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# Conducting clinical trials

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## Scenario of clinical trials in India

- The clinical trial industry rapidly expanded in the first decade of 21st century, but has faced some challenges due to regulatory reforms in 2012-13
- The main challenges perceived by international investigators and sponsors include
  - Delayed approval
  - Quality of ethics review
  - Shipment of samples: import and export
  - Overall deficiency of duly trained investigators and centers
  - Clause of compensation even for clinical trial participants
  - Recent requirement of audio visual recording of consent process for IND [investigational new drug] trials, only in specified situations

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# Scientific, ethical and regulatory reviews of clinical trials are critical

| Concerns in implementation of research protocols | Type of review | Some examples of available agencies/ mechanisms |
|---|---|---|
| Is the research question sound? | Scientific review | Institutional Scientific Advisory Committee<br>Indian Council of Medical Research |
| Is the safety and welfare of the research participants adequately protected? | Ethical review | Institutional Ethics Committee<br>Central/ National Ethics Committee |
| Are the research methods appropriate? | Regulatory review | Health Ministry Screening Committee<br>Drug Controller General of India<br>Genetic Engineering Approval Committee |



# Addressing ethical issues in clinical trials

- Is there a mechanism for independent ethical review? [Approvals from Ethics Committee and in country Regulatory Authority]
- Which mechanisms exist to ensure protection of human subjects throughout trial participation?
- Is there adequate community engagement and support?
- Informed consent
- Standard of care and post-trial support
- Use of placebos
- Confidentiality

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# Critical issues in trial implementation -1

- Informed consent procedure
- Screening and enrollment: Strict adherence to inclusion and exclusion criteria
- Good clinical and laboratory practice, quality control and quality assurance
- Adherence to intervention and follow-up
- Multi-centric trials: standardization of study protocols



# Critical issues in trial implementation -2

- Independent monitoring
- Safety assessment: Reporting and management of adverse and serious adverse events [clinical, laboratory and social/ familial]
- Reimbursements, compensation and grievance redressal
- Trial stoppage rules
- Documentation archival

# Impediments in clinical trial participation

At the level of patients

- Don't know about clinical trials
- Don't have access to clinical trials
- May be afraid or suspicious of research
- Can't afford to participate
- May not want to go against health care provider's wishes

At the level of health care providers

- Lack awareness of appropriate clinical trials
- Be unwilling to "lose control" of a person's care
- Believe that standard therapy is best
- Be concerned that clinical trials add administrative burdens





Thank you

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