

ELIGIBILITY CHECKLIST 4

E4

Patient ID: 1
 Patient Initials:
 Visit Number: 0 4
 Visit Date: / /
 month day year
 Interviewer ID:

(Clinic Coordinator completed)

- | | | | |
|------------|---|--|---|
| 01 | 1. Since the first study visit, has the patient experienced a significant asthma exacerbation as defined in the Manual of Operations? | <input checked="" type="checkbox"/> ₁ Yes | <input type="checkbox"/> ₀ No |
| 02 | 2. Has the patient taken any non-study anti-asthma medications since the first study visit? | <input checked="" type="checkbox"/> ₁ Yes | <input type="checkbox"/> ₀ No |
| 03 | 3. On average in the last 4 weeks of the run-in period, did the patient use the rescue inhaler less than 6 puffs per week? | <input type="checkbox"/> ₁ Yes | <input type="checkbox"/> ₀ No |
| 03A | If Yes , was the PC ₂₀ for methacholine more than 8 mg/ml at Visit 1? | <input checked="" type="checkbox"/> ₁ Yes | <input type="checkbox"/> ₀ No |
| 04 | 4. On average in the last 4 weeks of the run-in period, did the patient use the rescue inhaler more than 56 puffs per week? | <input checked="" type="checkbox"/> ₁ Yes | <input type="checkbox"/> ₀ No |
| 05 | 5. On average in the last 4 weeks of the run-in period, did the patient demonstrate the ability to adhere to the scheduled use of the metered dose inhaler at least 75% of the time (<i>at least 42 puffs each week since visit 2</i>)? | <input type="checkbox"/> ₁ Yes | <input checked="" type="checkbox"/> ₀ No |
| 06 | 6. On average during the run-in period, has the patient recorded symptoms in the symptom diary at least 5 days per week? | <input type="checkbox"/> ₁ Yes | <input checked="" type="checkbox"/> ₀ No |
| 07 | 7. Is there any new information that makes the patient ineligible according to the eligibility criteria? If Yes , describe _____ | <input checked="" type="checkbox"/> ₁ Yes | <input type="checkbox"/> ₀ No |

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08 8. Does the patient wish to withdraw consent from the study? 1 Yes 0 No

09 9. Is there any other reason for which this patient should not be included in the study? 1 Yes 0 No

10 10. Is the patient eligible? *If any of the shaded boxes are filled in, the patient is NOT eligible.* 1 Yes 0 No
☞ If **No**, please complete the Termination of Study Participation form (TERM).

If the patient is eligible and will participate in the study, run the randomization program. If an electronic connection is impossible, call the DCC at (717) 531 - 4262.

11 11. Study drug packet number. _____