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

Identifying Information

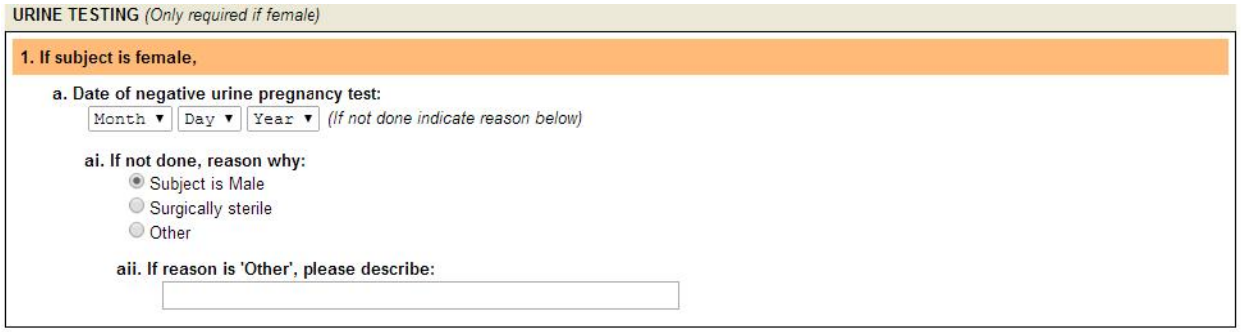
PtID	**1. Patient ID: CTR3-____ ____ ____- ____ ____ ____ ____**
Namecode	**2. Initials: ____ ____ ____**

ExtendedFollowUp

Urine Testing *(Only required if female)*

PregTestDt	**1. If subject is female,**
PregTestNotDoneMF	**a. Date of negative urine pregnancy test: ___ ___ / ___ ___ /___ ___ mm/dd/yy (If not done indicate reason below)** ai. If not done, why: *Dropdown list (Premenstrual, Surgically sterile, Male, Other)* aii. If reason is 'Other,' please describe:
PregTestNotDOneDs	_____

Template should look like previous forms:



Closed-Loop Data Review

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 to continue the Extended Closed-Loop at Home Use period?** ☐Yes ☐No *(If no, complete the End of Extended Closed-Loop at Home and Final Status forms and collect all system study supplies)*

Home Use Device Preparation

QCMeter **QCMeterDs** **QCKetone** **QCKetoneDs**	**1. Was QC testing successful with the study blood glucose meter using two different concentrations of control solution?** ☐Yes ☐No **1b. If No, please indicate why not:** _____ **2. Was QC testing successful with the study blood ketone meter using two different concentrations of control solution?** ☐Yes ☐No **2b. If No, please indicate why not:** _____

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?**

SevHyper	☐Yes ☐No (If Yes, complete an Adverse Event Form) *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?
AdverseEvent	☐Yes ☐No (If Yes, complete an Adverse Event Form)

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.