# 40. Visit 5 - Date of Visit 5

| Number | Question | Answers |
|--------|----------|---------|
| 40.1 | Date of Visit 5 | [____] [____] [____] *(dd-mm-yyyy)* |
| 40.2 | Is Visit 5 date 25 to 31 days after Visit 3 date? | Automatic Calculation on Castor |

# 41. Visit 5 - Concomitant Medications

| Number | Question | Answers |
|--------|----------|---------|
| 41.1 | Concomitant Medications | |

Please complete Concomitant Medications Log

# 42. Visit 5 - Adverse Events

| Number | Question | Answers |
|--------|----------|---------|
| 42.1 | Adverse Events | |

Please complete Adverse Events Log

# 43. Visit 5 - Glucose Review

| Number | Question | Answers |
|---|---|---|
| 43.1 | Was Glucose Management Assessed? <br> *If Glucose Management not assessed, this is a Protocol breach* | ◯ YES <br> ◯ NO |
| 43.1.1 | Does the participant report any level 2 or level 3 hypoglycaemic events since last visit? | ◯ YES <br> ◯ 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** | Please record any level 2 or 3 hypoglycaemic events in the Hypoglycaemic Events Log |
| 43.1.1.2 | Hypoglycaemic Events | |
| 43.2 | Insulin administration | ◯ Subcutaneous injections <br> ◯ Pump |
| 43.3 | Daily basal insulin dose (average of last 7 days) | [....................] units/day |
| 43.4 | Daily bolus insulin dose (average of last 7 days) | [....................] units/day |
| 43.5 | Total daily insulin dose (average of last 7 days) | |
| | **CGM summary data from previous 2 weeks** | |
| 43.6 | Are summary data from CGM readings over the 2 weeks prior to this visit available? | ◯ YES <br> ◯ NO |

| | | | |
|---|---|---|---|
| 43.6.1 | Number of days CGM worn over preceding 14 days | | days |
| 43.6.2 | Percentage of time CGM was active over preceding 14 days | | % |
| 43.6.3 | Mean blood glucose level over preceding 14 days | | mmol/L |
| 43.6.4 | Blood glucose percentage time above 13.9 mmol/L over preceding 14 days | | % |
| 43.6.5 | Blood glucose percentage time from 10.1 to 13.9mmol/L over preceding 14 days | | % |
| 43.6.6 | Blood glucose percentage time from 3.9 to 10.0 mmol/L over preceding 14 days | | % |
| 43.6.7 | Blood glucose percentage time from 3.0 to 3.8 mmol/L over preceding 14 days | | % |
| 43.6.8 | Blood glucose percentage time below 3.0 mmol/L over preceding 14 days | | % |

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

43.6.10     Glycaemic variability index over preceding 14 days.      [................] %CV

# 44. Visit 5 - Ketone Review

| Number | Question | Answers |
|--------|----------|---------|
| | **Ketone Readings** | |
| 44.1 | Have there been Ketone measures since the last visit? | ○ YES<br>○ NO |
| 44.1.1 | Number of ketone measurements taken since last visit | [................................] |
| 44.1.2 | 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. | |
| 44.1.4 | 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. | |
| 44.1.6 | Have there been any DKA events since the last visit? | ○ YES<br>○ NO |
| | **DKA Events** | |
| 44.1.6.2 | DKA Events | |
| | If the participant has experienced any DKA events please complete the DKA Events Log | |

# 45. Visit 5 - Questionnaires

| Number | Question | Answers |
|---|---|---|
| 45.1 | Has the KCCQ questionnaire been completed? | ○ YES<br>○ NO |

If 'Has the KCCQ questionnaire been completed?' is equal to 'YES' answer this question:

| 45.1.1 | Add KCCQ | |
|---|---|---|

# Repeating Data 'Safety Bloods'

## Visit 5 - Samples

## Form Safety Bloods

| Number | Question | Answers |
|--------|----------|---------|
| 1.1 | Date of blood sample | [____] [____] [_____] *(dd-mm-yyyy)* |
| 1.2 | Haemoglobin | [_____] |
| 1.3 | Haemoglobin Unit | ○ g/L <br> ○ g/dL |
| 1.4 | Is the haemoglobin value within the expected range? | |
| 1.5 | Sodium | [_____] mmol/L |
| 1.6 | Potassium | [_____] mmol/L |
| 1.7 | Urea | [_____] mmol/L |
| 1.8 | Creatinine | [_____] μmol/L |
| 1.9 | Glucose | [_____] mmol/L |
| 1.10 | eGFR | [_____] <br> mL/min/1.73m2 |

**SOPHIST**

# Repeating Data 'Urine Sample'

## Form Urine sample

| Number | Question | Answers |
|--------|----------|---------|
| 1.1 | Date of urine sample | [ ] [ ] [ ] *(dd-mm-yyyy)* |
| 1.2 | Albumin | [ ] mg/L |
| 1.3 | Albumin check | |
| 1.4 | Creatinine | [ ] |
| 1.5 | Creatinine Units | ○ μmol/L  ○ mmol/L |
| 1.6 | Urine albumin/creatinine ratio | [ ] mg/mmol creat |
| 1.7 | Sodium | [ ] mmol/L |