Preclinical Candidate Development

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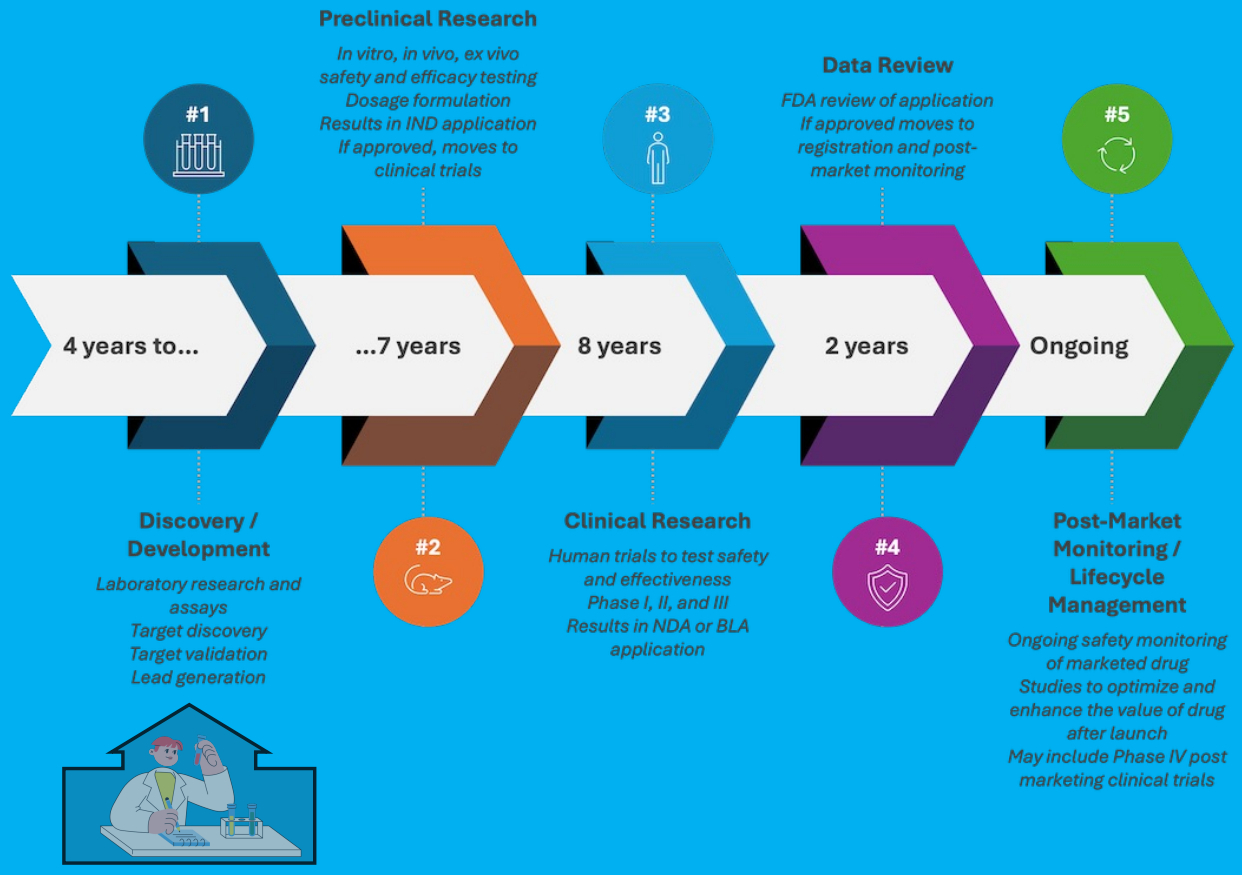
Where Are You On The Drug Development Journey?



Preclinical Drug Candidate Development is a Complex and Time-Consuming Process

Biotechnology and pharmaceutical start-ups often face financial, scientific, and physical resource constraints. As a result, they may struggle to outsource their critical preclinical drug development needs to a single integrated CRO capable of delivering the demanding standards of scientific rigour and excellence at every stage of the discovery and development journey.

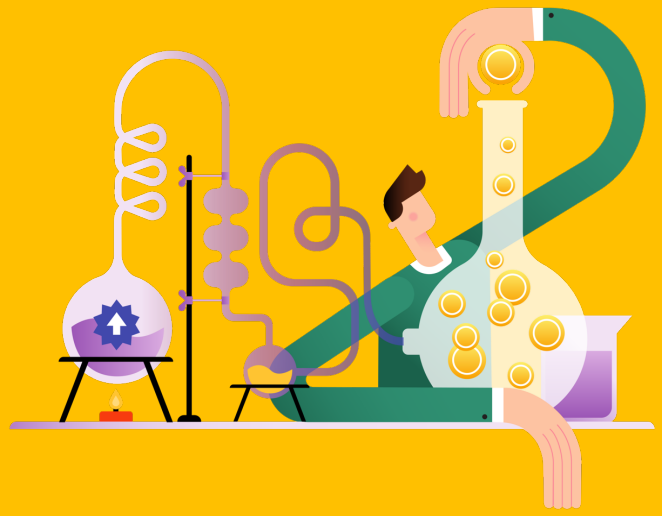
It’s About Managing Your Resources

With new compounds, evaluation of the potential risks and hazards associated with potential drug candidates happens at a crucial time. Investors are considering ongoing financial support in anticipation of significant financial return, while developers are calculating the likelihood of scientific success based on their understanding of complex data and regulatory requirements.

Early collaboration with a laboratory partner experienced in supporting organisations with limited resources helps to avoid the common mistakes that developers make with their investors when communicating, presenting, and interpreting testing data.

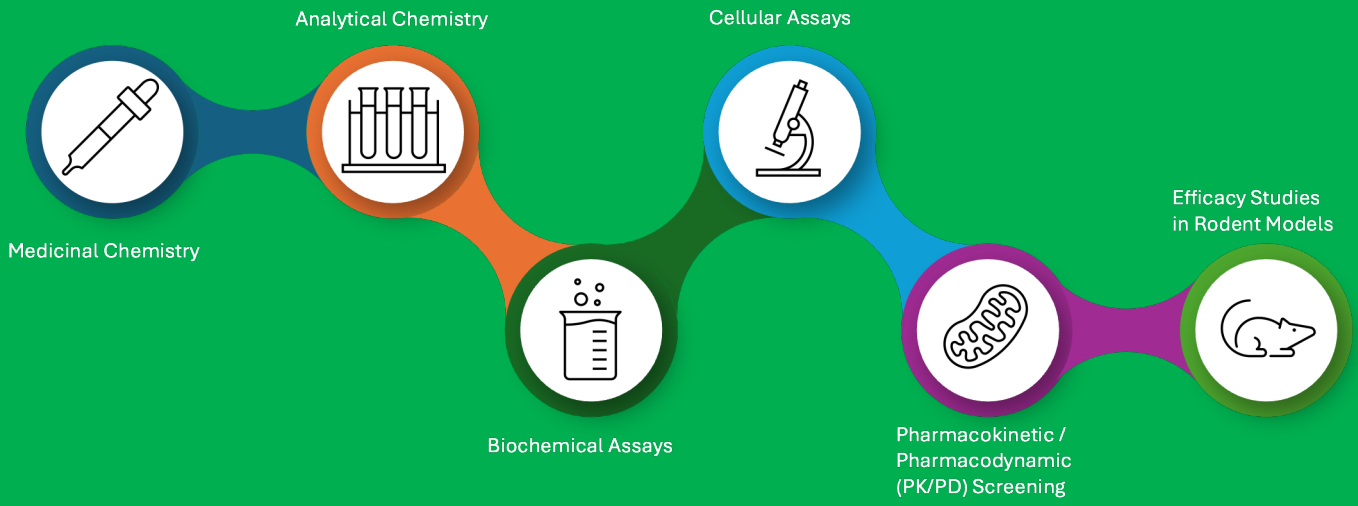
And Finding The Right Partner

With over 100 candidate development projects completed, our objective is to foster collaboration between developers, their investors, and our multidisciplinary experts by co-developing risk mitigation strategies across hit identification, synthesis, lead optimisation and candidate selection.



This approach builds consensus on the most appropriate and cost-effective study design, resulting in a customised cross-specialty bundle of non-GLP studies that delivers all the data necessary to make critical go/no-go decisions - on time and in budget.

Supporting Your Drug Candidate Development Journey At Every Step



Medicilon are experts in developing small molecule drugs, Proteolysis Targeting Chimeras (PROTACS), Antibody-Drug Conjugates (ADCs), and Antibody-oligonucleotide conjugates (AOCs). In collaboration with Medicilon, Hoeford offers access to a Preclinical Candidate Development Package tailored for developers of these and other novel drugs to advance their drug candidates to the next development stage with confidence.

Essential Lead Optimisation and Non-GLP Assays

Medicinal Chemistry:

Medicinal chemistry testing uses CADD/AIDD to develop and optimise the chemical properties and structural attributes of early-stage drug candidates, thereby enhancing potency, bioavailability, overall efficacy, and the predictability of interactions.

Tests under this category may include solubility assessments, stability testing under various conditions, determination of metabolic stability, and structural modification analysis. At this stage, we can also undertake parallel research to design synthetic route scalability for manufacturing consistency, as well as compound management logistics.

Analytical Chemistry:

Analytical chemistry plays a critical role in ensuring the purity, stability, and quality of drug compounds during the initial stages of development.

This involves advanced analytical techniques such as high-performance liquid chromatography (HPLC), mass spectrometry, and nuclear magnetic resonance (NMR) spectroscopy.

Tests conducted may include purity analysis, identification of potential impurities, determination of degradation products, and confirmation of compound structure.

Biochemical Assays:

Biochemical assays provide insights into the interactions between early-stage drug candidates and their molecular targets, helping to ensure the development of selective and effective therapeutic candidates.

Tests may include enzyme activity assays, receptor binding studies, determination of target specificity, and identification of off-target effects.

Cellular Assays:

Cellular assays involve evaluating the impact of drug candidates on cell viability, proliferation, and signalling pathways.

This is essential to identify potential adverse cellular responses and confirm the specificity and efficacy of the drug candidates in relevant cell types.
Tests may include cytotoxicity assays, cell signalling pathway analyses, determination of cell-specific responses, and assessment of target cell specificity.

Pharmacokinetic/Pharmacodynamic (PK/PD) Screening:

PK/PD screening provides crucial data on the absorption, distribution, metabolism, and excretion (ADME) profiles of early-stage drug candidates.

This helps to identify and mitigate any potential unpredictability in the compound's pharmacokinetic and pharmacodynamic profiles.

Tests may include assessment of absorption kinetics, distribution in various tissues, and its effect on various metabolic pathways.

Efficacy Studies in Rodent Models:

Efficacy studies in rodent models offer valuable insights into the therapeutic responses and potential safety risks associated with early-stage drug candidates.

These studies help validate the therapeutic potential and identify any potential efficacy uncertainties in preclinical settings.

The inclusion of *in vivo* PK-PD-efficacy studies at early stages during lead identification and optimization stages of a drug development programme can significantly accelerate the selection of the most promising compounds.

Tests may include tumour growth inhibition assays, disease-specific model evaluations, determination of biomarker responses, and safety profile evaluations in animal models.

Mitigating Risk, Maximising Potential

Successful preclinical drug candidate development requires a collaborative approach, with active communication, shared decision-making, and a unified vision between the developer, the investor, and the testing laboratory. Choosing the right laboratory partner at this stage is crucial to ensuring a clear understanding of safety, compliance, and risk.

Leveraging the expertise of our experienced consultants in the development and design of studies facilitates the most appropriate regulatory testing roadmap, minimises obstacles and streamlines the path to successful market introduction. Collaboration serves to mitigate risks, optimise outcomes, and foster confidence and justification for further investment, development, and commercialisation.

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World-class integrated preclinical research and testing services

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