SPIROMETRY DATA FORM, SDF
QUESTION BY QUESTION (QxQ), VERSION 1.0

I. GENERAL INSTRUCTIONS

The Spirometry Data Form (SDF) is to be completed during the participant's clinic visit. Do NOT begin pulmonary function testing prior to completing the Pulmonary Function Eligibility Form (PFE).

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.**

Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box. Enter leading zeroes where necessary to fill all boxes (e.g., enter 0.25 rather than .25).

II. INSTRUCTIONS FOR INIDIVIDUAL ITEMS

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 two possible choices. If 'No' is selected, go to Item 3.

> **Item 1a.**   Record the time (i.e., hour/minute) pre-bronchodilator spirometry began in the HH:MM AM/PM format in the space provided.

Item 2.

> **Item 2a.**   Record the reported/best pre-bronchodilator FEV_1 value in L-BTPS in the space provided.

> **Item 2b.**   Record the reported/best pre-bronchodilator FVC value in L-BTPS in the space provided.

> **Item 2c.**   Select **Save and Reload** in CDART to automatically calculate the participant's FEV_1/FVC ratio based on the values entered in Items 2a and 2b. *NOTE: If Item 2a and/or 2b is missing or not entered appropriately, Item 2c will not calculate accordingly.*

Item 3.   Select only one option among the two possible choices. If 'No' is selected, go to Item 5.

Item 3a. Record the time (i.e., hour/minute) first puff of ipratropium administered in the HH:MM AM/PM format in the space provided.

Item 3b. Record the time (i.e., hour/minute) post-bronchodilator spirometry began in the HH:MM AM/PM format in the space provided.

Item 4.

Item 4a. Record the reported/best post-bronchodilator FEV_1 value in L-BTPS in the space provided. *NOTE: If Item 4a is missing or not entered appropriately, Item 7a in the IEC form will not auto-populate accordingly.*

Item 4b. Record the reported/best post-bronchodilator FVC value in L-BTPS in the space provided.

Item 4c. Select **Save and Reload** in CDART to automatically calculate the participant's FEV1/FVC ratio based on the values entered in Items 4a and 4b. *NOTE: If Item 4a and/or 4b is missing or not entered appropriately, Item 4c will not calculate, and Item 7b in the IEC form will not auto-populate accordingly.*

Item 5. Record the peak expiratory flow (PEF) value in L/sec in the space provided.

Item 6. Select only one option among the two possible choices. If 'No' is selected, go to Item 7.

Item 6a. Explain the complications during spirometry in the space provided.

Item 7. Record any other comments related to the spirometry procedure in the space provided.

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