

Clinical Trials: Regulatory Oversight in Drug Development

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DESCRIPTION

Clinical trials in the United States (US) are closely regulated to ensure that new medical products are safe and effective before they reach the public. The U.S. Food and Drug Administration (USFDA) plays a central role in this process by overseeing the development, testing and approval of drugs, biologics and medical devices. Through a structured regulatory system, the agency ensures that clinical research follows scientific standards while protecting the rights and safety of participants.

Before a clinical trial can begin in the US, researchers or sponsors must submit an investigational New Drug Application (NDA). This submission includes data from laboratory and preclinical studies, information about the drug's composition and detailed plans for how the trial will be conducted. The Food and Drug Administration (FDA) reviews this information to determine whether it is reasonably safe to proceed with human testing. If no major concerns are identified within a specified review period, the trial may move forward.

Clinical trials regulated by the FDA are generally conducted in phases, each designed to answer specific research questions. Early-stage trials focus on safety, dosage and how the drug behaves in the body. Later phases evaluate effectiveness and compare the new treatment to existing options. Throughout these stages, researchers must follow strict protocols and report findings accurately. The FDA monitors ongoing trials through regular updates and inspections to ensure compliance with regulatory standards.

Participant safety is a primary concern in all FDA-regulated trials. Ethical principles such as informed consent are strictly enforced, ensuring that individuals understand the risks and benefits before agreeing to participate. Institutional Review Boards review study protocols to confirm that they meet ethical and scientific requirements. These boards operate independently and are responsible for protecting the welfare of participants throughout the study.

The FDA also establishes guidelines known as Good Clinical Practice (GCP), which outline how trials should be conducted, recorded and reported. These guidelines ensure consistency and reliability across studies. Investigators are required to maintain

accurate records, follow approved protocols and report adverse events promptly. Failure to comply with these requirements can result in penalties, suspension of trials or rejection of study data.

Data integrity is another critical aspect of FDA oversight. Sponsors must ensure that all collected data is accurate, complete and verifiable. The FDA may conduct inspections of clinical trial sites, laboratories and data management systems to confirm that standards are being met. Electronic systems used in trials must comply with regulations that ensure secure data handling and proper documentation of any changes made to the data.

Once clinical trials are completed, sponsors submit a New Drug Application (NDA) or Biologics License Application (BLA) to the FDA. This submission includes comprehensive data on safety, effectiveness, labeling and manufacturing processes. The FDA reviews this information carefully before deciding whether to approve the product for public use. In some cases, advisory committees composed of independent experts are consulted to provide additional perspectives on the data.

Even after a drug is approved, the FDA continues to monitor its safety through post-marketing surveillance. This phase involves collecting data on long-term effects and identifying any rare or unexpected adverse reactions. Healthcare providers, patients and manufacturers are encouraged to report issues through systems such as the FDA Adverse event reporting system. This ongoing monitoring helps ensure that approved products remain safe for widespread use.

CONCLUSION

The FDA plays a vital role in overseeing clinical trials in the US. Through a comprehensive regulatory framework, it ensures that new medical products are evaluated rigorously while protecting participant safety. Challenges remain in the regulatory landscape, including balancing the need for rapid access to new therapies with the requirement for thorough evaluation. Ensuring diversity in clinical trial populations is another ongoing concern, as it affects how well study results apply to different groups. From initial application to post-marketing surveillance, the agency's involvement is essential in maintaining

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public confidence in the healthcare system. As medical science advances, the FDA regulatory processes continue to evolve,

supporting innovation while upholding high standards of safety and effectiveness.