

## INCLUSION/EXCLUSION CRITERIA FORM

ID NUMBER:

FORM CODE: IEC  
VERSION: 2.0 11/01/2021

Event: \_\_\_\_\_

0a) Date of Collection:   /   /

0b) Staff Code:

**Instructions:** This form should be completed immediately after the participant signs the informed consent. This form helps determine study eligibility along with information captured on the ITF, PID, DEM, ANT, CAA, and SDF forms. After completing this form and the others required, please run the Participant Eligibility Report for eligibility status and study group information.

**I am going to ask you a series of questions to determine if you are eligible for the study. Please answer as completely and accurately as possible.**

1) (Do not ask participant) Participant's age:

years old

*NOTE: This field will populate based on the age calculated in the DEM.*

2) Do you currently or have you ever smoked cigarettes (that is, at least 100 cigarettes in your life)?

No<sub>0</sub> → **Go to 3**

Yes<sub>1</sub>

2a) For how many years have you or did you smoke?

.  years

2b) On average, how many packs of cigarettes do you or did you smoke each day?

.  packs

2c) (Do not ask participant) Participant's number of smoking pack-years (number of years smoking x number of packs per day):

.  pack-years

*NOTE: This value will be automatically calculated in the DMS.*

3) Have you ever been diagnosed with COPD, emphysema, or chronic bronchitis?

No<sub>0</sub>

Yes<sub>1</sub>

4) (Do not ask participant) Participant's assigned sex at birth:

Male<sub>1</sub> → **Go to 5**

Female<sub>2</sub>

Declines to answer<sub>3</sub>

*NOTE: This field will populate based on the assigned sex at birth entered in the DEM.*

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4a) Are you of child-bearing potential?

- No<sub>0</sub>  
 Yes<sub>1</sub>  
 Don't know<sub>2</sub>

4b) Is there any chance you are pregnant?

- No<sub>0</sub>  
 Yes<sub>1</sub>

4c) Do you have plans to become pregnant in the next three years?

- No<sub>0</sub>  
 Yes<sub>1</sub>

5) (Do not ask participant) Participant's Body Mass Index (BMI):

kg/m<sup>2</sup>

*NOTE: This field will populate based on the BMI calculated in the ANT.*

6) (Do not ask participant) Participant's CAAT score:

*NOTE: This field will populate based on the CAAT score calculated in the CAA.*

7) (Do not ask participant) Participant's spirometry values:

7a) Post-bronchodilator FEV<sub>1</sub> % predicted:

%

7b) Post-bronchodilator FEV<sub>1</sub>/FVC ratio:

%

7c) Pre-bronchodilator FEV<sub>1</sub> % predicted:

%

7d) Pre-bronchodilator FEV<sub>1</sub>/FVC ratio:

%

7e) Pre-bronchodilator FVC % predicted:

%

*NOTE: Fields 7a-7e will populate based on the spirometry values calculated in the SDF.*

**Next, I am going to ask you about other medical conditions.**

8) Do any of the following statements apply to you?

8a) You have been diagnosed with severe kyphoscoliosis  
(severe curvature of the spine) or neuromuscular weakness.

No<sub>0</sub>                      Yes<sub>1</sub>

                    

8b) You have been diagnosed with HIV/AIDS.

                    

8c) You have been diagnosed with lung cancer.

                    

8d) You have been diagnosed with a cancer that spread to multiple  
locations in the body.

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**I am now going to ask you about some medical procedures you may have had in the past.**

9) Do any of the following statements apply to you?

- |  | <u>No</u> <sub>0</sub>   | <u>Yes</u> <sub>1</sub>  |
|--|--------------------------|--------------------------|
| 9a) You have had an organ transplant.  | <input type="checkbox"/> | <input type="checkbox"/> |
| 9b) You have had endobronchial valve therapy.  | <input type="checkbox"/> | <input type="checkbox"/> |
| 9c) You have had difficulties with pulmonary function tests, spirometry, or lung function testing. | <input type="checkbox"/> | <input type="checkbox"/> |

**Next, I am going to ask you about your medication and drug use as well as problems you may have had in the past with certain medications.**

10) Do any of the following statements apply to you?

- |  | <u>No</u> <sub>0</sub>   | <u>Yes</u> <sub>1</sub>  |
|--|--------------------------|--------------------------|
| 10a) You have a hypersensitivity to or intolerance of albuterol sulfate, ipratropium bromide, Atrovent, Pro-Air, Ventolin, or Proventil or any components of these inhalers. | <input type="checkbox"/> | <input type="checkbox"/> |
| 10b) You are currently taking prednisone or other corticosteroid at more than 10 mg every day or 20 mg every other day.  | <input type="checkbox"/> | <input type="checkbox"/> |
| 10c) You have used any illegal drugs, not including marijuana, in the past 30 days.  | <input type="checkbox"/> | <input type="checkbox"/> |
| 10d) You have used Ritalin as an IV drug.  | <input type="checkbox"/> | <input type="checkbox"/> |
| 10e) You have used heroin.   | <input type="checkbox"/> | <input type="checkbox"/> |
| 10f) You have used illegal IV drugs at all within the past 10 years.   | <input type="checkbox"/> | <input type="checkbox"/> |
| 10g) You have used illegal IV drugs more than five times ever.   | <input type="checkbox"/> | <input type="checkbox"/> |

11) Are you currently taking any immunosuppressives such as CellCept, Imuran, or Cytoxan?

- No<sub>0</sub> → **Go to 12**  
 Yes<sub>1</sub>

11a) If Yes, please list: \_\_\_\_\_

11b) (*Do not ask participant*) Does the participant take any immunosuppressives that result in ineligibility?

- No<sub>0</sub>  
 Yes<sub>1</sub>

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**These next questions address a few other issues that may affect your eligibility.**

12) Do any of the following statements apply to you?

- |   | <u>No</u> <sub>0</sub>   | <u>Yes</u> <sub>1</sub>  |
|---|--------------------------|--------------------------|
| 12a) You plan to leave the area in the next three years.  | <input type="checkbox"/> | <input type="checkbox"/> |
| 12b) You currently reside in any kind of long-term care facility.   | <input type="checkbox"/> | <input type="checkbox"/> |
| 12c) You are related by blood to a parent or sibling also participating in this study (i.e., they are a biological relative). | <input type="checkbox"/> | <input type="checkbox"/> |

*Temporary Exclusion Criteria (if Yes to any of the following, participant will need to be re-screened at a later date):*

**I would now like to ask you about conditions that may have occurred in the last six weeks. If one of these applies to you, we will need to re-screen you after six weeks have passed.**

13) Do any of the following statements apply to you?

- |  | <u>No</u> <sub>0</sub>   | <u>Yes</u> <sub>1</sub>  |
|--|--------------------------|--------------------------|
| 13a) <input type="checkbox"/> You have had an upper respiratory infection in the past six weeks.   | <input type="checkbox"/> | <input type="checkbox"/> |
| 13b) <input type="checkbox"/> You have had a heart attack within the past six weeks.   | <input type="checkbox"/> | <input type="checkbox"/> |
| 13c) <input type="checkbox"/> You have had unstable heart disease, heart failure, or uncontrolled irregular heartbeat in the past six weeks. | <input type="checkbox"/> | <input type="checkbox"/> |
| 13d) <input type="checkbox"/> You have had eye, chest, or abdominal surgery within the past six weeks.                                       | <input type="checkbox"/> | <input type="checkbox"/> |

**Now I would like to ask you about conditions that may have occurred in the last 30 days. If one of these applies to you, we will need to re-screen you after 30 days have passed.**

14) Do any of the following statements apply to you?

- |  | <u>No</u> <sub>0</sub>   | <u>Yes</u> <sub>1</sub>  |
|--|--------------------------|--------------------------|
| 14a) <input type="checkbox"/> You have had an acute exacerbation of COPD, either solely participant-identified or that has been clinically treated, in the past 30 days.           | <input type="checkbox"/> | <input type="checkbox"/> |
| 14b) <input type="checkbox"/> You have used additional steroids beyond what you usually take, or you have increased the dose of the steroids you usually take in the past 30 days. | <input type="checkbox"/> | <input type="checkbox"/> |

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15) Have you taken antibiotics in the last 30 days?

- No<sub>0</sub> → **Go to 16**  
 Yes<sub>1</sub>

15a) Are you taking the antibiotics as part of a long-term or suppressive treatment?

- No<sub>0</sub>  
 Yes<sub>1</sub>

15b) Have you been taking these long-term antibiotics continuously for at least six weeks?

- No<sub>0</sub>  
 Yes<sub>1</sub>

15c) (*Do not ask participant*) Does the antibiotic therapy described in 15a and 15b make the participant ineligible?

- No<sub>0</sub>  
 Yes<sub>1</sub>

*(For female participants only. If the participant is male, go to 17.)*

**If you have given birth in the last three months, we will need to re-screen you once three months has passed.**

16) Have you given birth in the last three months?

- No<sub>0</sub>  
 Yes<sub>1</sub>

*If the participant answers Yes to questions 17-22, consult physician regarding eligibility.*

**I have just a few more questions about other diseases that might affect your eligibility. Please answer to the best of your ability.**

17) Have you ever been diagnosed with any other heart or lung disease?

- No<sub>0</sub> → **Go to 18**  
 Yes<sub>1</sub>

17a) Please describe: \_\_\_\_\_

17b) (*Do not ask participant*) Does the heart or lung disease listed in 17a make the participant ineligible?

- No<sub>0</sub>  
 Yes<sub>1</sub>

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18) Have you ever had any other kind of lung surgery?

No<sub>0</sub> → **Go to 19**

Yes<sub>1</sub>

18a) Please describe: \_\_\_\_\_

18b) (*Do not ask participant*) Does the lung surgery listed in 18a make the participant ineligible?

No<sub>0</sub>

Yes<sub>1</sub>

19) Do you have any other significant illness?

No<sub>0</sub> → **Go to 20**

Yes<sub>1</sub>

19a) Please describe: \_\_\_\_\_

19b) (*Do not ask participant*) Does the illness listed in 19a make the participant ineligible?

No<sub>0</sub>

Yes<sub>1</sub>

20) Do you have any metal implants in your chest, including cardiac stents, defibrillator, or pacemaker?

No<sub>0</sub> → **Go to 21**

Yes<sub>1</sub>

20a) Please describe: \_\_\_\_\_

20b) (*Do not ask participant*) Does the metal implant listed in 20a make the participant ineligible?

No<sub>0</sub>

Yes<sub>1</sub>

21) Have you ever or are you currently undergoing chemotherapy or radiation treatments?

No<sub>0</sub> → **Go to 22**

Yes<sub>1</sub>

21a) Please describe: \_\_\_\_\_

21b) (*Do not ask participant*) Does the chemotherapy or radiation treatment listed in 21a make the participant ineligible?

No<sub>0</sub>

Yes<sub>1</sub>

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22) Are you currently enrolled in any other clinical trial or research study?

- No<sub>0</sub> → **Go to 23**  
 Yes<sub>1</sub>

22a) Please describe: \_\_\_\_\_

22b) Are you part of the control group in this study?

- No<sub>0</sub>  
 Yes<sub>1</sub>  
 Don't know<sub>2</sub>  
 Does not apply<sub>3</sub>

22c) (*Do not ask participant*) Does the study described in 22a make the participant ineligible?

- No<sub>0</sub>  
 Yes<sub>1</sub>

23) Have you ever been diagnosed with asthma?

- No<sub>0</sub> → **Go to End**  
 Yes<sub>1</sub>

23a) If Yes, is the asthma considered severe as defined by therapy with (*choose only one*):

- Current GINA Step 4 or higher therapy (medium dose ICS/LABA or high dose ICS or add-on LAMA; Medium dose  $\geq$  250 fluticasone propionate, = 100 fluticasone furoate, > 200 beclomethasone, > 400 budesonide, > 220 mometasone)<sub>1</sub>  
 Three or more unscheduled healthcare visits (provider/urgent care/ER) for asthma in the past 12 months<sub>2</sub>  
 One asthma hospitalization in the past 12 months<sub>3</sub>  
 Not considered severe<sub>4</sub>

**END OF FORM**