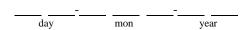
## **ATS-DLD Respiratory Questionnaire**

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:

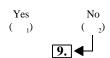


5. Visit ID:

- <u>V</u> 2
- **6.** Form version date:

#### 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):



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

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

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

Y	es	No
(	1)	( 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:

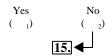
Yes	$\begin{pmatrix} & & \\ & & 1 \end{pmatrix}$
No	$\begin{pmatrix} & & \\ & & 2 \end{pmatrix}$
Does not apply	( 3)
	13.

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):



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

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

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

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:



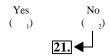
**18.** For how many years have you had trouble with phlegm:

# 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.



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



#### E. Wheezing

- 21. Does your chest ever sound wheezy or whistling
  - **a.** When you have a cold:

Yes No ( 2)

**b.** Occasionally apart from colds:

Yes No ( 2)

c. Most days or nights:

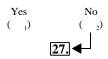
Yes No ( 2)

# 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:



**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 No ( 2)

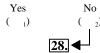
**26.** Have you ever required medicine or treatment for the(se) attack(s):

Yes No ( 2)

#### F. Breathlessness

27. Disabled from walking

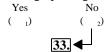
**a.** Are you disabled from walking by any condition other than heart or lung disease:



**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:



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

Yes No

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

Yes No

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

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

Yes No ( 2)

#### G. Chest colds and chest illness

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

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



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



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

# illnesses

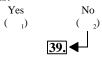
#### H. Past illnesses

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

Have you ever had any of the following:

**38.** Attacks of bronchitis

**a.** Attacks of bronchitis:



**b.** Was it confirmed by a doctor:

c. At what age was your first attack:

age in years

39. Pneumonia (include bronchopneumonia)

a. Pneumonia: Yes No

**b.** Was it confirmed by a doctor:

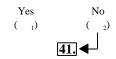


c. At what age did you first have it:

age in years

40. Hayfever

**a.** Hayfever:



**b.** Was it confirmed by a doctor:

**c.** At what age did it start:

age in years

## 41. Chronic bronchitis

**a.** Have you ever had chronic bronchitis:



- **b.** Do you still have it: Yes No  $\begin{pmatrix} 1 \end{pmatrix}$   $\begin{pmatrix} 1 \end{pmatrix}$   $\begin{pmatrix} 1 \end{pmatrix}$
- c. Was it confirmed by a doctor:

  Yes

  No

  (1)
  (2)
- **d.** At what age did it first start:  $\frac{}{\text{age in years}}$

## 42. Emphysema

**a.** Have you ever had emphysema:



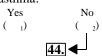
- **b.** Do you still have it: Yes No
- c. Was it confirmed by a doctor:

  Yes
  No
  (1)
  (2)
- **d.** At what age did it first start:

  age in years

#### 43. Asthma

**a.** Have you ever had asthma:



- **b.** Do you still have it: Yes No
- **d.** At what age did it first start:  $\frac{}{\text{age in years}}$
- **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:

If "Yes", please specify:

**b.** Any chest operations:

If "Yes", please specify:

c. Any chest injuries:

If "Yes", please specify:

**45.** Has a doctor ever told you that you had heart trouble:



**46.** Have you ever had treatment for heart trouble in the past 10 years:

**47.** Has a doctor ever told you that you have high blood pressure:



**48.** Have you had any treatment for high blood pressure (hypertension) in the past 10 years:

Participant ID:	 	 

## I. Occupational history

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



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



**51.** Specify job/industry:

job/industry	

**52.** Total years worked:



**53.** Was dust exposure:

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

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



**55.** Specify job/industry:

job/industry

**56.** Total years worked:



**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:

# \	ears	

c. Position/job title:

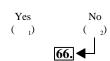
position/job title	

**d.** Business, field or industry:

busir	ness/field/in	dustry	

## 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):



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

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

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

vears

**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):



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



week:

per week now:

Not at all

Moderately

Yes No

Yes No

**c.** Asthma: Yes No

Yes

No

Yes No

Don't know

Don't know

e. Other chest condition:

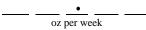
Slightly

Deeply

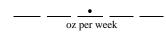
K. Family history

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

**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  $tobacco = 1 \frac{1}{2} oz$ ):



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



**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):



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

age in years

2)

Yes No

Don't know

blank):

**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	(	2

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

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

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		11. Date of birth:		
1. Clinical center ID:		day mon	year	
<b>2.</b> Participant ID:		C. Medical history		
<b>3.</b> Name code:		<b>12.</b> Has a doctor ever told you that you have any of the following conditions ( <i>check all that apply</i> )		
<b>4.</b> Date completed:		a. Congestive heart failure:	(	1)
•		<b>b.</b> Stroke:	(	1)
day mon year	r	<b>c.</b> Obstructive sleep apnea:	(	1)
<b>5.</b> Visit ID: <u>V</u>	1	<b>d.</b> Diabetes:	(	1)
<u> </u>		e. Cirrhosis (liver failure):	(	1)
<b>6.</b> Form version date:		f. Gout:	(	1)
1 1 - J U L - 1	1	g. Hepatitis/liver disease:	(	1)
day mon year	r	h. Neurological disease:	(	1)
B. Demographic information		i. Cancer:	(	1)
7. Gender (check only one):		j. Psychiatric disease:	(	1)
Male (	)	k. Heart attack:	(	1)
Female (	1) 2)	l. Angina:	(	1)
`	27	m. High blood pressure:	(	1)
<b>8.</b> Ethnicity (check only one):			(	
Hispanic/Latino/Spanish (	1)	n. Kidney disease:	(	1)
Not Hispanic/Latino/Spanish (	2)	o. Rheumatoid arthritis:	(	1)
9. Race (check only one):		<b>p.</b> Renal artery stenosis:	(	1)
White (	1)	<b>q.</b> Other conditions (specify):	(	1)
Black or African American (	2)			
Asian	.)	specify		
American Indian or Alaskan Native (	3) 4)	r. None:	(	1)
Hawaiian or other Pacific Islander (	5)			
Other (specify) (	6)			
specify				
<b>10.</b> Age:				
year	S			

specify

**k.** Other (specify):

I. None:

Broccoli Sprout Extracts Trial (BEST)

#### 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:

 $\binom{\text{Yes}}{1}$   $\binom{\text{No}}{2}$ 

\_V\_1\_

- 15. In the last two weeks have you taken any anticoagulants (check all that apply)
  - a. Warfarin (Coumadin®):
  - **b.** Aspirin:
  - **c.** Clopidogrel (Plavix®):
  - **d.** Dabigatran (Pradax®):
  - **e.** Other (specify):

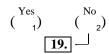
	specify		
f. None:		( 1	)

- **16.** Other prescription medications
  - a. Have you taken any other prescription medications in the last two weeks:

1)

**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:



- 18. When do you use oxygen
  - a. At rest:

**b.** What is the flow rate:

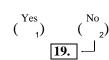
c. During sleep:

Yes	No
$\begin{pmatrix} 1 \end{pmatrix}$	( 2)
	18e.

**d.** What is the flow rate:

•	
 L/min	

e. With exertion:



**f.** What is the flow rate:

•	
L/min	

- E. Administrative information
- **19.** Date form reviewed:

_		_
day	mon	year

20. Clinic coordinator PIN:

1.	Clinic	coordinator	signature	(do not ke	y):

0

## **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:

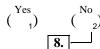
day	mon	year

- **5.** Visit ID:
- **6.** Form version date:

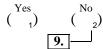
_15	JU	L - 1 1
day	mon	year

### **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*):



- **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:



**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	(	
I have shortness of breath when hurrying		
on flat ground or when walking up a slight		

11111	(	
I walk slower than people of my age because	se	
of my shortness of breath	(	

I have to stop walking because of shortness
of breath when walking at my own pace on
flat ground

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

l am too b	reathless	to leave 1	my hou:	se or I		
get breathl	less when	dressing	or und	ressing	(	5)

## **10.** Since your <u>last clinic visit</u>, 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

	_				Sev	erity			
		No	ne	M	ild	Mod	erate	Sev	vere
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.** 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					
		M	ild	Mod	lerate	Se	vere
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)
n.		(	1)	(	2)	(	3)
n.		(	1)	(	2)	(	3)
0.		(	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:

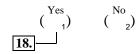
Y	es	N	lo
(	1)	(	2)
		14.	J

). SJ	pecify ev	vent(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.

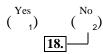
14. Other significant medical events or illnesses since the last visit:

**15.** Is this V2:



#### C. Study drug

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



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

	•	

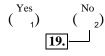
17.	Why were doses missed
	(check all that apply)

a. Forgot:	(	1)

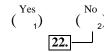
r	ame	side	effect

## D. Study procedures

- **18.** Pulse oximetry (V2)
  - a. Was pulse oximetry performed:



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



- 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	(	(ر

21.	<b>Expired Breath Condensate aliquots</b>
	collected (check all that apply)

- **a.** None ( <sub>1</sub>)
- **b.** Aliquot 1 for JHU  $_{1}$
- c. Aliquot 2 for JHU
- **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*):

Y	es	N	ol
(	1)	(	2)

**25.** Urine collected (*V4*):

Ŋ	/es	N	Ю
(	1)	(	2

**26.** Pregnancy test (*V4*):

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

### E. Forms completed

**27.** Were the following procedures and their forms completed

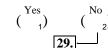
	Yes	No
<b>a.</b> ATS-DLD Respiratory Questionnaire (AT) [V2]:	( 1)	( 2)
<b>b.</b> St. Georges Respiratory Questionnaire (SG) [V2 and V4]:	( 1)	( <sub>2</sub> )
c. Pulmonary Function		

- Testing (PF) [V2 and V4]:  $\binom{1}{2}$
- **d.** Physical Exam (PE) [V2 and V4]: ( 1) ( 2)

## F. Bronchoscopy eligibility

#### **28.** COPD

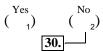
**a.** COPD exacerbation in last 6 weeks:



**b.** Comment:

### 29. Health status

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



**b.** Comment:

comr	nent	ς

### 30. Medications

**a.** Change in medications since last visit:

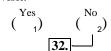


**b.** Comment:

	comments	

#### **31.** Nosebleed

a. Nosebleed since last clinic visit:



**b.** Comment:

comments

### 32. Anticoagulant

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



**b.** Comment:

comments

Broccoli	Sprout	Extracts	Trial	(BEST)
Dioccon	Sprout	LAttacts	111111	(DEDI)

Participant ID:	 	 	
Vicit ID:			

- 33. Lidocaine/local anesthetic allergy
  - a. Allergic to lidocaine or local anesthetic:





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:



- **35.** Clinic coordinator PIN:
- **36.** Clinic coordinator signature:

Reference #:

## **Blisterpack Dispensing and Capsule Counting Form**

Purpose: To record the issuance of blisterpacks and count of capsules returned.

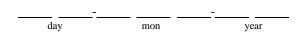
When: V3 and V5 and whenever a blisterpack is dispensed to the participant or returned and retained by the clinic.

By whom: Coordinator or pharmacist.

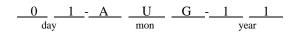
**Instructions:** Key into BEST data system at www.besttrial.org within 10 working days.

## A. Clinical center, participant, and visit identification

- Clinical center ID:
- Participant ID:
- Name code:
- Date form completed:



- Visit ID: 5. (indicate "N" if not associated with a study visit)
- Form version date:



## B. Study drug dispensed

7. Was study drug dispensed:



Date dispensed:

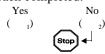


Blisterpack ID (key information from label):

affix blisterpack label here

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

Were label fill-ins on blisterpack completed:



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:



Date study blisterpack returned: **12**.



**13**. Blisterpack ID:

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

Yes No Not applicable

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

Visit ID:  23. Were any blisterpacks expected but not returned:  Yes No  (())  25.   24. Reasons expected blisterpacks were not returned  (check all that apply)  a. Consumed and discarded: b. Lost/destroyed: c. Forgot, still at home: d. Participant will return at later date: e. Other (specify):  reason  Administrative information  25. Date form reviewed:  day mon year  26. Clinic coordinator PIN:  27. Clinic coordinator signature:			Participant II	):	
23. Were any blisterpacks expected but not returned:  Yes No (1) (2) (25. 4  24. Reasons expected blisterpacks were not returned (check all that apply)  a. Consumed and discarded: b. Lost/destroyed: c. Forgot, still at home: d. Participant will return at later date: e. Other (specify):  reason  Administrative information  25. Date form reviewed:				·	
24. Reasons expected blisterpacks were not returned (check all that apply)  a. Consumed and discarded: b. Lost/destroyed: c. Forgot, still at home: d. Participant will return at later date: e. Other (specify):  reason  Administrative information  25. Date form reviewed:  day mon year  26. Clinic coordinator PIN:					
24. Reasons expected blisterpacks were not returned (check all that apply)  a. Consumed and discarded: b. Lost/destroyed: c. Forgot, still at home: d. Participant will return at later date: e. Other (specify):  reason  Administrative information  25. Date form reviewed:  day mon year  26. Clinic coordinator PIN:	23.	We	re any blisterpacks		
(check all that apply)  a. Consumed and discarded:  b. Lost/destroyed:  c. Forgot, still at home:  d. Participant will return at later date:  e. Other (specify):  reason  Administrative information  25. Date form reviewed:  day mon year  26. Clinic coordinator PIN:					
(check all that apply)  a. Consumed and discarded:  b. Lost/destroyed:  c. Forgot, still at home:  d. Participant will return at later date:  e. Other (specify):  reason  Administrative information  25. Date form reviewed:  day mon year  26. Clinic coordinator PIN:				25. ◀	
b. Lost/destroyed: c. Forgot, still at home: d. Participant will return at later date: e. Other (specify):  reason  Administrative information  25. Date form reviewed:  day mon year  26. Clinic coordinator PIN:	24.			terpacks were not re	turned
b. Lost/destroyed: c. Forgot, still at home: d. Participant will return at later date: e. Other (specify):  reason  Administrative information  25. Date form reviewed:  day mon year  26. Clinic coordinator PIN:		a.	Consumed and d	liscarded:	( 1
d. Participant will return at later date: e. Other (specify):  reason  Administrative information  25. Date form reviewed:  day mon year  26. Clinic coordinator PIN:					( 1
reason  Administrative information  25. Date form reviewed:  day mon year  26. Clinic coordinator PIN:					
Administrative information  25. Date form reviewed:  day mon year  26. Clinic coordinator PIN:				return at later date:	
Administrative information  25. Date form reviewed:  day mon year  26. Clinic coordinator PIN:		ι.	Other (specify).		1.
25. Date form reviewed:  day mon year  26. Clinic coordinator PIN:				reason	
day mon year  26. Clinic coordinator PIN:	Admi	inistra	ative information		
day mon year  26. Clinic coordinator PIN:	25	Dat	te form reviewed:		
26. Clinic coordinator PIN:	20.	Dat	ie form feviewed.		
26. Clinic coordinator PIN:				mon -	Veer
			•		year
27. Clinic coordinator signature:	26	OI:		Λ.	
	26.	Clir	nic coordinator Pir	··	· ·

**15**. How many capsules were left in blisterpack:

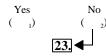
<b>16</b> .	Confirm that photocopy of returned blisterpack has
	been attached to this form:

Yes No

If "No," specify reason:

specify

17. Was a second blisterpack returned:



**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 No ( 2)

If "No," specify reason:

specify

Reference #:
--------------

## **Eligibility Form**

Purpose: To document eligibility.

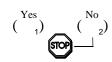
When: V2, after spirometry and results from V1 required tests are reviewed.

specify

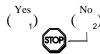
**Instructions**: If participant is eligible, key into BEST data system at www.besttrial.org before V3. Do not key form for participants who fail eligibility.

A. Clinical center, participant and visit identification		C. Eligibility
<b>1.</b> Clinical center ID:		Inclusion criteria
1. Chinear center ID.	·	<b>10.</b> Age 40 years or older:
<b>2.</b> Participant ID:		$\binom{\text{Yes}}{1} \bigcap \binom{\text{No}}{2}$
<b>3.</b> Name code:		
4. Date completed:		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):
day mon	 year	$\begin{pmatrix} \text{Yes} & \text{No} \\ ( & 1 \end{pmatrix} & \underline{} & ( & 2 \end{pmatrix}$
•	•	STOP
5. Visit ID:	<u>V</u> 2	
<b>6.</b> Form version date:		12. Physician diagnosed COPD:  Yes  No
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	1	( <sub>1</sub> ) ( <sub>2</sub> )
B. Demographic Information		<b>13.</b> Post-bronchodilator FEV <sub>1</sub>
7. Gender (check only one):		a. Post-bronchodilator FEV <sub>1</sub> 40-80%
Male	( 1)	predicted at V2:
Female	( 2)	$\binom{\operatorname{Yes}}{1} \qquad \binom{\operatorname{No}}{2}$
<b>8.</b> Ethnicity (check only one):		SIOP —
Hispanic/Latino/Spanish	( 1)	<b>b.</b> FEV <sub>1</sub> % predicted at V2:
Not Hispanic/Latino/Spanish	( 2)	%
9. Race (check only one):		14. Post bronchodilator FEV <sub>1</sub> /FVC
White	( 1)	a. Post bronchodilator FEV <sub>1</sub> /FVC
Black or African American	$\begin{pmatrix} & & \\ & & 2 \end{pmatrix}$	ratio < 0.70 at V2:
Asian	$\begin{pmatrix} & & \\ & & \end{pmatrix}$	$\begin{pmatrix} \text{Yes} & \text{No} \\ \begin{pmatrix} 1 \end{pmatrix} & \begin{pmatrix} 2 \end{pmatrix} \end{pmatrix}$
American Indian or Alaskan Native	$\begin{pmatrix} & & \\ & & 4 \end{pmatrix}$	<b>STOP</b>
Hawaiian or other Pacific Islander	( 5)	<b>~</b>
Other (specify)	$\begin{pmatrix} & & \\ & & \end{pmatrix}$	<b>b.</b> FEV <sub>1</sub> /FVC demonstrated at V2:

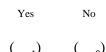
15. Signed consent form:



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



17. Results from required tests at V1 reviewed



a. Blood for CBC, chemistry panel, TSH:



**b.** Urine analysis:



**c.** Pregnancy test:

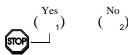


Not applicable

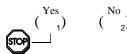


#### **Exclusion criteria**

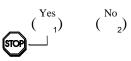
18. COPD exacerbation requiring treatment within the last 6 weeks:



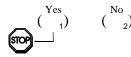
19. Significant respiratory (other than COPD), cardiovascular, neuropsychiatric, renal, gastrointestinal, or genitourinary disease that may interfere with participation in the study or interpretation of the results (consult with study physician):



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



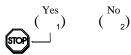
21. Cancer (other than non-melanoma skin cancer or localized prostate cancer) within last 5 years:



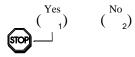
22. Currently pregnant, lactating, or unwilling to practice adequate birth control for duration of the study:

No Not applicable

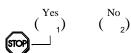
23. Allergic to local anesthesia:



**24.** Allergic to broccoli sprout extracts:



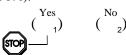
25. Anticoagulant (Warfarin) use within past 2 weeks:



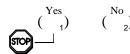
26. Oxygen saturation

a. Pulse oximetry:  $SpO_2$  (%)

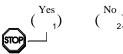
**b.** Resting hypoxemia (< 90%):



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



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



**29.** Patient eligible to schedule bronchoscopy:



#### D. Administrative information

**30.** Date form reviewed by coordinator:



- **31.** Clinic coordinator PIN: \_\_\_\_ \_\_\_
- **32.** Clinic coordinator signature (*do not key*):
- **33.** Date form reviewed by study physician:



- **34.** Study physician PIN: \_\_\_\_ \_\_\_
- **35.** Study physician signature (*do not key*):

Reference #:

## **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. Id	entifying information	15.	Calcium:	
				mg/dL
1.	Clinical center ID:		Total Protein:	
2.	Participant ID:			gm/dL
3.	Name code:	17.	Albumin:	<u> </u>
3.	<del></del>			gm/dL
4.	Date completed:	18.	Total Bilirubin:	<u> </u>
				mg/dL
	day mon ye	19.	AST:	
5.	Visit ID:			U/L
6	Form version date:	20.	ALT:	
6.	Form version date:			U/L
	2 3 - M A R - 1 ye		Alkaline Phosphatase:	
	day mon ye	ai		U/L
B. S	pecimen collection	22.	WBC:	x10 <sup>4</sup> /cu mm
				ATO /eu min
B	lood	23.	Hemoglobin:	gm/dL
7.	Date of blood collection:			g d.2
		24.	Hematocrit:	
	day mon ye	ear	DI 1	
8.	Sodium:	25.	Platelets:	x10 <sup>5</sup> /cu mm
0.	mEq/L		Tall.	_
9.	Potassium:	26.	TSH:	μ IU/mL
7.	mEq/L		rine	
10.	Chloride:	O	rine	
200	mEq/L	27.	Date of urine collection:	
11.	Bicarbonate:		<del></del>	
	mE	q/L	day	mon year
12.	BUN:		pH:	<u>•</u>
	mg/	/dL		
13.	Creatinine:	29.	Specific gravity:	<u> </u>
	$\overline{\mathrm{mg/dL}}$			

mg/dL

**14.** Glucose:

1. Glucose (0-4+):	Protein (0-4+):  Glucose (0-4+):  Blood (0-4+):  Sediment:  Normal Abnormal  ( 1) ( 2)  mormal values  st laboratory values outside of normal range:  a. Lab parameter (eg, ALT)  b. clinically significant  Yes No
1. Glucose (0-4+):	Glucose (0-4+):  Blood (0-4+):  Sediment:  Normal Abnormal ( 1) ( 2)  normal values  st laboratory values outside of normal range:  a. Lab parameter (eg, ALT)  b. clinically significant Yes No
Abnormal   Normal   Abnormal	Blood (0-4+):  Sediment:  Normal Abnormal ( ) ( )  normal values  st laboratory values outside of normal range:  a. Lab parameter (eg, ALT)  b. clinically significant  Yes No
Abnormal values  List laboratory values outside of normal range:  a. Lab parameter (eg, ALT)  b. clinically significant  Yes No  (1) (2)  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 Report (SR) form as appropriate for severe abnormalities.  Administration information  39. Date form reviewed by coordinator:  (1) (2)  (2) (3)  (3)  (4)  (5)  (6)  (7)  (7)  (7)  (8)  (8)  (9)  (9)  (9)  (9)  (1)  (1)  (1)  (2)  (1)  (2)  (3)  (4)  (4)  (5)  (5)  (6)  (7)  (7)  (7)  (8)  (9)  (9)  (9)  (9)  (9)  (1)  (1)  (1	Sediment:  Normal Abnormal  (1) (2)  normal values  st laboratory values outside of normal range:  a. Lab parameter (eg, ALT)  b. clinically significant  Yes No
Abnormal values  List laboratory values outside of normal range:  a. Lab parameter (eg, ALT)  b. clinically significant Yes No  34	normal values  st laboratory values outside of normal range:  a. Lab parameter (eg, ALT)  b. clinically significant  Yes No
List laboratory values outside of normal range:   a. Lab parameter (eg, ALT)   b. clinically significant     Yes   No     44.	st laboratory values outside of normal range:  a. Lab parameter (eg, ALT)  b. clinically significant  Yes No
a. Lab parameter (eg, ALT)  b. clinically significant Yes No  4	a. Lab parameter (eg, ALT)  b. clinically significant  Yes No
Yes No  (1) (2)  (1) (2)  (1) (2)  (1) (2)  (1) (2)  (1) (2)  (1) (2)  (1) (2)  If clinically significant, clinic should complete an Unusual Event (UE) form or a Serious Adverse Report (SR) form as appropriate for severe abnormalities.  Administration information  9. Date form reviewed by coordinator:  ———————————————————————————————————	Yes No
4	
5	
S	
If clinically significant, clinic should complete an Unusual Event (UE) form or a Serious Adverse Report (SR) form as appropriate for severe abnormalities.  Administration information  Date form reviewed by coordinator:	
If clinically significant, clinic should complete an Unusual Event (UE) form or a Serious Adverse Report (SR) form as appropriate for severe abnormalities.  Administration information  Date form reviewed by coordinator:	
If clinically significant, clinic should complete an Unusual Event (UE) form or a Serious Adverse Report (SR) form as appropriate for severe abnormalities.  Administration information  Date form reviewed by coordinator:	( 1) ( 2)
Report (SR) form as appropriate for severe abnormalities.  Administration information  Date form reviewed by coordinator:	
day mon year  10. Clinic coordinator PIN:	If clinically significant, clinic should complete an Unusual Event (UE) form or a Serious Adverse Report (SR) form as appropriate for severe abnormalities.  ministration information
40. Clinic coordinator PIN:	Date form reviewed by coordinator:
<del></del>	day mon year
11 Clinia annulimetan disentum (de met hom)	Clinic coordinator PIN:
1. Chinic coordinator signature (ao not key):	Clinic coordinator signature (do not key):
	Date form reviewed by study physician:

44.

**43.** Study physician PIN:

Study physician signature (do not key):

## **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	g. CV (Clinic Visit Form):
identification  1. Clinical center ID:	<b>h.</b> DD (Blisterpack Dispensing and Capsule Counting Form): ( 1)
	<b>i.</b> EG (Eligibility Form): ( 1)
2. Participant ID:	<b>j.</b> LD (Laboratory Data Form):
2 Nama aadar	<b>k.</b> P1 (Phone Contact 1): ( 1)
<b>3.</b> Name code:	<b>I.</b> P2 (Phone Contact 2): ( 1)
4. Date completed:	<b>m.</b> P3 (Phone Contact 3):
	<b>n.</b> PE (Physical Examination Form): ( 1)
day mon year	<b>o.</b> PF (Pulmonary Function Testing): ( 1)
	<b>p.</b> PI (Participant Information): ( 1)
5. Visit ID:	<b>q.</b> SG (St. George's Respiratory Questionnaire):  ( 1)
<b>6.</b> Form version date:	<b>r.</b> SS (Specimen Shipment Sheet): ( 1)
$ \begin{array}{c ccccccccccccccccccccccccccccccccccc$	s. ST (Specimen Box Transmittal Sheet): ( 1)
7. Was visit or phone contact missed completely:	<b>t.</b> Other ( <i>specify</i> ):
Yes $\begin{pmatrix} Yes & No \\ 1 & \begin{pmatrix} 2 \end{pmatrix} \end{pmatrix}$	form/questionnaire
( 1) ( 2)	<b>u.</b> N/A, none missed: ( <sub>1</sub> )
B. Missed visit information	0 Providence (1/4   1   1/4   4   1 )
8. Forms/questionnaires missed	9. Procedures missed (check all that apply)
(check all that apply)	<b>a.</b> EBC: ( <sub>1</sub> )
<b>a.</b> AT (ATS-DLD Respiratory Questionnaire):	<b>b.</b> Blood for plasma:
, , , , , , , , , , , , , , , , , , , ,	c. Blood for serum:
<b>b.</b> BB (BAL Processing Form): ( <sub>1</sub> )	<b>d.</b> Blood for PBMCs: ( <sub>1</sub> )
<b>c.</b> BH (Baseline History Form): ( 1)	<b>e.</b> Blood for CBC, chemistry panel: ( <sub>1</sub> )
<b>d.</b> BK (Blisterpack Accountability Log): ( 1)	
e. BL (Bronchoalveolar Lavage/ Bronchial Brushings/Nasal Brushings	
Form): ( 1)	
<b>f.</b> BP (Blood Processing Form): ( 1)	

Broccoli Sprout Extracts Trial (BEST)		
<b>10.</b> Reason for missed visit or data (check all that apply)		
a. Participant was ill:	(	1)
<b>b.</b> Participant was temporarily away from area:	(	1)
c. Participant refused procedure:	(	1)
<b>d.</b> Participant has permanently moved from area:	(	<sub>1</sub> )
e. Unable to contact participant:	(	1)
f. Participant forgot:	(	1)
<b>g.</b> Other (specify):	(	1)
C. Administrative information		
<b>12.</b> Date form reviewed:		
day mon	year	
13. Clinic coordinator PIN:		
<b>14.</b> Clinic coordinator signature:		

Participant ID: Visit ID:

## **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
	identific		• •		

- **1.** Clinical center ID: \_\_\_\_ \_\_\_ \_\_\_
- **2.** Participant ID: \_\_\_\_ \_\_ \_\_\_ \_\_\_
- **3.** Name code: \_\_\_\_ \_\_ \_\_\_ \_\_\_
- **4.** Date of phone contact:

_		_
day	mon	year

5. Visit ID:

**6.** Form version date:

### B. Post-procedure adverse event check

7. Date of bronchoscopy/brushings:



P 1 Visit ID:

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: ( <sub>1</sub>) ( <sub>2</sub>)

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

s 0 17 skip b if none is checked under

	For items 9-17, skip b if none is checked under a.				a. Se	everity	y				b.	Statu	S
		No	one	M	ild	Mod	erate	Sev	vere	Reso	lved	Unre	solved
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)

Other symptoms or medical events:



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

	ir res, specify other symptoms of medical events a	and rate the sev			everi				b.	Statu	s
		M	ild ]	Mod	erate	Se	vere	Rese	olved	Unre	solved
19.	Other symptom or medical event #1:										
		(	1)	(	2)	(	3)	(	1)	(	2)
	specify										
20.	Other symptom or medical event #2:										
		(	1)	(	2)	(	3)	(	1)	(	2)
	specify										
21.	Other symptom or medical event #3:										
		(	1)	(	2)	(	3)	(	1)	(	2)
	specify										

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).

study medication:	obiems taking	
	$\binom{\text{Yes}}{1}$	( No
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*):

Participant ID:

Visit ID:

P 1

## **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:

**6.** Form version date:

#### B. Phone contact 1 (P1) check

7. Was the P1 form completed:

$$\binom{\text{Yes}}{1}$$
  $\binom{\text{No}}{2}$ 

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

- 9. Missed study capsules
  - **a.** Has participant missed any doses of study capsules:

**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)
(	4)

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

1	`
(	1)

specify side effects

- **d.** Lost study capsules:
- e. Too busy: ( 1)
- **f.** Other (specify):

specify other reason

Visit ID: P 2

## 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.	Syı	mptoms	Severity									
			N	one	M	lild	Mod	lerate	Sev	vere		
	a.	Nausea:	(	(0	(	1)	(	2)	(	3)		
	b.	Vomiting:	None         Mild         Moderate         Severe           ( 0)         ( 1)         ( 2)         ( 3)           ( 0)         ( 1)         ( 2)         ( 3)           ( 0)         ( 1)         ( 2)         ( 3)									
	c.	Poor appetite:	(	(0	(	1)	(	2)	(	3)		
	d.	Bad taste in mouth:	(	(0	(	1)	(	2)	(	3)		
	e.	Heartburn:	$ \begin{pmatrix} & & & & & & & & & & & & & & & & & & $	3)								
	f.	Headache:	(	(0	(	1)	(	2)	( 3) ( 3) ( 3) ( 3) ( 3) ( 3)	3)		
	g.	Fatigue:	(	0	(	1)	(	2)	(	3)		
	h	Skin rach:	(	`	(	`	(	`	(	`		

**h.** Skin rash: ( <sub>0</sub>) ( <sub>1</sub>) ( <sub>2</sub>) ( <sub>3</sub>) **i.** Bloating: ( <sub>0</sub>) ( <sub>1</sub>) ( <sub>2</sub>) ( <sub>3</sub>)

**j.** Diarrhea: ( 0) ( 1) ( 2) ( 3) **k.** Abdominal discomfort: ( 0) ( 1) ( 2) ( 3)

**12.** Other symptoms or medical events:



**13.** Rate severity of other symptoms or medical events

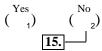
Do not ask the participant about each of the symptoms listed below. Only fill in information for self reported symptoms. If symptom(s) are not listed, report on blank line.

<i>J</i> ~ <i>J</i>	<b>1</b>			Sev	erity		
		M	lild	Mod	erate	Sev	vere
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)
0.		(	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:



**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:



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

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



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

#### F. Administrative information

18. Who was interviewed (check all that apply)

a. Participant:

**b.** Other (specify):

specify relationship to participant

**19.** Date form reviewed:

day	mon	year

**20.** Clinic coordinator PIN:

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

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:

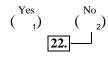
		_=
day	mon	year

5. Visit ID:

**6.** Form version date:

2	_3	_ M	_A_	<u>R</u> –	1	2
da	ay		mon		ye	ar

- B. Post-procedures adverse event check
  - 7. Bronchoscopy/brushings
    - **a.** V5 bronchoscopy and/or brushings attempted or completed:



**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:

Y	es .	N	О
(	1)	(	2)

If "Yes," specify problem(s):

Visit ID: P 3

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						
		N	one	M	ild	Mod	erate	Sev	ere	Reso	olved	Unre	solved
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)
<b>15.</b>	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:



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

		a. Severity			b. Status						
		Mi	ild	Mod	erate	Sev	vere	Resc	olved	Unre	solved
19.	Other symptom or medical event #1:										
		(	1)	(	2)	(	3)	(	1)	(	2)
	specify other symptom or medical event										
20.	Other symptom or medical event #2:										
		(	1)	(	2)	(	3)	(	1)	(	2)
	specify other symptom or medical event										
21.	Other symptom or medical event #3:										
		(	1)	(	2)	(	3)	(	1)	(	2)
	specify other symptom or medical event										

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

Poor

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

Excellent ( 1)
Good ( 2)
Fair ( 3)

**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)

Inactive drug (placebo)

Don't know

(1)

## E. Treatment unmasking

**26.** Was treatment unmasking envelope distributed to participant:

 $\binom{\text{Yes}}{1}$   $\binom{\text{No}}{2}$ 

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*):

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		<b>12.</b> Weight (measured; enter only a or b)		
1. Clinical center ID:		a. In pounds:	lbs	
<b>2.</b> Participant ID:		<b>b.</b> Kilograms:	kg	
<b>3.</b> Name code:		C. Physical examination		
4. Date completed:		13. General:		
		Normal	(	1)
day mon	year	Abnormal	(	2)
5. Visit ID:		If abnormal, please describe:		
<b>6.</b> Form version date:		specify		
_07JU_L	- 1 1	<b>14.</b> HEENT:		
day mon	year	Normal	(	<sub>1</sub> )
B. Vital parameters		Abnormal	(	1) 2)
7. Blood pressure		If abnormal, please describe:		
a. Systolic:	mmHg	specify		
<b>b.</b> Diastolic:		<b>15.</b> Chest:		
	mmHg	Normal	(	1)
8. Heart rate:		Abnormal	(	2)
	bpm	If abnormal, please describe:		
<b>9.</b> Oxygen saturation (room air):		zy we'ne, man, preside deservee.		
	%	specify		
<b>10.</b> Respiratory rate:		16. Cardiovascular:		
	per minute		(	`
11. Height (measured; enter only a or b)	)	Normal	(	1)
	_	Abnormal	(	<sub>2</sub> )
<b>a.</b> Inches: in	nches	If abnormal, please describe:		
<b>b.</b> Centimeters:	•	specify		
cm	_			

Broccoli Sprout Extracts Trial (BEST)		Visit ID:
17. Abdomen:		
Normal	( 1)	
Abnormal	( 2)	
If abnormal, please describe:		
specify		
<b>18.</b> Extremities:		
Normal	( 1)	
Abnormal	( 2)	
If abnormal, please describe:		
specify		
19. Neurologic:		
Normal	( 1)	
Abnormal	( 2)	
If abnormal, please describe:		
specify		
D. Administrative information		
<b>20.</b> Date form reviewed by coordinator:		
day mon	year	
21. Clinic coordinator PIN:		
<b>22.</b> Clinic coordinator signature ( <i>do not ke</i>	y):	
<b>23.</b> Date form reviewed by physician:		
day mon	year	
24. Study physician PIN:		
<b>25.</b> Study physician signature ( <i>do not key</i> ):	:	

Participant ID:

Reference #:
--------------

## **Pulmonary Function Testing**

**Purpose:** To record results of pulmonary function tests.

When: V2 and V4.

**Instructions**: Record the best FEV<sub>1</sub> 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	<b>9.</b> Choose one predominant race category as identified by participant (used to calculate predicted values):
1. Clinical center ID:	White ( 1)
<b>2.</b> Participant ID:	Black ( 2) Latino/Hispanic ( 3)
<b>3.</b> Name code:	Other (specify) $\begin{pmatrix} 3 \\ 4 \end{pmatrix}$
4. Date testing completed:	specify
day mon year	Did the participant take any of the following medications before visit:
5. Visit ID:	<b>10.</b> A short-acting bronchodilator in the past 4 hours ( <i>Atrovent, Combivent, albuterol, ipratropium, Ventolin, Proventil</i> ):
<b>6.</b> Form version date:	$\begin{pmatrix} \text{Yes} & \text{No} \\ 1 & \begin{pmatrix} \text{No} \\ 2 \end{pmatrix} \end{pmatrix}$
<u>0 2 - J U N - 1 1</u>	( 1) ( 2)
day mon year <b>B. General PFT data</b>	<b>11.</b> A long-acting bronchodilator in the past 12 hours ( <i>Serevent, Advair, salmeterol, theophylline, Dulera, Symbicort</i> ):
7. Height (measured; enter only a or b)	$\binom{\text{Yes}}{1} \qquad \binom{\text{No}}{2}$
<b>a.</b> Inches:	<b>12.</b> A longer acting bronchodilator in the past 24 hours ( <i>tiotropium</i> , <i>Spiriva</i> ):
<b>b.</b> Centimeters:	$\binom{\operatorname{Yes}}{1}$ $\binom{\operatorname{No}}{2}$
	C. Pre-bronchodilator data
8. Weight (measured; enter only a or b)	<b>13.</b> Note which spirometer brand was used:
<b>a.</b> In pounds:	Viasys/CareFusion ( 1)
lbs	Collins ( 2)
<b>b.</b> Kilograms:	KoKo ( 3)
kg	Other (specify) ( 4)
	specify

14.	Pre-bronchodilator FVC:	<u> </u>	
		Liters	

**16.** Predicted FEV<sub>1</sub> (from Manual of Procedures or as calculated online at http://www.besttrial.org):

•		
 Lite	rs	

**17.** Percent predicted pre-bronchodilator FEV<sub>1</sub>:



Calculation: (100 x pre-bronchodilator FEV<sub>1</sub>/ predicted FEV<sub>1</sub>; ie, 100 x item 15/item 16)

D. Post-bronchodilator data

- 20. Post bronchodilator FEV<sub>1</sub>/FVC ratio:



Calculation: (post-bronchodilator FEV<sub>1</sub>/ post-bronchodilator FVC; ie, item 19/item 18)

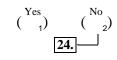
**21.** Percent predicted post-bronchodilator FEV<sub>1</sub>:



Calculation: (100 x post-bronchodilator FEV<sub>1</sub>/predicted FEV<sub>1</sub>; ie, 100 x item 19/item 16)

### E. Diffusion capacity

22. Was DLCO performed:

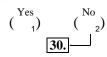


**23.** DLCO:

•	
mL\min\mmHg	

F.	Lung	vol	umes

**24.** Were lung volumes completed:



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

Plethysmography	(	1)
Helium dilution	(	2)

#### G. Administrative information

**30.** Date form reviewed:

_		=
day	mon	year

**31.** Clinic coordinator PIN:

32.	Clinic coordinator signature:	

## **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

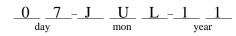
- **1.** Clinical center ID: \_\_\_\_ \_\_ \_\_\_
- 3. Name code:
- **4.** Date of randomization:

_		_
day	mon	year

5. Visit ID:

<u>V</u> 3

**6.** Form version date:



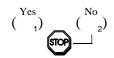
## B. Eligibility criteria

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



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

**8.** Was V3 bronchoscopy successful:



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 co	ordinator	PIN:				_
11. (	Clinic co	ordinator	signatu	re (do	not ke	ey):	

**Randomization data** (generated by DCC data system)

**12.** Kit ID:

<u>B</u> \_\_\_\_ \_

#### NOTE:

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

1 of 1

## **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):



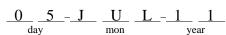
- 3. Name code:
- 4. Screening visit date:



**5.** Visit ID:



**6.** Form version date:



## **B.** Eligibility

#### **Inclusion criteria**

7. Age 40 years or older:



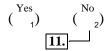
**8.** Ten or more pack years smoking history (10 pack-years = 1 pack a day for 10 years; 2 packs a day for 5 years, etc):



9. Physician diagnosed COPD:



- 10. Lung function criteria
  - **a.** FEV<sub>1</sub> 40-80% and FEV<sub>1</sub>\FVC < 0.70 predicted within past 6 months:



**b.** Date demonstrated:



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):

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:

$$\binom{\text{Yes}}{1}$$
  $\binom{\text{No}}{2}$ 

**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):

$$\binom{\text{Yes}}{1}$$
  $\binom{\text{No}}{2}$ 

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

Y	es .	N	Ю
(	1)	(	2)

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

 $\begin{pmatrix} \text{Yes} & & & \text{No} \\ \begin{pmatrix} & & & \\ & & & \end{pmatrix} & & \begin{pmatrix} & & & \\ & & & & \end{pmatrix}$ 

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

17. Allergic to local anesthesia:

 $\begin{pmatrix} \text{Yes} & & \begin{pmatrix} \text{No} \\ & 1 \end{pmatrix} & \begin{pmatrix} & & \\ & & 2 \end{pmatrix} \end{pmatrix}$ 

**18.** Allergic to broccoli sprout extracts:

 $\binom{\text{Yes}}{1}$   $\binom{\text{No}}{2}$ 

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

 $\binom{\text{Yes}}{1}$   $\binom{\text{No}}{2}$ 

20. Oxygen saturation

**b.** Resting hypoxemia  $(O_2 < 90\%)$ :

 $\binom{\text{Yes}}{1}$   $\binom{\text{No}}{2}$ 

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:

 $\binom{\text{Yes}}{1}$   $\binom{\text{No}}{2}$ 

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

Yes No

23. Urine collected:

 $\binom{\text{Yes}}{1}$   $\binom{\text{No}}{2}$ 

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 ( No ( 2

- D. Administrative information
- **26.** Date form reviewed:

day mon year

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

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	B. Adverse event	
	<b>8.</b> Type of report (check only one):	
<b>1.</b> Clinical center ID:	New	( 1)
2. Participant ID:	Follow-up	( 2)
2. Farticipant ID	Other (specify)	( 3)
<b>3.</b> Name code:		
	type of report	
<b>4.</b> Date of report:	9. Participant information	
	a. Age:	
day mon year	<b></b> 11g0.	years
<b>5.</b> Visit ID:	<b>b.</b> Gender:	
(Indicate "N" as visit ID if SAE is not associated with a particular study visit)	$\binom{\text{Male}}{1}$	Female ( 2)
<b>6.</b> Form version date:	10. Date of event onset:	
$\underbrace{\begin{array}{ccccccccccccccccccccccccccccccccccc$	day mon	year
7. Sequential number of this SR form:	11. Adverse event	
(First SAE reported on any one date is number 01; if more SAEs are reported on the same day for the	a. Event:	
same participant, number additional forms sequentially)	<b>b.</b> Laboratory value (if applicable incl.	ude units):
	12. Was adverse event unexpected (check of	only one):
	Yes	( 1)
	No	( 2)
	Unsure	( ,

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

	Y	es	N	О
<b>a.</b> Doctor's office visit:	(	1)	(	2)
<ul><li>b. Outpatient procedure at hospital:</li></ul>	(	1)	(	2)
<b>c.</b> ER visit or urgent care visit:	(	1)	(	2)
<b>d.</b> Hospital admission or	,	,		`

- **d.** Hospital admission or extended hospital stay: (1) (2
- **e.** Disability/incapacity:  $\binom{1}{1}$   $\binom{2}{2}$  **f.** Life threatening event:  $\binom{1}{1}$   $\binom{2}{2}$
- g. Death: ( 1) ( 2)

  h. Congenital malformation: ( 1) ( 2)
- **i.** Overdose of study capsules:  $\binom{1}{1}$
- 14. Hospitalization
  - **a.** Was the participant hospitalized:

Yes (Yes	( No 2)
	15.

**b.** Reason for hospitalization:

-			

**c.** Date admitted:

_		_
day	mon	year
Data disabargadi		

**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	No
( <sub>1</sub> )	( 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:



23. Date study capsules restarted:

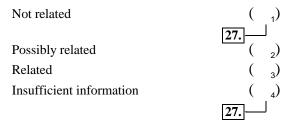
_		_
day	mon	year

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

$$\begin{pmatrix} \text{Yes} & \begin{pmatrix} \text{No} \\ 1 \end{pmatrix} & \begin{pmatrix} \frac{\text{No}}{2} \end{pmatrix} \end{pmatrix}$$

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:



**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	vear

- **28.** Clinic coordinator PIN:
- **29.** Clinic coordinator signature (*do not key*):
- **30.** Date form reviewed by study physician:

		_ <u></u>
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.		

Participant ID: Visit ID:

Broccoli Sprout Extracts Trial (BEST)