



# EXACERBATION SUBSTUDY INDUCED SPUTUM WORKSHEET

For post albuterol FEV<sub>1</sub> > 0.8 L and < 1.5 L

ID NUMBER:

FORM CODE: EIP  
VERSION: 1.0 02/12/2020

Event \_\_\_\_\_

0a) Form Date:   /   /     0b) Staff Code

0c) Date Collected:   /   /

0d) Procedure Start Time:   :   AM<sub>1</sub> / PM<sub>2</sub> (circle one)

**Instructions:** This form should be completed during the participant's Exacerbation substudy visits if post albuterol FEV<sub>1</sub> > 0.8 L and < 1.5 L. If FEV<sub>1</sub> > 1.5 L use the EIW form instead of this form.

0e) Was sputum induction performed on this participant?

- No<sub>0</sub>  
 Yes<sub>1</sub> → **Go to 1**

0f) Reason sputum induction was not performed:

- Participant could not perform acceptable spirometry<sub>1</sub>  
 PI felt not safe<sub>2</sub>  
 Participant refused<sub>3</sub>  
 Other<sub>4</sub>

Of1) If other, please specify: \_\_\_\_\_

**Note: If sputum induction was not performed, go to 23 after completing item 0f.**

1) Best pre-sputum induction, pre-bronchodilator FEV<sub>1</sub>   .  L

2) Best pre-sputum induction, post-bronchodilator FEV<sub>1</sub>   .  L

3) **10% fall in post-bronchodilator FEV<sub>1</sub>**   .

(Calculation: FEV<sub>1</sub> from item 2 above multiplied by 0.9)

4) **20% fall in post-bronchodilator FEV<sub>1</sub>**   .

(Calculation: FEV<sub>1</sub> from item 2 above multiplied by 0.8)

5) **FEV<sub>1</sub> 95% of pre-bronchodilator**   .

(Calculation: FEV<sub>1</sub> from item 1 above multiplied by 0.95)

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**Instructions:** Remind subject 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.

6)	2 min at 0.9% NaCl Sputum produced?	<input type="checkbox"/> No <sub>0</sub>	<input type="checkbox"/> Yes <sub>1</sub> → <b>Go to 15</b>
7)	Spirometry Does FEV <sub>1</sub> drop < 20%?	<input type="checkbox"/> No <sub>0</sub> → <b>Go to 15</b>	<input type="checkbox"/> Yes <sub>1</sub>
8)	3 min at 0.9% NaCl Sputum produced?	<input type="checkbox"/> No <sub>0</sub>	<input type="checkbox"/> Yes <sub>1</sub> → <b>Go to 15</b>
9a)	Spirometry Does FEV <sub>1</sub> drop < 10%?	<input type="checkbox"/> No <sub>0</sub>	<input type="checkbox"/> Yes <sub>1</sub> → <b>Go to 11</b>
9b)	Does FEV <sub>1</sub> drop 10-19% or more than 200 mL (whichever is greater)?	<input type="checkbox"/> No <sub>0</sub>	<input type="checkbox"/> Yes <sub>1</sub>
9c)	Does FEV <sub>1</sub> drop ≥ 20% or 400 mL (whichever is greater)?	<input type="checkbox"/> No <sub>0</sub>	<input type="checkbox"/> Yes <sub>1</sub> → <b>Go to 15</b>
10a)	Repeat spirometry effort twice more: Does FEV <sub>1</sub> drop ≤ 19% or less than 200 mL (whichever is greater)?	<input type="checkbox"/> No <sub>0</sub>	<input type="checkbox"/> Yes <sub>1</sub>
10b)	Does FEV <sub>1</sub> drop ≥ 20% or 400 mL (whichever is greater)?	<input type="checkbox"/> No <sub>0</sub>	<input type="checkbox"/> Yes <sub>1</sub> → <b>Go to 15</b>
11)	5 min at 3% NaCl Sputum produced?	<input type="checkbox"/> No <sub>0</sub>	<input type="checkbox"/> Yes <sub>1</sub> → <b>Go to 15</b>
12a)	Spirometry Does FEV <sub>1</sub> drop < 10%?	<input type="checkbox"/> No <sub>0</sub>	<input type="checkbox"/> Yes <sub>1</sub> → <b>Go to 14</b>
12b)	Does FEV <sub>1</sub> drop 10-19% or more than 200 mL (whichever is greater)?	<input type="checkbox"/> No <sub>0</sub>	<input type="checkbox"/> Yes <sub>1</sub>
12c)	Does FEV <sub>1</sub> drop ≥ 20% or 400 mL (whichever is greater)?	<input type="checkbox"/> No <sub>0</sub>	<input type="checkbox"/> Yes <sub>1</sub> → <b>Go to 15</b>
13a)	Repeat spirometry effort twice more: Does FEV <sub>1</sub> drop ≤ 19% or less than 200 mL (whichever is greater)?	<input type="checkbox"/> No <sub>0</sub>	<input type="checkbox"/> Yes <sub>1</sub>
13b)	Does FEV <sub>1</sub> drop ≥ 20% or 400 mL (whichever is greater)?	<input type="checkbox"/> No <sub>0</sub>	<input type="checkbox"/> Yes <sub>1</sub> → <b>Go to 15</b>

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14)	5 min at 4% NaCl Sputum produced?	<input type="checkbox"/> No <sub>0</sub>	<input type="checkbox"/> Yes <sub>1</sub>
15)	Spirometry Is FEV <sub>1</sub> <95% pre-bronchodilator value (from question 5)%?	<input type="checkbox"/> No <sub>0</sub>	<input type="checkbox"/> Yes <sub>1</sub>

16) Procedure End Time:   :   AM<sub>1</sub> / PM<sub>2</sub> (circle one)

17) Was the induction terminated early?  
 No<sub>0</sub> → **Go to 19**  
 Yes<sub>1</sub>

18) Reason terminated early:  
 FEV<sub>1</sub> dropped ≥20%<sub>1</sub>  
 Participant requested to stop<sub>2</sub>  
 Other<sub>3</sub>

18a) Specify Other: \_\_\_\_\_

19) Did the participant require additional albuterol?  
 No<sub>0</sub> → **Go to 23**  
 Yes<sub>1</sub>

*If participant's FEV<sub>1</sub> dropped ≥20% from baseline and/or if a 2<sup>nd</sup> dose of albuterol was required, conduct a 3 trial spirometry test post the sputum induction and record values here:*

FEV <sub>1</sub>		
20)	Trial #1	
21)	Trial #2	
22)	Trial #3	

23) Was a sputum sample collected from the participant?  
 No, Neither Induced or Spontaneous<sub>0</sub>  
 Yes, Induced Sample<sub>1</sub>  
 Yes, Induced and Spontaneous Sample<sub>2</sub>  
 Yes, Spontaneous Sample<sub>3</sub>

**END OF FORM**