

Case Report Form

Subject ID:

- The CRFS must be completed using black ink.
- All fields must be completed.
- The CRFs must be written clearly and in CAPITAL letters.
- Corrections must be crossed-through once, initialed, dated and the appropriate correction made.
- Any tests that have not been performed please indicate this by completing the field with 'ND' to stand for not done.
- For any dates that may not be known please complete the field with 'UK' to indicate unknown.
- All data completed on the CRF must be extracted and consistent with the source documents where applicable.
- The CI/PI Certification form must be submitted along with the CRFs on completion of all visits.