

ELIGIBILITY CHECKLIST 4

Subject ID: 2
 Subject Initials: _____
 Visit Number: 3
 Visit Date: _____ / _____ / _____
 month day year
 Interviewer ID: _____

(Clinic Coordinator completed)

- | | | |
|--------------|---|---|
| E4_01 | 1. Is the subject's pre-bronchodilator FEV ₁ less than 55% predicted? | <input checked="" type="checkbox"/> ₁ Yes <input type="checkbox"/> ₀ No |
| E4_02 | 2. Since the first study visit, has the subject experienced a significant asthma exacerbation as defined in the Manual of Operations? | <input checked="" type="checkbox"/> ₁ Yes <input type="checkbox"/> ₀ No |
| E4_03 | 3. Has the subject taken any non-study anti-asthma medications since the first study visit? | <input checked="" type="checkbox"/> ₁ Yes <input type="checkbox"/> ₀ No |
| E4_04 | 4. Did the subject use the Azmacort [®] inhaler less than twice a day on more than 4 days during the last two weeks of the run-in period? | <input checked="" type="checkbox"/> ₁ Yes <input type="checkbox"/> ₀ No |
| E4_05 | 5. On average during the run-in period, has the subject recorded peak flow measurements and symptoms in the symptom diary at least 5 days per week? | <input type="checkbox"/> ₁ Yes <input checked="" type="checkbox"/> ₀ No |
| E4_06 | 6. Did the subject adhere at least 80% of the time to the scheduled dose of colchicine (2 capsules per day) between Visit 2 and Visit 3? | <input type="checkbox"/> ₁ Yes <input checked="" type="checkbox"/> ₀ No |
| E4_07 | 7. Has the subject shown evidence of colchicine intolerance since the last visit? | <input checked="" type="checkbox"/> ₁ Yes <input type="checkbox"/> ₀ No |

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E4_08 8. Is there any new information that makes the subject ineligible according to the eligibility criteria?
If **Yes**, describe _____ ₁ Yes ₀ No

E4_09 9. Does the subject wish to withdraw consent from the study? ₁ Yes ₀ No

E4_10 10. Is there any other reason for which this subject should not be included in the study? ₁ Yes ₀ No

E4_11 11. Is the subject eligible? *If any of the shaded boxes are filled in, the subject is NOT eligible.* ₁ Yes ₀ No

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

E4_12 12. Prior to entry, was the subject taking a dose greater than 800 µg daily of steroid inhaler? ₁ Yes ₀ No

E4_13 13. Study drug packet number. _____