Metabolic Control Study
Hypoglycemic and Hyperglycemic Events Form

tblPCLHypoHyperEvents

Identifying Information

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

The closed loop system will be stopped if the participant (1) has > 3 episodes of hypoglycemia defined as a blood glucose ≤ 50 mg/dL in a 24 hour period or > 4 episodes of hypoglycemia (≤ 50 mg/dL) at anytime during the use of the closed loop system, (2) has one severe hypoglycemia episode defined by seizure, loss of consciousness, or requiring assistance of another due to altered state of consciousness, or (3) develops DKA.

Hypoglycemic Events (*Please complete an Adverse Event Form for any episodes meeting criteria for a reportable AE*)

1. Did the subject have any episodes of hypoglycemia requiring treatment? ☐Yes ☐No   **CLHypoEpisReqTx**

2. If yes, complete the following for each hypoglycemic event: **(below fields in tblPCLHypoEventsDetail)**

Date and Time CLHypoEventDtTm	Glucose Result CLHypoGlucRes CLHypoGlucResNA	Closed Loop Functioning? CLHypoFunc	Treatment CLHypoTxDs	Meets Criteria Above? CLHypoMeetCrit
__ __ / __ __ / __ __ mm/dd/yyyy __ __ : __ __ ☐AM ☐PM	_____mg/dL **OR** ☐Not Available			
__ __ / __ __ / __ __ mm/dd/yyyy __ __ : __ __ ☐AM ☐PM	_____mg/dL **OR** ☐Not Available			
__ __ / __ __ / __ __ mm/dd/yyyy __ __ : __ __ ☐AM ☐PM	_____mg/dL **OR** ☐Not Available			
__ __ / __ __ / __ __ mm/dd/yyyyy __ __ : __ __ ☐AM ☐PM	_____mg/dL **OR** ☐Not Available			
__ __ / __ __ / __ __ mm/dd/yyyy __ __ : __ __ ☐AM ☐PM	_____mg/dL **OR** ☐Not Available			

Hyperglycemic Events (*Please complete an Adverse Event Form for any episodes meeting criteria for a reportable AE*)

1. Did the subject have any episodes of hyperglycemia requiring a manual bolus? ☐Yes ☐No   **CLHyperEpisReqBol**

2. If yes, complete the following for each hyperglycemic event: **(below fields in tblPCLHyperEventsDetail)**

Date and Time CLHyperEventDtTm	Glucose Result CLHyperGlucRes CLHyperGlucResNA	Serum Ketone Result CLHyperKetoneRes CLHyperKetoneResNA	Closed Loop Functioning? CLHyperFunc	Treatment CLHyperTxDs
__ __ / __ __ / __ __ mm/dd/yyyy __ __ : __ __ ☐AM ☐PM	_____mg/dL **OR** ☐Not Available	_____mmol/L **OR** ☐Not Available		
__ __ / __ __ / __ __ mm/dd/yyyy __ __ : __ __ ☐AM ☐PM	_____mg/dL **OR** ☐Not Available	_____mmol/L **OR** ☐Not Available		
__ __ / __ __ / __ __ mm/dd/yyyy __ __ : __ __ ☐AM ☐PM	_____mg/dL **OR** ☐Not Available	_____mmol/L **OR** ☐Not Available		
__ __ / __ __ / __ __ mm/dd/yyyy __ __ : __ __ ☐AM ☐PM	_____mg/dL **OR** ☐Not Available	_____mmol/L **OR** ☐Not Available		
__ __ / __ __ / __ __ mm/dd/yyyy __ __ : __ __ ☐AM ☐PM	_____mg/dL **OR** ☐Not Available	_____mmol/L **OR** ☐Not Available		

Comments   FormCmts