

CPN MAY06-8-01 Case Report Form (CRF) Fax Cover Sheet



To: **QAS, Mayo Clinic-Rochester**

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From: _____

Fax: _____

Pages attached including cover sheet: _____

Phone: _____

PID # _____

Date: _____

CRFs attached (please check all that apply):

Pre-Registration Visit:

- 1. Pre-registration
- 10. Clinical Lab Data – C-Reactive Protein
- 3. Screen Failure, if applicable

Prior to Registration/Randomization Visit:

- 11. Clinical Laboratory Data – Hematology
- 12. Clinical Laboratory Data – Blood Chemistry
- 13. Clinical Laboratory Data – Urine
- 28. Pregnancy Testing Results
- 7. Physical Exam
- 8. AE and Concomitant Meds Evaluation (?)
- 9. Concomitant Medications
- 5. Symptom Assessment
- 4. Medical/Surgical History
- 16. Risk Assessment
- 19. Bronchial Biopsy Results
- 22. Biopsy Specimen Submission
- 23. Blood Specimen Submission
- 25. Biomarker Results – BAL
- 26. Biomarker Results - Immunohistochemistry

After Receiving Bronchoscopy Results:

- 3. Screen Failure, if applicable

Registration/Randomization Visit:

- 2. Registration/Randomization
- 5. Symptom Assessment
- 29. Agent Label

Telephone Interview for (check one)

- Week 2 Month 2 Month 4 Month 5

- 15. Compliance – Phone Interview
- 24. Agent Interruption Continuation, if applicable
- 8. AE and Concomitant Medications Evaluation
- 9. Concomitant Medications, if applicable
- 20. Adverse Events, if applicable

Month 1 Visit:

- 14. Compliance
- 24. Agent Interruption Continuation
- 8. AE and Concomitant Medications Evaluation
- 9. Concomitant Medications, if applicable
- 20. Adverse Events, if applicable
- 12. Clinical Laboratory Data – Blood Chemistry

Month 3 Visit:

- 14. Compliance
- 24. Agent Interruption Continuation
- 8. AE and Concomitant Medications Evaluation
- 9. Concomitant Medications, if applicable
- 20. Adverse Events, if applicable
- 7. Physical Exam
- 11. Clinical Laboratory Data – Hematology
- 12. Clinical Laboratory Data – Blood Chemistry
- 13. Clinical Laboratory Data – Urine
- 29. Agent Label

Month 6 Visit or Early Termination:

- 14. Compliance
- 24. Agent Interruption Continuation
- 10. Clinical Laboratory Data – C-Reactive Protein
- 22. Biopsy Specimen Submission
- 19. Bronchial Biopsy Results
- 23. Blood Specimen Submission
- 11. Clinical Laboratory Data – Hematology
- 12. Clinical Laboratory Data – Blood Chemistry
- 13. Clinical Laboratory Data – Urine
- 7. Physical Exam
- 8. AE and Concomitant Medications Evaluation
- 9. Concomitant Medications, if applicable
- 20. Adverse Events, if applicable
- 25. Biomarker Results – BAL
- 26. Biomarker Results – Immunohistochemistry
- 27. QOL Questionnaire: Was It Worth It?

Follow-up Phone Call < 30 days of Month 6, Early Termination, or Continued Follow-up for Adverse Events:

- 36. Follow-up Telephone Call
- 8. AE and Concomitant Meds Evaluation
- 20. Adverse Events, if applicable

Participant Complete and Off-Study with No Adverse Events:

- 29. Off Study
- 31. Verification

Any Time/As Needed:

- 34. Comments
- 3. Screen Failure
- 20. Adverse Events
- 24. Agent Interruption/Continuation
- 32. Death Report
- 33. Outcome of Pregnancy
- Other: Specify _____