14. Visit 2 - Date of Visit 2

Number	Question	Answers
14.1	Date of Visit 2	[ ] [ ] [ ] *(dd-mm-yyyy)*
14.2	Is Date of Visit 2 between 4 and 26 days after Date of Visit 1?	**Automatic Calculation on Castor**

15. Visit 2 - Concomitant Medications

Number	Question	Answers
15.1	Concomitant Medications	

Please complete Concomitant Medications Log

16. Visit 2 - Adverse Events

Number	Question	Answers
16.1	Adverse Events	

Please complete Adverse Events Log

17. Visit 2 - Glucose Review

Number	Question	Answers
17.1	Was Glucose Management Assessed? *If Glucose Management not assessed, this is a Protocol breach*	◯ YES ◯ NO
17.1.1	Does the participant report any level 2 or level 3 hypoglycaemic events since last visit? *If there has been a level 3 hypoglycaemic event since last visit, participant is ineligible for trial. Complete the hypoglycaemic repeating data.*	◯ YES ◯ NO
	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	
17.1.1.2	**Please record any level 2 or 3 hypoglycaemic events in the Hypoglycaemic Events Log**	
17.1.3	Has the participant registered with a CGM diabetes management device, e.g. Libreview or Dexcom?	◯ YES ◯ NO

18. Visit 2 - Ketone Review

Number	Question	Answers
18.1	Have there been any Ketone measures taken since the last visit?	○ YES ○ NO
18.1.1	Number of ketone measurements taken since last visit	[............................]
18.1.2	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 (0.6 mmol/L) and then come down below this. If it then went up again that would be a new distinct event.

Number	Question	Answers
18.1.4	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 (1.5 mmol/L) and then come down below this. If it then went up again that would be a new distinct event.

Number	Question	Answers
18.1.6	Have there been any DKA events since the last visit?	○ YES ○ NO

If there has been a DKA event since last visit, participant is ineligible for trial. Complete the DKA repeating data.

	DKA Events	
18.1.6.2	**Please complete DKA Log**	