EXACERBATION ASSESSMENT FORM (VISIT 1)

ID NUMBER:									

FORM CODE: EAF
VERSION: 2.0 05/14/2019

Event: _____

0a) Date of Collection: ☐☐ / ☐☐ / ☐☐☐☐ 0b) Staff Code: ☐☐☐

Instructions: *This form should be completed during the participant's Exacerbation Substudy Visit 1. Please note that items 1 and 2 are populated based on the TEA data collection form entry.*

1) Date of phone contact ☐☐ / ☐☐ / ☐☐☐☐

2) Date symptoms first started ☐☐ / ☐☐ / ☐☐☐☐

3) Was the participant able to present to the clinical center within seven days of exacerbation event onset?

☐ No$_0$ → **End Form**

☐ Yes$_1$

4) Are the exacerbation event symptoms ongoing?

☐ No$_0$

☐ Yes$_1$ → **Go to 5**

4a) If No, when did the exacerbation event symptoms stop? ☐☐ / ☐☐ / ☐☐☐☐

4b) Has it been more than 48 hours since the symptoms stopped?

☐ No$_0$

☐ Yes$_1$ → **End Form; participant does not meet inclusion criteria for exacerbation visit 1.**

Review of Symptoms

5) Since the start of your exacerbation symptoms, have you experienced an increase and/or change in the following **major** symptoms for at least two or more consecutive days?

	No$_0$	Yes$_1$
5a) Shortness of breath	☐	☐
5b) Change in sputum discharge color (yellow/green)	☐	☐
5c) Sputum volume	☐	☐

6) Since the start of your exacerbation symptoms, have you experienced an increase in the following **minor** symptoms for at least two or more consecutive days?

	No$_0$	Yes$_1$
6a) Nasal discharge	☐	☐
6b) Wheeze	☐	☐
6c) Sore throat	☐	☐
6d) Cough	☐	☐
6e) Fever	☐	☐

Physical Assessment

7) Do you suspect any conditions other than or in addition to Acute Exacerbation COPD (AECOPD)?

☐ No$_0$ → **Go to 8**

☐ Yes$_1$

If Yes, please specify the conditions that were ruled out.

7a) ☐ Pneumonia

7b) ☐ Acute Respiratory Failure

7c) ☐ Other

7c1) If Other, please specify: _____

Physical Assessment / Vital Signs

8) Body weight ☐☐☐.☐ kg

9) Body Mass Index (BMI) ☐☐.☐ kg/m^2

Note: *The BMI value will automatically calculate in the DMS using height from Visit 5 ANT2.*

10) Temperature ☐☐☐.☐ ° C

11) Respiratory Rate ☐☐ breaths/min

12) Heart Rate ☐☐☐ beats/min

13) Systolic Blood Pressure ☐☐☐ mm Hg

14) Diastolic Blood Pressure ☐☐☐ mm Hg

15) O2 saturation ☐☐☐ %

15a) Do you currently use supplemental oxygen?

☐ No$_0$ → **Go to 16**

☐ Yes$_1$

15a1) Is this a newly prescribed oxygen therapy?

☐ No$_0$

☐ Yes$_1$

15a2) Is it an increase to your usual oxygen therapy?

☐ No$_0$

☐ Yes$_1$

16) Was a chest examination conducted?

☐ No$_0$ → **Go to 17**

☐ Yes$_1$

If Yes, which of the following were present during the chest examination?

	No$_0$	Yes$_1$
16a) Wheezes	☐	☐
16b) Crackles/ rales	☐	☐
16c) Rhonchi sounds	☐	☐
16d) Diminished breath sounds	☐	☐
16e) Increased respiratory rate and/ or labored breathing	☐	☐

Exacerbation Event Determination

*Definition: A probable exacerbation event is defined as an increase in two or more major symptoms **or** one major symptom and two minor symptoms.*

17) Is this a probable exacerbation event based on the above definition?

☐ No$_0$ → **Go to 18**

☐ Yes$_1$

17a) If Yes, what is the event duration to date?

☐ Less than 1 day$_1$

☐ 1-2 days$_2$

☐ 3-5 days$_3$

☐ 1 week$_4$

☐ More than 1 week$_5$

17b) Suspected cause (etiology)

☐ Infection$_1$

☐ Weather$_2$

☐ Treatment non-compliance$_3$

☐ Unknown$_4$

Exacerbation Event Treatment

18) Was the participant's clinical treatment or medication(s) changed?

☐ No$_0$ → **Go to 19**

☐ Yes$_1$

If Yes, Complete items 18a-18g.

18a) Antibiotics

☐ No$_0$→ **Go to 18b**

☐ Yes$_1$

18a1) If Yes, please specify: _____

18a2) Number of days prescribed: ☐☐☐

18b) Oral glucocorticosteroids

☐ No$_0$ → **Go to 18c**

☐ Yes$_1$

18b1) Number of days prescribed: ☐☐☐

18c) New inhaled glucocorticosteroid

☐ No$_0$ → **Go to 18d**

☐ Yes$_1$

18c1) Number of days prescribed: ☐☐☐

18d) Increased inhaled glucocorticosteroid dosage

☐ No$_0$ → **Go to 18e**

☐ Yes$_1$

18d1) Number of days prescribed: ☐☐☐

18e) Methylxathines (new)

☐ No$_0$ → **Go to 18f**

☐ Yes$_1$

16e1) Number of days prescribed: ☐☐☐

18f) ß$_2$-agonists (short-acting) (new or increased)

☐ No$_0$ → **Go to 18g**

☐ Yes$_1$

18f1) Number of days prescribed: ☐☐☐

18g) Other significant clinical treatments or medications

☐ No$_0$ → **Go to 19**

☐ Yes$_1$

18g1) If Yes, please specify: _____

18g1a) Number of days prescribed: ☐☐☐

18g2) If Yes, please specify: _____

18g2a) Number of days prescribed: ☐☐☐

18g3) If Yes, please specify: _____

18g3a) Number of days prescribed: ☐☐☐

18g4) If Yes, please specify: _____

18g4a) Number of days prescribed: ☐☐☐

19) If the participant meets criteria for sputum induction, do you support him/her proceeding to sputum induction?

☐No$_0$

☐Yes$_1$

END OF FORM