

INDUCED SPUTUM WORKSHEET, ISP QUESTION BY QUESTION (QxQ), VERSION 1.0

I. GENERAL INSTRUCTIONS

The Induced Sputum Worksheet (ISP) is to be completed during the participant's clinic visit if their post albuterol FEV₁ is less than 50% but greater than or equal to 35% predicted.

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

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 0c.** Record the start time (i.e., hour/minute) of the sputum induction procedure in the HH:MM AM/PM format in the space provided.
- Item 0d.** Select only one option among the two possible choices. If 'Yes' is selected, go to Item 1.
- Item 0e.** Select only one option among the five possible choices. If 'Other' is selected, go to Item 0e1.
 - Item 0e1.** Specify other reason sputum induction was not performed on the participant in the space provided.

All options above with the exception of 'Other' in Item 0e, the participant may return within the 30-day window for the sputum induction.

If sputum induction was not performed, go to Item 30 after completing Item 0e.

- Item 1.** Select only one option among the two possible choices. If 'No' is selected, go to Item 2.
 - Item 1a.** Record the number of albuterol puffs given to the participant in the space provided.
- Items 2-4.** Record the baseline FEV₁ value during pre-sputum induction the first, second, and third time it is measured in the space provided.

- Item 5.** Record the name of the study staff or PI who reviewed the baseline spirometry measures in the space provided.
- Item 6.** Select only one option among the two possible choices. If 'No' is selected, go to Item 23.
- Item 7.** Record the best FEV₁ value from Trials #1-3 in the first space provided for calculations. Then, select **Save and Reload** at the bottom of the page/screen, and CDART will multiply this value by 0.9 to prefill the second space provided. **NOTE: Use this CDART calculated value to determine if saline is to be increased to the next highest concentration for next inhalation period.**
- Item 8.** Record the best FEV₁ value from Trials #1-3 in the first space provided for calculations. Then, select **Save and Reload** at the bottom of the page/screen, and CDART will multiply this value by 0.8 to prefill the second space provided. **NOTE: Use this CDART calculated value to discontinue the procedure and give albuterol. Perform PFTs at 10 minutes post administration.**

First 7 minutes measure:

- Item 9.** Record the FEV₁ value at 1 minute at 0.9% NaCl. If FEV₁ drops less than 20%, continue.
- Item 10.** Record the FEV₁ value at 2 minutes at 0.9% NaCl. If FEV₁ drops less than 20%, continue.
- Item 11.** Record the FEV₁ value at 5 minutes at 0.9% NaCl. If FEV₁ drops less than 20%, continue.
- Item 12.** Record the FEV₁ value at 7 minutes at 0.9% NaCl. If FEV₁ drops less than 20%, continue.
- Item 13.** Select only one option among the two possible choices. If 'No' is selected, go to Item 23. **NOTE: If FEV₁ drops greater than or equal to 20%, then stop the sputum induction procedure.**
- Item 13a.** Select only one option among the two possible choices. **NOTE: If FEV₁ drops less than 10%, increase to 3% NaCl after the sample is collected. If FEV₁ drops equal to or between 10-19%, continue at 0.9% NaCl.**

Second 7 minutes measure:

- Item 14.** Record the FEV₁ value at 1 minute. If FEV₁ drops less than 20%, continue.
- Item 15.** Record the FEV₁ value at 2 minutes. If FEV₁ drops less than 20%, continue.
- Item 16.** Record the FEV₁ value at 5 minutes. If FEV₁ drops less than 20%, continue.
- Item 17.** Record the FEV₁ value at 7 minutes. If FEV₁ drops less than 20%, continue.
- Item 18.** Select only one option among the two possible choices. If 'No' is selected, go to Item 23. **NOTE: If FEV₁ drops greater than or equal to 20%, then stop the sputum induction procedure.**

- Item 18a.** Select only one option among the three possible choices. **NOTE: If continuing, use the same saline concentration if FEV₁ drops equal to or between 10-19%. If FEV₁ drops less than 10%, use the next highest saline concentration.**

Third 7 minutes measure:

- Item 19.** Record the FEV₁ value at 1 minute. If FEV₁ drops less than 20%, continue.
- Item 20.** Record the FEV₁ value at 2 minutes. If FEV₁ drops less than 20%, continue.
- Item 21.** Record the FEV₁ value at 5 minutes. If FEV₁ drops less than 20%, continue.
- Item 22.** Record the final FEV₁ value at 7 minutes, and the sputum induction is complete.

Item 22a. Select only one option among the two possible choices.

Remind participant to rinse mouth and cheeks thoroughly, gargle – spit into sink. Clear throat, scraping throat and roof of mouth – spit into sink. Blow nose – discard. Deep cough from chest and spit into sputum sample cup. DO NOT HAWK OR SCRAPE when producing sample. Passively bring it past the throat into the cup!

- Item 23.** Record the time (i.e., hour/minute) the sputum induction procedure ended in the HH:MM AM/PM format in the space provided.
- Item 24.** Select only one option among the two possible choices. If 'No' is selected, go to Item 26.
- Item 25.** Select only one option among the three possible choices. If 'Other' is selected, go to Item 25a.

Item 25a. Specify other reason sputum induction was terminated early in the space provided.

Item 26. Select only one option among the two possible choices. If 'No' is selected, go to Item 30.

NOTE: If the participant's FEV₁ dropped greater than or equal to 20% from baseline and/or if a second dose of albuterol was required, conduct a post-induction spirometry, and record the values in Items 27-29.

- Items 27-29.** Record the FEV₁ value during post-induction spirometry the first, second, and third time it is measured in the space provided.
- Item 30.** Select only one option among the four possible choices.

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