47. Visit 6 - Date of Visit 6

Number	Question	Answers
47.1	Date of Visit 6	[____] [____] [____] *(dd-mm-yyyy)*
47.2	Is Visit 6 date 67 to 73 days after Visit 3 date?	Automatic Calculation on Castor

48. Visit 6 - Concomitant Medications

Number	Question	Answers
48.1	Concomitant Medications	
	Please complete Concomitant Medictions Log	

49. Visit 6 - Adverse Events

Number	Question	Answers
49.1	Adverse Events	
	Please complete Adverse Events Log	

50. Visit 6 - Glucose Review

Number	Question	Answers
50.1	Was Glucose Management Assessed? *If Glucose Management not assessed, this is a Protocol breach*	○ YES ○ NO
50.1.1	Does the participant report any level 2 or level 3 hypoglycaemic events since last visit?	○ YES ○ NO
	Does the participant report any level 2 or level 3 hypoglycaemic events since last visit?" to "Level 3 hypoglycaemic event is defined as requiring hospitalisation and/or assistance of another person to actively administer carbohydrate, glucagon, or other resuscitative actions. These episodes may be associated with sufficient neuroglycopaenia to induce seizure or coma. Plasma glucose measurements may not be available during such an event, but neurological recovery attributable to the restoration of plasma glucose to normal is considered sufficient evidence that the event was induced by a low plasma glucose concentration	
	Hypoglycaemic Events	
50.1.1.2	Hypoglycaemic Events Please record any level 2 or 3 hypoglycaemic events in the Hypoglycaemic Events Log	

51. Visit 6 - Ketone Review

Number	Question	Answers
	Ketone Readings	
51.1	Have there been Ketone measures since the last visit?	○ YES ○ NO
51.1.1	Number of ketone measurements taken since last visit	[_____]
51.1.2	Number of episodes with ketone levels between 0.6 and 1.5 mmol/L (inclusive of endpoints).	[_____]
	A distinct episode is a period where ketones have gone above the threshold (0.6mmol/L) and then come down below this. If it then went up again that would be a new distinct event.	
51.1.4	Number of episodes with ketone levels greater than 1.5 mmol/L	[_____]
	A distinct episode is a period where ketones have gone above the threshold (1.5mmol/L) and then come down below this. If it then went up again that would be a new distinct event.	
51.1.6	Have there been any DKA events since the last visit?	○ YES ○ NO
	DKA Events	
51.1.6.2	DKA Events	

If the participant has experienced any DKA events please complete the DKA Events Log