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Perspective

Clinical Research at the Crossroads

Raja Chakraverty[1]* and Tatini Debnath[2]

[1]*Department of Pharmacology and Toxicology, Institute of Post Graduate Medical Education and Research, Kolkata, West Bengal, India*

[2]*NUHM Pharmacist, West Bengal, India*

***Corresponding Author:** Raja Chakraverty, Department of Pharmacology and Toxicology, Institute of Post Graduate Medical Education and Research, Kolkata, West Bengal, India.

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Drug discovery and development process helps in bringing up new pharmacological interventions to prevent, cure disease in a safe and effective manner. It is a multi-disciplinary and expensive process. Drug development process starts with a target identification and validation, followed by drug candidates discovery, and lead drug compound having favorable pharmaceutical safety and pharmacokinetic profile Medicinal chemistry and pharmaceutics also play a crucial role from the beginning of the drug discovery and development process, involving chemical synthesis (including compliance with current Good Manufacturing Practice, cGMP), characterization, purification, chemical alteration, stability determination, and formulation of the drug candidate. The experiment upon first-in-human (FIH) doses are based on NOAEL (the No-Observed-Adverse-Event- Level) category the values obtained from the coherent interspecies dose extrapolation and sensitive toxicology species, and with regards to congruous safety factor. The Preclinical evaluation, an Investigational New Drug (IND) application is submitted to the regulatory agency FDA (United States Food and Drug Administration) or European Medicine Agency (EMEA) encompasses all preclinical parameters (pharmaceutical, chemical, safety, efficacy, toxicology and other factors) along with a proposed hypothesis for clinical study protocol. Clinical drug development can be initiated after evaluation of the IND (Investigational New Drug) by the regulatory agency and a clinical study approval by a local Institutional Review Board (IRB). Phase 1 studies involve use of human volunteers to assess human safety and pharmacokinetics. The drugs with admissible safety profiles then enter Phase 2 for efficacy reassessment. These include the studies to evaluate effects on disease-relevant biomarkers and the data to exhibit direct effects on small patient sampling targeting the disease. Controlled trials are commonly planned to compare effects of the new drug with a placebo or to a standard treatment (due to ethical issues). Drugs showing positive efficacy continue to Phase 3, much larger trials examining efficacy as well as safety. Drugs emerging from these trials with pertinent evidence of safety and efficacy are submitted for marketing approval via a New Drug Application (NDA). Followed by a review and approval by the regulatory agency, the drug enters Phase 4 or post-marketing surveliance. Perhaps the most rapidly growing area in drug delivery involves nanotechnology and use of nanoparticles. Nanoparticles ranging in size between 1 and 100 nm. have more bioavailability, providing sustained drug release, and enabling targeted delivery to the specific sites in the body. These effects can help improve efficacy and decrease toxicity of drugs. Furthermore, specific forms of nanoparticles, in addition to serving as drug delivery vehicles, can also serve as imaging agents, biosensors, and diagnostic agents.

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