**GUIDANCE 33**

**CLINICAL RESEARCH AND TRIAL MANAGEMENT TOOL**

Guidance taken from the following references: <https://trialsjournal.biomedcentral.com/articles/10.1186/1745-6215-11-78>.

A successful trial requires a structured, practical, businesslike approach to manage a project. Some important and required managerial expertise include the following:

1. Appoint a trial manager who would invest time effort from the inception of the trial, designing a trial, practically implement the trial by delegating appropriate authority to the investigative team to successfully complete the trial with a desired outcome.
2. Important components in the life cycle of trial management are:
   1. Project planning
   2. Establishing a team consisting of individuals with specific experience to the objectives of the trial.
   3. Providing appropriate training to study staff
   4. Establishing a time line and processes for successful completion of individual components of a trial.
   5. Finding logistical, physical (site assessment and site responsibility), financial and technical, clinical, laboratory, radiology and computer resources required for a trial
   6. Establish processes and SOPs for initiating, planning, executing, monitoring and controlling trial operations
   7. Establishing a statistical team for analyzing and reporting results
   8. Working with IRB to secure approval and ensuring ethical and regulatory compliance
   9. Establishing realistic and practical recruitment program including subject transportation and reimbursement for research subjects
   10. Enrolling and consenting research subjects
   11. Developing data collection instruments and case report form to a specific trial
   12. Developing and maintaining study logs, drug/device inventory logs, enrollment logs, adverse evet logs and training records
   13. Identifying issues that arise during a trial and resolve issues efficiently and effectively
   14. Maintaining proper inventory of study drugs/devices
   15. Developing safety reports and reporting adverse events
   16. Identifying trial deviations and
   17. Identifying and using software for trial management
   18. Readying for study monitor visits and FDA and other regulatory audits.