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# Design and Analysis of Clinical Trials Concept and Methodology

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Abstract: Clinical research is an alternative terminology used to describe medical research. Clinical research involves people, and it is generally carried out to evaluate the efficacy of a therapeutic drug, a medical/surgical procedure, or a device as a part of treatment and patient management. However, clinical trials are those studies that assess the potential of a therapeutic drug/device in the management, control, and prevention of disease. The recent focus of federal funding on comparative effectiveness research underscores the importance of clinical trials in the practice of evidence-based medicine and health care reform. The impact of clinical trials not only extends to the individual patient by establishing a broader selection of effective therapies, but also to society as a whole by enhancing the value of health care. According to WHO, the clinical trial is any research study that prospectively assigns human to one or more health-related interventions to evaluate the efR. H. American Recovery and Reinvestment Act of 2009. 1st Ed 2009. fects on health outcomes. The clinical trials can be divided in various phase which five phases 0,1,1,111 and IV trials.

**Keywords:** Clinical trials, phase I trial, phase II trial, phase IV trial, clinical research.

#### REFERENCES

- [1]. Microbes, clinical trials, drug discovery, and vaccine development: the current perspectives. Kandi V, Suvvari TK, Vadakedath S, Godishala V. Borneo J Pharm. 2021;4:311–323. [Google Scholar]
- [2]. Research question, objectives, and endpoints in clinical and oncological research: a comprehensive review. Purna Singh A, Shahapur PR, Vadakedath S, et al. Cureus. 2022;14:0. [PMC free article] [PubMed] [Google Scholar]
- [3]. Information about clinical trial. Available from : URL http://www.tmple.edu/about -trials.html
- [4]. Clinical trial wikipedia, the free encyclopedia. Jan 28 200.available from:url://en.wikipedia.org/wiki/clinical trial.28 jan 2008
- [5]. Kulkarni S. K., Hand Book of Experimental pharmacology 3<sup>rd</sup> ed vallabhprakashan new delhi, 2004, 21.
- [6]. Itkar S., Pharmaceutical Management, 3rd ed, Niraliprakashanpune, 2007, 13.4-13.5
- [7]. Rogers MA. What are the phases of intervention research American speechlanguage-hearing association, 2013.
- [8]. D. Hui, I. Glitza, G. Chisholm, S. Yens, E. Bruera attrition rates, reasons and predictive factors in supportive factors in supportive and palliative oncology clinical trials.
- [9]. J.A. DiMasi, H.G. Grabowski, R.W. Hansen the cost of drug development.
- [10]. C. Heneghan, B. Goldacre, K.R. Mahtani why clinical trial outcomes fail to translate into benefits for patients.
- [11]. T. Godskesen, M.G. Hansson, P. Nygren, K. Nordin, U. Kihlbom hope for a cure and altruism are the main motives behind participation in phase 3 clinical trials.
- [12]. K. Getz predicting successful site perfomacne
- [13]. Pharmacist Career Profile: Clinical Research /investigational Drug, available from :URL: http://en.wikipedia.org/wiki/randomized-controlled t rial.
- [14]. Mello MM, Studdert DM, Brennan TA. The rise of litigation in human subjects research. Ann Intern Med. 2003;139(1):40–45. [PubMed] [Google Scholar]

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- [15]. Steinbrook R. Protecting research subjects—the crisis at Johns Hopkins. N Engl J Med. 2002;346(9):716–720. [PubMed] [Google Scholar]
- [16]. Guidance for Industry . E6. Good clinical practice-consolidated guidance. US Department of Health and Human Services; Bethesda, MD: 1996. [Google Scholar]
- [17]. Clinical trial designs. Nair B. Indian Dermatol Online J. 2019;10:193–201. [PMC free article] [PubMed] [Google Scholar]

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