

## Key roles and responsibilities of Regulatory Authorities:

**Establish Guidelines:** Regulatory authorities are responsible for setting clear guidelines that ensure clinical research is safe, transparent, ethical and effective. They establish rules for how trials should be designed, how participants should be protected and how data must be collected and reported. Their goal is to maintain high standards in clinical trials to protect participants and ensure trustworthy results.

**Protocol Review and Approval:** Regulatory authorities review clinical trial protocols to make sure the study is scientifically sound, ethical and protects the rights and safety of participants. They approve protocols only if they meet all rules and guidelines, helping ensure the trial is trustworthy and safe.

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**Participant Protection:** A key responsibility of regulatory authorities is to protect the rights, safety and well-being of people participating in clinical trials. They do this by setting rules to make trials ethical and safe, reviewing and approving trial documents such as protocol, monitoring trials for any issues and ensuring that participants are fully informed and cared for throughout the study.

**Ethical Conduct:** Authorities make sure clinical trials follow ethical rules and that participants give informed consent freely and with full understanding.

**Inspections:** Regulatory authorities inspect clinical trials to ensure compliance with rules. They check documents, consent forms, safety reports and trial conduct. Inspections help protect participants and verify that trial data is accurate and reliable.

**Drug Approval and Safety:** Regulatory authorities review data from preclinical and clinical trials to ensure a drug is safe, effective and of good quality before approval. They evaluate all evidence, approve the drug for marketing if benefits outweigh risks and continue monitoring its safety after approval.

Thus, regulatory authorities in clinical trials ensure that the new drugs and treatments are safe, work well and are tested ethically. They approve trial protocols, monitor safety during and after trials and uphold high standards in medical research to protect participants and ensure reliable results.