ATS-DLD Respiratory Questionnaire

When: V2.
Instructions: Coordinator should administer questionnaire to participant. Ask the questions as written. Key into BEST data system at www.besttrial.org within 10 working days.

A. Clinical center, participant and visit identification

1. Clinical center ID: ____ ____ ____ ____

2. Participant ID: ____ ____ ____ ____ ____

3. Name code: ____ ____ ____ ____ ____

4. Date administered:

____ ____-____ ____ ____-____ ____
day mon year

5. Visit ID: V 2

6. Form version date:

2 6-O C T-1 1
day mon year

B. Cough

7. Do you usually have a cough *(count a cough with first smoke or on first going out-of-doors; exclude clearing of throat)*:

Yes (1) No (2)

→ **9.**

8. Do you usually cough as much as 4 to 6 times a day, 4 or more days out of the week:

Yes (1) No (2)

9. Do you usually cough at all on getting up, or first thing in the morning:

Yes (1) No (2)

10. Do you usually cough at all during the rest of the day or at night:

Yes (1) No (2)

IF "No" TO ALL ITEMS 7-10, CHECK "Does not apply" AND SKIP TO ITEM 13.

11. Do you usually cough like this on most days for 5 consecutive months or more during the year:

Yes (1)
No (2)
Does not apply (3)

→ **13.**

12. For how many years have you had this cough:

____ ____
years

C. Phlegm

13. Do you usually bring up phlegm from your chest *(count phlegm with the first smoke or on the first going out-of-doors; exclude phlegm from the nose; count swallowed phlegm)*:

Yes (1) No (2)

→ **15.**

14. Do you usually bring up phlegm like this as much as twice a day, 4 or more days out of the week:

Yes (1) No (2)

15. Do you usually bring up phlegm at all on getting up or first thing in the morning:

Yes (1) No (2)

16. Do you usually bring up phlegm at all during the rest of the day or at night:

Yes (1) No (2)

IF "No" TO ALL ITEMS 13-16, CHECK "Does not apply" AND SKIP TO ITEM 19.

17. Do you bring up phlegm like this on most days for 3 consecutive months or more during the year:

Yes (1)
No (2)
Does not apply (3)

19. ◄

18. For how many years have you had trouble with phlegm:

___ ___ # years

D. Episodes of cough and phlegm

19. Have you had periods or episodes of (increased*) cough and phlegm lasting for 3 weeks or more each year:

**For individuals who usually have cough and/or phlegm.*

Yes (1) No (2)

21. ◄

20. For how long have you had at least 1 such episode per year:

___ ___ # years

E. Wheezing

21. Does your chest ever sound wheezy or whistling

a. When you have a cold:
Yes (1) No (2)

b. Occasionally apart from colds:
Yes (1) No (2)

c. Most days or nights:
Yes (1) No (2)

IF "No" TO ALL ITEMS 21a-c, SKIP TO ITEM 23.

22. For how many years has this been present:

___ ___ # years

23. Have you ever had an ATTACK of wheezing that has made you feel short of breath:

Yes (1) No (2)

27. ◄

24. How old were you when you had your first such attack:

___ ___ age in years

25. Have you had 2 or more such episodes:

Yes (1) No (2)

26. Have you ever required medicine or treatment for the(se) attack(s):

Yes (1) No (2)

F. Breathlessness

27. Disabled from walking

a. Are you disabled from walking by any condition other than heart or lung disease:

Yes (1) No (2)

28. ◄

b. If "Yes," please describe and proceed to item 33:

_____
nature of condition(s)

28. Are you troubled by shortness of breath when hurrying on the level or walking up a slight hill:

Yes (1) No (2)

33. ◄

29. Do you have to walk slower than people of your age on the level because of breathlessness:

Yes (1) No (2)

30. Do you ever have to stop for breath when walking at your own pace on the level:

Yes (1) No (2)

31. Do you ever have to stop for breath after walking about 100 yards (or after a few minutes) on the level:

Yes (1) No (2)

32. Are you too breathless to leave the house or breathless on dressing or undressing:

Yes (1) No (2)

G. Chest colds and chest illness

33. If you get a cold, does it usually go to your chest *(usually means more than 1/2 the time)*:

Yes (1)
No (2)
Don't get colds (3)

34. During the past 3 years, have you had any chest illnesses that have kept you off work, indoors at home, or in bed:

Yes (1) No (2) → **37.**

35. Did you produce phlegm with any of these chest illnesses:

Yes (1) No (2)

36. In the last 3 years, how many such illnesses, with (increased) phlegm, did you have which lasted a week or more:

____ ____ # illnesses

H. Past illnesses

37. Did you have any lung trouble before the age of 16:

Yes (1) No (2)

Have you ever had any of the following:

38. Attacks of bronchitis

a. Attacks of bronchitis:

Yes (1) No (2) → **39.**

b. Was it confirmed by a doctor:

Yes (1) No (2)

c. At what age was your first attack:

____ ____ age in years

39. Pneumonia *(include bronchopneumonia)*

a. Pneumonia:

Yes (1) No (2) → **40.**

b. Was it confirmed by a doctor:

Yes (1) No (2)

c. At what age did you first have it:

____ ____ age in years

40. Hayfever

a. Hayfever:

Yes (1) No (2) → **41.**

b. Was it confirmed by a doctor:

Yes (1) No (2)

c. At what age did it start:

____ ____ age in years

41. Chronic bronchitis

a. Have you ever had chronic bronchitis:
Yes (1) No (2)
→ **42.**

b. Do you still have it: Yes (1) No (2)

c. Was it confirmed by a doctor: Yes (1) No (2)

d. At what age did it first start: ___ ___ age in years

42. Emphysema

a. Have you ever had emphysema:
Yes (1) No (2)
→ **43.**

b. Do you still have it: Yes (1) No (2)

c. Was it confirmed by a doctor: Yes (1) No (2)

d. At what age did it first start: ___ ___ age in years

43. Asthma

a. Have you ever had asthma:
Yes (1) No (2)
→ **44.**

b. Do you still have it: Yes (1) No (2)

c. Was it confirmed by a doctor: Yes (1) No (2)

d. At what age did it first start: ___ ___ age in years

e. If you no longer have it, at what age did it stop: ___ ___ age in years

44. Have you ever had

a. Any other chest illness:
Yes (1) No (2)

If "Yes", please specify:

_____

b. Any chest operations:
Yes (1) No (2)

If "Yes", please specify:

_____

c. Any chest injuries:
Yes (1) No (2)

If "Yes", please specify:

_____

45. Has a doctor ever told you that you had heart trouble:
Yes (1) No (2)
→ **47.**

46. Have you ever had treatment for heart trouble in the past 10 years:
Yes (1) No (2)

47. Has a doctor ever told you that you have high blood pressure:
Yes (1) No (2)
→ **49.**

48. Have you had any treatment for high blood pressure (hypertension) in the past 10 years:
Yes (1) No (2)

I. Occupational history

49. Have you ever worked full time (30 hours per week or more) for 6 months or more:

Yes (1) No (2) → **59.**

50. Have you ever worked for a year or more in any dusty job:

Yes (1) No (2) → **54.**

51. Specify job/industry:

_____
job/industry

52. Total years worked: ___ ___ # years

53. Was dust exposure:

Mild (1)
Moderate (2)
Severe (3)

54. Have you ever been exposed to gas or chemical fumes in your work

Yes (1) No (2) → **58.**

55. Specify job/industry:

_____
job/industry

56. Total years worked: ___ ___ # years

57. Was fume exposure:

Mild (1)
Moderate (2)
Severe (3)

58. What has been your usual occupation or job *(the one you have worked the longest)*

a. Specify job/occupation:

_____
job/occupation

b. Number of years employed in this occupation:

___ ___ # years

c. Position/job title:

_____
position/job title

d. Business, field or industry:

_____
business/field/industry

J. Tobacco smoking

59. Have you ever smoked cigarettes *("No" means less than 20 packs of cigarettes or 12 oz of tobacco in a lifetime or less than 1 cigarette a day for a year)*:

Yes (1) No (2) → **66.**

60. Do you now smoke cigarettes (as of 1 month ago):

Yes (1) No (2)

61. How old were you when you first started regular cigarette smoking:

___ ___ age in years

62. If you have stopped smoking cigarettes completely, how old were you when you stopped *(if not leave blank)*:

___ ___ age in years

63. How many cigarettes do you smoke per day now:

___ ___ # cigarettes/day

64. On the average of the entire time you smoked, how many cigarettes did you smoke per day:

___ ___ # cigarettes/day

65. Do or did you inhale the cigarette smoke *(check only one)*:

Not at all	(1)
Slightly	(2)
Moderately	(3)
Deeply	(4)

66. Have you ever smoked a pipe regularly *("Yes" means more than 12 oz tobacco in a lifetime)*:

Yes (1) No (2) → **72.**

67. How old were you when you started to smoke a pipe regularly:

___ ___ age in years

68. If you have stopped smoking a pipe completely, how old were you when you stopped *(if not leave blank)*:

___ ___ age in years

69. On the average of the entire time you smoked a pipe, how much pipe tobacco did you smoke per week *(a standard pouch of tobacco = 1 1/2 oz):*

___ ___ • ___ ___ oz per week

70. How much pipe tobacco are you smoking per week now:

___ ___ • ___ ___ oz per week

71. Do or did you inhale the pipe smoke:

Not at all	(1)
Slightly	(2)
Moderately	(3)
Deeply	(4)

72. Have you ever smoked cigars regularly *("Yes" means more than 1 cigar a week for a year)*:

Yes (1) No (2) → **78.**

73. How old were you when you started smoking cigars regularly:

___ ___ age in years

74. If you have stopped smoking cigars completely, how old were you when you stopped *(if not leave blank)*:

___ ___ age in years

75. On the average over the entire time you smoked cigars, how many cigars did you smoke per week:

___ ___ # cigars/week

76. How many cigars are you smoking per week now:

___ ___ # cigars/week

77. Do or did you inhale the cigar smoke:

Not at all	(1)
Slightly	(2)
Moderately	(3)
Deeply	(4)

K. Family history

78. Was your **father** ever told by a doctor that he had a chronic lung condition such as

a. Chronic bronchitis:

Yes	(1)
No	(2)
Don't know	(3)

b. Emphysema:

Yes	(1)
No	(2)
Don't know	(3)

c. Asthma:

Yes	(1)
No	(2)
Don't know	(3)

d. Lung cancer:

Yes	(1)
No	(2)
Don't know	(3)

e. Other chest condition:

Yes	(1)
No	(2)
Don't know	(3)

79. Is your **father** currently alive:

Yes (1)
No (2)
Don't know (3)

→ **82.**

80. Please specify age if living or age at death *(enter only a or b)*:

a. Age if living: ____ ____ age in years

b. Age at death: ____ ____ age in years

81. Please specify cause of death *(if living, leave blank)*:

_____
cause of death

82. Was your **mother** ever told by a doctor that she had a chronic lung condition such as

a. Chronic bronchitis:
Yes (1)
No (2)
Don't know (3)

b. Emphysema:
Yes (1)
No (2)
Don't know (3)

c. Asthma:
Yes (1)
No (2)
Don't know (3)

d. Lung cancer:
Yes (1)
No (2)
Don't know (3)

e. Other chest condition:
Yes (1)
No (2)
Don't know (3)

83. Is your **mother** currently alive:

Yes (1)
No (2)
Don't know (3)

→ **86.**

84. Please specify age if living or age at death *(enter only a or b)*:

a. Age if living: ____ ____ age in years

b. Age at death: ____ ____ age in years

85. Please specify cause of death *(if living, leave blank)*:

_____
cause of death

L. Administration information *(for clinical use only)*

86. Date form completed:

____ ____-____ ____ ____-____ ____
day mon year

87. Clinic coordinator PIN: ____ ____ ____

88. Clinic coordinator signature:

_____

BEST

Reference #: _____

Baseline History Form

Purpose: To document general health status.

When: To be filled out by the coordinator at the time of V1.

Instructions: Key into BEST data system at www.besttrial.org withing 10 working days.

A. Clinical center, participant and visit identification

1. Clinical center ID: ____ ____ ____ ____

2. Participant ID: ____ ____ ____ ____ ____

3. Name code: ____ ____ ____ ____ ____

4. Date completed:

____ ____ – ____ ____ ____ – ____ ____
day mon year

5. Visit ID: V 1

6. Form version date:

1 1 – J U L – 1 1
day mon year

B. Demographic information

7. Gender *(check only one):*

Male (1)
Female (2)

8. Ethnicity *(check only one):*

Hispanic/Latino/Spanish (1)
Not Hispanic/Latino/Spanish (2)

9. Race *(check only one):*

White (1)
Black or African American (2)
Asian (3)
American Indian or Alaskan Native (4)
Hawaiian or other Pacific Islander (5)
Other *(specify)* (6)

_____
specify

10. Age: ____ ____
years

11. Date of birth:

____ ____ – ____ ____ ____ – ____ ____
day mon year

C. Medical history

12. Has a doctor ever told you that you have any of the following conditions *(check all that apply)*

a. Congestive heart failure: (1)
b. Stroke: (1)
c. Obstructive sleep apnea: (1)
d. Diabetes: (1)
e. Cirrhosis *(liver failure):* (1)
f. Gout: (1)
g. Hepatitis/liver disease: (1)
h. Neurological disease: (1)
i. Cancer: (1)
j. Psychiatric disease: (1)
k. Heart attack: (1)
l. Angina: (1)
m. High blood pressure: (1)
n. Kidney disease: (1)
o. Rheumatoid arthritis: (1)
p. Renal artery stenosis: (1)
q. Other conditions *(specify):* (1)

_____
specify

r. None: (1)

13. COPD status

a. How many times have you had flare-ups of your COPD (emphysema or chronic bronchitis) that has required treatment *(such as antibiotics, corticosteroids)* in the past year *(check only one):*

None (1)
One (2)
Two (3)
Three or more (4)

b. Have you had flare-ups of your COPD (emphysema or chronic bronchitis) that has required treatment *(such as antibiotics, corticosteroids)* in the past six weeks:

Yes (1) No (2)

14. In the past 2 weeks, have you taken any of the following medications for COPD *(check all that apply)*

a. Short-acting beta-agonist (SABA) (eg, Albuterol, Proventil®, Ventolin®, Xopenex®): (1)

b. Short-acting anticholinergic bronchodilator (eg, Ipratropium): (1)

c. Combination SABA and short-acting anticholinergics (eg, Combivent®): (1)

d. Long-acting beta-agonist (LABA) (eg, Salmeterol, Formoterol, Arformoterol): (1)

e. Inhaled corticosteroids (IC) (eg, Fluticasone, Budesonide, Flunisolide, Mometasone): (1)

f. Combination LABA/IC (eg, Advair®, Symbicort®, Dulera®): (1)

g. Long-acting anticholinergic bronchodilator (eg, Tiotropium): (1)

h. Leukotriene modifiers (eg, Montelukast, Zafirlukast, Zileuton): (1)

i. Methylxanthines (eg, Theophylline): (1)

j. Systemic corticosteroids (eg, Prednisone, Methylprednisolone, Dexamethasone): (1)

k. Other *(specify):* (1)

_____
specify

l. None: (1)

15. In the last two weeks have you taken any anticoagulants *(check all that apply)*

a. Warfarin (Coumadin®): (1)

b. Aspirin: (1)

c. Clopidogrel (Plavix®): (1)

d. Dabigatran (Pradax®): (1)

e. Other *(specify):* (1)

_____
specify

f. None: (1)

16. Other prescription medications

a. Have you taken any other prescription medications in the last two weeks:

Yes (1) No (2)

17. ⌐

b. List all other prescription medications you have taken in the last two weeks:

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

D. Supplemental oxygen use

17. Do you currently use supplemental oxygen:

Yes (1) No (2)

19. ⌐

18. When do you use oxygen

a. At rest:

Yes (1) No (2)

18c. ⌐

b. What is the flow rate: ____ • ____ L/min

c. During sleep:

Yes (1) No (2)

18e. ⌐

d. What is the flow rate: ____ • ____ L/min

e. With exertion:

Yes (1) No (2)

19. ⌐

f. What is the flow rate: ____ • ____ L/min

E. Administrative information

19. Date form reviewed:

____ ____–____ ____ ____–____ ____
day mon year

20. Clinic coordinator PIN: ____ ____ ____

21. Clinic coordinator signature *(do not key):*

_____

BEST

Reference #: _____

Clinic Visit Form

Purpose: To record information about interval medical history, lab reports, forms and visit procedures

When: V2 and V4.

Instructions: Complete form at clinic visit. Key into BEST data system at http://www.besttrial.org within 10 working days.

A. Clinical center, participant and visit identification

1. Clinical center ID: ____ ____ ____ ____

2. Participant ID: ____ ____ ____ ____ ____

3. Name code: ____ ____ ____ ____ ____

4. Date completed:

____ ____ – ____ ____ ____ – ____ ____
day mon year

5. Visit ID: ____ ____

6. Form version date:

1 5 – J U L – 1 1
day mon year

B. Interval history

7. Phone contacts

a. Did you have any unscheduled phone contacts with this clinic since the last study visit *(ignore calls to change appointment time or schedule phone visits):*

( ) Yes (1) ( ) No (2) → **8.**

b. If Yes, specify how many: ____ ____

8. Visits to healthcare provider

a. Did you have any visits to healthcare provider(s) (including non-study visits to this clinic) for COPD or COPD treatment:

( ) Yes (1) ( ) No (2) → **9.**

b. If Yes, specify how many: ____ ____

9. Which of the following statements best describes the degree of shortness of breath that you experience *(check only one):*

- I am not troubled by shortness of breath except with strenuous exercise (0)
- I have shortness of breath when hurrying on flat ground or when walking up a slight hill (1)
- I walk slower than people of my age because of my shortness of breath (2)
- I have to stop walking because of shortness of breath when walking at my own pace on flat ground (3)
- I have to stop for breath after walking less than 100 yards or after only a few minutes when walking on flat ground at my own pace (4)
- I am too breathless to leave my house or I get breathless when dressing or undressing (5)

10. Since your last clinic visit, rate the severity of the following symptoms *(ask about all listed symptoms (a-k))*

Mild: Just noticeable, and considered unpleasant, but does not interfere with usual activities or sense of well-being.
Moderate: Interferes with usual activities or sense of well-being, but does not limit the participant
Severe: Prevents activities or participant seeks medical care

		Severity			
		None	**Mild**	**Moderate**	**Severe**
a.	Nausea:	(0)	(1)	(2)	(3)
b.	Vomiting:	(0)	(1)	(2)	(3)
c.	Poor appetite:	(0)	(1)	(2)	(3)
d.	Bad taste in mouth:	(0)	(1)	(2)	(3)
e.	Heartburn:	(0)	(1)	(2)	(3)
f.	Headache:	(0)	(1)	(2)	(3)
g.	Fatigue:	(0)	(1)	(2)	(3)
h.	Skin rash:	(0)	(1)	(2)	(3)
i.	Bloating:	(0)	(1)	(2)	(3)
j.	Diarrhea:	(0)	(1)	(2)	(3)
k.	Abdominal discomfort:	(0)	(1)	(2)	(3)

11. Other symptoms: Yes ( ) No ( ) → **13.**

12. Rate severity of other symptoms.

Do not ask the participant about each of the symptoms listed below. Only fill in information for self reported symptoms. If symptom(s) are not listed, report on blank line and complete severity information (item a-o).

		Severity		
		Mild	**Moderate**	**Severe**
a.	Allergic reactions:	(1)	(2)	(3)
b.	Edema:	(1)	(2)	(3)
c.	Hypertension:	(1)	(2)	(3)
d.	Hypotension:	(1)	(2)	(3)
e.	Fever:	(1)	(2)	(3)
f.	Flushing:	(1)	(2)	(3)
g.	Weight gain:	(1)	(2)	(3)
h.	Blurred vision:	(1)	(2)	(3)
i.	_____	(1)	(2)	(3)
j.	_____	(1)	(2)	(3)
k.	_____	(1)	(2)	(3)
l.	_____	(1)	(2)	(3)
m.	_____	(1)	(2)	(3)
n.	_____	(1)	(2)	(3)
o.	_____	(1)	(2)	(3)

Note: For items 10 and 12, clinic should complete an Unusual Events (UE) form or a Serious Adverse Event (SR) form as appropriate (see MOP) for all symptoms rated as severe.

13. Serious adverse events

a. Since the last study visit, has the participant experienced a serious adverse event or been hospitalized:

Yes (1) No (2)

14.

b. Specify event(s):

_____

_____

For hospitalization(s) or other serious adverse events that occurred after a patient enrolled in the study, complete a Serious Adverse Event (SR) form.

14. Other significant medical events or illnesses since the last visit:

_____

_____

15. Is this V2:

Yes (1) No (2)

18.

C. Study drug

16. Missed study capsules

a. Since receiving the study blisterpack, has the participant missed any doses of study capsules:

Yes (1) No (2)

18.

b. How many doses *(1 dose = 3 capsules):*

____ ____ • ____ ____

17. Why were doses missed *(check all that apply)*

a. Forgot: (1)

b. Ran out of capsules: (1)

c. Side effects *(specify):* (1)

_____
name side effects

d. Misplaced/lost study capsules: (1)

e. Too busy: (1)

f. Other *(specify):* (1)

_____
identify reason

D. Study procedures

18. Pulse oximetry *(V2)*

a. Was pulse oximetry performed:

Yes (1) No (2)

19.

b. If Yes, specify results: ____ ____ ____
%

19. Exhaled Breath Condensate (EBC) specimens collected *(V2 and V4):*

Yes (1) No (2)

22.

20. Pre-assessment conditions met

a. No food or beverage for one hour prior to EBC collection *(check only one):*

Yes (1)
No (2)
Don't know (3)

b. EBC collected before spirometry *(check only one):*

Yes (1)
No (2)
Don't know (3)

21. Expired Breath Condensate aliquots collected *(check all that apply)*

- **a.** None (1)
- **b.** Aliquot 1 for JHU (1)
- **c.** Aliquot 2 for JHU (1)
- **d.** Aliquot 3 for JHU (1)

22. Blood collected *(V2 and V4)*

	Yes	No
a. Plasma *(green top):*	(1)	(2)
b. Serum *(gold top):*	(1)	(2)
c. PBMCs *(green/red top):*	(1)	(2)

23. Comments on EBC/blood collections:

_____

_____

_____

24. Blood for CBC, chemistry panel, TSH collected *(V4):*

Yes (1) No (2)

25. Urine collected *(V4):*

Yes (1) No (2)

26. Pregnancy test *(V4):*

- Yes (1)
- No (2)
- Not applicable (3)

E. Forms completed

27. Were the following procedures and their forms completed

	Yes	No
a. ATS-DLD Respiratory Questionnaire (AT) *[V2]:*	(1)	(2)
b. St. Georges Respiratory Questionnaire (SG) *[V2 and V4]:*	(1)	(2)
c. Pulmonary Function Testing (PF) *[V2 and V4]:*	(1)	(2)
d. Physical Exam (PE) *[V2 and V4]:*	(1)	(2)

F. Bronchoscopy eligibility

28. COPD

a. COPD exacerbation in last 6 weeks:

Yes (1) No (2)

29. ____

b. Comment:

_____
comments

29. Health status

a. Significant change in health status since last clinic visit:

Yes (1) No (2)

30. ____

b. Comment:

_____
comments

30. Medications

a. Change in medications since last visit:

Yes (1) No (2)

31. ____

b. Comment:

_____
comments

31. Nosebleed

a. Nosebleed since last clinic visit:

Yes (1) No (2)

32. ____

b. Comment:

_____
comments

32. Anticoagulant

a. Taken anticoagulant in last 5 days *(eg, coumadin):*

Yes (1) No (2)

33. ____

b. Comment:

_____
comments

33. Lidocaine/local anesthetic allergy

a. Allergic to lidocaine or local anesthetic:

Yes (1) No (2)

34.

b. Comment:

_____
comments

NOTE: If any item in section F (items 28-33) is answered ''Yes,'' consult with study physician before scheduling bronchoscopy.

G. Administrative information

34. Date form reviewed:

____ ____–____ ____ ____–____ ____
day mon year

35. Clinic coordinator PIN: ____ ____ ____

36. Clinic coordinator signature:

_____

Blisterpack Dispensing and Capsule Counting Form

Purpose: To record the issuance of blisterpacks and count of capsules returned.
When: V3 and V5 and whenever a blisterpack is dispensed to the participant or returned and retained by the clinic.
By whom: Coordinator or pharmacist.
Instructions: Key into BEST data system at www.besttrial.org within 10 working days.

A. Clinical center, participant, and visit identification

1. Clinical center ID: ____ ____ ____ ____

2. Participant ID: ____ ____ ____ ____ ____

3. Name code: ____ ____ ____ ____ ____

4. Date form completed:

____ ____-____ ____ ____-____ ____
day mon year

5. Visit ID: ____ ____
(indicate "N" if not associated with a study visit)

6. Form version date:

0 1 - A U G - 1 1
day mon year

B. Study drug dispensed

7. Was study drug dispensed:

Yes (1) No (2)

11. ←

8. Date dispensed:

____ ____-____ ____ ____-____ ____
day mon year

9. Blisterpack ID *(key information from label)*:

affix blisterpack label here

Make sure the issuance of the study drug is recorded on the Blisterpack Accountability Log (BK).

10. Were label fill-ins on blisterpack completed:

Yes (1) No (2)

Stop ←

*If item 10 is marked "No," **STOP**, do not proceed until the item can be answered "Yes."*

C. Blisterpack storage/return

11. Was study blisterpack returned:

Yes (1) No (2)

23. ←

12. Date study blisterpack returned:

____ ____-____ ____ ____-____ ____
day mon year

13. Blisterpack ID: **B -** ____ ____ ____ ____

14. Was blisterpack kept in freezer for the entire time *(check only one)*:

Yes (1)
No (2)
Not applicable (3)

If "No," specify length of time blisterpack not kept in freezer and where it was stored:

_____

_____

_____

15. How many capsules were left in blisterpack:

___ ___

16. Confirm that photocopy of returned blisterpack has been attached to this form:

Yes (1) No (2)

If "No," specify reason:

_____
specify

17. Was a second blisterpack returned:

Yes (1) No (2) → **23.**

18. Date blisterpack returned:

___ ___-___ ___ ___-___
day mon year

19. Blisterpack ID: **B -** ___ ___ ___ ___

20. Was blisterpack kept in freezer for the entire time *(check only one)*:

Yes (1)
No (2)
Not applicable (3)

If "No," specify length of time blisterpack not kept in freezer and where it was stored:

_____

_____

_____

21. How many capsules were left in blisterpack:

___ ___

22. Confirm that photocopy of returned blisterpack has been attached to this form:

Yes (1) No (2)

If "No," specify reason:

_____
specify

23. Were any blisterpacks expected but not returned:

Yes (1) No (2) → **25.**

24. Reasons expected blisterpacks were not returned *(check all that apply)*

a. Consumed and discarded: (1)
b. Lost/destroyed: (1)
c. Forgot, still at home: (1)
d. Participant will return at later date: (1)
e. Other *(specify)*: (1)

_____
reason

D. Administrative information

25. Date form reviewed:

___ ___-___ ___ ___-___
day mon year

26. Clinic coordinator PIN: ___ ___ ___

27. Clinic coordinator signature:

_____

BEST

Reference #: _____

Eligibility Form

Purpose: To document eligibility.

When: V2, after spirometry and results from V1 required tests are reviewed.

Instructions: If participant is eligible, key into BEST data system at www.besttrial.org before V3. Do not key form for participants who fail eligibility.

A. Clinical center, participant and visit identification

1. Clinical center ID: ____ ____ ____ ____

2. Participant ID: ____ ____ ____ ____ ____

3. Name code: ____ ____ ____ ____ ____

4. Date completed:

____ ____ – ____ ____ ____ – ____ ____
day mon year

5. Visit ID: V 2

6. Form version date:

2 7 – J U L – 1 1
day mon year

B. Demographic Information

7. Gender *(check only one):*

Male (1)
Female (2)

8. Ethnicity *(check only one):*

Hispanic/Latino/Spanish (1)
Not Hispanic/Latino/Spanish (2)

9. Race *(check only one):*

White (1)
Black or African American (2)
Asian (3)
American Indian or Alaskan Native (4)
Hawaiian or other Pacific Islander (5)
Other *(specify)* (6)

_____
specify

C. Eligibility

Inclusion criteria

10. Age 40 years or older:

Yes (1) No (2) → STOP

11. Ten or more pack years smoking history
(10 pack-years = 1 pack a day for 10 years; 2 packs a day for 5 years, etc):

Yes (1) No (2) → STOP

12. Physician diagnosed COPD:

Yes (1) No (2) → STOP

13. Post-bronchodilator FEV_1

a. Post-bronchodilator FEV_1 40-80% predicted at V2:

Yes (1) No (2) → STOP

b. FEV_1 % predicted at V2: ____ ____ ____ %

14. Post bronchodilator FEV_1/FVC

a. Post bronchodilator FEV_1/FVC ratio < 0.70 at V2:

Yes (1) No (2) → STOP

b. FEV_1/FVC demonstrated at V2:

____ • ____ ____

15. Signed consent form:

Yes (1) No (2) STOP

16. Willing to ingest no more than 1 serving of cruciferous vegetables per week during run in and treatment periods *(refer to flash card):*

Yes (1) No (2) STOP

17. Results from required tests at V1 reviewed

	Yes	No
a. Blood for CBC, chemistry panel, TSH:	(1)	(2) STOP
b. Urine analysis:	(1)	(2) STOP

c. Pregnancy test:

Yes (1)
No (2) STOP
Not applicable (3)

Exclusion criteria

18. COPD exacerbation requiring treatment within the last 6 weeks:

Yes (1) STOP No (2)

19. Significant respiratory (other than COPD), cardiovascular, neuropsychiatric, renal, gastrointestinal, or genitourinary disease that may interfere with participation in the study or interpretation of the results *(consult with study physician):*

Yes (1) STOP No (2)

20. Acute myocardial infarction or acute coronary syndrome within the last 6 months:

Yes (1) STOP No (2)

21. Cancer (other than non-melanoma skin cancer or localized prostate cancer) within last 5 years:

Yes (1) STOP No (2)

22. Currently pregnant, lactating, or unwilling to practice adequate birth control for duration of the study:

Yes (1) STOP
No (2)
Not applicable (3)

23. Allergic to local anesthesia:

Yes (1) STOP No (2)

24. Allergic to broccoli sprout extracts:

Yes (1) STOP No (2)

25. Anticoagulant (Warfarin) use within past 2 weeks:

Yes (1) STOP No (2)

26. Oxygen saturation

a. Pulse oximetry: ____ ____ ____ SpO_2 (%)

b. Resting hypoxemia *(< 90%):*

Yes (1) STOP No (2)

27. Calculated Glomerular Filtration Rate (GFR) < 30 mL/min:

Yes (1) No (2)

28. Any of the liver enzymes (AST, ALT, Alkaline Phos) greater than 4 times above the upper limit of normal:

Yes (1) No (2)

29. Patient eligible to schedule bronchoscopy:

Yes (1) No (2)

D. Administrative information

30. Date form reviewed by coordinator:

____ ____–____ ____ ____–____ ____
day mon year

31. Clinic coordinator PIN: ____ ____ ____

32. Clinic coordinator signature *(do not key):*

_____

33. Date form reviewed by study physician:

____ ____–____ ____ ____–____ ____
day mon year

34. Study physician PIN: ____ ____ ____

35. Study physician signature *(do not key):*

_____

Laboratory Data Form

Purpose: To document laboratory data.
When: To be filled by the coordinator after clinic receives lab results for collections at V1, V4.
Instructions: Transfer results from lab report to this form. Key into BEST data system at www.besttrial.org within 10 working days.

A. Identifying information

1. Clinical center ID: ____ ____ ____ ____

2. Participant ID: ____ ____ ____ ____ ____

3. Name code: ____ ____ ____ ____ ____

4. Date completed:

____ ____-____ ____ ____-____ ____
day mon year

5. Visit ID: ____ ____

6. Form version date:

2 3-M A R-1 2
day mon year

B. Specimen collection

Blood

7. Date of blood collection:

____ ____-____ ____ ____-____ ____
day mon year

8. Sodium: ____ ____ ____ mEq/L

9. Potassium: ____ • ____ mEq/L

10. Chloride: ____ ____ ____ mEq/L

11. Bicarbonate: ____ ____ mEq/L

12. BUN: ____ ____ mg/dL

13. Creatinine: ____ • ____ mg/dL

14. Glucose: ____ ____ ____ mg/dL

15. Calcium: ____ ____ • ____ ____ mg/dL

16. Total Protein: ____ • ____ gm/dL

17. Albumin: ____ • ____ gm/dL

18. Total Bilirubin: ____ • ____ mg/dL

19. AST: ____ ____ ____ U/L

20. ALT: ____ ____ ____ U/L

21. Alkaline Phosphatase: ____ ____ ____ U/L

22. WBC: ____ • ____ x10^4/cu mm

23. Hemoglobin: ____ ____ • ____ ____ gm/dL

24. Hematocrit: ____ ____ • ____ ____ %

25. Platelets: ____ ____ • ____ ____ x10^5/cu mm

26. TSH: ____ ____ • ____ ____ µ IU/mL

Urine

27. Date of urine collection:

____ ____-____ ____ ____-____ ____
day mon year

28. pH: ____ ____ • ____ ____

29. Specific gravity: ____ • ____ ____ ____

30. Protein (0-4+): ____

31. Glucose (0-4+): ____

32. Blood (0-4+): ____

33. Sediment: Normal (1) Abnormal (2)

C. Abnormal values

List laboratory values outside of normal range:

	a. Lab parameter (eg, ALT)	b. clinically significant Yes	No
34.	_____	(1)	(2)
35.	_____	(1)	(2)
36.	_____	(1)	(2)
37.	_____	(1)	(2)
38.	_____	(1)	(2)

If clinically significant, clinic should complete an Unusual Event (UE) form or a Serious Adverse Event Report (SR) form as appropriate for severe abnormalities.

D. Administration information

39. Date form reviewed by coordinator:

____ ____-____ ____ ____-____ ____
day mon year

40. Clinic coordinator PIN: ____ ____ ____

41. Clinic coordinator signature *(do not key)*:

_____

42. Date form reviewed by study physician:

____ ____-____ ____ ____-____ ____
day mon year

43. Study physician PIN: ____ ____ ____

44. Study physician signature *(do not key)*:

_____

BEST Reference #: _____

Missed Data/Procedures

Purpose: Record information about what study data are missing.

When: After a visit window has closed for a randomized participant and visit/contact procedures were missed. Complete a separate Missed Data (MD) form for each visit that is missed or that has missing data.

Instructions: Key into BEST data system at www.besttrial.org within 10 working days.

A. Clinical center, participant and visit identification

1. Clinical center ID: ____ ____ ____ ____

2. Participant ID: ____ ____ ____ ____ ____

3. Name code: ____ ____ ____ ____ ____

4. Date completed:

____ ____–____ ____ ____–____ ____
day mon year

5. Visit ID: ____ ____

6. Form version date:

2 6 – O C T – 1 1
day mon year

7. Was visit or phone contact missed completely:

Yes (1) No (2)

B. Missed visit information

8. Forms/questionnaires missed *(check all that apply)*

a. AT (ATS-DLD Respiratory Questionnaire): (1)

b. BB (BAL Processing Form): (1)

c. BH (Baseline History Form): (1)

d. BK (Blisterpack Accountability Log): (1)

e. BL (Bronchoalveolar Lavage/ Bronchial Brushings/Nasal Brushings Form): (1)

f. BP (Blood Processing Form): (1)

g. CV (Clinic Visit Form): (1)

h. DD (Blisterpack Dispensing and Capsule Counting Form): (1)

i. EG (Eligibility Form): (1)

j. LD (Laboratory Data Form): (1)

k. P1 (Phone Contact 1): (1)

l. P2 (Phone Contact 2): (1)

m. P3 (Phone Contact 3): (1)

n. PE (Physical Examination Form): (1)

o. PF (Pulmonary Function Testing): (1)

p. PI (Participant Information): (1)

q. SG (St. George's Respiratory Questionnaire): (1)

r. SS (Specimen Shipment Sheet): (1)

s. ST (Specimen Box Transmittal Sheet): (1)

t. Other *(specify):* (1)

_____
form/questionnaire

u. N/A, none missed: (1)

9. Procedures missed *(check all that apply)*

a. EBC: (1)

b. Blood for plasma: (1)

c. Blood for serum: (1)

d. Blood for PBMCs: (1)

e. Blood for CBC, chemistry panel: (1)

10. Reason for missed visit or data *(check all that apply)*

a. Participant was ill: (1)

b. Participant was temporarily away from area: (1)

c. Participant refused procedure: (1)

d. Participant has permanently moved from area: (1)

e. Unable to contact participant: (1)

f. Participant forgot: (1)

g. Other *(specify):* (1)

_____

_____

11. Additional notes/explanations:

_____

_____

_____

_____

_____

C. Administrative information

12. Date form reviewed:

____ ____–____ ____ ____–____ ____
day mon year

13. Clinic coordinator PIN: ____ ____ ____

14. Clinic coordinator signature:

_____

BEST

Reference #: _____

Phone Contact 1

Purpose: To screen for adverse events post V3 bronchoscopy/brushings and review study drug instructions.

When: One day post V3 bronchoscopy/brushings. If participant cannot be reached on the day after V3, then complete as soon as participant can be reached up to 7 days after V3. After 7 days combine phone visits 1 and 2 and complete both the P1 and P2 forms.

Instructions: Coordinator completes form during telephone interview with participant. Key into BEST data system at www.besttrial.org within 10 working days.

A. Clinical center, participant and visit identification

1. Clinical center ID: ____ ____ ____ ____

2. Participant ID: ____ ____ ____ ____ ____

3. Name code: ____ ____ ____ ____ ____

4. Date of phone contact:

____ ____–____ ____ ____–____ ____
day mon year

5. Visit ID: P 1

6. Form version date:

2 3 – M A R – 1 2
day mon year

B. Post-procedure adverse event check

7. Date of bronchoscopy/brushings:

____ ____–____ ____ ____–____ ____
day mon year

Items 8-21 refer to the time period since participant's bronchoscopy and/or brushings.

8. Did participant have any problems after the bronchoscopy/brushings: Yes (1) No (2)

If "Yes," specify problem:

_____

_____

_____

Ask participant about each of the symptoms (9-17) and to rate the severity and status of reported symptoms.

Mild: Just noticeable, and considered unpleasant, but does not interfere with usual activities or sense of well-being
Moderate: Interferes with usual activities or sense of well-being
Severe: Prevents activities or participant seeks medical care

For items 9-17, skip b if none is checked under a.

		a. Severity				b. Status	
		None	Mild	Moderate	Severe	Resolved	Unresolved
9.	Fever:	(0)	(1)	(2)	(3)	(1)	(2)
10.	Chills:	(0)	(1)	(2)	(3)	(1)	(2)
11.	Chest pain:	(0)	(1)	(2)	(3)	(1)	(2)
12.	Nosebleed:	(0)	(1)	(2)	(3)	(1)	(2)
13.	Sore throat:	(0)	(1)	(2)	(3)	(1)	(2)
14.	Wheezing:	(0)	(1)	(2)	(3)	(1)	(2)
15.	Shortness of breath:	(0)	(1)	(2)	(3)	(1)	(2)
16.	Cough:	(0)	(1)	(2)	(3)	(1)	(2)
17.	Coughing up blood:	(0)	(1)	(2)	(3)	(1)	(2)

18. Other symptoms or medical events: Yes (1) No (2)

22. ←

If "Yes," specify other symptoms or medical events and rate the severity and status.

		a. Severity			b. Status	
		Mild	Moderate	Severe	Resolved	Unresolved
19.	Other symptom or medical event #1: _____ specify	(1)	(2)	(3)	(1)	(2)
20.	Other symptom or medical event #2: _____ specify	(1)	(2)	(3)	(1)	(2)
21.	Other symptom or medical event #3: _____ specify	(1)	(2)	(3)	(1)	(2)

Note: For items 9-21, complete either an Unusual Event (UE) form or Serious Adverse Event Report (SR) form as appropriate for all symptoms rated as "Severe" (see MOP).

C. Study capsules

Review instructions with participant (take 3 capsules from one blister once a day; store blister pack in zip-locked bag in freezer).

22. Was study blisterpack stored in the freezer:

(Yes 1) (No 2)

If ''No,'' specify reason and where blisterpack was stored:

_____

_____

23. Has participant started taking study capsules yet:

(Yes 1) (No 2)

If ''No,'' specify reason:

_____

_____

24. Has participant had any problems taking study medication:

(Yes 1) (No 2)

If ''Yes,'' specify problem:

_____

_____

D. Administrative information

25. Who was interviewed *(check all that apply)*

a. Participant: (1)

b. Other *(specify):* (1)

_____
specify relationship to participant

26. Date form reviewed:

____ ____–____ ____ ____–____ ____
day mon year

27. Clinic coordinator PIN: ____ ____ ____

28. Clinic coordinator signature *(do not key):*

_____

BEST

Reference #: _____

Phone Contact 2

Purpose: To assess study medication adherence and screen for side effects/adverse events.

When: Seven to fourteen days after V3.

Instructions: Coordinator completes form during telephone interview with participant. Key into BEST data system at www.besttrial.org within 10 working days.

A. Clinical center, participant and visit identification

1. Clinical center ID: ____ ____ ____ ____

2. Participant ID: ____ ____ ____ ____ ____

3. Name code: ____ ____ ____ ____ ____

4. Date of phone contact:

____ ____ – ____ ____ ____ – ____ ____
day mon year

5. Visit ID: P 2

6. Form version date:

0 1 – A U G – 1 1
day mon year

B. Phone contact 1 (P1) check

7. Was the P1 form completed:

Yes (1) No (2)

If "No," complete both P1 and P2 forms during P2 contact.

C. Study drug

8. Has participant had any issues with study capsules:

Yes (1) No (2)

If, "Yes," specify issue(s):

_____

_____

9. Missed study capsules

a. Has participant missed any doses of study capsules:

Yes (1) No (2)

11.

b. How many doses were missed *(1 dose = 3 capsules):*

____ ____ • ____ ____
doses

10. Why were study capsules missed *(check all that apply)*

a. Forgot: (1)

b. Ran out of study capsules: (1)

c. Side effects: *(specify):* (1)

_____
specify side effects

d. Lost study capsules: (1)

e. Too busy: (1)

f. Other *(specify):* (1)

_____
specify other reason

D. Adverse event screen

Items 11-15 refer to the time since the last clinic visit.

For item 11, ask participant about each of the symptoms (a-k) and to rate the severity of reported symptoms.

Mild: Just noticeable, and considered unpleasant, but does not interfere with usual activities or sense of well-being
Moderate: Interferes with usual activities or sense of well-being
Severe: Prevents activities or participant seeks medical care

11. Symptoms

		Severity			
		None	**Mild**	**Moderate**	**Severe**
a.	Nausea:	(0)	(1)	(2)	(3)
b.	Vomiting:	(0)	(1)	(2)	(3)
c.	Poor appetite:	(0)	(1)	(2)	(3)
d.	Bad taste in mouth:	(0)	(1)	(2)	(3)
e.	Heartburn:	(0)	(1)	(2)	(3)
f.	Headache:	(0)	(1)	(2)	(3)
g.	Fatigue:	(0)	(1)	(2)	(3)
h.	Skin rash:	(0)	(1)	(2)	(3)
i.	Bloating:	(0)	(1)	(2)	(3)
j.	Diarrhea:	(0)	(1)	(2)	(3)
k.	Abdominal discomfort:	(0)	(1)	(2)	(3)

12. Other symptoms or medical events:

Yes ( ) No ( ) → **14.**

13. Rate severity of other symptoms or medical events

Do not ask the participant about each of the symptoms listed below. Only fill in information for self reported symptoms. If symptom(s) are not listed, report on blank line.

		Severity		
		Mild	**Moderate**	**Severe**
a.	Allergic reactions:	(1)	(2)	(3)
b.	Edema:	(1)	(2)	(3)
c.	Hypertension:	(1)	(2)	(3)
d.	Hypotension:	(1)	(2)	(3)
e.	Fever:	(1)	(2)	(3)
f.	Flushing:	(1)	(2)	(3)
g.	Weight gain:	(1)	(2)	(3)
h.	Blurred vision:	(1)	(2)	(3)
i.	_____	(1)	(2)	(3)
j.	_____	(1)	(2)	(3)
k.	_____	(1)	(2)	(3)
l.	_____	(1)	(2)	(3)
m.	_____	(1)	(2)	(3)
n.	_____	(1)	(2)	(3)
o.	_____	(1)	(2)	(3)

Note: For items 11 and 13, complete either an Unusual Event (UE) form or a Serious Adverse Event Report (SR) form as appropriate for all symptoms rated as "Severe" (see MOP).

14. Serious adverse events

a. Since the last study visit, has the participant experienced a serious adverse event or been hospitalized:

(Yes 1) (No 2)

15.

b. Specify event(s):

_____

_____

Remember to complete an SR form to report hospitalization.

15. Other significant medical events or illnesses since the last visit:

_____

_____

E. Upcoming study visits

16. Visit 4 appointment confirmed:

(Yes 1) (No 2)

If ''No,'' confirm scheduled appointment or reschedule if needed.

17. Visit 5 (bronchoscopy/brushings) appointment confirmed:

(Yes 1) (No 2)

If ''No,'' confirm scheduled appointment or reschedule if needed.

F. Administrative information

18. Who was interviewed *(check all that apply)*

a. Participant: (1)

b. Other *(specify):* (1)

_____
specify relationship to participant

19. Date form reviewed:

____ ____–____ ____ ____–____ ____
day mon year

20. Clinic coordinator PIN: ____ ____ ____

21. Clinic coordinator signature *(do not key):*

_____

BEST

Reference #: _____

Phone Contact 3

Purpose: To screen for side effects and other events post V5 bronchoscopy/brushings; to evaluate participant's experience in BEST and document distribution of unmasking envelope.

When: One day post V5 bronchoscopy/brushings. If participant cannot be reached one day post V5, complete within one week after V5. If V5 was missed, complete form as soon as possible.

Instructions: Coordinator completes form during telephone interview with participant. Key into BEST data system at www.besttrial.org within 10 working days.

A. Clinical center, participant and visit identification

1. Clinical center ID: ____ ____ ____ ____

2. Participant ID: ____ ____ ____ ____ ____

3. Name code: ____ ____ ____ ____ ____

4. Date of phone contact:

____ ____–____ ____ ____–____ ____
day mon year

5. Visit ID: P 3

6. Form version date:

2 3 – M A R – 1 2
day mon year

B. Post-procedures adverse event check

7. Bronchoscopy/brushings

a. V5 bronchoscopy and/or brushings attempted or completed:

Yes (1) No (2)

22. ____

b. Date bronchoscopy and/or brushings attempted or completed:

____ ____–____ ____ ____–____ ____
day mon year

Items 8-21 refer to the time period since V5 bronchoscopy/brushings.

8. Did participant have any problems after the bronchoscopy/brushings:

Yes (1) No (2)

If "Yes," specify problem(s):

_____

_____

_____

Ask participant about each of the symptoms (9-17) and to rate the severity and status of reported symptoms.

Mild: Just noticeable, and considered unpleasant, but does not interfere with usual activities or sense of well-being
Moderate: Interferes with usual activities or sense of well-being
Severe: Prevents activities or participant seeks medical care

For items 9-17, skip b if none is checked under a.

		a. Severity				b. Status	
		None	Mild	Moderate	Severe	Resolved	Unresolved
9.	Fever:	(0)	(1)	(2)	(3)	(1)	(2)
10.	Chills:	(0)	(1)	(2)	(3)	(1)	(2)
11.	Chest pain:	(0)	(1)	(2)	(3)	(1)	(2)
12.	Nosebleed:	(0)	(1)	(2)	(3)	(1)	(2)
13.	Sore throat:	(0)	(1)	(2)	(3)	(1)	(2)
14.	Wheezing:	(0)	(1)	(2)	(3)	(1)	(2)
15.	Shortness of breath:	(0)	(1)	(2)	(3)	(1)	(2)
16.	Cough:	(0)	(1)	(2)	(3)	(1)	(2)
17.	Coughing up blood:	(0)	(1)	(2)	(3)	(1)	(2)

18. Other symptoms or medical events:

Yes (1) No (2) → **22.**

If "Yes," specify other symptoms or medical events and rate the severity and status.

		a. Severity			b. Status	
		Mild	Moderate	Severe	Resolved	Unresolved
19.	Other symptom or medical event #1: _____ specify other symptom or medical event	(1)	(2)	(3)	(1)	(2)
20.	Other symptom or medical event #2: _____ specify other symptom or medical event	(1)	(2)	(3)	(1)	(2)
21.	Other symptom or medical event #3: _____ specify other symptom or medical event	(1)	(2)	(3)	(1)	(2)

Note: For items 9-21, complete either an Unusual Event (UE) form or a Serious Adverse Event Report (SR) form as appropriate for all symptoms rated as "Severe" (see MOP).

C. Exit questions

22. How would you rate your experience as a participant in the study *(check only one):*

- Excellent (1)
- Good (2)
- Fair (3)
- Poor (4)

23. How could we have improved the study:

_____

_____

_____

_____

24. Additional comments about the study:

_____

_____

_____

D. Study medication assignment

25. Which study medication do you think you were taking *(check only one):*

- Active drug (sulforaphane) (1)
- Inactive drug (placebo) (2)
- Don't know (3)

E. Treatment unmasking

26. Was treatment unmasking envelope distributed to participant:

(Yes 1) (No 2)

If ''No,'' specify reason and skip to item 29:

_____
specify reason

27. Date treatment unmasking envelope distributed:

____ ____–____ ____ ____–____ ____
day mon year

28. Method of distribution of treatment unmasking envelope *(check only one):*

- Mail (1)
- In-person (2)
- Other *(specify)* (3)

_____
specify

F. Administrative information

29. Who was interviewed *(check all that apply)*

- **a.** Participant: (1)
- **b.** Other *(specify):* (1)

_____
relationship to participant

30. Date form reviewed:

____ ____–____ ____ ____–____ ____
day mon year

31. Clinic coordinator PIN: ____ ____ ____

32. Clinic coordinator signature *(do not key):*

_____

BEST

Reference #: _____

Physical Examination Form

Purpose: To document physical exam findings.

When: V2 and V4.

Instructions: This form should be filled out by the person completing the examination. Key into BEST data system at www.besttrial.org within 10 working days.

A. Clinical center, participant and visit identification

1. Clinical center ID: ____ ____ ____ ____

2. Participant ID: ____ ____ ____ ____ ____

3. Name code: ____ ____ ____ ____ ____

4. Date completed:

____ ____ – ____ ____ ____ – ____ ____
day mon year

5. Visit ID: ____ ____

6. Form version date:

0 7 – J U L – 1 1
day mon year

B. Vital parameters

7. Blood pressure

a. Systolic: ____ ____ ____ mmHg

b. Diastolic: ____ ____ ____ mmHg

8. Heart rate: ____ ____ ____ bpm

9. Oxygen saturation *(room air):* ____ ____ ____ %

10. Respiratory rate: ____ ____ per minute

11. Height *(measured; enter only a or b)*

a. Inches: ____ ____ • ____ inches

b. Centimeters: ____ ____ ____ • ____ cm

12. Weight *(measured; enter only a or b)*

a. In pounds: ____ ____ ____ lbs

b. Kilograms: ____ ____ ____ kg

C. Physical examination

13. General:

Normal (1)
Abnormal (2)

If abnormal, please describe:

_____
specify

14. HEENT:

Normal (1)
Abnormal (2)

If abnormal, please describe:

_____
specify

15. Chest:

Normal (1)
Abnormal (2)

If abnormal, please describe:

_____
specify

16. Cardiovascular:

Normal (1)
Abnormal (2)

If abnormal, please describe:

_____
specify

17. Abdomen:

Normal (1)
Abnormal (2)

If abnormal, please describe:

_____
specify

18. Extremities:

Normal (1)
Abnormal (2)

If abnormal, please describe:

_____
specify

19. Neurologic:

Normal (1)
Abnormal (2)

If abnormal, please describe:

_____
specify

D. Administrative information

20. Date form reviewed by coordinator:

____ ____–____ ____ ____–____ ____
day mon year

21. Clinic coordinator PIN: ____ ____ ____

22. Clinic coordinator signature *(do not key):*

_____

23. Date form reviewed by physician:

____ ____–____ ____ ____–____ ____
day mon year

24. Study physician PIN: ____ ____ ____

25. Study physician signature *(do not key):*

_____

BEST

Reference #: _____

Pulmonary Function Testing

Purpose: To record results of pulmonary function tests.

When: V2 and V4.

Instructions: Record the best FEV_1 and the best FVC after examining all of the acceptable curves, even if they do not come from the same curve. Please note that if a patient requires a rescue medication during the pulmonary function testing period that testing must be discontinued. Key into BEST data system at http://www.besttrial.org within 10 working days.

A. Clinical center, participant and visit identification

1. Clinical center ID: ____ ____ ____ ____

2. Participant ID: ____ ____ ____ ____ ____

3. Name code: ____ ____ ____ ____ ____

4. Date testing completed:

____ ____ – ____ ____ ____ – ____ ____
day mon year

5. Visit ID: ____ ____

6. Form version date:

0 2 – J U N – 1 1
day mon year

B. General PFT data

7. Height *(measured; enter only a or b)*

a. Inches: ____ ____ • ____ ____
inches

b. Centimeters: ____ ____ ____ • ____ ____
cm

8. Weight *(measured; enter only a or b)*

a. In pounds: ____ ____ ____
lbs

b. Kilograms: ____ ____ ____
kg

9. Choose one predominant race category as identified by participant *(used to calculate predicted values):*

White (1)
Black (2)
Latino/Hispanic (3)
Other *(specify)* (4)

_____
specify

Did the participant take any of the following medications before visit:

10. A short-acting bronchodilator in the past 4 hours *(Atrovent, Combivent, albuterol, ipratropium, Ventolin, Proventil):*

Yes (1) No (2)

11. A long-acting bronchodilator in the past 12 hours *(Serevent, Advair, salmeterol, theophylline, Dulera, Symbicort):*

Yes (1) No (2)

12. A longer acting bronchodilator in the past 24 hours *(tiotropium, Spiriva):*

Yes (1) No (2)

C. Pre-bronchodilator data

13. Note which spirometer brand was used:

Viasys/CareFusion (1)
Collins (2)
KoKo (3)
Other *(specify)* (4)

_____
specify

14. Pre-bronchodilator FVC: ____ • ____ ____
Liters

15. Pre-bronchodilator FEV_1: ____ • ____ ____
Liters

16. Predicted FEV_1 *(from Manual of Procedures or as calculated online at http://www.besttrial.org):*

____ • ____ ____
Liters

17. Percent predicted pre-bronchodilator FEV_1:

____ ____
%

Calculation: (100 x pre-bronchodilatorFEV_1/ predicted FEV_1; ie, 100 x item 15/item 16)

D. Post-bronchodilator data

18. Post-bronchodilator FVC: ____ • ____ ____
Liters

19. Post-bronchodilator FEV_1: ____ • ____ ____
Liters

20. Post bronchodilator FEV_1/FVC ratio:

____ • ____ ____

Calculation: (post-bronchodilator FEV_1/ post-bronchodilator FVC; ie, item 19/item 18)

21. Percent predicted post-bronchodilator FEV_1:

____ ____
%

Calculation: (100 x post-bronchodilator FEV_1/ predicted FEV_1; ie, 100 x item 19/item 16)

E. Diffusion capacity

22. Was DLCO performed:

( ) Yes (1) ( ) No (2)

24.

23. DLCO: ____ ____ • ____
mL\min\mmHg

F. Lung volumes

24. Were lung volumes completed:

( ) Yes (1) ( ) No (2)

30.

25. Method of lung volume measure *(check only one):*

Plethysmography ( ) 1
Helium dilution ( ) 2

26. TLC: ____ ____ • ____ ____
Liters

27. SVC: ____ • ____ ____
Liters

28. FRC: ____ • ____ ____
Liters

29. RV: ____ • ____ ____
Liters

G. Administrative information

30. Date form reviewed:

____ ____–____ ____ ____–____ ____
day mon year

31. Clinic coordinator PIN: ____ ____ ____

32. Clinic coordinator signature:

_____

BEST

Reference #: _____

Randomization Form

Purpose: To document eligibility and treatment assignment.

When: V3, after successful bronchoscopy.

Instructions: Key into BEST data system at www.besttrial.org to obtain treatment assignment.

A. Clinical center, participant and visit identification

1. Clinical center ID: ____ ____ ____ ____

2. Participant ID: ____ ____ ____ ____ ____

3. Name code: ____ ____ ____ ____ ____

4. Date of randomization:

____ ____ – ____ ____ ____ – ____ ____
day mon year

5. Visit ID: V 3

6. Form version date:

0 7 – J U L – 1 1
day mon year

B. Eligibility criteria

7. Has Eligibility Form (EG) been completed and data entered:

( ) Yes (1) ( ) No (2) → STOP

Do not continue until patient's eligibility documented on EG form and EG form is data entered.

8. Was V3 bronchoscopy successful:

( ) Yes (1) ( ) No (2) → STOP

NOTE: To be considered a successful bronchoscopy the following must occur:

1) Patient tolerated procedure with no adverse events that would preclude a followup bronchoscopy.
2) At least one of the following was obtained:
a) Bronchial brushing
b) One BAL collection

C. Administrative information

9. Date form reviewed:

____ ____ – ____ ____ ____ – ____ ____
day mon year

10. Clinic coordinator PIN: ____ ____ ____

11. Clinic coordinator signature *(do not key):*

_____

Randomization data *(generated by DCC data system)*

12. Kit ID: B ____ ____ ____ ____

NOTE:

- *Print copy of treatment assignment from data system and attach to this form.*
- *Affix bottom of RZ kit label on DD form*

BEST

Reference #: _____

Screening Form

Purpose: To check preliminary eligibility criteria.

When: V1, after initial forms and procedures are completed.

Instructions: This form must be keyed for all participants evaluated for the study. Key into BEST data system at www.besttrial.org within 10 working days.

A. Clinical center, participant and visit identification

1. Clinical center ID: ____ ____ ____ ____

2. Participant ID *(from next sequentially numbered label on Clinic Label Sheet):*

Affix participant ID label here

3. Name code: ____ ____ ____ ____ ____

4. Screening visit date:

____ ____ – ____ ____ ____ – ____ ____
day mon year

5. Visit ID: V 1

6. Form version date:

0 5 – J U L – 1 1
day mon year

B. Eligibility

Inclusion criteria

7. Age 40 years or older:

(Yes 1) (No 2)

8. Ten or more pack years smoking history *(10 pack-years = 1 pack a day for 10 years; 2 packs a day for 5 years, etc):*

(Yes 1) (No 2)

9. Physician diagnosed COPD:

(Yes 1) (No 2)

10. Lung function criteria

a. FEV_1 40-80% and FEV_1\FVC < 0.70 predicted within past 6 months:

(Yes 1) (No 2)

11.

b. Date demonstrated:

____ ____ – ____ ____ ____ – ____ ____
day mon year

NOTE: Use online calculator if needed; eligibility is based on Hankinson (NHANES III) predicted values.

11. Willing to ingest no more than 1 serving of cruciferous vegetables per week during run-in and treatment periods *(refer to flash card):*

(Yes 1) (No 2)

WARNING: If any of items 7-11 are ''No,'' participant currently is not eligible; items must be ''Yes'' at V2 for participant to be eligible.

Exclusion criteria

12. COPD exacerbation requiring treatment in the last 6 weeks:

(Yes 1) (No 2)

13. Significant respiratory, cardiovascular, neuropsychiatric, renal, gastrointestinal, or genitourinary disease that may interfere with participation in the study or interpretation of the results *(consult with study physician):*

(Yes 1) (No 2)

14. Acute myocardial infarction or acute coronary syndrome within the last 6 months:

(Yes 1) (No 2)

15. Cancer (other than non-melanoma skin or localized prostate) within last 5 years:

Yes (1) No (2)

16. Currently pregnant, lactating, or unwilling to practice adequate birth control for duration of the study:

Yes (1)
No (2)
Not applicable (3)

17. Allergic to local anesthesia:

Yes (1) No (2)

18. Allergic to broccoli sprout extracts:

Yes (1) No (2)

19. Anticoagulant (Warfarin) use within past 2 weeks:

Yes (1) No (2)

20. Oxygen saturation

a. Pulse oximetry: ____ ____ ____ %

b. Resting hypoxemia (O_2 < 90%):

Yes (1) No (2)

WARNING: If any of items 12-20 are ''Yes,'' participant currently is not eligible; items must be ''No'' at V2 for participant to be eligible.

C. Procedures

21. Signed consent form:

Yes (1) No (2)

22. Blood for CBC, chemistry panel, TSH collected:

Yes (1) No (2)

23. Urine collected:

Yes (1) No (2)

24. Pregnancy test:

Yes (1)
No (2)
Not applicable (3)

WARNING: If any of items 21-24 are ''No,'' procedures must be completed before V2 for participant to be eligible.

25. Does the participant appear to be eligible for the study:

Yes (1) No (2)

D. Administrative information

26. Date form reviewed:

____ ____–____ ____ ____–____ ____
day mon year

27. Clinic coordinator PIN: ____ ____ ____

28. Clinic coordinator signature *(do not key):*

_____

BEST

Reference #: _____

Serious Adverse Event Report

Purpose: To report a serious adverse event (SAE).

Definition of SAE:
Any event that results in any of the following outcomes: death, a life-threatening adverse drug experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. Also, important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug experience when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

When: Complete report within 3 working days of a clinical center learning of a serious adverse event, even if some information is missing. The DCC will confirm receipt; if receipt is not confirmed within 24 hours, contact the DCC (call DCC staff or Central Office at 443-287-3170 or e-mail bestdcc@jhsph.edu). Resubmit form with updates (information that was not available when report was initially submitted) by filling in new information and initialing and dating new information. Complete a follow-up report form(s) as required.

By Whom: Study physician and clinic coordinator.

Instructions: Fax completed form to DCC at 443-438-1377. Make sure items 10 and 11a are consistent between initial and follow-up reports. Key into BEST data system at www.besttrial.org within 10 working days.

A. Clinical center, participant and visit identification

1. Clinical center ID: ____ ____ ____ ____

2. Participant ID: ____ ____ ____ ____ ____

3. Name code: ____ ____ ____ ____ ____

4. Date of report:

____ ____ – ____ ____ ____ – ____ ____
day mon year

5. Visit ID: ____ ____
(Indicate "N" as visit ID if SAE is not associated with a particular study visit)

6. Form version date:

0 3 – A U G – 1 1
day mon year

7. Sequential number of this SR form: ____ ____
(First SAE reported on any one date is number 01; if more SAEs are reported on the same day for the same participant, number additional forms sequentially)

B. Adverse event

8. Type of report *(check only one):*

New (1)
Follow-up (2)
Other *(specify)* (3)

_____
type of report

9. Participant information

a. Age: ____ ____ years

b. Gender:

Male (1) Female (2)

10. Date of event onset:

____ ____ – ____ ____ ____ – ____ ____
day mon year

11. Adverse event

a. Event:

_____

b. Laboratory value *(if applicable include units):*

_____

12. Was adverse event unexpected *(check only one):*

Yes (1)
No (2)
Unsure (3)

13. Was the adverse event associated with any of the following

	Yes	No
a. Doctor's office visit:	(1)	(2)
b. Outpatient procedure at hospital:	(1)	(2)
c. ER visit or urgent care visit:	(1)	(2)
d. Hospital admission or extended hospital stay:	(1)	(2)
e. Disability/incapacity:	(1)	(2)
f. Life threatening event:	(1)	(2)
g. Death:	(1)	(2)
h. Congenital malformation:	(1)	(2)
i. Overdose of study capsules:	(1)	(2)

14. Hospitalization

a. Was the participant hospitalized:

Yes (1) No (2)

15.

b. Reason for hospitalization:

_____

_____

_____

c. Date admitted:

____ ____–____ ____ ____–____ ____
day mon year

d. Date discharged:

____ ____–____ ____ ____–____ ____
day mon year

15. Current status of the adverse event *(check only one):*

Resolved (1)
Active (2)

17.

16. Date resolved:

____ ____–____ ____ ____–____ ____
day mon year

C. Study drug and procedures

17. Was participant on study capsules at the onset of the adverse event:

Yes (1) No (2)

19.

18. Days on study capsules: ____ ____

19. Relationship of adverse event to study capsules *(check only one):*

Not related (1)
Possibly related (2)
Probably related (3)
Definitely related (4)
Insufficient information (5)
Unknown (6)
N/A, participant not on study capsules (7)

20. Change in study capsule use due to event *(check only one):*

No change (1)

24.

Temporarily stopped (2)
Permanently stopped (3)
N/A, participant not on study capsules (4)

24.

If study capsules stopped, complete an Unusual Event (UE) form.

21. Date study capsules stopped:

____ ____–____ ____ ____–____ ____
day mon year

22. Were study capsules restarted:

Yes (1) No (2)

24.

23. Date study capsules restarted:

____ ____–____ ____ ____–____ ____
day mon year

24. Was participant taking any other medications at the time of the event:

Yes (1) No (2)

List concomitant medications in narrative or attach a separate sheet (specify drug and dosage).

25. Was adverse event related to a study procedure or the study design, other than study capsules:

Not related (1)
27.
Possibly related (2)
Related (3)
Insufficient information (4)
27.

26. Procedures and/or study design features that were possibly related or related to event *(use narrative if more space needed):*

_____

_____

D. Administrative information

27. Date form reviewed by coordinator:

____ ____–____ ____ ____–____ ____
day mon year

28. Clinic coordinator PIN: ____ ____ ____

29. Clinic coordinator signature *(do not key):*

_____

30. Date form reviewed by study physician:

____ ____–____ ____ ____–____ ____
day mon year

31. Study physician PIN: ____ ____ ____

32. Study physician signature *(do not key):*

_____

E. Adverse event narrative

33. *Describe event and clinical significance. Describe study treatment at the time of the event and changes to treatment because of the event. Explain any pre-existing or persistent conditions, and report lab values that may have contributed to this event. Provide information on recovery or any sequelae. If participant died, provide complete details.*

Type or print legibly.