# Visit: 0

* Week: -4
* Day: -28

## Administrative

* ☐ Informed Consent / Assent
* ☐ Inclusion / Exclusion Criteria
* ☐ Dispense (return) diaries
* ☐ Diary Completion (Assessment)
* ☐ Email / Telephone Monitoring

## Safety

* ☐ Medical History
* ☐ Concomitant Therapies
* ☐ Spirometry: Pre-Study Drug

## Efficacy

* ☐ Lung Volumes: Pre-Study Drug
* ☐ Exercise oximetry (clinic)
* ☐ WHOQOL
* ☐ Dyspnea & Fatigue Score

# Visit: 1

* Week: 0
* Day: 0

## Administrative

* ☐ Diary Completion (Assessment)
* ☐ Email / Telephone Monitoring
* ☐ Drug Administration
* ☐ Drug Administration Log

## Safety

* ☐ Medical History
* ☐ Concomitant Therapies
* ☐ Adverse Events
* ☐ Vital Signs
* ☐ Physical Examination
* ☐ Clinical Laboratory Tests
* ☐ Spirometry: Pre-Study Drug
* ☐ Spirometry: Post-Study Drug
* ☐ Chest X-Ray

## Efficacy

* ☐ Lung Volumes: Pre-Study Drug
* ☐ Limited Chest HRCT
* ☐ Exercise oximetry (clinic)
* ☐ Serum Biomarkers
* ☐ WHOQOL
* ☐ Dyspnea & Fatigue Score

# Visit: 2

* Week: 4
* Day: 28

## Administrative

* ☐ Diary Completion (Assessment)
* ☐ Email / Telephone Monitoring
* ☐ Drug Administration
* ☐ Drug Administration Log

## Safety

* ☐ Medical History
* ☐ Concomitant Therapies
* ☐ Adverse Events
* ☐ Vital Signs
* ☐ Physical Examination
* ☐ Clinical Laboratory Tests

## Efficacy

* ☐ WHOQOL
* ☐ Dyspnea & Fatigue Score

# Visit: 3

* Week: 8
* Day: 56

## Administrative

* ☐ Diary Completion (Assessment)
* ☐ Email / Telephone Monitoring
* ☐ Drug Administration
* ☐ Drug Administration Log

## Safety

* ☐ Medical History
* ☐ Concomitant Therapies
* ☐ Adverse Events
* ☐ Vital Signs
* ☐ Physical Examination
* ☐ Clinical Laboratory Tests
* ☐ Spirometry: Pre-Study Drug

## Efficacy

* ☐ Lung Volumes: Pre-Study Drug
* ☐ Exercise oximetry (clinic)
* ☐ WHOQOL
* ☐ Dyspnea & Fatigue Score

# Visit: 4

* Week: 12
* Day: 84

## Administrative

* ☐ Diary Completion (Assessment)
* ☐ Email / Telephone Monitoring
* ☐ Drug Administration
* ☐ Drug Administration Log

## Safety

* ☐ Medical History
* ☐ Concomitant Therapies
* ☐ Adverse Events
* ☐ Vital Signs
* ☐ Physical Examination
* ☐ Clinical Laboratory Tests
* ☐ Spirometry: Pre-Study Drug

## Efficacy

* ☐ Lung Volumes: Pre-Study Drug
* ☐ Exercise oximetry (clinic)
* ☐ Serum Biomarkers
* ☐ WHOQOL
* ☐ Dyspnea & Fatigue Score

# Visit: 5

* Week: 16
* Day: 112

## Administrative

* ☐ Diary Completion (Assessment)
* ☐ Email / Telephone Monitoring
* ☐ Drug Administration
* ☐ Drug Administration Log

## Safety

* ☐ Medical History
* ☐ Concomitant Therapies
* ☐ Adverse Events
* ☐ Vital Signs
* ☐ Physical Examination
* ☐ Clinical Laboratory Tests
* ☐ Chest X-Ray

## Efficacy

* ☐ WHOQOL
* ☐ Dyspnea & Fatigue Score

# Visit: 6

* Week: 20
* Day: 140

## Administrative

* ☐ Diary Completion (Assessment)
* ☐ Email / Telephone Monitoring
* ☐ Drug Administration
* ☐ Drug Administration Log

## Safety

* ☐ Medical History
* ☐ Concomitant Therapies
* ☐ Adverse Events
* ☐ Vital Signs
* ☐ Physical Examination
* ☐ Clinical Laboratory Tests
* ☐ Spirometry: Pre-Study Drug

## Efficacy

* ☐ Lung Volumes: Pre-Study Drug
* ☐ Exercise oximetry (clinic)
* ☐ WHOQOL
* ☐ Dyspnea & Fatigue Score

# Visit: 7

* Week: 24
* Day: 168

## Administrative

* ☐ Diary Completion (Assessment)
* ☐ Email / Telephone Monitoring
* ☐ Drug Administration
* ☐ Drug Administration Log

## Safety

* ☐ Medical History
* ☐ Concomitant Therapies
* ☐ Adverse Events
* ☐ Vital Signs
* ☐ Physical Examination
* ☐ Clinical Laboratory Tests
* ☐ Spirometry: Pre-Study Drug

## Efficacy

* ☐ Lung Volumes: Pre-Study Drug
* ☐ Exercise oximetry (clinic)
* ☐ Serum Biomarkers
* ☐ WHOQOL
* ☐ Dyspnea & Fatigue Score

# Visit: 8

* Week: 28
* Day: 196

## Administrative

* ☐ Diary Completion (Assessment)
* ☐ Email / Telephone Monitoring
* ☐ Drug Administration
* ☐ Drug Administration Log

## Safety

* ☐ Medical History
* ☐ Concomitant Therapies
* ☐ Adverse Events
* ☐ Vital Signs
* ☐ Physical Examination
* ☐ Clinical Laboratory Tests

## Efficacy

* ☐ Limited Chest HRCT
* ☐ WHOQOL
* ☐ Dyspnea & Fatigue Score

# Visit: 9

* Week: 32
* Day: 224

## Administrative

* ☐ Diary Completion (Assessment)
* ☐ Email / Telephone Monitoring
* ☐ Drug Administration
* ☐ Drug Administration Log

## Safety

* ☐ Medical History
* ☐ Concomitant Therapies
* ☐ Adverse Events
* ☐ Vital Signs
* ☐ Physical Examination
* ☐ Clinical Laboratory Tests
* ☐ Spirometry: Pre-Study Drug
* ☐ Chest X-Ray

## Efficacy

* ☐ Lung Volumes: Pre-Study Drug
* ☐ Exercise oximetry (clinic)
* ☐ WHOQOL
* ☐ Dyspnea & Fatigue Score

# Visit: 10

* Week: 36
* Day: 252

## Administrative

* ☐ Diary Completion (Assessment)
* ☐ Email / Telephone Monitoring
* ☐ Drug Administration
* ☐ Drug Administration Log

## Safety

* ☐ Medical History
* ☐ Concomitant Therapies
* ☐ Adverse Events
* ☐ Vital Signs
* ☐ Physical Examination
* ☐ Clinical Laboratory Tests
* ☐ Spirometry: Pre-Study Drug

## Efficacy

* ☐ Lung Volumes: Pre-Study Drug
* ☐ Exercise oximetry (clinic)
* ☐ Serum Biomarkers
* ☐ WHOQOL
* ☐ Dyspnea & Fatigue Score

# Visit: 11

* Week: 40
* Day: 280

## Administrative

* ☐ Diary Completion (Assessment)
* ☐ Email / Telephone Monitoring
* ☐ Drug Administration
* ☐ Drug Administration Log

## Safety

* ☐ Medical History
* ☐ Concomitant Therapies
* ☐ Adverse Events
* ☐ Vital Signs
* ☐ Physical Examination
* ☐ Clinical Laboratory Tests

## Efficacy

* ☐ WHOQOL
* ☐ Dyspnea & Fatigue Score

# Visit: 12

* Week: 44
* Day: 308

## Administrative

* ☐ Diary Completion (Assessment)
* ☐ Email / Telephone Monitoring
* ☐ Drug Administration
* ☐ Drug Administration Log

## Safety

* ☐ Medical History
* ☐ Concomitant Therapies
* ☐ Adverse Events
* ☐ Vital Signs
* ☐ Physical Examination
* ☐ Clinical Laboratory Tests
* ☐ Spirometry: Pre-Study Drug

## Efficacy

* ☐ Lung Volumes: Pre-Study Drug
* ☐ Exercise oximetry (clinic)
* ☐ WHOQOL
* ☐ Dyspnea & Fatigue Score

# Visit: Follow Up

* Week: 48
* Day: 336

## Administrative

* ☐ Diary Completion (Assessment)
* ☐ Email / Telephone Monitoring
* ☐ Drug Administration Log

## Safety

* ☐ Medical History
* ☐ Concomitant Therapies
* ☐ Adverse Events
* ☐ Vital Signs
* ☐ Physical Examination
* ☐ Clinical Laboratory Tests
* ☐ Spirometry: Pre-Study Drug
* ☐ Chest X-Ray

## Efficacy

* ☐ Lung Volumes: Pre-Study Drug
* ☐ Exercise oximetry (clinic)
* ☐ Serum Biomarkers
* ☐ WHOQOL
* ☐ Dyspnea & Fatigue Score

# Visit: Early Termination

* Week: 52
* Day: 364

## Administrative

* ☐ Diary Completion (Assessment)

## Safety

* ☐ Medical History
* ☐ Concomitant Therapies
* ☐ Adverse Events
* ☐ Vital Signs
* ☐ Physical Examination
* ☐ Clinical Laboratory Tests
* ☐ Spirometry: Pre-Study Drug
* ☐ Chest X-Ray

## Efficacy

* ☐ Lung Volumes: Pre-Study Drug
* ☐ Exercise oximetry (clinic)
* ☐ Serum Biomarkers
* ☐ WHOQOL
* ☐ Dyspnea & Fatigue Score