**FINAL REPORT FORM**

**INSTRUCTIONS TO THE PRINCIPAL INVESTIGATOR:** *This form is required upon completion of the study or closure of study site. Obtain an electronic copy of this form and encode all information required in the space provided. Print the report in A4 size paper; then date and sign this form before submission.*

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| --- | --- | --- |
| **TSURERC CODE:** | | |
| **STUDY PROTOCOL TITLE:** | | |
| **PRINCIPAL INVESTIGATOR:** | | |
| **STUDY PROTOCOL APPROVAL DATE:** <dd/mm/yyyy> | | |
| **Email:** | **Telephone:** | **Mobile:** |
| **STUDY SITE:** <Name and address> | | |
| **STUDY SITE ADDRESS:** | | |
| **SPONSOR:** | | |
| **SPONSOR CONTACT PERSON:** | | |
| **Email:** | **Telephone:** | **Mobile:** |
| **REPORT SUBMISSION DATE:** (to be filled out by TSURERC)  **<dd/mm/yyyy>** | | |
| 1. Number of study participants in the beginning of the study: | | |
| 1. Number of participants at the end of the study: | | |
| 1. Number of participants who received the test articles: | | |
| 1. Summary of amendments to the original protocol (including dates of approval): | | |
| 1. Summary of SAE reported: | | |
| 1. Summary of anticipated risks (other than SAEs) documented in the conduct of study: | | |
| 1. Summary of SUSAR reported: | | |
| 1. Summary of unanticipated risks (others than SUSAR) documented in the conduct of study: | | |
| 1. Summary of participants’ complaints or grievances documented regarding conduct of study: | | |
| 1. Summary of benefits documented: | | |
| 1. If terminated early, specify reason for termination: | | |
| 1. *Continuing Review Application Submission* dates with corresponding TSURERC action: | | |
| 1. Summary of study materials used (for non-clinical research): | | |
| 1. List of treatments or interventions: | | |
| 1. Duration of the study: | | |
| 1. Study objectives and summary of results: | | |
| 1. List of informed consent form used (version/date) and attach most recent version: | | |
| **DATE OF LAST REVIEW:** <dd/mm/yyyy> | | |
| **SIGNATURE OF Principal Investigator:** | | |
| **DATE SUBMITTED:** <dd/mm/yyyy> | | |
| **RECEIVED BY:** | | |

**RECOMMENDATIONS (for TSURERC use only)**

|  |  |  |  |
| --- | --- | --- | --- |
| **COMMENTS OF PRIMARY REVIEWER** (i.e. compliance with the terms of the approved protocol including post-approval review requirements, and overall assessment of risks against benefits in the conduct of study) | | | |
| **RECOMMENDED ACTION:**   * APPROVE * REQUEST INFORMATION: (specify) * RECOMMEND FURTHER ACTION: (specify) * PENDING, IF MAJOR CLARIFICATIONS ARE REQUIRED BEFORE A DECISION CAN BE MADE | | | |
| **PRIMARY REVIEWER** |  | **Signature:** |  |
| Date: <dd/mm/yyyy> |  | **Name:** | <Title, Name, Surname> |
| **TSURERC SECRETARIAT** |  | **Signature:** |  |
| Date: <dd/mm/yyyy> |  | **Name:** | <Title, Name, Surname> |
| **TSURERC CHAIRPERSON** |  | **Signature:** |  |
| Date: <dd/mm/yyyy> |  | **Name:** | <Title, Name, Surname> |