



INSTRUCTIONS FOR EXACERBATION SUBSTUDY DAILY SYMPTOM DIARY EDA and EDD, VERSIONS 1.0, QUESTION BY QUESTION (QxQ)

I. GENERAL INSTRUCTIONS

The Exacerbation Substudy Daily Symptom Diary is given to the participant during the Exacerbation Substudy Visit 1. The information from the page 1 cover page of the Daily Symptom Diary should be filled in for the participant by the study coordinator. The participant should return the completed diary at the next scheduled Exacerbation visit, Visit 2. After the participant has returned the completed Exacerbation Substudy Daily Symptom Diary at Exacerbation Substudy, the information from the page 1 cover page of the Daily Symptom Diary is to be entered into the Exacerbation Substudy Daily Symptom Diary Page 1 (EDA) form. Data from pages 2 through 81 will be entered into the Exacerbation Substudy Daily Symptom Diary (EDD) form. Each day of the diary will be entered in as a new occurrence.

II. DETAILED INSTRUCTIONS FOR EDA FORM

Page 1, Cover Page Information: The page 1, cover page information consists of the key fields which uniquely identify each daily symptom diary.

- 0a. **Date of Entry:** Record the date the data from the daily diary are being entered. Select the date from the pop-up calendar in the data management system (DMS) or type the date in the space provided. Dates should be entered in the mm/dd/yyyy format.
- 0b. **Staff Code:** Record the SPIROMICS staff code of the person who is entering 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 SPIROMICS data, please contact the GIC in order to receive your own individual staff code.
- 0c. **Start Date of Daily Diary:** Record the participant's Daily Diary start date.
- 0d. **End Date of Daily Diary:** Record the participant's Daily Diary end date.
- 0e. **Date of Exacerbation Substudy Follow-up Visit:** Record the date of the participant's Exacerbation Substudy follow-up visit.

Save and close the form.

III. DETAILED INSTRUCTIONS FOR EDD FORM

The EDD should be completed after the EDA. Please enter responses for every day for which the participant answered questions. You do not have to account for any missing days.

Item 1. **Daily Diary Date:** Enter the date the participant recorded.

Items 2 – 15. Enter the answers recorded by the participant for each question. Questions the participant left blank should be entered as permanently missing. If any questions have more than one answer marked, enter as unresolvable.

Save and close the form.