

## Visit 4- Closed-Loop Transitional Training Visit

### tblClosedLoopTransitional

#### Identifying Information

|             |   |
|-------------|---|
| <b>PtID</b> | 1. Patient ID: CTR3-____-_____<br>2. Initials: ____ |
|-------------|---|

#### Visit Information

|                |  |
|----------------|--|
| <b>VisitDt</b> | 1. Visit Date: ____/____/____ mm/dd/yy<br>2. Study ID of Investigator: ____ - ____ |
|----------------|--|

#### Physical Examination *(Only required if female)*

|   |  |
|---|--|
| <b>PregTestDt</b><br><b>PregTestNotDoneMF</b> | 1. If subject is female,<br>a. Date of negative urine pregnancy test: ____/____/____ mm/dd/yy (If not done indicate reason below)<br>ai. If not done, why: <i>Dropdown list (Premenstrual, Surgically sterile, Male, Other)</i><br>aii. If reason is 'Other,' please describe: _____ |
|---|--|

#### Closed-Loop Supplies

|   |   |
|---|---|
| <b>DiAsSN</b><br><b>TranslatorBoxSN</b><br><b>TranslatorBoxNotUsed</b><br><b>DexcomReceiverSN</b><br><b>DexcomReceiverNotUsed</b><br><b>DexcomTransmitterSN</b> | 1. DiAs Serial Number: _____<br>2. Translator Box Serial Number: _____ <input type="checkbox"/> N/A, no translator box used<br>3. Dexcom Receiver Serial Number: _____ <input type="checkbox"/> N/A, no receiver used<br>4. Dexcom Transmitter Serial Number: _____ |
|---|---|

### Closed-Loop Training and Assessment

1. How many days prior to Closed-Loop Training Visit did the subject insert the CGM sensor used for this admission? [SensorDays](#)  
☐1-day ☐2-days ☐3-days ☐4-days ☐5-days ☐ >5-days
2. Were the following training and assessment steps completed successfully and in the opinion of the investigator, are the subject and companion ready for closed-loop use of the system at home? ☐Yes ☐No [SubEligibility](#)
  - ) Pump parameters entered in the study system were confirmed by the study investigator.
  - ) Subject and companion able to connect CGM and pump to DiAs.
  - ) Subject and companion able to switch the system between its operational modes (Closed-Loop, Pump (Open-Loop), Stopped mode, Safety mode) appropriately.
  - ) Subject and companion able to calibrate the CGM.
  - ) Subject and companion able to access and interpret the CGM trace using the DiAs system.
  - ) Subject and companion able to administer insulin with a meal and give correction insulin as needed using the DiAs.
  - ) Subject and companion able to inform the DiAs system of a hypoglycemia treatment and understands the system must be informed after each ~16 grams of glucose is consumed.
  - ) Subject and companion participated in a period of light exercise while training with the DiAs system.
  - ) Subject and companion demonstrate clear understanding of the DiAs system interface and how to react to safety/alert messages.