Source Data

Source data

- All data collected must have back up source data in the participant's medical record because it:
  - Allows for Source Data Verification (SDV).
  - Allows other healthcare professionals to know about the trial and any assessments completed during visits.

- Template medical notes continuation sheets are provided and can be used if wished. If used, these should be filed in the medical notes.

- Worksheets are provided and can be used if wished. If used to record source data, they must be filed in the medical record, however, please note that the worksheets do not cover everything which is required to be recorded in the medical notes.

Source data

All Visits

- Date of visit.
- Confirmation of how participant identity was verified.
- Details of any notable findings at the visit and any action taken.
- Record of blood samples taken, urine samples collected and pregnancy tests done.
- Copy of blood, urine and pregnancy test results signed and dated by delegated doctor to be added when obtained.
- Changes to concomitant medications (*or state there were no changes*).
- Adverse events (*or state there were none*).
- Confirmation that the visit was carried out as per protocol.
- Name and signature of research staff completing the visit.

Source data

Visit 1

- Front coloured card/sheet/sticker to state they are a research participant.
- Copy of signed Informed Consent Form.
- Copy of Participant Information Sheet (PIS) participant has consented to.
- Copy of GP letter informing GP of participation.
- Confirmation that the participant has had the PIS for at least 24 hours.

Eligibility Confirmation Form

- Must be completed **before** randomisation.
- Must be dated and signed by doctor on Delegation Log.
- Must be filed in the medical record.

Source data

Assessments

- Medical history if not elsewhere in medical notes.
- NYHA class.
- Height and weight.
- Waist and hip circumferences.
- For women deemed not of childbearing potential document how this was confirmed.
- Physical examination normal/abnormal and action taken if appropriate.
- Copy of all test printouts signed and dated by doctor on delegation log. This includes laboratory results, imaging reports and ECG printouts. Information of any action taken to also be included if appropriate.
- Vital signs (i.e. blood pressure and pulse).
- Document details of education/review of glucose and ketone management provided to participant.
- Insulin doses, glucose (including CGM data) and ketone readings.
- Hypoglycaemic and DKA events.
- Trial paper questionnaires (i.e. KCCQ, DTSQs, DTSQc and EQ-5D-5L).
- 6 minute-walk test results (i.e. distance walked and number of stops).