



Protocol Diabetes

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Site Number


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Subject Number

## Diabetes Hypoglycemic Event

### 1 Diabetes Hypoglycemia

1.1	Reported Term for the Clinical Event	<b>CETERM</b>										
1.2	Category for Clinical Event	<b>CECAT</b>										
1.3	Any hypoglycemic events experienced?	<input type="radio"/> Yes <b>CEYN</b> <input type="radio"/> No										
1.4	Sponsor Defined ID	<b>CESPID</b>										
1.5	Date of Event (DD-MMM-YYYY)	<table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table> <b>CESTDAT</b>										
1.6	Time of Event (24 hour clock)	<table border="1"><tr><td></td><td></td><td></td><td></td><td></td></tr></table> <b>CESTTIM</b>										
1.7	When did the hypoglycemic event occur?	<input type="radio"/> Between Bedtime and Waking <b>WHENOCC</b> <input type="radio"/> Between Waking and Bedtime										
1.8	In the opinion of the investigator, was this an adverse event?	<input type="radio"/> Yes <b>WASAEYN</b> <input type="radio"/> No										
1.9	Was a glucose measurement obtained at the time of the event?	<input type="radio"/> Yes <b>LBPERF</b> <input type="radio"/> No										
1.10	Glucose Result	<b>LBORRES</b>										
1.11	Glucose Units	<input type="radio"/> mg/dL <b>LBORRESU</b> <input type="radio"/> mmol/L										
1.12	Exposure Category	<b>ECCAT or EXCAT</b>										
1.13	Date (DD-MMM-YYYY)	<table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table> <b>ECSTDAT or EXSTDAT</b>										

 <b>Protocol Diabetes</b>	<div style="border: 1px solid black; width: 40px; height: 30px; display: inline-block;"></div> <div style="border: 1px solid black; width: 40px; height: 30px; display: inline-block;"></div>		<div style="border: 1px solid black; width: 40px; height: 30px; display: inline-block;"></div> <div style="border: 1px solid black; width: 40px; height: 30px; display: inline-block;"></div> <div style="border: 1px solid black; width: 40px; height: 30px; display: inline-block;"></div> <div style="border: 1px solid black; width: 40px; height: 30px; display: inline-block;"></div> <div style="border: 1px solid black; width: 40px; height: 30px; display: inline-block;"></div>				
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Diabetes Hypoglycemic Event			
1 Diabetes Hypoglycemia			
1.14	Time (24 hour clock)	<div style="border: 1px solid black; width: 100px; height: 20px; position: relative;"> <div style="position: absolute; left: 0; top: 0; bottom: 0; border-right: 1px solid black;"></div> <div style="position: absolute; left: 25%; top: 0; bottom: 0; border-right: 1px solid black;"></div> <div style="position: absolute; left: 50%; top: 0; bottom: 0; border-right: 1px solid black;"></div> <div style="position: absolute; left: 75%; top: 0; bottom: 0; border-right: 1px solid black;"></div> <div style="position: absolute; left: 100%; top: 0; bottom: 0;"></div> </div>	<i>ECSTTIM or EXSTTIM</i>
1.15	Dose		<i>ECDSTXT or EXDSTXT</i>
1.16	Units		<i>ECDOSU or EXDOSU</i>
2 Diabetes Anit-Hyperglycemic Med			
2.1	Category for Medication		<i>HYPOMED_CMCAT</i>
2.2	Subcategory for Medication		<i>CMSCAT</i>
2.3	Date (DD-MMM-YYYY)	<div style="border: 1px solid black; width: 200px; height: 20px; position: relative;"> <div style="position: absolute; left: 0; top: 0; bottom: 0; border-right: 1px solid black;"></div> <div style="position: absolute; left: 16.6%; top: 0; bottom: 0; border-right: 1px solid black;"></div> <div style="position: absolute; left: 33.3%; top: 0; bottom: 0; border-right: 1px solid black;"></div> <div style="position: absolute; left: 50%; top: 0; bottom: 0; border-right: 1px solid black;"></div> <div style="position: absolute; left: 66.6%; top: 0; bottom: 0; border-right: 1px solid black;"></div> <div style="position: absolute; left: 83.3%; top: 0; bottom: 0; border-right: 1px solid black;"></div> <div style="position: absolute; left: 100%; top: 0; bottom: 0;"></div> </div>	<i>CMSTDAT</i>
2.4	Time (24 hour clock)	<div style="border: 1px solid black; width: 100px; height: 20px; position: relative;"> <div style="position: absolute; left: 0; top: 0; bottom: 0; border-right: 1px solid black;"></div> <div style="position: absolute; left: 25%; top: 0; bottom: 0; border-right: 1px solid black;"></div> <div style="position: absolute; left: 50%; top: 0; bottom: 0; border-right: 1px solid black;"></div> <div style="position: absolute; left: 75%; top: 0; bottom: 0; border-right: 1px solid black;"></div> <div style="position: absolute; left: 100%; top: 0; bottom: 0;"></div> </div>	<i>CMSTTIM</i>
2.5	Dose		<i>CMDSTXT</i>
2.6	Units		<i>CMDOSU</i>
2.7	Date (DD-MMM-YYYY)	<div style="border: 1px solid black; width: 200px; height: 20px; position: relative;"> <div style="position: absolute; left: 0; top: 0; bottom: 0; border-right: 1px solid black;"></div> <div style="position: absolute; left: 16.6%; top: 0; bottom: 0; border-right: 1px solid black;"></div> <div style="position: absolute; left: 33.3%; top: 0; bottom: 0; border-right: 1px solid black;"></div> <div style="position: absolute; left: 50%; top: 0; bottom: 0; border-right: 1px solid black;"></div> <div style="position: absolute; left: 66.6%; top: 0; bottom: 0; border-right: 1px solid black;"></div> <div style="position: absolute; left: 83.3%; top: 0; bottom: 0; border-right: 1px solid black;"></div> <div style="position: absolute; left: 100%; top: 0; bottom: 0;"></div> </div>	<i>MLSTDAT</i>
2.8	Time (24 hour clock)	<div style="border: 1px solid black; width: 100px; height: 20px; position: relative;"> <div style="position: absolute; left: 0; top: 0; bottom: 0; border-right: 1px solid black;"></div> <div style="position: absolute; left: 25%; top: 0; bottom: 0; border-right: 1px solid black;"></div> <div style="position: absolute; left: 50%; top: 0; bottom: 0; border-right: 1px solid black;"></div> <div style="position: absolute; left: 75%; top: 0; bottom: 0; border-right: 1px solid black;"></div> <div style="position: absolute; left: 100%; top: 0; bottom: 0;"></div> </div>	<i>MLSTTIM</i>
3 Diabetes Hypo Symptoms			
3.1	Category for Clinical Event		<i>SYMPTOMS_CECAT</i>
3.2	Were signs/symptoms present? (If yes, complete the following)	<input type="radio"/> Yes <input type="radio"/> No	<i>CEYN</i>



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**Diabetes Hypoglycemic Event****3 Diabetes Hypo Symptoms**

3.3	Sweating	<input type="radio"/> Yes <input type="radio"/> No	<b>SWEATING_CEOCCUR</b>
3.4	Tremors/Trembling	<input type="radio"/> Yes <input type="radio"/> No	<b>TREMORS_CEOCCUR</b>
3.5	Dizziness	<input type="radio"/> Yes <input type="radio"/> No	<b>DIZZINESS_CEOCCUR</b>
3.6	Cognitive Impairment	<input type="radio"/> Yes <input type="radio"/> No	<b>COGNITIVE_CEOCCUR</b>
3.7	Loss of Consciousness	<input type="radio"/> Yes <input type="radio"/> No	<b>LOC_CEOCCUR</b>
3.8	Convulsions/Seizure	<input type="radio"/> Yes <input type="radio"/> No	<b>SEIZURE_CEOCCUR</b>
3.9	Coma	<input type="radio"/> Yes <input type="radio"/> No	<b>COMA_CEOCCUR</b>
3.10	Other (Specify)	<input type="radio"/> Yes <input type="radio"/> No	<b>OTHER_CEOCCUR</b>
3.11	Specify Other		<b>OTHER_CETERM</b>

**4 Precipitating Factors**

4.1	Category for Findings About		<b>FACAT</b>
4.2	Findings About Object of the Observation		<b>FAOBJ</b>
4.3	Were any precipitating factors reported?	<input type="radio"/> Yes <input type="radio"/> No	<b>HPFYN</b>

	<div style="display: flex; justify-content: space-around;"> <div style="border: 1px solid black; width: 40px; height: 30px;"></div> <div style="border: 1px solid black; width: 40px; height: 30px;"></div> <div style="border: 1px solid black; width: 40px; height: 30px;"></div> </div> <div style="text-align: center;">Site Number</div>		<div style="display: flex; justify-content: space-around;"> <div style="border: 1px solid black; width: 40px; height: 30px;"></div> <div style="border: 1px solid black; width: 40px; height: 30px;"></div> <div style="border: 1px solid black; width: 40px; height: 30px;"></div> <div style="border: 1px solid black; width: 40px; height: 30px;"></div> <div style="border: 1px solid black; width: 40px; height: 30px;"></div> </div> <div style="text-align: center;">Subject Number</div>				
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Diabetes Hypoglycemic Event			
4 Precipitating Factors			
4.4	Alcohol Consumption	<input type="radio"/> Yes <input type="radio"/> No	<b>ALCPF_FAORRES</b>
4.5	Concurrent Illness	<input type="radio"/> Yes <input type="radio"/> No	<b>ILLPF_FAORRES</b>
4.6	Deviation from Dosing Instructions	<input type="radio"/> Yes <input type="radio"/> No	<b>DSDVPF_FAORRES</b>
4.7	Missed, Delayed or Smaller Meal	<input type="radio"/> Yes <input type="radio"/> No	<b>MEALPF_FAORRES</b>
4.8	Physical Activity	<input type="radio"/> Yes <input type="radio"/> No	<b>PAPF_FAORRES</b>
4.9	Other (Specify)	<input type="radio"/> Yes <input type="radio"/> No	<b>OTHPH_FAORRES</b>
4.10	Specify Other		<b>OTHPH_FATEST</b>
5 HYPO TREATMENT			
5.1	Category for Medication		<b>HTG_CMCAT</b>
5.2	Was any treatment given for the hypoglycemic event? (If yes, complete the following)	<input type="radio"/> Yes <input type="radio"/> No	<b>HTGYN</b>
5.3	Drink	<input type="radio"/> Yes <input type="radio"/> No	<b>DRINK_CMOCCUR</b>
5.4	Food	<input type="radio"/> Yes <input type="radio"/> No	<b>FOOD_CMOCCUR</b>



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### 5 HYPO TREATMENT

5.5	Glucose Tablets	<input type="radio"/> Yes <input type="radio"/> No	<b>TABLET_CMOCCUR</b>
5.6	Glucose Injection	<input type="radio"/> Yes <input type="radio"/> No	<b>INJECT_CMOCCUR</b>
5.7	Intravenous Glucose	<input type="radio"/> Yes <input type="radio"/> No	<b>IV_CMOCCUR</b>
5.8	If treatment given, indicate if assistance was needed	<input type="radio"/> None - Subject Treated Self <input type="radio"/> Subject was Capable of Treating Self, but Received Assistance <input type="radio"/> Subject was Not Capable of Treating Self, and Required Assistance	<b>TRTADMIN_TXASSIST_FAORRES</b>