SOURCE
SPIROMICS Study of Early COPD Progression

FOLLOW-UP STATUS FORM, FUS
VERSION 1.0, QUESTION BY QUESTION (QxQ)

I. GENERAL INSTRUCTIONS

The Follow-up Status Form (FUS) is interviewer administered and to be completed during the follow-up phone conversation with study participants at 18 months and either (1) when scheduling the 3-year follow-up visit or (2) in the clinic during the 3-year follow-up visit.

NOTES:
- For the 18-month follow-up phone call, all questions should be answered thinking back to the baseline visit as the last SOURCE contact.
- For the 3-year follow-up clinic visit, all questions should be answered thinking back to the 18-month follow-up phone call as the last SOURCE contact.

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 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.

NOTE: Read the script preceding Item 1 <u>exactly</u> as written to the participant. <mark>The script is only applicable when completing the 18-month follow-up phone call, not during the 3-year follow-up clinic visit.</mark>

Item 1. Select only one option among the nine possible choices.
- If 'Contacted and alive' or 'Participant mailed in form' is selected, go to Item 2.
- If 'Contacted and refused interview' is selected, go to Item 1d.
- If 'Not contacted, reported deceased' is selected, go to Item 1a.
- If any other option is selected, **Go to End** of the form, **Save and Close** the form, and **End the call**.

Item 1a. Record the date the participant died in the MM/DD/YYYY format either by selecting the pop-up calendar in CDART or entering the date in the space provided.

Item 1b. Record the city, state, and country where the participant died in the space provided.

Item 1c. Select only one option among the two possible choices.
- If 'No' is selected, **Go to End** of the form, **Save and Close** the form, and **End the call**.
- If 'Yes' is selected, go to Item 2a.

Item 1d. Select only one option among the three possible choices.
- If 'No' is selected, **Go to End** of the form, **Save and Close** the form, **End the call**, and **Complete the RSW form**.
- If 'Yes, willing to be contacted' is selected, go to Item 1d1; then **Go to End** of the form, **Save and Close** the form, and **End the call**.
- If 'Yes, willing to be contacted and next visit already scheduled' is selected, **Go to End** of the form, **Save and Close** the form, and **End the call**.

Items 1d1a-1d1b. Use the check boxes to answer all that apply for which SOURCE visit(s) the participant is willing to be contacted.

HOSPITALIZATIONS

NOTE: Read the script preceding Item 2 <u>exactly</u> as written to the participant.

Item 2. Select only one option among the two possible choices. If 'No' is selected, go to Item 9.

Item 2a. Record the participant's number of hospitalizations since their last contact in the space provided. *NOTE: CDART will only open the corresponding number of hospitalization items. For example, if you enter '04', the items for the first four hospitalizations will only be activated (items for the fifth and sixth hospitalizations will remain greyed out).*

NOTE: Read the script preceding Item 3 <u>exactly</u> as written to the participant.

Item 3.

Item 3a. Record the date the participant was admitted to the hospital for the first time since their last contact in the MM/DD/YYYY format either by selecting the pop-up calendar in CDART or entering the date in the space provided.

Item 3b. Record the name of the medical facility where the participant was admitted for the first time since their last contact in the space provided.

Item 3c. Record the address of the medical facility where the participant was admitted for the first time since their last contact in the space provided.

Item 3d.

Items 3d1-3d4. Record the First (3d1), Second (3d2), Last (3d3), and Maternal Last (3d4) names the participant was admitted to the hospital under for the first time since their last contact in the spaces provided.

NOTE:

- If participant is alive and had only 1 hospitalization since their last contact, go to Item 9.
- If participant is deceased and had only 1 hospitalization since their last contact, **Go to End** of the form, **Save and Close** the form, and **End the call**.

Items 4-4d4.   For the participant's second hospitalization, follow the instructions as in Items 3-3d4 as the question pattern is identical (if applicable).

NOTE:

- If participant is alive and had only 2 hospitalizations since their last contact, go to Item 9.
- If participant is deceased and had only 2 hospitalizations since their last contact, **Go to End** of the form, **Save and Close** the form, and **End the call**.

Items 5-5d4.   For the participant's third hospitalization, follow the instructions as in Items 3-3d4 as the question pattern is identical (if applicable).

NOTE:

- If participant is alive and had only 3 hospitalizations since their last contact, go to Item 9.
- If participant is deceased and had only 3 hospitalizations since their last contact, **Go to End** of the form, **Save and Close** the form, and **End the call**.

Items 6-6d4.   For the participant's fourth hospitalization, follow the instructions as in Items 3-3d4 as the question pattern is identical (if applicable).

NOTE:

- If participant is alive and had only 4 hospitalizations since their last contact, go to Item 9.
- If participant is deceased and had only 4 hospitalizations since their last contact, **Go to End** of the form, **Save and Close** the form, and **End the call**.

Items 7-7d4.   For the participant's fifth hospitalization, follow the instructions as in Items 3-3d4 as the question pattern is identical (if applicable).

NOTE:

- If participant is alive and had only 5 hospitalizations since their last contact, go to Item 9.
- If participant is deceased and had only 5 hospitalizations since their last contact, **Go to End** of the form, **Save and Close** the form, and **End the call**.

Items 8-8d4.   For the participant's sixth hospitalization, follow the instructions as in Items 3-3d4 as the question pattern is identical (if applicable).

NOTE:

- If participant is alive, go to Item 9.
- If participant is deceased, **Go to End** of the form, **Save and Close** the form, and **End the call**.

NOTE: It is important that the EARLIEST hospitalization be recorded first (Item 3) working forwards towards the hospitalization closest to the current date since the last contact.

NOTE: Read the script preceding Item 9 <u>exactly</u> as written to the participant.

Item 9.   Select only one option among the two possible choices. If 'No' is selected, go to Item 13.

NOTE: Please read the current contact information in the CIF form to the participant to confirm that it is still the latest information.

Item 10.   Select only one option among the two possible choices. If 'Yes' is selected, **Go to the CIF form** and enter the participant's updated home address.

Item 11.   Select only one option among the two possible choices. If 'Yes' is selected, **Go to the CIF form** and enter the participant's updated primary phone number.

Item 12.   Select only one option among the two possible choices. If 'Yes' is selected, **Go to the CIF form** and enter the participant's updated email address.

NOTE: Please read the current contacts information in the CIF form to the participant to confirm that it is still the latest information.

Item 13.   Select only one option among the two possible choices. If 'Yes' is selected, **Go to the CIF form** and enter the participant's updated contacts.

Item 14.   Select only one option among the two possible choices. If 'No' is selected, **Go to End** of the form, **Save and Close** the form, and **End the call**.

   Item 14a.   Record the name(s) of the study or trial the participant has enrolled in since their last contact in the space provided.

NOTE: Read the script following Item 14a <u>exactly</u> as written to the participant. Select the script choice per whether 'the next contact is by telephone', 'the next contact is a clinic visit that has been scheduled', or 'the next contact is a clinic visit that has not been scheduled. <mark>The script is only applicable when completing the 18-month follow-up phone call, not during the 3-year follow-up clinic visit.</mark>

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