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** | Yesor 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: |  |