

**ELIGIBILITY CHECKLIST 4**

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

*(Clinic Coordinator completed)*

- |              |   |   |
|--------------|---|---|
| <b>E4_01</b> | 1. Is the subject's pre-bronchodilator FEV <sub>1</sub> less than 55% predicted?  | <input checked="" type="checkbox"/> <sub>1</sub> Yes <input type="checkbox"/> <sub>0</sub> No |
| <b>E4_02</b> | 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"/> <sub>1</sub> Yes <input type="checkbox"/> <sub>0</sub> No |
| <b>E4_03</b> | 3. Has the subject taken any non-study anti-asthma medications since the first study visit?   | <input checked="" type="checkbox"/> <sub>1</sub> Yes <input type="checkbox"/> <sub>0</sub> No |
| <b>E4_04</b> | 4. Did the subject use the Azmacort <sup>®</sup> 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"/> <sub>1</sub> Yes <input type="checkbox"/> <sub>0</sub> No |
| <b>E4_05</b> | 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"/> <sub>1</sub> Yes <input checked="" type="checkbox"/> <sub>0</sub> No |
| <b>E4_06</b> | 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"/> <sub>1</sub> Yes <input checked="" type="checkbox"/> <sub>0</sub> No |
| <b>E4_07</b> | 7. Has the subject shown evidence of colchicine intolerance since the last visit?   | <input checked="" type="checkbox"/> <sub>1</sub> Yes <input type="checkbox"/> <sub>0</sub> 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 \_\_\_\_\_  <sub>1</sub> Yes  <sub>0</sub> No

**E4\_09** 9. Does the subject wish to withdraw consent from the study?  <sub>1</sub> Yes  <sub>0</sub> No

**E4\_10** 10. Is there any other reason for which this subject should not be included in the study?  <sub>1</sub> Yes  <sub>0</sub> No

**E4\_11** 11. Is the subject eligible? *If any of the shaded boxes are filled in, the subject is NOT eligible.*  <sub>1</sub> Yes  <sub>0</sub> 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?  <sub>1</sub> Yes  <sub>0</sub> No

**E4\_13** 13. Study drug packet number. \_\_\_\_\_