**CRF design: Key elements to consider including**

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| Unique pseudonymised subject ID | Every page |
| Date of visit/assessment | Every page |
| Demography | Screening/Baseline |
| Physical examination | Screening/Baseline; carried out by medically qualified individual |
| Medical History | Screening/Baseline |
| Inclusion and Exclusion criteria met (eligibility) | Prior to inclusion; signed off by PI/medically qualified individual |
| Primary and secondary endpoints | Baseline and subsequent treatment visits; include timepoints if relevant |
| Randomisation | Baseline |
| Treatment compliance | After randomisation/Subsequent visits (as applicable) |
| Safety data | After consent/randomisation/Subsequent visits (as applicable) |
| (Serious) adverse events | After consent/randomisation/Subsequent visits (as applicable); assessed and signed off by PI/medically qualified individual |
| Concomitant medications | Baseline and subsequent visits |
| Completion/withdrawal (final visit) | End of study |
| Confirmation of accuracy/completeness of data | By section or at the end of the whole CRF, depending on length and complexity. PI or delegate. |