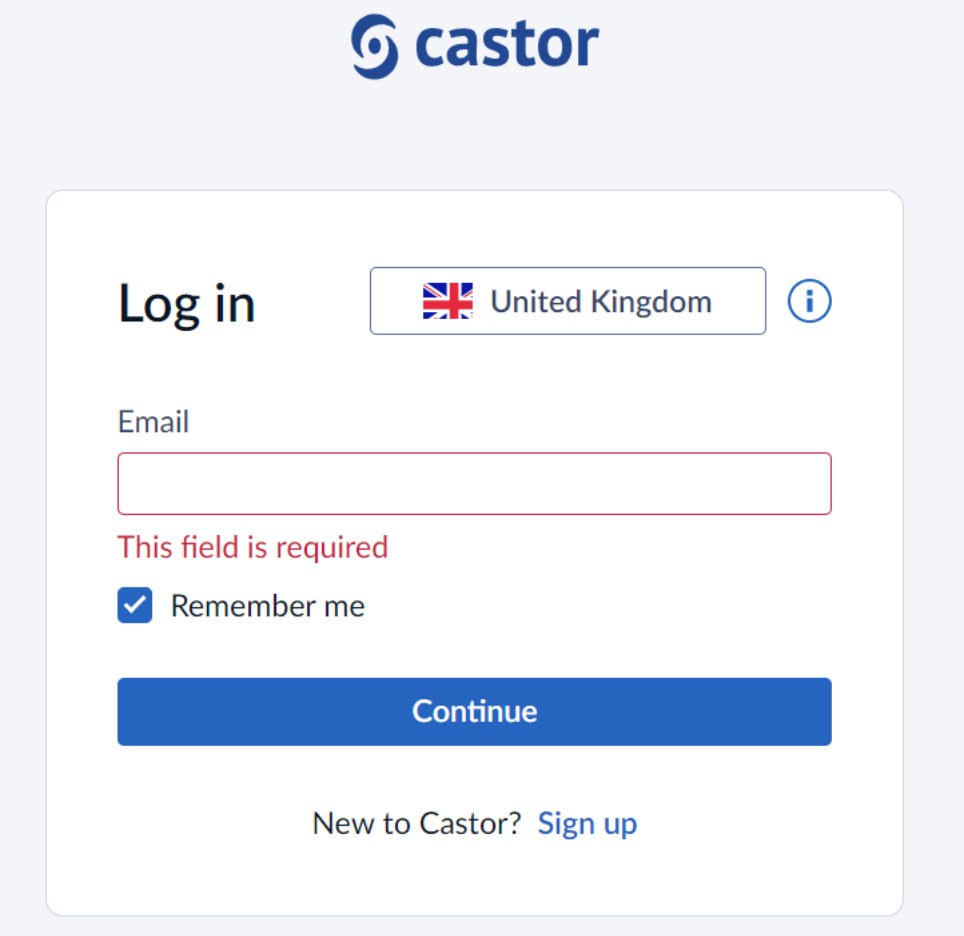# Data Collection & Data Entry

Castor eCRF

- Data entry is performed in the electronic case report form (eCRF) using the Castor.

- This can be accessed here: https://uk.castoredc.com/

- It is a secure, hosted system that is GCP-compliant.

Castor training

- Inform the Data Manager which site team members need access to Castor.

- Access to a test site will be provided.

- Castor training will be provided by the Data Management Team.

- Castor training consists of:
  - Brief data training sheet to enter test data & become familiar with Castor.
  - Supported by a data entry guideline document.
  - PI data verification guidelines.
  - Additional one-to-one training if required.

- Access to the live system will be given when training is completed and the person is delegated this task on the Delegation Log.

- The Data Management Team can be contacted on: SOPHIST-DM@dundee.ac.uk

Paper sheets

- Sites will be provided with medical notes continuation sheets and worksheets for each visit.

- Additional separate worksheets will also be provided with the first 4 to be reviewed at each visit:

  o Concomitant Medication Log

  o AE Log

  o DKA events log

  o Hypoglycaemic events log

  o Discontinuation of Trial Medication sheet

  o Completion/Early Withdrawal sheet

  o Eligibility Form worksheet

- The use of these sheets are optional. Worksheets will not be monitored and should not be archived at the end of the trial. If used to record source data they must be filed in the medical notes.

- Questionnaires – ensure the correct questionnaires are completed at each visit.