

CITY Visit Information (Contact) Worksheet

Subject ID: _____ Namecode: _____

1. Name of person conducting contact: _____

2. Contact date:

____ / ____ / ____ ☐ Missed
(mm/dd/yyyy)

If **Missed**, reason (select only one):

- | | | |
|--|---|--|
| <input type="checkbox"/> Bad weather | <input type="checkbox"/> Subject on vacation | <input type="checkbox"/> Poor outcome |
| <input type="checkbox"/> Travel difficulty | <input type="checkbox"/> Visits too lengthy | <input type="checkbox"/> Good outcome |
| <input type="checkbox"/> Financial issue | <input type="checkbox"/> Investigator away | <input type="checkbox"/> Adverse event |
| <input type="checkbox"/> Poor health | <input type="checkbox"/> Clinic appointment not available | <input type="checkbox"/> Unknown |
| <input type="checkbox"/> Personal issue | <input type="checkbox"/> Site forgot to schedule | <input type="checkbox"/> Other |
| <input type="checkbox"/> Work issue | <input type="checkbox"/> Difficulty contacting subject | |

2a. If **Other**, describe:

OUT OF WINDOW

☐ Contact was completed out of window

1. Reason contact was completed out of window (select only one):

- | | | |
|--|---|--|
| <input type="checkbox"/> Bad weather | <input type="checkbox"/> Subject on vacation | <input type="checkbox"/> Poor outcome |
| <input type="checkbox"/> Travel difficulty | <input type="checkbox"/> Visits too lengthy | <input type="checkbox"/> Good outcome |
| <input type="checkbox"/> Financial issue | <input type="checkbox"/> Investigator away | <input type="checkbox"/> Adverse event |
| <input type="checkbox"/> Poor health | <input type="checkbox"/> Clinic appointment not available | <input type="checkbox"/> Unknown |
| <input type="checkbox"/> Personal issue | <input type="checkbox"/> Site forgot to schedule | <input type="checkbox"/> Other |
| <input type="checkbox"/> Work issue | <input type="checkbox"/> Difficulty contacting subject | |

1a. If **Other**, describe:

CITY Follow Up Contact Form

Participant ID: _____ Namecode: _____

NON IN-PERSON CONTACT INFORMATION**1. Select who participated in the contact:**

- ☐ Participant only
- ☐ Participant and parent/ guardian
- ☐ Parent/guardian only – participant was not available/refused
- ☐ Other

1a. If Other, describe: _____**CGM TRAINING non-in person contacts at 1 week, 4 weeks, 19 weeks****1. Was CGM training provided to the participant and/or caregiver during the contact?**☐ Yes ☐ No**1a. If Yes, what was the need for the training? (select all that apply).****Participant and/or caregiver required additional training on:**

- ☐ Sensor insertion
- ☐ Sensor placement/skin reaction and adhesion
- ☐ CGM device/alerts
- ☐ CGM Calibration
- ☐ Remote monitoring/SHARE
- ☐ Downloading CGM data to Clarity
- ☐ Reviewing glucose trends/graphs
- ☐ CGM troubleshooting
- ☐ Other

If Other, describe: _____

CGM SENSOR USE

1. Based on participant's self-report, on average how many days per week does the participant use the study CGM sensor?

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7

1a. If less than 6, indicate reason (select any of the following that apply):

- ☐ Skin irritation
- ☐ Uncomfortable or painful for to wear
- ☐ Alarms too frequently
- ☐ Does not provide accurate readings
- ☐ Too difficult to operate
- ☐ Too busy to use it
- ☐ Forget to use it
- ☐ Does not provide information that is helpful for diabetes management
- ☐ Too big or interfered with certain clothing or activity/exercise
- ☐ Other

If Other, describe: _____

2. If 0 days, has the participant discontinued CGM use?

☐ Yes ☐ No

3. Based on participant's self-report, on average how many weeks per month does the participant use the study CGM?

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ Not applicable (1 week visit and has not been using for a month)

CGM BENEFIT HANDOUT

1. Was the participant reminded about the benefits of using CGM?

☐ Yes ☐ No

CITY Diabetes Medical History Updates (A) Worksheet

Subject ID: _____ Namecode: _____

ADVERSE EVENTS OR ADVERSE DEVICE EFFECTS (ADE)

1. Did any of the following occur since last visit?

a. Reportable Hypoglycemic event: ☐ Yes ☐ No

If Yes, complete AE form and Hypoglycemic Event form.

b. Definite or Probable Reportable Severe Hyperglycemic or DKA Event: ☐ Yes ☐ No

If Yes, complete AE form and Severe Hyperglycemia or DKA Event form.

c. Other reportable adverse event or adverse device effect (ADE): ☐ Yes ☐ No

If Yes, complete AE or ADE form.

MEDICAL CONDITIONS

1. Did the participant report a new medical condition that does not meet the definition of a reportable adverse event and has not previously been recorded on the Medical Conditions Form?

☐ Yes ☐ No

If Yes, please complete the Medical Conditions Form.

DEVICE DEFICIENCIES OR ISSUES

1. Did the participant report having any reportable device deficiencies or issues while using a study device since the last contact?

☐ Yes ☐ No

If Yes, complete the Device Deficiencies or Issues Form.

MEDICATIONS

1. Did the participant report any changes or new medications since the last contact?

☐ Yes ☐ No

If Yes, please update the Medications Form.

INSULIN

1. Did the participant report any changes in insulin type or insulin delivery method since the last contact?

☐ Yes ☐ No

If Yes, please update the Insulin Form.

CITY Follow-up Complete the Contact Worksheet

Patient ID: _____

Namecode: _____

SOURCE DOCUMENTATION

1. Were any of the data for this visit/contact transcribed from another source (e.g., medical record, study visit worksheet) rather than directly entered on the website?

☐ Yes ☐ No

If yes, complete the following:

1a. Source used (check all that apply):

- ☐ CRF worksheet
- ☐ Electronic medical record (EMR)
- ☐ Written patient chart
- ☐ Discharge summary
- ☐ Test/lab result
- ☐ Other _____