Review Article

CLINICAL TRIALS

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As the main method by which novel treatment interventions are assessed for their safety, effectiveness, and general clinical utility, clinical trials are an essential component of contemporary biomedical and pharmacological research. Human subjects are used in this methodically planned research, which are carried out in compliance with strict scientific procedures and moral guidelines. Phase I studies are vital in laying the groundwork for later research, despite their small nature. Phase II studies are carried out on a wider sample of patients who usually have the condition of interest. once Phase I is successfully completed. To determine the novel intervention's effectiveness and safety on a larger scale, these randomized controlled trials (RCTs) compare it to conventional therapies or placebos. Phase III trial data serve as the foundation for regulatory submissions and approval decisions. After successful completion, the results are examined by regulatory bodies like the Central.
Phase IV trials, commonly referred to as post-marketing monitoring studies, continue clinical examination even after a treatment has received regulatory clearance. These studies encompass sizable and varied populations and are carried out in real-world environments. Monitoring long-term safety, identifying uncommon or delayed side effects, and evaluating the intervention's efficacy in regular clinical practice are the main goals.
Phase IV studies are essential for maintaining patient safety, and if new concerns are discovered, they may result in changes to treatment recommendations or regulatory measure.

Keywords: Clinical trials; Drug development; Randomized controlled trials (RCTs), Patient safety Pharmacovigilance, Regulatory approval, Good Clinical Practice (GCP)

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