64. Visit 8 - Date of Visit 8

Number	Question	Answers
64.1	Date of Visit 8	[ ] [ ] [ ] *(dd-mm-yyyy)*
64.2	Is Visit 8 date 137 to 143 days after Visit 3 date?	

65. Visit 8 - NYHA Class

Number	Question	Answers
65.1	NYHA Class	○ I - No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnoea (shortness of breath). ○ II - Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnoea (shortness of breath). ○ III - Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, or dyspnoea. ○ IV - Unable to carry on any physical activity without discomfort. Symptoms of heart failure at rest. If any physical activity is undertaken, discomfort increases.

66. Visit 8 - Concomitant Medications

Number	Question	Answers
66.1	Concomitant Medications	

Please complete the Concomitant Medications Log

67. Visit 8 - Adverse Events

Number	Question	Answers
67.1	Adverse Events	

Please complete the Adverse Events Log

68. Visit 8 - Glucose Review

Number	Question	Answers
68.1	Was Glucose Management Assessed? *If Glucose Management not assessed, this is a Protocol breach*	○ YES ○ NO
68.1.1	Does the participant report any level 2 or level 3 hypoglycaemic events since last visit?	○ 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

68.1.1.2	Hypoglycaemic Events

 Please record any level 2 or 3 hypoglycaemic events in the Hypoglycaemic Events Log

69. Visit 8 - Ketone Review

Number	Question	Answers
	Ketone Readings	
69.1	Have there been Ketone measures since the last visit?	○ YES ○ NO
69.1.1	Number of ketone measurements taken since last visit	[............................]
69.1.2	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.	
69.1.4	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.	
69.1.6	Have there been any DKA events since the last visit?	○ YES ○ NO
	DKA Events	
69.1.6.2	DKA Events If the participant has experienced any DKA events please complete the DKA Events Log	

68. Completion of Trial/Early Withdrawal - Completion of Trial/Early Withdrawal

Number	Question	Answers
68.1	Did the participant complete the trial?	○ Yes ○ No
68.2	Date of Completion/Withdrawal	▢ ▢ ▢ *(dd-mm-yyyy)*
68.3	Is Date of Completion/Withdrawal before Date of Visit 1?	**Automatic Calculation in Castor**
68.1.1	If participant did not complete the trial, what was the main reason (tick one only) *If field's value is equal to Pregnancy: a Pregnancy Notification Form must be completed.*	○ Advice from GP/other healthcare professional ○ Adverse event ○ Participant's choice ○ Pregnancy ○ On advice of investigator ○ Lost to follow-up ○ Died ○ Screen fail ○ Other
68.4	Details Calculation	
68.4.1	Please give details	▢

To be electronically verified by the PI once participant has completed the trial and all data entered