|  |  |  |  |
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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*** |
|  | |  |  |