SOURCE
SPIROMICS Study of Early COPD Progression

FOLLOW-UP MEDICAL HISTORY FORM, MHF
QUESTION BY QUESTION (QxQ), VERSION 1.0

I. GENERAL INSTRUCTIONS

The Follow-up Medical History Form (MHF) is to be completed by the study coordinator during the participant's 18-month follow-up phone call and 3-year follow-up clinic visit.

NOTE:
- For the 18-month follow-up phone call, all questions should be answered thinking back to the baseline visit as the last SOURCE contact (not the last 6-month follow-up phone call in which an FUQ is completed).
- 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 (not the last 6-month follow-up phone call in which an FUQ is completed).

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 a follow-up visit 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 to the participant.

Item 1.   Select only one option among the two possible choices.

Item 2.   Select only one option among the two possible choices. If 'No' is selected, go to Item 3.

  Item 2a.   Select only one option among the three possible choices.

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

Item 4.   Eyes, ears, nose, throat

Items 4a-4f. Select only one option among the two possible choices. If 'Yes' is selected in any of these items, go to the corresponding item (i.e., Items 4a1-4f1).

Items 4a1-4f1. Please explain the problem(s) in the space(s) provided.

Items 5-15. Follow the instructions in Items 4a-4f and Items 4a1-4f1, respectively, for the following areas as the question patterns are identical:

- **Cardiovascular** – Items 5a-5o and 5a1-5o1
- **Gastrointestinal** – Items 6a-6i and Items 6a1-6i1
- **Pulmonary/vascular** – Items 7a-7i and Items 7a1-7i1
- **Oncology/hematology** – Items 8a-8c and Items 8a1-8c1
- **Genitourinary and reproductive** – Items 9a-9d and Item 9a1-9d1
- **Endocrine** – Items 10a-10c and Items 10a1-10c1
- **Neurology** – Items 11a-11d and Items 11a1-11d1
- **Muscular/skeletal** – Items 12a-12g and Items 12a1-12g1
- **Dermatology** – Items 13a-13d and Items 13a1-13d1
- **Infectious disease** – Items 14a-14c and Items 14a1-14c1
- **Psychiatric** – Items 15a-15c and Items 15a1-15c1

Item 16. Select only one option among the two possible choices. If 'Yes' is selected, go to the corresponding items (i.e., Items 16a-16e).

Items 16a-16e. Please list other significant problem(s) not reported in Items 4-15 in the space(s) provided.

NOTE: Read the script preceding Item 17 to the participant.

Item 17. Select only one option among the five possible choices. If 'Never' is selected, go to Item 25.

Items 18-19. Select only one option among the five possible choices.

NOTE: If '1 or 2' is selected in Item 18 <u>AND</u> 'Never' is selected in Item 19, go to Item 25.

Items 20-24. Select only one option among the five possible choices.

Items 25-26. Select only one option among the three possible choices.

Item 27.

Items 27a-27c. Select only one option among the two possible choices.

NOTE: Items 28-33 are for <u>FEMALE</u> participants <u>ONLY</u>. If the participant is <u>MALE,</u> Go to End of the form, and Save and Close the form.

Item 28. Select only one option among the two possible choices. If 'No' is selected, go to Item 29.

Item 28a. Record the participant's age that menopause occurred since their last SOURCE contact in the space provided.

Item 29. Select only one option among the two possible choices. If 'No' is selected, go to Item 30.

Item 29a. Record the number of years the participant used oral contraceptive since their last SOURCE contact in the space provided.

Item 30. Select only one option among the two possible choices. If 'No' is selected, go to Item 31.

Item 30a. Record the number of years the participant used hormone replacement therapy since their last SOURCE contact in the space provided.

Item 31. Select only one option among the two possible choices.

Item 32. Select only one option among the two possible choices. If 'No' is selected, go to Item 33.

Item 32a. Record the total number of months the participant breastfed since their last SOURCE contact in the space provided if 'Yes' is selected in Item 32. *NOTE: Sum all months from all pregnancies since their last SOURCE contact.*

Item 33. Select only one option among the two possible choices. If 'No' is selected, **Go to End** of the form, and **Save and Close** the form.

Item 33a. Select only one option among the two possible choices.

Item 33b. Record the participant's age when their ovary or ovaries were removed since their last SOURCE contact in the space provided.

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