

# Important Elements of an IIT Synopsis

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## Synopsis including:

- The study title
- A description of the study type (Prospective or Retrospective, Interventional or non-interventional, single center or multicenter, Comparative or Observational)
- A background section that outlines why the study is being conducted. It should also include a brief literature review of similar studies and key supporting references
- The hypothesis
- The primary objective or aim of the study
- The primary endpoint and any secondary and exploratory endpoints
- Inclusion and exclusion criteria
- The sample size along with the sample size calculation
- Estimated time for IRB/EC approval
- Estimated study duration
- Publication plan: targeted meetings for abstract submissions and targeted journals for manuscript submission
- The proposed study budget

## Items To Submit/Upload:

- Curricula Vitae for the investigator(s)
- Current year's W-9 form for the sponsoring entity