**Source data: Key elements to include, with dates**

|  |  |
| --- | --- |
| Information sheet provided to potential participant |  |
| Informed consent obtained |  |
| Inclusion and exclusion criteria assessed (eligibility)  | Medically qualified staff |
| Randomisation/trial entry |  |
| Visits and phone calls |  |
| Treatment and dosing decisions |  |
| Changes to medication (concomitant) |  |
| Trial related decisions relating to care of subject |  |
| Adverse events | Assessment by medically qualified staff |
| Withdrawal/termination/end of trial data |  |