

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*)

- | | | | |
|-------------------------------------|--------------------------------------|--------------------------------------|--------------------------------------|
| <input type="checkbox"/> 0 Baseline | <input type="checkbox"/> 8 Visit 8 | <input type="checkbox"/> 16 Visit 16 | <input type="checkbox"/> 24 Visit 24 |
| <input type="checkbox"/> 1 Visit 1 | <input type="checkbox"/> 9 Visit 9 | <input type="checkbox"/> 17 Visit 17 | <input type="checkbox"/> 25 Visit 25 |
| <input type="checkbox"/> 2 Visit 2 | <input type="checkbox"/> 10 Visit 10 | <input type="checkbox"/> 18 Visit 18 | <input type="checkbox"/> 26 Visit 26 |
| <input type="checkbox"/> 3 Visit 3 | <input type="checkbox"/> 11 Visit 11 | <input type="checkbox"/> 19 Visit 19 | <input type="checkbox"/> 27 Visit 27 |
| <input type="checkbox"/> 4 Visit 4 | <input type="checkbox"/> 12 Visit 12 | <input type="checkbox"/> 20 Visit 20 | <input type="checkbox"/> 28 Visit 28 |
| <input type="checkbox"/> 5 Visit 5 | <input type="checkbox"/> 13 Visit 13 | <input type="checkbox"/> 21 Visit 21 | <input type="checkbox"/> 29 Visit 29 |
| <input type="checkbox"/> 6 Visit 6 | <input type="checkbox"/> 14 Visit 14 | <input type="checkbox"/> 22 Visit 22 | <input type="checkbox"/> 30 Visit 30 |
| <input type="checkbox"/> 7 Visit 7 | <input type="checkbox"/> 15 Visit 15 | <input type="checkbox"/> 23 Visit 23 | <input type="checkbox"/> 31 Visit 31 |

For Sections B, C, and D,
Record information collected from a 3-day period in the last week.

B. GLUCOSE MONITORING

1. Is the person using a Continuous Glucose Monitoring System (CGMS)?

Y N

C. COMPLETENESS OF RECORD

1. Are there at least three glucose values available for at least three days?

Y N

2. Is the insulin dose information available for at least three days?

Y N

D. GLUCOSE

1. Total number of home blood glucose monitorings over three days:

2. Number of home blood glucose monitorings over three days that were less than 65 mg/dl:

3. Average of recorded **fasting** glucoses (over three days):

a. ____ . ____ b. ☐ ₁ mg/dl
☐ ₂ mmol/L

4. Average of **all** recorded glucoses (over three days):

a. ____ . ____ b. ☐ ₁ mg/dl
☐ ₂ mmol/L

5. **Lowest** recorded glucose (over three days):

a. ____ . ____ b. ☐ ₁ mg/dl
☐ ₂ mmol/L

6. **Highest** recorded glucose (over three days):

a. ____ . ____ b. ☐ ₁ mg/dl
☐ ₂ mmol/L

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).*

Site: _____ Screening ID: _____ - _____ Letters: _____ Visit Date: ____ / ____ / _____

E. INSULIN

1. Daily insulin routine (*check one*):

- ☐ ₁ No insulin
☐ ₂ 1-2 Injections per day
☐ ₃ 3 + Injections per day (MDI)
☐ ₄ Insulin Pump (CSII)

2. Average units/day of short acting insulin (*average over 3 day period*):

(e.g. Regular, LisPro, Novolog, Humalog, bolus doses if on pump)

____ . ____
units

3. Average units/day of intermediate/long acting insulin (*average over 3 day period*):

(e.g. Lantus, NPH, Lente, Ultralente, basal rate if on pump)

____ . ____
units

F. HYPOGLYCEMIA

Record information from any records or history by the participant since the last visit.

1. Have you experienced any severe hypoglycemic events (loss of consciousness, seizure, or assistance required from another person due to an altered state or consciousness) since the last visit?

Y N

If YES,

a. How many severe hypoglycemic events have occurred since the last visit?

If any **severe** hypoglycemic events have occurred since the last visit,
complete Adverse Event Report Form (**CTL13**) for each event.

G. CONTACT WITH DIABETES HEALTH CARE PROVIDER

Record the number of visits, emails, phone calls, or other contact since the last visit with:

1. Study associated: Diabetes Educator:

2. Study associated: Endocrinologist:

3. Study associated: other health care provider:

4. Non-study associated: Diabetes Educator:

5. Non-study associated: Endocrinologist:

6. Non-study associated: other health care provider:

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).*