

# Concept submission:

## How much info is required?

Please include the following details in your concept submission.

### Required

- Study rationale/goal
- Primary objective/endpoints
- Study design
- Follow-up visit schedule
- Estimated study duration
- Number of sites
- Preliminary publication plan
- Planned committees/labs
- Estimated study budget

### Optional

- Secondary study objectives/endpoints
- Key inclusion criteria
- Key exclusion criteria
- Efficacy variables/measures
- Safety variables/measures
- Cohorts/stratification
- Data Management Plan summary
- Statistical & analytical plan
- Sample size justification
- Number of subjects
- Duration of subject participation

# Protocol submission:

## How much info is required?

Please include the following details in your protocol submission.

### Required

- Study rationale/goal
- Primary objective/endpoints
- Study design
- Follow-up visit schedule
- Estimated study duration
- Number of sites
- Preliminary publication plan
- Planned committees/labs
- Estimated study budget
- Full protocol (Word or PDF)
- Indication if IRB approval is required
- Budget contact information

### Optional

- Secondary study objectives/endpoints
- Key inclusion criteria
- Key exclusion criteria
- Efficacy variables/measures
- Safety variables/measures
- Cohorts/stratification
- Data Management Plan summary
- Statistical & analytical plan
- Sample size justification
- Number of subjects
- Duration of subject participation