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| --- |
| **ADMINISTRATIVE INFORMATION** |
| Title of Protocol |  |
| Protocol Reference Number |  |
| Protocol Version Number (where applicable) |  |
| Date and Reference Number of the Trial Approval  |  |
| Actual Date(s) when the trial initiated of (at the Trial Centre(s): | **DD/MM/YYYY** |
| Meeting Date: | **DD/MM/YYYY** |
| Date report issued:  | **DD/MM/YYYY** |
| Data cut-off Date: | **DD/MM/YYYY** |
| Date of last closing data review: | **DD/MM/YYYY** |
| Date report issued: | **DD/MM/YYYY** |
| Names and contact of Principal Investigator  |  |
| Names and contact of Co-Investigator |  |
| Names of Sponsor (If applicable) |  |
| Name and address of the Contract research Organization (s) (CRO)where the clinical studies proving efficacy and safety of the product were conducted if applicable |  |
| Phase of Trial (if applicable) |  |
| Number of Clinical Trial Site. |  |
| List of Clinical Trial Sites |  |
| Duration of Clinical Trial |  |
| Name of Investigational Product (IP) strength, and dosage form. |   |
| IP Therapeutic indications |  |
| IP Route of Administration |  |
| IP Storage Information |  |
| **CURRENT TRIAL STATUS** |
| *Key Issues for Meeting Discussion* |   |
| *Study Site Status* |   |
| *Enrolment and Retention Status* |   |
| *Status of Outcome Measures and Biospecimens* |   |
| M*ajor Protocol Changes*  |   |
| *Unanticipated Problems* |   |
| *Protocol Deviations* |   |
| *Quality Management* |   |
| *Efficacy evaluation* |   |
| *Safety evaluation* |   |
| *Discussion and overall conclusion* |   |
| *Identified Study Challenges and Solutions* |   |
| *Figures* |   |
| *appendices* |  |
| **ADDITIONAL COMMENT FROM THE INVESTIGATOR**  |
|   |
| **REEPORT APPROVAL** |
| ***Names of Investigator*** | ***Date***  | ***Signature*** |
|  |  |  |