

BRONCHOSCOPY SUB-STUDY TEMPORARY EXCLUSION CRITERIA FORM, TEC QUESTION BY QUESTION (QxQ), VERSION 1.0

I. GENERAL INSTRUCTIONS

The Bronchoscopy Sub-study Temporary Exclusion Criteria Form (TEC) is to be completed during the phone call conducted to schedule the participant for the SOURCE Bronchoscopy Sub-study in order to determine whether the visit should be scheduled or delayed. This form should also be reviewed and completed at the beginning of the participant's clinic visit after informed consent has been obtained to ensure that the visit can be conducted safely. Please note that this study screener will be used in conjunction with any institutional requirements for COVID-19 screening in the days before and immediately at the start of visits.

Please answer every question on this form. *NOTE: All response options in the paper form may not appear in CDART (e.g., 'Don't know', 'Declines to answer', etc.).* Beside each item input is a small double bracket icon which looks like this: >>. Clicking this icon displays a field dialogue box in which the "Field Status" selection menu allows you to choose from the following options: 'Refused', 'No response', 'Doesn't know', 'Not applicable', 'Maximum value', 'Minimum value', and 'Missing'. **See MOP 6 – Section 3.2 for additional instructions on how to select a Field Status option.**

II. INSTRUCTIONS FOR INDIVIDUAL ITEMS

Each question should be read **exactly** as written to allow for consistency in screening data collection.

Header Information: Consists of key fields which uniquely identify each subject and recorded occurrence of a form. For the "ID NUMBER", record the 3-character, 6-digit number assigned to the specific participant. For the "Event", record if this is happening at Baseline or another event.

- Item 0a.** Record the date the data was collected or abstracted in the MM/DD/YYYY format either by selecting the pop-up calendar in CDART or entering the date in the space provided.
- Item 0b.** Record the SOURCE staff code of the person who collected or abstracted the data. This code is assigned to each person at each site by the GIC. If you do not have a staff code and are collecting SOURCE data, please contact the GIC in order to receive your own individual staff code.

NOTE: Read the script preceding **Item 1** **exactly** as written to the participant.

If 'Yes' to one or more of Items 1a-1e, the participant should be re-screened after 6 weeks.

Item 1.

Items 1a-1e. Select only one option among the two possible choices.

If 'Yes' to Item 2, the participant should be re-screened after 30 days.

Item 2. Select only one option among the two possible choices.

NOTE: Item 2 does not apply to participants who are on chronic prednisone therapy of < 10 mg per day or < 20 mg every other day or participants who are currently on chronic, prophylactic, or suppressive antibiotic therapy.

Item 3. Select only one option among the two possible choices.

- If 'Yes' is selected, please review with your PI before proceeding.

NOTE: Tuberculosis (TB) is a chronic infection that often affects the lungs and is rare in the US. Active TB is characterized by symptoms such as chronic coughing, coughing up blood, chest pain or pain when breathing or coughing, unintentional weight loss, loss of appetite, fatigue, fever, night sweats, and chills.

If 'Yes' or 'Don't know' to one or more of Items 4a-4l, the participant should be re-screened after 30 days.

Item 4.

Items 4a-4l. Select only one option among the two possible choices.

Select **Save and Close** at the bottom of the page/screen.