TASK DOCUMENTATION
[DKA Event]

Patient ID: PtID

DKA EVENT FORM	
	Definite Diabetic Ketoacidosis *(as defined by the DCCT) is defined as having all of the following:*) *Symptoms such as polyuria, polydipsia, nausea, or vomiting;*) *Serum ketones >1.5 mmol/L or large/moderate urine ketones*) *Either arterial blood pH <7.30 or venous pH <7.24 or serum bicarbonate <15;*) *Treatment provided in a health care facility*
DKAOccurDt **DKAOccurDtApprox**	1.　　**Date of Event: ___ ___ / ___ ___**　☐ Approximate *Approximate if necessary; for day of month, enter '01' when the month is known but day of month is not known.*
DKAMetCrit	2.　　**Did event meet study criteria listed above for DKA?** Select "Probably" if in the judgment of the investigator the participant had DKA but not enough information is available to categorize event as meeting above criteria. If event cannot be classified as definitely or probably meeting above criteria, then it should not be reported. ○ Definitely　○ Probably
GlucLevel **GlucLevelUnk**	3.　　**Glucose level: _____**　**[Range: 100.0-1500.0]** ☐Unknown
HCO3 **HCO3Unk**	4.　　**HCO3: _____**　　☐Unknown
pH **pHUnk**	5.　　**pH: _____**　　☐Unknown
BUN **BUNUnk**	6.　　**BUN: _____**　　☐Unknown
CerebEdema	7.　　**Symptomatic cerebral edema:** 　　　○ Yes　○ No　○ Unknown
EventCauseStdyDev **EventCauseBGM** **StripsLotNum** **StripsLotNumUnk** **EventCauseCGM** **SensLotNum**	**Cause of Event** **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)?**　¨ 　　○ Yes　○ No 　If *Yes*, complete the following: 　　**8a. Indicate any <u>study</u> device that may have contributed to the event:** 　　　☐Blood glucose meter 　　　Lot number of strips ____ ☐ Lot number of strips unknown 　　　☐CGM 　　　Lot number of sensor ____ ☐Lot number of sensor unknown

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SensLotNumUnk **EventCauseExpl** **EventCauseNonStdy**	**8b. What is thought to be the explanation?** ☐ User error ☐ Problem with the study device ☐ Both user error and problem with the study device **8d. Is there any indication of non-study-device-related factors that contributed to the occurrence of the event?** ○ Yes ○ No