

Pilot Study 3 of Outpatient Control-to-Range: Safety and Efficacy with Day-and-Night In-Home Use
End of Extended Closed-Loop at Home

Identifying Information

PtID 1. Patient ID: CTR3-____ - ____

Namecode 2. Initials: ____

tblExtendedEnd

Study Supplies Returned

StudySuppliesReturned Were all system study supplies returned?

☐ Yes ☐ No (*Please comment below*)

Comment:

Hemoglobin A1c

1. Date of Test: ____ / ____ / ____ dd/mm/yy **HbA1CTestDt**

2. HbA1C: ____ . ____ % **HbA1CTest**

3. Method in which HbA1c was obtained: *Dropdown list* **HbA1cMethod**

3a. If Other please specify: _____

Subject Questionnaire and Structured Interview

1. Did the subject and care giver complete the DiAs Questionnaire and Clarke Hypoglycemia Awareness Questionnaire? **QuestionnairesCompleted**

☐Yes ☐No (If no, please comment below)

Comment:

Medical History

PreExistMedCond

1. Have there been any new medical problems not previously recorded on the Medical Condition Form?

☐Yes ☐No (If Yes, please update the Medical Condition Form.)

Concomitant Medications

ConComMed

1. Have there been any changes in medications not previously recorded on the Medications Form?

☐Yes ☐No (If Yes, please update the Medications Form.)

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 an Adverse Event Form)

2. Did the subject have DKA not already reported?

☐Yes ☐No (If Yes, complete an Adverse 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](#)