# CGM Run-In End Visit

## Table: tblCTR3CGMRunInEnd

***Synopsis:***

Download the CGM device to evaluate whether it was used each day and obtain results of screening labs. Subjects that do not meet protocol criteria will not continue in the study.
The clinical site will download all devices given to the subject and send the data to the coordinating center.

**NOTE**: Subjects who are Dexcom CGM users with ≥5 days/week use over past 4 weeks may skip this phase and move directly to Visit 2- Study pump training and initiation.

### Visit Information Section

**(VISITINFORMATION_A _01)**

| | |
|---|---|
| **InvID** | **1. Name of Investigator _____** |
| **VisitDt** | **2. Visit Date: _____** |

**Identifying Information**

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

CGMRunInEnd

**Eligibility Asessment**

| | |
|---|---|
| **DexComSuccess** | þ **Subject successfully used the Dexcom CGM at home ≥5 d/wk during each week of use, or subject was given one extra week per protocol at investigator discretion and successfully used the CGM for ≥5 days during that extra week.** |
| **ScreeningSuccess** | þ **Results of all Screening Labs were within eligibility limits** |

***If you were unable to check the box for each Eligibility Assessment question above, the subject is no longer eligible to continue in the study. Please complete a Final Status form.***

## Medical History

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|---|---|
| **PreExistMedCond** | **1. Have there been any new medical problems not previously recorded on the Medical Condition Form?**<br>☐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?**<br>☐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?**<br>☐Yes ☐No ***(If Yes, complete an Adverse Event Form)*** |
| **SevHyper** | **2.Did the subject have a DKA not already reported?**<br>☐Yes ☐No ***(If Yes, complete an Adverse Event Form)***<br><br>***DKA is defined as follows by the DCCT, and has all of the following:***<br>• ***Symptoms such as polyuria, polydipsia, nausea, or vomiting;***<br>• ***Serum ketones or large/moderate urine ketones;***<br>• ***Either arterial blood pH <7.30 or venous pH <7.24 or serum bicarbonate <15; and***<br>• ***Treatment provided in a health care facility*** |
| **AdverseEvent** | **3.Have any adverse events or any unexpected medical occurrence occurred that has not already been reported?**<br>☐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.***