

39. Visit 5 - Date of Visit 5

| Number | Question | Answers |
|--------|--|--|
| 39.1 | Date of Visit 5 | <div> <div></div> <div></div> <div></div> </div> <i>(dd-mm-yyyy)</i> |
| 39.2 | Is Date of Visit 5 between 18 and 24 days after Date of Visit 4? | Automatic Calculation on Castor |

40. Visit 5 - Concomitant Medications

| Number | Question | Answers |
|--------|--|---------|
| 40.1 | Concomitant Medications | |
| | Please complete Concomitant Medications Log | |

41. Visit 5 - Adverse Events

| Number | Question | Answers |
|--------|---|---------|
| 41.1 | Adverse Events | |
| | Please complete Adverse Events Log | |

42. Visit 5 - Glucose Review

| Number | Question | Answers |
|--|--|---|
| 42.1 | Was Glucose Management Assessed? <i>If Glucose Management not assessed, this is a Protocol breach</i> | <input type="radio"/> YES <input type="radio"/> NO |
| 42.1.1 | Does the participant report any level 2 or level 3 hypoglycaemic events since last visit? | <input type="radio"/> YES <input type="radio"/> NO |
| <p>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 neuroglycopenia 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</p> | | |
| Hypoglycaemic Events | | |
| 42.1.1.2 | Please record any level 2 or 3 hypoglycaemic events in the Hypoglycaemic Events Log | |
| 42.2 | Insulin administration | <input type="radio"/> Subcutaneous injections <input type="radio"/> Pump |
| 42.3 | Daily basal insulin dose (average of last 7 days) | <input type="text"/> units/day |
| 42.4 | Daily bolus insulin dose (average of last 7 days) | <input type="text"/> units/day |
| 42.5 | Total daily insulin dose (average of last 7 days) | |
| CGM summary data from previous 2 weeks | | |
| 42.6 | Are summary data from CGM readings over the 2 weeks prior to this visit available? | <input type="radio"/> YES <input type="radio"/> NO |

| | | | |
|--------|--|----------------------|--------|
| 42.6.1 | Number of days CGM worn over preceding 14 days | <input type="text"/> | days |
| 42.6.2 | Percentage of time CGM was active over preceding 14 days | <input type="text"/> | % |
| 42.6.3 | Mean blood glucose level over preceding 14 days | <input type="text"/> | mmol/L |
| 42.6.4 | Blood glucose percentage time above 13.9 mmol/L over preceding 14 days | <input type="text"/> | % |
| 42.6.5 | Blood glucose percentage time from 10.1 to 13.9mmol/L over preceding 14 days | <input type="text"/> | % |
| 42.6.6 | Blood glucose percentage time from 3.9 to 10.0 mmol/L over preceding 14 days | <input type="text"/> | % |
| 42.6.7 | Blood glucose percentage time from 3.0 to 3.8 mmol/L over preceding 14 days | <input type="text"/> | % |
| 42.6.8 | Blood glucose percentage time below 3.0 mmol/L over preceding 14 days | <input type="text"/> | % |

42.6.9

Do blood glucose percentage times spent in each range
 add up to 100%?

Automatic Calculation on Castor

42.6.10

Glycaemic variability index over preceding 14 days

 %CV

43. Visit 5 - Ketone Review

| Number | Question | Answers |
|--|--|---|
| Ketone Readings | | |
| 43.1 | Have there been Ketone measures since the last visit? | <input type="radio"/> YES <input type="radio"/> NO |
| 43.1.1 | Number of ketone measurements taken since last visit | <input type="text"/> |
| 43.1.2 | Number of episodes with ketone levels between 0.6 and 1.5 mmol/L (inclusive of endpoints). | <input type="text"/> |
| 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. | | |
| 43.1.4 | Number of episodes with ketone levels greater than 1.5 mmol/L | <input type="text"/> |
| 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. | | |
| 43.1.6 | Have there been any DKA events since the last visit? | <input type="radio"/> YES <input type="radio"/> NO |
| DKA Events | | |
| 43.1.6.2 | If the participant has experienced any DKA events please complete the DKA Events Log. | |

44. Visit 5 - Questionnaires

| Number | Question | Answers |
|--------|---|---|
| 44.1 | Has the KCCQ questionnaire been completed? | <input type="radio"/> YES <input type="radio"/> NO |
| 44.1.1 | <p><i>If 'Has the KCCQ questionnaire been completed?' is equal to 'YES' answer this question:</i></p> <p>Add KCCQ</p> | Completed on Caſtor |

45. Visit 5 - Samples

| Number | Question | Answers |
|--------|----------------------|---|
| 45.1 | Safety Bloods | |
| | Date of blood sample | <div></div> <div></div> <div></div> <div>(dd-mm-yyyy)</div> |
| | Haemoglobin | <div></div> |
| | Haemoglobin Unit | <input type="radio"/> g/L <input type="radio"/> g/dL |
| | Sodium | <div></div> mmol/L |
| | Potassium | <div></div> mmol/L |
| | Urea | <div></div> mmol/L |
| | Creatinine | <div></div> µmol/L |
| | Glucose | <div></div> mmol/L |
| | eGFR | <div></div> mL/min/1.73m ² |

Repeating Data 'Urine Sample'

Form Urine sample



| Question | Answers |
|--------------------------------|---|
| Date of urine sample | <div><div></div><div></div><div></div></div> (dd-mm-yyyy) |
| Albumin | <div></div> mg/L |
| Creatinine | <div></div> <div>μmol/L or mmol/L</div> |
| Urine albumin/creatinine ratio | <div></div> mg/mmol |
| Sodium | <div></div> mmol/L |