

Site Number: _____ Screening ID: _____ - ____ First 3 Letters of First Name: _____

Complete this form for all prescribed changes in coded MMF study medication. With the exception of very short-term changes (less than 1 week), a *separate* form should be completed for all study medication changes, regardless of the reason for the change. Changes can be an alteration of dose and/or the frequency of administration.

A. REPORT INFORMATION

1. Date of report: _____ / _____ / _____
MM DD YYYY

2. Last attended study visit? (*check one*)

- | | | | |
|--|--|---|---|
| <input type="checkbox"/> ₂ Baseline | <input type="checkbox"/> ₆ Week 4 | <input type="checkbox"/> ₁₄ Month 9 | <input type="checkbox"/> ₂₆ Month 21 |
| <input type="checkbox"/> ₃ Week 1 | <input type="checkbox"/> ₇ Month 2 | <input type="checkbox"/> ₁₇ Month 12 | <input type="checkbox"/> ₂₉ Month 24 |
| <input type="checkbox"/> ₄ Week 2 | <input type="checkbox"/> ₈ Month 3 | <input type="checkbox"/> ₂₀ Month 15 | |
| <input type="checkbox"/> ₅ Week 3 | <input type="checkbox"/> ₁₁ Month 6 | <input type="checkbox"/> ₂₃ Month 18 | |

B. STUDY MEDICATION CHANGE INFORMATION

1. Date the study medication change became effective: _____ / _____ / _____
MM DD YYYY

Indicate the following information regarding the old and new dosing schedules:

- | | | |
|-------------------------------|---|---|
| a. Daily dose of MMF/placebo: | 2. Old Schedule | 3. New Schedule |
| | _____ mg | _____ mg |
| b. Frequency of dosing: | <input type="checkbox"/> ₁ Once a day | <input type="checkbox"/> ₁ Once a day |
| | <input type="checkbox"/> ₂ Twice daily | <input type="checkbox"/> ₂ Twice daily |
| | <input type="checkbox"/> ₃ Three times per day | <input type="checkbox"/> ₃ Three times per day |

4. Indicate reason(s) for change in dosing schedule:

- | | | | |
|--|-----|-----------------|-----|
| a. GI Toxicity (<i>e.g. diarrhea, nausea, vomiting, gastritis, or anorexia</i>)? | Y N | c. Neutropenia? | Y N |
| b. Leukopenia? | Y N | d. Other? | Y N |

IF OTHER,

1. Specify: _____

* If reason for change involved an adverse event complete an Adverse Event Report Form (MMF07)

Initials (first, middle, last) of person completing this form: _____
F M L

Date form completed: _____ / _____ / _____
MM DD YYYY

On all questions write "?" if the desired information is currently unavailable, but is being checked and will be known in future updates. Write "" if the desired information is permanently unavailable (i.e. will not be known in any future updates).*