ADVERSE EVENTS FORM, AES
QUESTION BY QUESTION (QxQ), VERSION 1.0

I. GENERAL INSTRUCTIONS

The Adverse Events Form (AES) is to be completed if a participant has an adverse event. It should be completed by the study physician (or by the study coordinator then confirmed by the study physician).

This form can be completed at Baseline or Follow-up visits, Bronchoscopy Sub-study visits, or for any unexpected adverse event.

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: $\gg$. 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

CDART allows multiple adverse events to be recorded for Items 2 through 2g. Collect data for all adverse events reported.

To add multiple events, you will start a new occurrence of the form. To do this, click on the "Add New Form or Mark as Missing" icon located in the second column from the right (a white page with a blue plus sign). This will bring up a dialog box that reads: "Select Number of Next Occurrence". Make sure it says "next" in the text box, and then click "Add". Once you have done this, it will bring up another AES form, and you can select the study visit the AE is associated with. **See MOP 6 – Section 3.6 for additional instructions on how to enter a new occurrence of a form.**

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.

Item 1. Select only one option among the six possible choices. **Please do not** include symptoms related to pulmonary disease that are recorded on other data collection forms. If 'Other' is selected, go to Item 1a.

    Item 1a. Describe other visit this adverse event is associated with in the space provided.

Item 2. Describe the adverse event in the space provided.

Item 2a. Record the start date of this adverse event in the MM/DD/YYYY format either by selecting the pop-up calendar in CDART or entering the date in the space provided.

Item 2b. Record the stop date of this adverse event in the MM/DD/YYYY format either by selecting the pop-up calendar in CDART or entering the date in the space provided.

For the next item, the clinician should inquire further (e.g., *"How often does this happen?", "Does this interfere with your daily activities?"*) in order to make a judgment about the *severity* of the problem. The clinician should then select "**Mild**", "**Moderate**' or "**Severe**" in the box provided, according to their judgment of severity. In rating severity, the clinician should keep in mind the general definitions of mild, moderate, and severe as well as the specific definition of severe given for each of the individual problems listed, which are defined on the data collection form.

Item 2c. Select only one option among the three possible choices. Severity of adverse events may have varied over the rating period. Record the **HIGHEST** severity rating determined.

Item 2d. Select only one option among the seven possible choices.

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

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

Item 2g. Provide a narrative description of the adverse event in the space provided.

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