Pilot Study 3 of Outpatient Control-to-Range: Safety and Efficacy with Day-and-Night In-Home Use

Contact Information

Identifying Information

PtID	**1. Patient ID: CTR3-____ ____ ____- ____ ____ ____ ____**
Namecode	**2. Initials: ____ ____ ____**

OvernightPhoneContact

Contact Information

PhCallDt	**1. Contact Date: ___ ___ / ___ ___ /___ ___ mm/dd/yy**
NonPContType	**2. Mode of Communication:** ☐ Phone ☐ Text ☐ Email ☐ Office Visit
PrsnSpk	**2. Person contacted:** ☐**Subject** ☐**Other**
PrsnSpkDs	**If Other, complete the following:** **Relationship to Subject: _____**
CallerID	**4. ID of Person Contacting Subject: ___ - ___ ___ ___**

Prior to completion of the contact during the initial trial period, the subject's data from previous day and night must be reviewed.

Closed-Loop Data Review

SystemUsed80Pct	**Was the system used at least 80% of the time in open-loop during the day and 80% of the time in closed-loop at night? *Note: Must be yes to qualify as a successful day of system use during 3-5 day trial period*.** ☐Yes ☐No ☐**N/A, subject has progressed past 3-5 day trial period**

SystemProblems **SystemProblemsDs**	**Did the subject have any significant problems with the system such as:**) **Receiving any significant error messages related to meal bolusing, CGM calibration announcement, etc.**) **Responding to system alert messages**) **Extended loss of communication with remote monitoring**) **Other aspects of the system operation** ☐Yes ☐No **a. If Yes, please describe:** _____ _____ _____ _____
MeterHighOrLow **MeterHighOrLowDs**	**Did the subject have any occurrences of BG meter readings <50 mg/dl or >400 mg/dl in the absence of any infusion set failure?** ☐Yes ☐No **b. If Yes, please describe:** _____ _____ _____ _____
SystemUseSuccess	**In the opinion of the investigator, did the subject meet criteria for successful system use for this day?** ☐Yes ☐No

Adverse Events Since Last Contact

SevHypo	**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)** **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**
AdverseEvent	**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)**