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

Identifying Information

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

tblExtendedInitiation

Eligibility Assessment

SubEligibility	☐ **During home use of the system, the subject met the following criteria to continue to the Extended Closed-Loop at Home Use period:** o Did not experience severe hypoglycemia or hyperglycemia/DKA (not associated with infusion set failure) o Did not develop >1.0 mmol/L ketones on 3 or more study days due to prolonged periods of inadequate insulin delivery recommended o Study staff were able to contact the subject or the care partner without difficulty and in a timely manner o The subject used the system appropriately including the following: ▪ Responded to system alarms and treated hypo- and hyperglycemia appropriately ▪ Avoided deviating from his/her regular daily routine in regard to diet and exercise and maintained his or her usual sleep schedule ▪ Avoided consuming more than 3 alcoholic drinks in any one day ▪ Performed a fingerstick BG at least 7 times daily (before meals, about 2 hours after meals and at bedtime) and/or appropriate fingerstick BG testing by investigator discretion ▪ Avoided use of closed-loop mode during periods of illness with an elevated temperature >101.5 degrees Fahrenheit, periods of significant illness, or during periods of use of medications such as epinephrine for the emergency treatment of a severe allergic reactions or asthma attack in addition to use of oral or injectable glucocorticoids

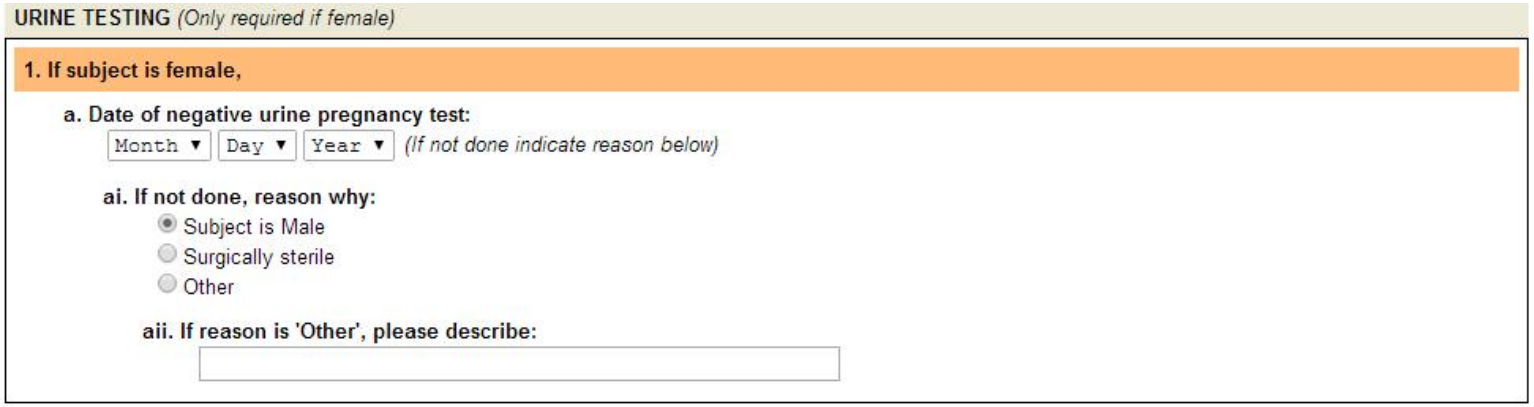
Subject and Companion Consent

ExtendedConsentSubject	**1. please indicate the date the addendum consent was signed by the subject:** ___ ___ / ___ ___ /___ ___ mm/dd/yy
ExtendedConsentCompanion	**2. please indicate the date the addendum consent was signed by the companion:** ___ ___ / ___ ___ /___ ___ mm/dd/yy

Urine Testing *(Only required if female)*

PregTestDt PregTestNotDoneMF	**1. If subject is female,** **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: _____

Template should look like previous forms:



Home Use Device Preparation

QCMeter	**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:** _____
QCKetone	**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:** _____