Pre-IND Safety and Efficacy

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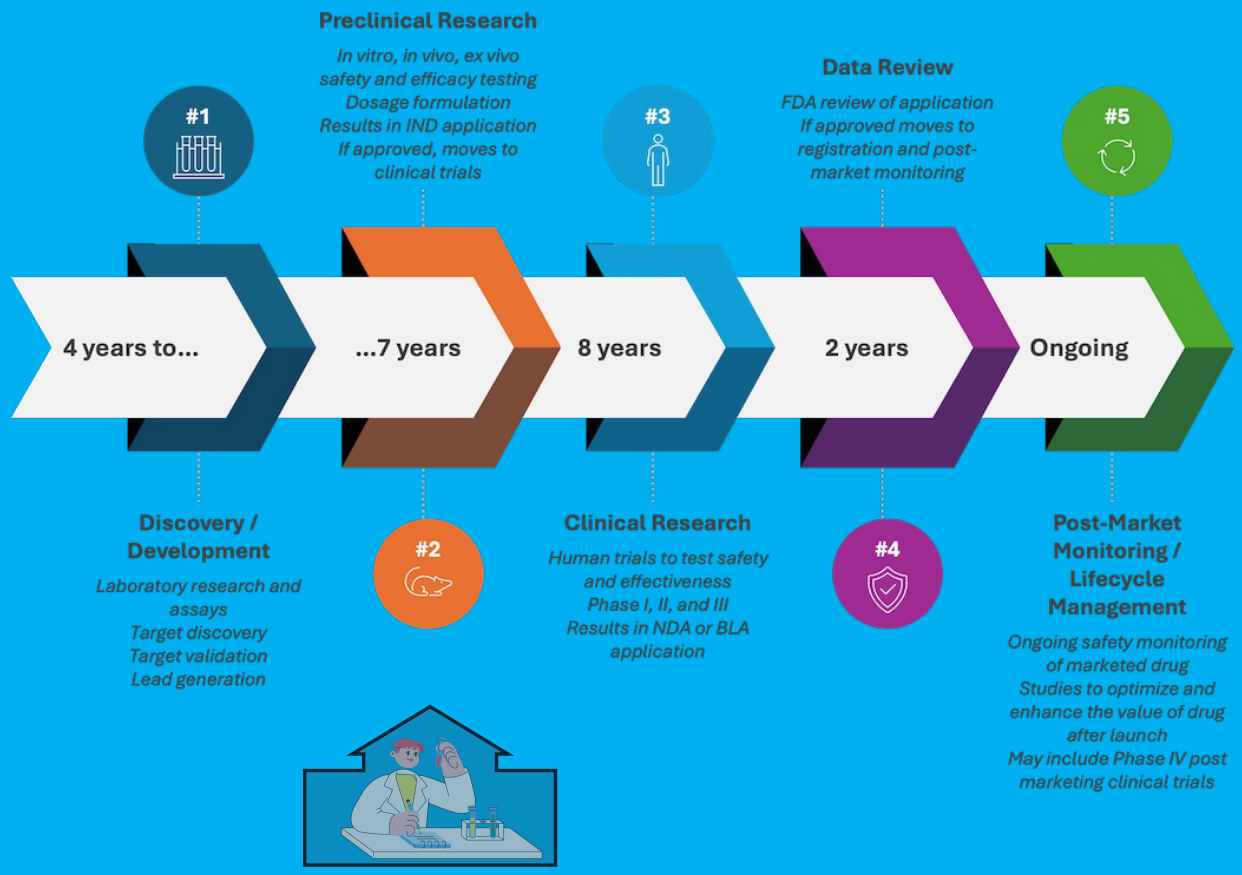
Where Are You On The Drug Development Journey?



Set Your Pre-IND Safety and Efficacy Testing on the Path to Regulatory Approval

The transition from preclinical development to Investigational New Drug (IND) submission is a pivotal phase that marks the initiation of formal communication with regulatory authorities, such as the U.S. FDA or the U.K. MHRA. Regulatory approval at the IND stage is a prerequisite for conducting clinical trials and signifies that the investigational drug has demonstrated sufficient safety and potential efficacy to justify its progression to human testing.

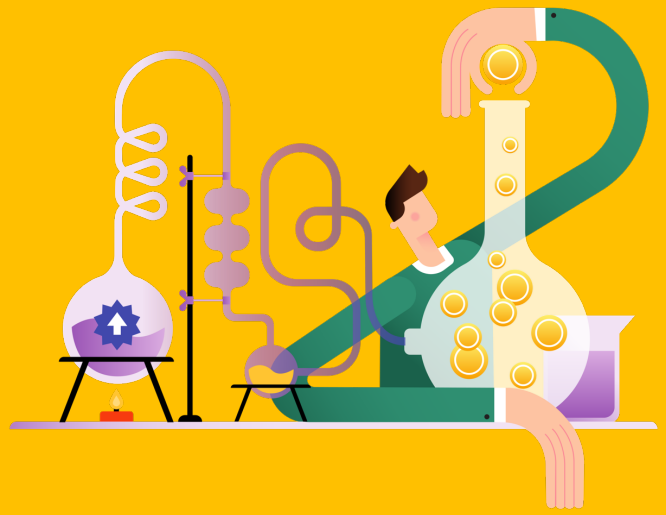
It’s About Building On Your Success

The successful transition to the IND stage is also a significant milestone for investors because it instils confidence in the drug programme's viability and potential for success. Moving to the later stages of clinical development enhances the likelihood of bringing the drug to market, addressing unmet medical needs and contributing to commercial success.

The IND submission process allows for a comprehensive review of preclinical data, enabling regulators and sponsors to make informed decisions. Positive regulatory interactions and feedback can lead to refinements in study design, thereby optimising the overall drug development pathway and opening the door to increased funding and support for further clinical development phases.

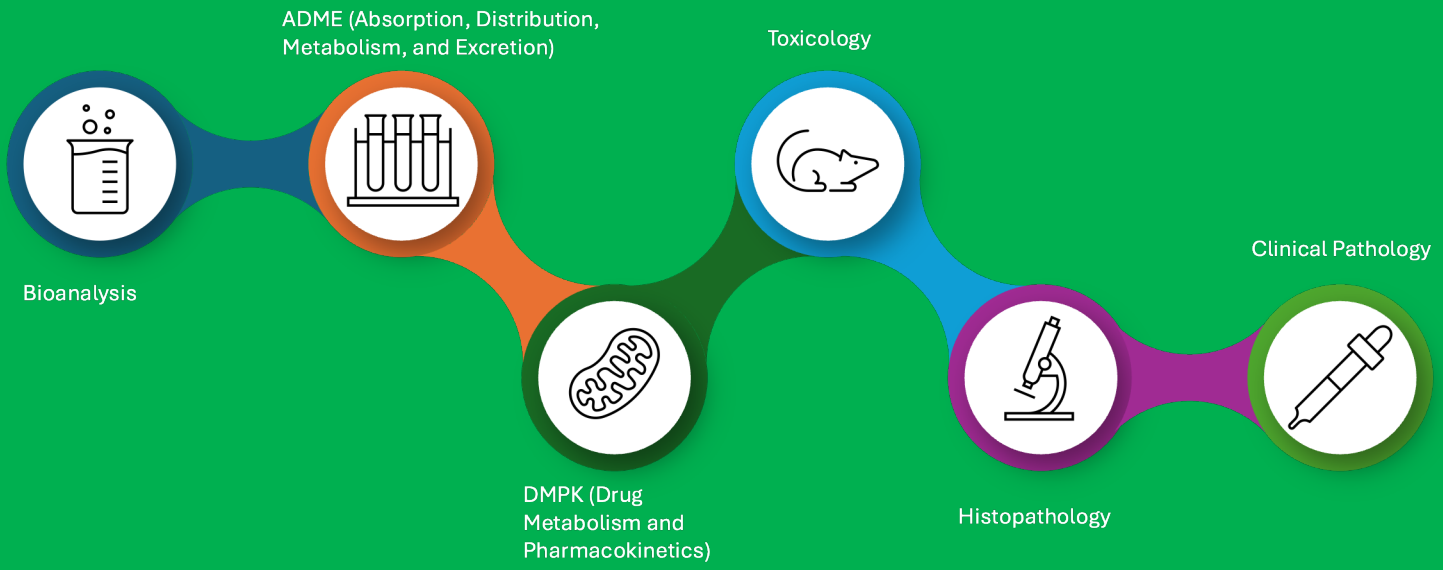
And Working With The Right Partner

As biotechnology, biopharmaceutical, and pharmaceutical companies reach this juncture, the emphasis on robust and comprehensive Pre-IND safety and efficacy testing becomes paramount and choosing the right testing partner emerges as a cornerstone in this process. The synergy between the drug developer and the testing partners enables seamless integration of different testing types within a consolidated platform.



This can propel the drug's development journey by streamlining and optimising the regulatory testing process, ensuring compliance while significantly influencing cost management and shortening the time to market - a critical competitive advantage.

Supporting Your Pre-IND Safety and Efficacy Testing At Every Step



In collaboration with Medicilon, Hoeford offers access to a Pre-IND Safety and Efficacy platform that encompasses the fully array of integrated testing types individually bundled for developers and their investors by a committed and experienced team who will help you to optimise the regulatory pathway and position your drug candidate for approval and success.

Integrated GLP-Compliant Safety and Efficacy Testing

Bioanalysis:

Rigorous assessment of drug concentrations and metabolites in biological matrices, ensuring accurate pharmacokinetic profiles.

Bioanalysis is pivotal in safety and efficacy testing for the optimisation of dosing and evaluation of a drug's behaviour in the body,

ADME (Absorption, Distribution, Metabolism, and Excretion):

Thorough evaluation of a drug's behaviour within an organism, providing invaluable insights into its bioavailability, potential interactions and likelihood of adverse effects.

ADME testing guides drug developers in refining formulations, enhancing therapeutic efficacy, and ensuring the overall safety profile of the drug during preclinical and clinical development stages.

DMPK (Drug metabolism and Pharmacokinetics:

While ADME studies encompass the processes of how the body affects a drug, DMPK testing specifically focuses on the drug's metabolic transformations and its overall pharmacokinetic profile, providing insights into how the drug, in turn, affects the body.

This involves understanding how the drug is broken down and processed over time (metabolised), often in the liver.

The nature of these metabolites and their activity can influence the drug's efficacy and safety.

Toxicology:

Through rigorous examination of dose-response relationships, toxicology studies identify possible toxic effects on organs and tissues to inform does optimisation, establish safety margins, and ensure the overall well-being of subjects in preclinical and clinical trials.

This critical assessment guides regulatory compliance and contributes to the development of safe and effective pharmaceutical interventions.

Histopathology:

Histopathology studies are crucial in safety and efficacy testing, providing microscopic examination of tissues to identify structural changes caused by a drug candidate.

These studies reveal potential adverse effects at the cellular and tissue levels, aiding in the comprehensive assessment of a drug's impact on organs.

Histopathological data informs safety evaluations, guides dose adjustments, and plays an important role in shaping the drug's clinical trajectory.

Clinical Pathology:

While histopathology examines tissues to understand structural changes at a microscopic level, clinical pathology analyses blood and bodily fluids to assess biochemical and cellular parameters for systemic health evaluation.

These studies provide critical data on haematological and biochemical parameters, offering insights into potential adverse effects on organs and overall physiological health.

By monitoring these markers, clinical pathology contributes to safety evaluations and dose optimisation, and laying a foundation for the subsequent progression of the drug candidate in clinical development.

Accelerated Transition From Preclinical to Clinical Stages

A well-structured and integrated Pre-IND testing platform is crucial for assessing drug safety, optimising development pathways, and ensuring compliance. The right testing partner brings together expertise, tailored solutions, and regulatory navigation, which contribute to cost-efficient, timely, and risk-mitigated drug development. The partnership streamlines processes, addresses challenges, and accelerates the transition to clinical testing, ultimately enhancing the likelihood of successful market entry for the drug candidate.

Hoeford and Medicilon are dedicated to providing drug developers with a comprehensive suite of preclinical testing services to support seamless pre-IND and CTA applications. We are committed to competitive pricing, fast turnaround times, and meeting the demanding standards of scientific rigour and excellence that regulators require.

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World-class integrated preclinical research and testing services

Hoeford Research Limited
Hoeford Point, Barwell Lane
Gosport, Hampshire, PO13 0AU
United Kingdom
www.hoeford.com
+44 (0) 2382 122944

Shanghai Medicilon Inc.
2300 Xuanhuang Road
Pudong, Shanghai 201301
China
www.medicilon.com
+86 21 6898 5800