Site Number: __ __ __ __ Screening ID: __ __ __ __ - __ Participant Letters: __ __ __

Complete this form at Baseline and for all regularly scheduled follow-up visits.

A. VISIT INFORMATION

1. Visit Date: __ __ / __ __ __ / __ __ __ __ (DAY / MONTH / YEAR)

2. For which visit is this form being completed? *(check one)*

☐ 0	Baseline	☐ 8	Visit 8	☐ 16	Visit 16	☐ 24	Visit 24
☐ 1	Visit 1	☐ 9	Visit 9	☐ 17	Visit 17	☐ 25	Visit 25
☐ 2	Visit 2	☐ 10	Visit 10	☐ 18	Visit 18	☐ 26	Visit 26
☐ 3	Visit 3	☐ 11	Visit 11	☐ 19	Visit 19	☐ 27	Visit 27
☐ 4	Visit 4	☐ 12	Visit 12	☐ 20	Visit 20	☐ 28	Visit 28
☐ 5	Visit 5	☐ 13	Visit 13	☐ 21	Visit 21	☐ 29	Visit 29
☐ 6	Visit 6	☐ 14	Visit 14	☐ 22	Visit 22	☐ 30	Visit 30
☐ 7	Visit 7	☐ 15	Visit 15	☐ 23	Visit 23	☐ 31	Visit 31

B. CONCOMITANT MEDICATIONS

1. Are there <u>any changes since the previous visit</u> in prescription or non-prescription medications or supplements that you are taking other than insulin? Y N

If the change in medication was due to an *adverse event*,
complete an Adverse Event Report Form (**CTL13**) if ≥ Grade 2 severity.

If YES,

a. Are you taking or have you taken any <u>NEW</u> medications or supplements <u>since the last visit</u>? Y N

If YES, list NEW medications/supplements:

1) _____
   a) For what? _____
2) _____
   a) For what? _____
3) _____
   a) For what? _____
4) _____
   a) For what? _____

b. Have you <u>DISCONTINUED</u> the use of any prescription or non-prescription medications or supplements <u>since the last visit</u>? Y N

If YES, list DISCONTINUED medications or supplements:

1) _____
2) _____
3) _____
4) _____

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

Date form completed: __ __ / __ __ __ / __ __ __ __ (DAY / MONTH / YEAR)

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).*