

CPN MAY04-4-01 Case Report Form (CRF) Fax Cover Sheet



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

Fax: **507-284-1902**

Phone: 507-538-0268

From: _____

Fax: _____

Pages attached including cover sheet: _____

Phone: _____

PID # _____

Date: _____

CRFs attached (please check all that apply):

Pre-Registration Visit:

- 2. Pre-registration
- 18. Physical Exam
- 12-13. Symptom Assessment
- 14-15. Concomitant Medications
- 17. Med/Surgical History
- 19. Clinical Lab Data-Hematology
- 20. Clinical Lab Data-Blood Chemistry
- 32-33. Risk Assessment
- 35. Pregnancy Testing Results

Day #1 Run-In Phase:

- 4. Run-In Phase
- 36. Agent Label

Day #14 Run-In Phase:

- 16. AE and Con Meds Evaluation Form
- 14-15. Concomitant Medications, if applicable
- 21-25. Adverse Events, if applicable
- 27. Agent Compliance Phone Interview

Day #28 Run-In Phase:

- 18. Physical Exam
- 35. Pregnancy Test Result
- 16. AE and Con Meds Evaluation Form
- 14-15. Concomitant Medications, if applicable
- 21-25. Adverse Events, if applicable
- 26. Agent Compliance
- 11. CPN Blood Specimen Submission
- 9. Surveillance Biopsies
- 10. CPN Tissue Specimen Submission (Research)
- 6. EGD Results
- 7. Research Biopsies (Formalin)
- 8. Research Biopsies (Frozen)

Registration/Randomization:

- 5. Registration/Randomization
- 36. Agent Label

Day #14 Intervention Phase:

- 16. AE and Con Meds Evaluation Form
- 14-15. Concomitant Medications, if applicable
- 21-25. Adverse Events, if applicable
- 27. Agent Compliance Phone Interview

Day #28 Intervention Phase:

- 18. Physical Exam
- 16. AE and Con Meds Evaluation Form
- 14-15. Concomitant Medications, if applicable
- 21-25. Adverse Events, if applicable
- 26. Agent Compliance
- 19. Clinical Lab Data-Hematology
- 20. Clinical Lab Data-Blood Chemistry
- 11. CPN Blood Specimen Submission
- 10. CPN Tissue Specimen Submission (Research)
- 6. EGD Results
- 7. Research Biopsies (Formalin)
- 8. Research Biopsies (Frozen)

Participant Complete and Off-Study with No Adverse Events:

- 29. Off Study
- 31. Verification

Continued Follow-up for Adverse Events:

- 21-25. Adverse Events

Any Time/As Needed:

- 34. Comments
- 3. Screen Failure
- 21-25. Adverse Events
- 28. Agent Interruption/Continuation
- 30. Death Report
- Other: Specify _____