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Clinical Research and its role in Clinical Pharmacy

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Opinion Article

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ABOUT THE STUDY

Clinical research is a field of healthcare science that evaluates the safety and efficacy of human-use drugs, equipment, diagnostic instruments, and treatment regimens. These can be used to prevent disease, cure it, diagnose it, or relieve symptoms. Clinical research and clinical practice is not the same thing. Through clinical practice, established therapies are employed, whereas evidence is acquired in clinical research to establish a therapy. The word "clinical research" refers to the bibliography of a drug/device/entire biologic, or any test object from its origin in the lab through its introduction to the consumer market and beyond. Once a potential candidate or molecule has been found in the laboratory, it is submitted to pre-clinical or animal trials in which several elements of the test article are evaluated (including its safety, toxicity, if appropriate, and efficacy, if practicable at this early stage).

In the United States, data from pre-clinical studies or other supporting evidence, case studies of off label use, and so on are submitted in support of an Investigational New Drug application (IND) application for FDA review when a test article is unapproved or has not yet been cleared by the Food and Drug Administration (FDA), or when an approved or cleared test article is used in a way that significantly increases the risks (or decreases the acceptability of the risks). If the results are to be reported to the FDA or stored for inspection at any point in the future (in the case of an already approved test article, if intended to submit or hold for inspection by the FDA in support of a change in labeling or advertising). If the device is a major risk device or is not exempt from prior FDA submission, the FDA application would be for an Investigational Device Exemption (IDE). Furthermore, whether or not the research requires prior submission to the FDA, clinical research may necessitate approval from the Institutional Review Board (IRB) or Research Ethics Board (REB), as well as other institutional committee reviews, such as the

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Privacy Board, Conflict of Interest Committee, Radiation Safety Committee, Radioactive Drug Research Committee, and so on. Clinical research review criteria will be determined by which federal regulations the research is subject to (e.g., DHHS if federally funded, FDA as previously discussed) and which regulations the institutions subscribe to, in addition to any more stringent criteria added by the institution in response to state or local laws/policies or accreditation entity recommendations. This additional layer of review (IRB/REB in particular) is critical to human subject protection, especially when you consider that research subject to FDA regulations for prior submission is frequently allowed to proceed 30 days after submission to the FDA, unless the FDA specifically informs the researcher not to initiate the study. Clinical research is typically conducted in academic medical facilities and related research study locations. These institutes and places give academic institution reputation as well as access to bigger metropolitan regions, allowing a broader pool of medical participants to engage. Internal Institutional Review Boards at these academic medical institutes monitor the ethical conduct of medical research. The clinical research ecosystem is a complex network of locations, pharmaceutical corporations, and academic research institutes. As a result, a burgeoning area of technology for managing clinical research data and operational aspects has emerged. E-Clinical systems are often used in clinical management to help automate the management and conduct of clinical trials. In the European Union, the European Medicines Agency (EMA) works similarly for research done in their territory. These human investigations are conducted in four stages with study volunteers who have consented to participate in the clinical trials.

New medication clinical trials are often separated into four phases. Each stage of the medication approval procedure is treated as its own clinical study. The drug-development process often takes many years to complete all four phases. If the medicine successfully completes Phases I, II, and III, it is typically approved for use in the wider public by the national regulatory body. Post-approval investigations are referred to as Phase IV studies. The first phase includes 20 to 100 healthy volunteers or persons with the disease/condition. This research typically lasts many months and is intended to evaluate safety and dose. Phase II comprises a higher number of individual individuals ranging from 100 to 300, whilst phase III includes between 1000 and 3000 participants to obtain additional data about the medicine. 70% of medications get advanced to the next stage.