

TEMPORARY INCLUSION/EXCLUSION CRITERIA

ID NUMBER:

FORM CODE: IEC
 VERSION:1.0 05/01/2025

Event: _____

0a) Date of Collection: / /

0b) Staff Code:

Instructions: This form should be completed immediately after the participant signs the informed consent before proceeding with the study visit. Some of the information collected on this form may determine if the participant is eligible for the study visit at this point in time or if the participant should be re-screened for completion of the study visit at a later date. Please read form notes carefully to determine whether the participant's response to a given item may affect their current eligibility.

I am going to ask you a few questions which may affect your eligibility for the study visit at this point in time. Please answer as completely and accurately as possible.

Note: Items 1 through 7 were removed.

NOTE TO INTERVIEWER: Questions 8-11 do not affect current eligibility. These data are being collected for analysis purposes only.

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

- | | <u>No</u> ₀ | <u>Yes</u> ₁ |
|---|--------------------------|--------------------------|
| 8a) You have been diagnosed with severe kyphoscoliosis (severe curvature of the spine) or neuromuscular weakness. | <input type="checkbox"/> | <input type="checkbox"/> |
| 8b) You have been diagnosed with HIV/AIDS. | <input type="checkbox"/> | <input type="checkbox"/> |
| 8c) You have been diagnosed with lung cancer. | <input type="checkbox"/> | <input type="checkbox"/> |
| 8d) You have been diagnosed with a cancer that spread to multiple locations in the body. | <input type="checkbox"/> | <input type="checkbox"/> |

I am now going to ask you about some medical procedures you may have had.

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

- | | <u>No</u> ₀ | <u>Yes</u> ₁ |
|--|--------------------------|--------------------------|
| 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"/> |

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

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

- | | <u>No</u> ₀ | <u>Yes</u> ₁ |
|--|--------------------------|--------------------------|
| 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?

- No₀ → **Go to 13**
 Yes₁

11a) If Yes, please list: _____

Note: Item 12 was removed.

NOTE TO INTERVIEWER: Questions 13-16 do affect current eligibility as indicated.

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> ₀ | <u>Yes</u> ₁ |
|---|--------------------------|--------------------------|
| 13a) You have had an upper respiratory infection in the past six weeks. | <input type="checkbox"/> | <input type="checkbox"/> |
| 13b) You have had a heart attack within the past six weeks. | <input type="checkbox"/> | <input type="checkbox"/> |
| 13c) You have had unstable heart disease, heart failure, or uncontrolled irregular heartbeat in the past six weeks. | <input type="checkbox"/> | <input type="checkbox"/> |
| 13d) 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.

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

No₀ Yes₁

14a) You have had an acute exacerbation of COPD, either solely participant-identified or that has been clinically treated, in the past 30 days.

14b) 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.

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

No₀ → **Go to 16**

Yes₁

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

No₀

Yes₁

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

No₀

Yes₁

Instructions: Item 16 is 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 have passed.

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

No₀

Yes₁

Instructions: If the participant answers Yes to any one of the questions 17-22, please consult the study physician regarding impact on eligibility for the study visit at this point in time, which is at their discretion/decision, or whether the participant should be re-screened at a later point in time.

I have just a few more questions about other diseases. Please answer to the best of your ability.

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

No₀ → **Go to 18**

Yes₁

17a) Please describe: _____

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

No₀ → **Go to 19**

Yes₁

18a) Please describe: _____

19) Do you have any other significant illness?

No₀ → **Go to 20**

Yes₁

19a) Please describe: _____

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

No₀ → **Go to 21**

Yes₁

20a) Please describe: _____

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

No₀ → **Go to 22**

Yes₁

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

No₀ → **Go to END**

Yes₁

22a) Please describe: _____

END OF FORM