**Clinical Trial Protocol Outline**

# Background/justification/rationale

## Description of disease being studied and problem being addressed

## Description of current therapy and any shortcomings

## Description of drug and its activity

## Description of any comparator drugs and justification for its use as the control

## Summaries of studies conducted to date

# Objectives

## Primary

## Secondary

# Study Design

## Single center or multicenter

## Phase

## Number and definition of arms

## Blinding

## Randomization if multiple arms

## Indication and patient population

## Sample size

## Duration and number of sites

# Study population

## Inclusion

## Exclusion

# Schedule of visits/assessments

## Screening/eligibility determination

## Consent

## Enrollment/randomization

## Baseline evaluation

## Treatment schedule

## Follow-up schedule

# Ethical and Regulatory Considerations

## Regulatory document collection

## IRB review

## Informed consent administration

# Study Procedures

# Clinical assessment

## Special procedures (QOL, bronchoscopy, biopsy, PK, genetic sampling, etc.)

## Laboratory testing

# Study drug and comparator

## Drug shipment/receipt

## Drug packaging

## Drug storage

## Drug preparation

## Drug dispensing and accountability

## Drug administration

## Contraindications/concomitant medications

## Breaking the blind

## Drug destruction

## Medication compliance assessment

# Adverse Experiences (AEs)

## Documentation of AEs

## Coding of AEs

## Serious Adverse Events

### Definition

### Reporting

## Expected AEs/toxicities

# Subject Completion and Early Withdrawal

## Procedures for completion

## Procedures for early withdrawals

## Reasons for withdrawals

# Data Collection

## Method of data collection

## Procedures for data collection

## Data submission

# Study Monitoring/Audits

# Data Analysis

## Sample size determination

## Efficacy analyses

## Safety analyses

## Other analyses (if applicable)

## Interim analyses (if applicable)

## Data Safety Monitoring Board (if applicable)

# Confidentiality

# Publication Policy

# References

# Appendices

## Declaration of Helsinki

## Template informed consent form

## Toxicity criteria

## Health status measurement scale

## Laboratory sample preparation and shipment

## Standardized clinical procedure methodology

## Standardized questionnaire instructions

## Standardized measurement instructions