

CPN MAY10-15-03 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:

- 1. Pre-registration

Pre-Registration/Screening:

- 3. Baseline Med/Surgical History
4. Baseline Symptoms
5. Pre-Intervention Adverse Events
6. Physical Exam
7. Tobacco/Alcohol Use Assessment
8. Pregnancy Specimen Data
9. AE and ConMed Evaluation
10. Concomitant Medications
12. Clinical Lab Data - Hematology
13. Clinical Lab Data - Blood Chemistry
14. Clinical Lab Data - Urine
18. Blood Specimen Submission

EGD Visit:

- 16. Surveillance Biopsies
19. Tissue Specimen Submission (Research)
15. EGD Results
17. Research Biopsies (Formalin)

If EGD and test results = Not Eligible:

- 1. Screening (Screen Fail = Yes)
28. Verification

Registration/Randomization = Eligible (Yippee!):

- 1. Screening (Screen Fail = No)
4. Registration/Randomization
9. AE and ConMed Evaluation
10. Concomitant Medications, if applicable
11. Adverse Events, if applicable
21. Intervention Administration

Telephone Interview for (check one)

- Week 1 Week 4 Week 8

- 9. AE and ConMed Evaluation
10. Concomitant Medications, if applicable
11. Adverse Events, if applicable

Post-Intervention (EGD#2) or Early Termination:

- 6. Physical Exam
9. AE and ConMed Evaluation
10. Concomitant Medications, if applicable
11. Adverse Events, if applicable
12. Clinical Lab Data - Hematology
13. Clinical Lab Data - Blood Chemistry
14. Clinical Lab Data - Urine
18. Blood Specimen Submission
19. Tissue Specimen Submission (Research)
15. EGD Results
17. Research Biopsies (Formalin)
22. Compliance
23. Agent Interruption/Modification
Was It Worth It Questionnaire

Follow-up Phone Call: <= 30 days of Post-Intervention visit, Early Termination, or Continued Follow-up for Adverse Events:

- 9. AE and Concomitant Meds Evaluation
11. Adverse Events, if applicable

Participant Complete and Off-Study with No Related Adverse Events:

- 24. Off Study
28. Verification

Any Time/As Needed:

- 27. Comments
1. Screening
11. Adverse Events
25. Death Report
26. Outcome of Pregnancy
Other: Specify \_\_\_\_\_