| **Study Title:**  |  |
| --- | --- |
| **REC reference:** |  | **EudraCT Number** (if applicable**):** |  |
| **Sponsor:**  |  | **IRAS number:** |  |

The minimum requirements for source data for each participant are specified in the table below and should not be amended.

|  |  |
| --- | --- |
| **Source Data Type** | **Location** |
| Dated statement that the participant has entered the clinical study (e.g. ‘patient enrolled in xxx study’) |  |
| Statement to confirm that the participant has signed the informed consent form for (specify version of consent form signed) and that they have been given a copy of the PIS and consent form (specify document versions)  |  |
| Visit Dates |  |
| Diagnoses made (including confirmation of disease/condition being treated) |  |
| Concomitant Medication in accordance with normal clinical practice |  |
| All Serious Adverse Events |  |
| Completed informed consent form  |  |
| Copy of GP letter |  |

The following information required in source data should be amended as required by the protocol and may be used to specify which data can be entered directly into the CRF as source (in line with protocol/monitoring plan):

| **Source Data Type** | **Location** |
| --- | --- |
| Medical History  |  |
| Demographics |  |
| Inclusion/Exclusion Criteria |  |
| Pregnancy Test  |  |
| Lab tests  |  |
| X-ray / imagery scans |  |
| Surgery notes |  |
| Automated instrument printouts |  |
| AEs / SAEs  |  |
| Study Termination Date/Participant Withdrawal date |  |

|  |  |
| --- | --- |
| **Compiled by (name and signature)** |  |
| **Complication date** |  |
| **Current Version number** |  |