

TREATMENT FAILURE

Subject ID: 2
 Subject Initials: _____
 Visit Number: 9
 Current Date: _____ / _____ / _____
month day year
 Interviewer ID: _____

(Clinic Coordinator completed)

TXF_01 1. Is this treatment failure visit replacing a regular scheduled visit? ₁ Yes ₀ No

TXF_01a If **Yes**, indicate visit number of scheduled visit _____

TXF_01b If **No**, indicate last regular visit completed _____

TXF_02 2. Date treatment failure conditions started _____ / _____ / _____
month day year

TXF_03 3. Did the subject experience an FEV₁ value ≤ 80% of the value recorded at Visit 3? ₁ Yes ₀ No

TXF_04 4. Did the subject have an FEV₁ ≤ 40% predicted? ₁ Yes ₀ No

TXF_05 5. Did the subject experience a fall in pre-bronchodilator PEFR to ≤ 65% of baseline (baseline defined as the average AM or PM pre-bronchodilator PEFR recorded during study week 4, just prior to steroid withdrawal) on two out of three consecutive scheduled measurements? ₁ Yes ₀ No

6. Did the subject experience one of the following conditions?

TXF_06a 6a. An increase in rescue inhaler use of ≥ 8 puffs per 24 hours over baseline rescue inhaler use for a period of 48 hours? ₁ Yes ₀ No

TXF_06b 6b. Use of rescue inhaler ≥ 16 total puffs per 24 hours for a period of 48 hours? ₁ Yes ₀ No

TXF_07 7. Did the subject refuse to take study medications due to lack of satisfaction with treatment regimen? ₁ Yes ₀ No

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8. Has the subject taken any of the following medications since the treatment failure conditions started?

TXF_08a

8a. Inhaled or Oral Steroids

₁ Yes ₀ No

TXF_08b

8b. Theophylline

₁ Yes ₀ No

TXF_08c

8c. Beta-Agonist via nebulizer

₁ Yes ₀ No

TXF_08d

8d. Cromolyn

₁ Yes ₀ No

TXF_08e

8e. Tilade

₁ Yes ₀ No

TXF_08f


8f. Ipratropium bromide

₁ Yes ₀ No

TXF_09

9. Is the subject a treatment failure? *If any of the shaded boxes are filled in, the subject is a treatment failure.*

₁ Yes ₀ No

 If Yes, please continue with the Treatment Failure data packet.