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Opinion Article

Primary Development and Preclinical Drug Safety

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DESCRIPTION

Preclinical development includes activities that combine drug discovery in the laboratory with initiation of human clinical trials. Preclinical studies can be designed to identify lead candidates from multiple hits. Selecting the optimal formulation; determining the route, frequency, and duration of exposure; ultimately, it supports the design of the intended clinical study. Although the details of each preclinical development package may vary, there are some common characteristics. We describe the pharmacokinetic profile and overall safety and identify patterns of toxicity using rodent and non-rodent mammalian models. One or more species can be used to determine the average residence time of a drug in the body. It depends on specific absorption, distribution, metabolism, and excretion properties. For drugs used to treat Alzheimer's disease and other brain disorders, the ability of the drug to cross the blood-brain barrier can be an important issue. Toxicology and safety studies identify potential target organs for side effects and define the therapeutic index for setting initial starting doses in clinical trials.

Critical preclinical safety studies typically require regulatory oversight according to international guidelines, including the US Food and Drug Administration's (FDA) Good Laboratory Practices and International Conference on Harmonization. Parallel preclinical development activities include clinical plan development and new drug preparation, including associated documentation, to meet the FDA's stringent regulatory guidelines for good manufacturing practices. A variety of commercial and government contract options are available for researchers wishing to promote their candidates. Government programs such as the Small Business Innovative Research and Small Business Technology Transfer Grants and expedited access to the National Institutes of Health's Intervention Development Pilot Program are available to assist applicants with preclinical program preparation and drug documentation. Support for preclinical research is also increasing, with funding and services from private foundations. Close cooperation with FDA.

Each product class may be subject to different types of preclinical studies. For example, a drug may undergo pharmacodynamic (effect of the drug on the body) (PD), pharmacokinetic (effect of the drug on the body) (PK), ADME, and toxicological studies. This data allows researchers to allometrically estimate safe starting doses for drugs in human clinical trials. Non-drug medical devices are not subject to these additional tests and can directly undergo Good Laboratory Practice (GLP) testing to ensure the safety of the device and its components. Some medical devices also undergo biocompatibility testing, which indicates whether a component or all components of the device are sustainable in a living model. Most preclinical studies must comply with GLP or ICH guidelines in order to be eligible for submission to regulatory bodies such as the US Food and Drug Administration. Both *in vitro* and *in vivo* tests are commonly performed. Drug toxicity studies include which organs this drug targets and whether it has long-term carcinogenic or disease-causing toxic effects. An applicant or drug sponsor is an individual or organization responsible for marketing a new drug, including responsibility for complying with applicable provisions of the Federal Food, Drug, and Cosmetic Act and related regulations. A "sponsor" is typically an individual, partnership, corporation, government agency, manufacturer, or academic institution. Drug Master File "DMF" A submission to FDA used to provide confidential information about facilities, processes, or items used to manufacture, process, pack, and hold human medicinal products.

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