

TASK DOCUMENTATION

[Hypoglycemic Event]

Patient ID: **PtID**

Hypoglycemia Event Information

	<p>Reportable hypoglycemia is defined as an event that required assistance of another person due to altered consciousness to actively administer carbohydrate, glucagon, or other resuscitative actions. This means that the participant was impaired cognitively to the point that the participant was unable to treat his or herself, was unable to verbalize his or her needs, was incoherent, disoriented, and/or combative, or experienced seizure or coma. By definition, events that meet these criteria are reported as Serious Adverse Events. Hypoglycemic events are also considered reportable if the above criteria are not met but emergency evaluation or treatment was obtained from a health care provider; these events are considered Adverse Events and not Serious Adverse Events unless one of the criteria for SAE is met.</p>
<p>HypoOccurDt HypoOccurDtApprox</p> <p>HypoApproxTime</p>	<p>1. Date of Event: ____/____/____ <input type="checkbox"/> Estimated</p> <p>1a. Indicate the approximate time of day of the event:</p> <p> <input type="radio"/> 00:01 – 03:00 <input type="radio"/> 03:01 – 06:00 <input type="radio"/> 06:01 – 09:00 <input type="radio"/> 09:01 – 12:00 <input type="radio"/> 12:01 – 15:00 <input type="radio"/> 15:01 – 18:00 <input type="radio"/> 18:01 – 21:00 <input type="radio"/> 21:01 – 00:00 <input type="radio"/> Unknown </p>
<p>GlucMeterCk</p> <p>GlucMeterRes GlucMeterResUnk</p>	<p>2. Was the glucose level checked on a home blood glucose meter?</p> <p><input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown</p> <p>2a. If Yes, what was the result? ____ mg/dL [Range: 0.00-500.00] <input type="checkbox"/> Unknown</p>
<p>SensorWear</p> <p>SensorGluc SensorGlucUnk</p>	<p>3. Was the participant wearing a CGM sensor at the time of the event?</p> <p><input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown</p> <p>3a. If Yes, what was the glucose reading at the time the event was identified?</p> <p>____ mg/dL [Range: 0.00-500.00] <input type="checkbox"/> Unknown</p>
<p>LastInsDoseDt LastInsDoseApprox LastInsDoseUnk</p> <p>LastInsApproxTime</p> <p>LastInsPriorToHypo</p>	<p>4. Last insulin dose prior to the hypoglycemia event :</p> <p>4a. Date: ____/____/____ <input type="checkbox"/> Estimated <input type="checkbox"/> Unknown</p> <p>4b. Indicate the approximate time:</p> <p> <input type="radio"/> 00:01 – 03:00 <input type="radio"/> 03:01 – 06:00 <input type="radio"/> 06:01 – 09:00 <input type="radio"/> 09:01 – 12:00 <input type="radio"/> 12:01 – 15:00 <input type="radio"/> 15:01 – 18:00 <input type="radio"/> 18:01 – 21:00 <input type="radio"/> 21:01 – 00:00 <input type="radio"/> Unknown </p> <p>4c. Was the last insulin dose prior to the event based off the CGM reading?</p> <p><input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown</p>
<p>HypoSeizure HypoLossCons HypoReqAssist HypoAmbulance</p>	<p>5. Please select all of the following that apply for this event:</p> <p> <input type="checkbox"/> Seizure <input type="checkbox"/> Loss of consciousness <input type="checkbox"/> Required assistance </p>

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<div>HypoEMT</div> <div>HypoHthCareProv</div>	<div><input type="checkbox"/> Ambulance Called</div> <div><input type="checkbox"/> EMT Assistance</div> <div><input type="checkbox"/> Evaluated or treated by healthcare provider (not EMT)</div>
<div>GlucGiven</div>	<div>6. Was glucagon given?</div> <div><input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown</div>
<div>HospOrER</div> <div>HospERTrtLoc</div> <div>HospNumDays</div> <div>HospNumDaysUnk</div>	<div>7. Was the participant hospitalized or treated in the Emergency Room?</div> <div><input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown</div> <div>If Yes,</div> <div>7a: Where was the participant treated?</div> <div><input type="radio"/> ICU only</div> <div><input type="radio"/> Floor only</div> <div><input type="radio"/> ICU and Floor</div> <div><input type="radio"/> Emergency Room only</div> <div><input type="radio"/> Unknown</div> <div>7b: If hospitalized, duration <i>(leave blank if participant was treated in the emergency room only):</i></div> <div>_____ days (use a midnight census and <i>estimate if necessary</i>) <input type="checkbox"/> Unknown</div>
<div>EventCauseStdyDev</div> <div>EventCauseBGM</div> <div>StripsLotNum</div> <div>StripsLotNumUnk</div> <div>EventCauseCGM</div> <div>SensLotNum</div> <div>SensLotNumUnk</div> <div>EventCauseExpl</div> <div>EventCauseNonStdy</div>	<div>Cause of Event</div> <div>8. Is there any evidence that a <u>study</u> device (e.g., blood glucose meter and/or CGM) contributed to the event (either device malfunction or improper use by user)?</div> <div><input type="radio"/> Yes <input type="radio"/> No</div> <div>If Yes, complete the following:</div> <div>8a. Indicate any <u>study</u> device that may have contributed to the event:</div> <div><input type="checkbox"/> Blood glucose meter</div> <div>Lot number of strips _____ <input type="checkbox"/> Lot number of strips unknown</div> <div><input type="checkbox"/> CGM</div> <div>Lot number of sensor _____ <input type="checkbox"/> Lot number of sensor unknown</div> <div>8b. What is thought to be the explanation?</div> <div><input type="radio"/> User error</div> <div><input type="radio"/> Problem with the study device</div> <div><input type="radio"/> Both user error and problem with the study device</div> <div>8d. Is there any indication of non-study-device-related factors that contributed to the occurrence of the event?</div> <div><input type="radio"/> Yes <input type="radio"/> No</div>
<div>HypoOutcome</div>	<div>9. Outcome:</div> <div><input type="radio"/> Fully recovered <input type="radio"/> Other <input type="radio"/> Unknown</div>