

Clinical trial protocol synopsis

- Title of the study
- Short title or Lay Title of the study
- Methodology which gives a brief overview of the clinical trial designs, randomization, blinding status, and placebo or active placebo control
- Study duration of the Clinical trial
- Single-Centric or Multi-centric study
- Primary and secondary objective of the study
- Number of subjects enrolled in the study
- Major inclusion and exclusion criteria
- Name of the test product
- Name of the reference product
- Brief explanation of the statistical methodology to be used in the study.
- References