

Joint Research Office

**EudraCT Report Checklist**

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| Sponsor ID no:  Trial short name:  CI name:  EudraCT: | Date Declared Ended:  Date End of Study Report due:  Date Full Data Set completed:  Date Checklist completed: |

**SRA/RM ATMP: Review the EudraCT report and confirm that the following have been completed:**

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| --- | --- | --- |
| **Item** | Yes  or N/A | **Comment** |
| **Trial Information** | | |
| Full Title of the trial |  |  |
| Sponsor Protocol code |  |  |
| Other identifiers (NCT, ISRCTN number) |  |  |
| Sponsor contact details |  |  |
| End of trial date |  |  |
| Main trial objectives (as per current approved protocol) |  |  |
| Recruitment start date |  |  |
| Long term follow-up |  |  |
| Number of subjects recruited (as per enrolment log) |  |  |
| **Subject Disposition** | | |
| Recruitment details (subjects, disease area, how they are identified etc.) |  |  |
| Screening details |  |  |
| Allocation Method (e.g. randomised controlled, non-randomised) |  |  |
| Blinding used |  |  |
| Blinding implementation details (e.g. over encapsulation) |  |  |
| Arm description (e.g. placebo, active comparator) |  |  |
| IMP name |  |  |
| Pharmaceutical form |  |  |
| Route of administration |  |  |
| Dosage and administration details |  |  |
| Number of subjects per arm |  |  |
| **Baseline Characteristics** | | |
| Reporting groups |  |  |
| Age characteristics |  |  |
| Gender characteristics |  |  |
| **End Points** | | |
| End points reporting groups |  |  |
| Statistical analyses (for each end point) |  |  |
| **Adverse Events (Discuss with PV Manager)** | | |
| Time Frame for AE reporting |  |  |
| Assessment type (systematic, non-systematic) |  |  |
| Dictionary used (e.g. MedDRA) |  |  |
| AE data (or justification given if data not included) |  |  |
| Number of subjects affected by Serious Adverse Events |  |  |
| Number of deaths |  |  |
| **More Information** | | |
| Substantial protocol amendments  (Are all substantial amendments listed and description given as per amendment log?) |  |  |
| Interruptions and restarts  (Are any temporary halts and recommencements listed?) |  |  |
| **Summary attachments** | | |
| Summary PDF attached to full dataset (optional) |  |  |
| **Posting Results** | | |
| All validation errors addressed  (Click ‘Validate full dataset’ to check) |  |  |
| Justification text entered for all warnings  (Justification text is required if a warning is displayed when ‘Validate full dataset’ is clicked) |  |  |
| PDF of full dataset created  (This should be after all validation errors and warnings have been addressed) |  |  |
| Full dataset PDF sent to Trial Statistician to review and confirm the statistical results are correct and consistent with the final study report. |  |  |
| Full dataset PDF sent to CI to review and confirm the content of the report is accurate. |  |  |
| Results posted on EudraCT |  | Date posted: |
| Full dataset PDF sent to CI to send to the ethics committee and file in the TMF. |  |  |
| Email sent to MHRA to notify them the report has been uploaded. |  |  |
| EudraCT Report filed in the sponsor file |  |  |

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| The above checklist represents that all data pertinent to the final study report submission in EudraCT has been completed and is accurate. | |
| Completed by (name): |  |
| Role: |  |
| Signature: |  |
| Date: |  |