Here's How to Accelerate Your Early Drug Candidate into the Clinic

The successful development of drug candidates is a pivotal goal of today's biopharmaceutical industry. However, as the complexity of drug development grows and the industry faces ever more challenges, there is an increasing need for partnering and collaboration.

Roberto Dorigatti, Senior Vice President of Integrated Development Programs at the Evotec company Aptuit

Over the past 20 years, drug discovery and drug development processes have changed dramatically. Instead of setting out to tackle projects single-handedly, pharma and biotech companies as well as startups, spin-offs or subsidiary companies are turning to collaborators for specific expertise. This allows for increased gains and efficiency in discovery and development pipelines.

Today, the acceleration of an early drug candidate into the clinic has become extremely critical, and companies strive to get their molecule into the clinic before their competitors do.

"Entering quickly into the clinic allows for an early clinical read-out, which can significantly save patent life, as well as enable quicker pipeline decision making," says Roberto Dorigatti, Senior Vice President of Integrated Development Programs at Aptuit, an Evotec company. *"Funding is also associated with milestone achievements, and generally, the entry into Phase I is a key step."*

Teamwork is key

Since its establishment in 1993, Evotec has supported a wide variety of partners ranging from virtual biotech startups to pharma. The company's experts are highly specialized and support

their partners and collaborators to accelerate novel agents through the pipeline. Their flexible business model and a collaborative and adaptable culture allow for the efficient delivery of multiple projects.

Grasping the importance of downstream processes is the key to quicker integration and an interdisciplinary approach. This revolves around the understanding and acceptance that not one person can be the expert, but that a team of experts is needed to ensure the best possible experiment design and processes.

What is INDiGO?

Evotec's INDiGO program picks up on this philosophy. INDiGO allows for the acceleration of early drug candidates into the clinic by managing all traditional drug processes in one project under one roof with one contractual obligation.

The program is custom-designed for each molecule and includes all development factors such as molecule type, form of dosage, therapeutic area but also strategic factors concerning specific company's business targets.

The execution of a project requires the involvement of a team of seasoned scientists and project management experts who have a long track record of successfully delivering candidates to clinic and beyond.

Evotec's INDiGO team includes experienced project managers, scientists and drug development professionals

Their expertise enables the acceleration of early drug candidates in less than 12 months, depending typically on the chemical complexity and associated synthetic challenges, drastically reducing the time from nomination to regulatory submission. The team covers all aspects of drug development in order to get an agent ready for human testing.

Advantages of INDiGO

Processes included and integrated in the INDiGO program are chemical route scouting, chemical development and drug substance manufacturing, material science, formulation development, analytics and clinical manufacturing of the drug product, as well as preclinical activities such as safety assessment, DMPK, bioanalysis including biomarkers.

In the final steps, the team also covers regulatory documentation preparation for filing of an IND or CTA. All these activates and run largely in parallel rather than sequentially reducing significantly delivery times.

"Evotec has a track record of achieving very aggressive and largely shorter than industry average project timelines from start of chemistry to regulatory submission," Roberto explains. "*Importantly, we consistently deliver to timelines agreed at contract signature, despite the many challenges normally found in drug development."*

Business aside, drug development projects include a lot of science as well. Evotec's team works in various fields, such as chemical route scouting, manufacturing, material science and safety assessments

Evotec's INDiGO team provides scientific and project-management expertise to progress its partner's project through the complex stages of drug development. The team includes leading drug development professionals with a pharma background, who can take rapid and scientifically sound decisions, whilst keeping regulatory implications in mind.

The fast-paced execution of the project, means that a professional project manager keeps up a fundamental and ongoing communication between Evotec and the partner. This is key for bringing the project to successful regulatory submission.

Additionally, *"Regulatory compliance and quality must be the top priority,"* says Roberto. *"And under no circumstances do we make compromises in these areas."*

Scientific leadership

Simultaneously, a dedicated seasoned drug development professional is appointed as scientific project leader who provides an overall scientific supervision and coordination.

"INDiGO® projects are managed by our most experienced project managers and leading world-class development professionals who implement tailored development strategies designed specifically for the molecule, therapeutic area and strategic needs," Roberto explains. *"In case of delays or unexpected events, our project managers can manage real-time adjustments in order to retain the agreed timelines.*

Easily tackling risks

When it comes to the acceleration of early drug candidates into the clinic, the question of risk arises. Therefore, during the development phase, the project manager guides the team in the definition of a detailed risk analysis discussed and agreed with the partner.

In this analysis all potential risks associated with plan and acceleration are assessed. In accordance with these risks, associated contingency and mitigation plans are created. This is an iterative exercise until the right compromise is found.

The timeline and budget are agreed upon early in the process. Evotec's experts troubleshoot in real time to manage unexpected events and prevent delays. This ultimately results in a time and cost saving for the client in comparison to smaller studies being run through multiple locations with a lack of oversight and cross talk.

Are you working on an early stage drug candidate? Do you need help in managing the development process and accelerating your candidate into the clinic? Get in touch with Evotec, benefit from their expertise and get your drug candidate into the clinic before your competitor does!

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