

Clinical Trial Protocol Outline
Submitted by: <i>Name, institutional affiliation, email address</i>
Study Title:
Investigators including PI:
Is this a cooperative group study proposal?
Trial Summary
Background & Rationale <ul style="list-style-type: none"> - Rationale - Overall Risk/ Benefit Assessment - Rational and Aims for Biomarker Assessments
Study Design
Hypothesis(es)
Study Schema <i>Experimental Treatment/ Assessment points:</i>
Objectives Primary objective: Secondary objectives: Tertiary/correlative objectives:
Study centers
Patient population
Inclusion criteria

Exclusion criteria
Efficacy Measures <i>Include measurement timeline(s)</i>
Statistical Methods/plan/ sample size justification
Treatment details -Dose and schedule -Study phase -Review of Safety -Total Study Duration -Pre-Treatment Criteria -Study Agents -General concomitant and Supportive care guidelines -Criteria for taking participant off protocol therapy -Duration of follow up -Criteria for taking a participant off study
Dosing Delay/ Dose Modifications -Dose Delay Criteria -Dose Modifications criteria -Criteria to resume treatment -Discontinuation Criteria
Safety considerations
Adverse Events <ul style="list-style-type: none"> – Expected Toxicities – Adverse E – vent Characteristics and Definitions – Procedures for AE and SAE Recording and Reporting . – Expedited adverse event reporting – Other safety consideration – Overdose – Expedited reporting to hospital risk management

<ul style="list-style-type: none">– Monitoring of adverse event and period of observation– Routine adverse event monitoring– Reposting by study sponsor/ Overall PI
Measurement of Effects
Data Reporting/ Regulatory Requirements <ul style="list-style-type: none">-Data reporting-Data Monitoring-Monitoring
Regulatory Consideration <ul style="list-style-type: none">-Protocol Reviews and Amendments-Informed consent-Study documentation-Records retention
Statistical Consideration
Feasibility considerations
Budget considerations
Publication Plan
Challenges & contingency
Ethics Registration Procedure