CGM Home Run-In Weekly Phone Contact
(Only completed by non-users of CGM or CGM users <5 d/wk for last 4 weeks)

Table: tblCTR3CGMRunInPhoneContact

1.1 Synopsis:

This phase will instruct the subject on how to use the study CGM device. The CGM Home Run-In Weekly contact will only be completed for subjects flagged as "non-users of CGM or CGM user <5 d/wk for last 4 weeks".

Identifying Information

PtID	1. Patient ID: CTR3-____ ____ ____- ____ ____ ____ ____
NameCode	2. Initials: ____ ____ ____

Phone Contact Information

PhCallDt	1. Call Date: ___ ___ / ___ ___ /___ ___ mm/dd/yy
PrsnSpk PrsnSpkDs	2. Person Spoken To: ☐Subject ☐Other If Other, complete the following: Relationship to Subject: _____
CallerID	3. ID of Person Completing Call: ___ - ___ ___ ___

Sensor Use

SensorDays

SensorDaysSkinIrritation

SensorDaysAlarmsTooFrequently

SensorDaysInaccurateReadings

SensorDaysTooDifficult

SensorDaysTooBusy

SensorDaysForgetToUSe

SensorDaysInfoNotHelpful

SensorDaysFailure

SensorDaysOther

SensorProblems

SensorDaysDs

SensorProblemsConnectingSensorProblemsDidNotInsert

SensorProblemsBleeding

SensorProblemsPulledOut

SensorProblemsRemoved

SensorProblemsStopped

SensorProblemsOther

SensorProblemsDs

1. How many days per week did the subject report using the sensor?

☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7

a. If *less than 7*, indicate reason (select any of the following that apply):

☐Skin irritation
☐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
☐Sensor failure/device malfunction
☐Other

If *Other*, complete the following:
Describe:

_____

2. Did the subject report have any problems while using the sensor since the last contact?

☐Yes ☐No

a. If Yes, complete the following:

Did any of the following occur?

☐ Problem connecting transmitter to receiver
☐ Sensor did not insert properly
☐ Too much bleeding at the area of sensor insertion
☐ The sensor was pulled out accidentally
☐ The subject removed the sensor due to discomfort
☐ The sensor stopped working early
☐ Other

If *Other*, complete the following:
Describe:

_____

Adverse Events Since Last Contact

SevHypo

1. Did the subject have a severe hypoglycemic episode requiring assistance of another person to administer carbohydrate, glucagon or other resuscitative actions not already reported?

☐Yes ☐No (If Yes, complete a Severe Hypo Event Form)

2. Did the subject have a DKA not already reported?

☐Yes ☐No (If Yes, complete a DKA Event Form)

SevHyper

DKA is defined as follows by the DCCT, and has all of the following:

- **Symptoms such as polyuria, polydipsia, nausea, or vomiting;**
- **Serum ketones or large/moderate urine ketones;**
- **Either arterial blood pH <7.30 or venous pH <7.24 or serum bicarbonate <15; and**
- **Treatment provided in a health care facility**

3. Have any adverse events or any unexpected medical occurrence occurred that has not already been reported?

☐Yes ☐No (If Yes, complete an Adverse Event Form)

AdverseEvent

Comments **Comments**

If subject had severe hypoglycemia or DKA, the subject is no longer eligible to continue in the study. Please complete a Final Status form.

If there have been any changes made in insulin therapy, please submit the changes in the Insulin Therapy Form.