

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

Complete this form for any study visit that was missed and not rescheduled *at any time*. The visit window period for all visits after the first month is fourteen days around the target visit date (with the exception of monthly visits for EBV or CBC monitoring). Do not complete this form for participants who are inactive.

A. VISIT INFORMATION

1. Which visit was missed? (*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"/> 44 Monthly EBV |
| <input type="checkbox"/> 5 Week 3 | <input type="checkbox"/> 11 Month 6 | <input type="checkbox"/> 23 Month 18 | <input type="checkbox"/> 55 Monthly CBC |

B. PARTICIPANT INFORMATION

1. Has there been any contact with the participant concerning the missed visit? Y N

IF YES,

a. What was the primary reason for the missed visit? (*check one*):

- 1 Illness, surgery, or hospitalization (*If checked, must fill out Adverse Event Form*)
- 2 Moved to less convenient location
- 3 Conflicting responsibilities (job, family)
- 4 Subject no longer wishes to participate in the study
- 9 Other

1. If Other, specify: _____

2. Is the participant expected to continue with future follow-up visits? Y N

IF NO, complete Medication Withdrawal (MMF08W) and Change of Status (MMF10) Forms

IF YES,

a. Is the participant willing to continue taking the study medication as described by the protocol? Y N

IF YES, participant **must** make an appointment to visit the designated clinic in order to receive a new supply of study medication and to return unused study medication from the previous visit.

Under **no** circumstances will new study medication be supplied through the mail.

IF NO, complete a Medication Withdrawal Form (MMF08W)

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).*