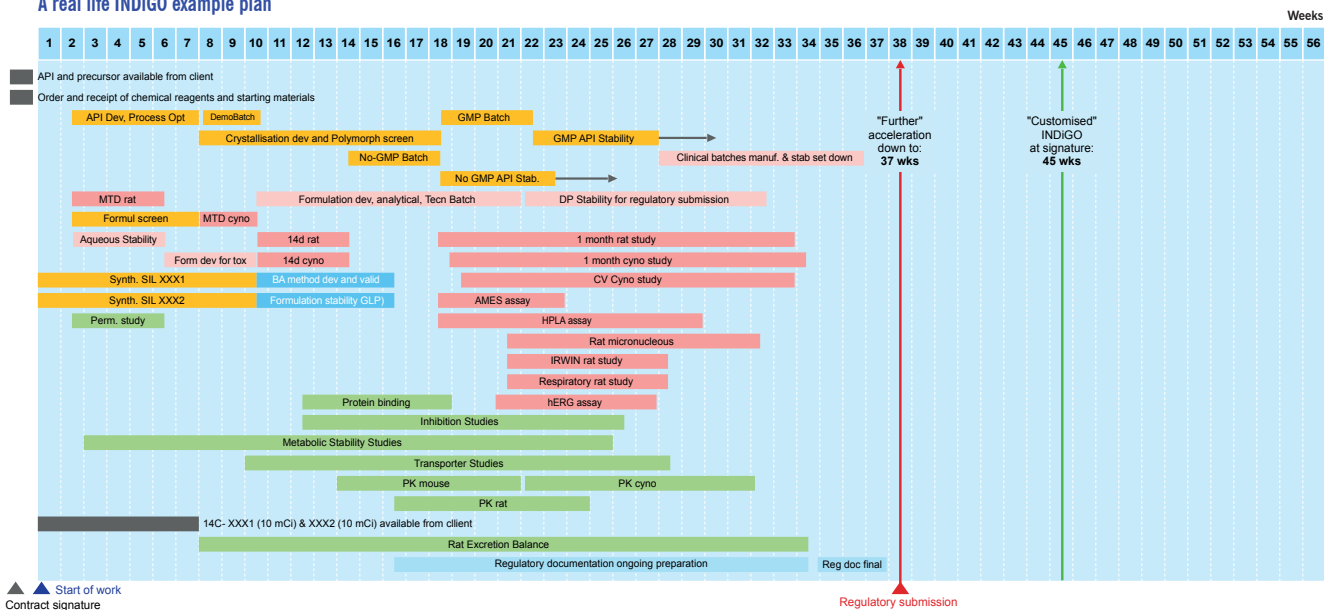
- ▶ **More than 40 different functions across multiple disciplines**
- ▶ **Managed on an operational level by more than 100 experienced drug development professionals**
- ▶ **Industry leading timelines and excellent track record of on-time delivery**
- ▶ **36 completed programs in the last 5 years**
- ▶ **High rate of client retention after first successful INDiGO program**

Evotec INDiGO: Partnering with the experts – reliably designed drug development project plans with accelerated timelines.

“Standard” plan: starting point for customisation



A real life INDiGO example plan



Find out how Evotec INDiGO integrated approach can *reduce risk, accelerate development schedules and boost the efficiency* of your drug development program.