1. Due to the rapidly changing dynamics of the condition/disease, it has become necessary for the South African Health Products Regulatory Authority (SAHPRA) to introduce a two-weekly public health emergency (PHE) Abridged Interim Safety and Futility Monitoring Report Form for clinical trials.
2. This form is to be completed two-weekly from the date of approval of the clinical trial by SAHPRA. Fill in reports even if enrolment has not yet started.
3. This form does not replace the required six-monthly Progress Report Form for clinical trials.
4. The applicant/sponsor must complete Parts A, B and C.
5. Part A specifically applies to the study participants in South Africa.
6. Part B focuses on Suspected Unexpected Serious Adverse Reactions (SUSARS) for all sites and all participants in this study.
7. Part C enables the Sponsor/Applicant to raise any other areas of concern with regards to futility and safety.

# CLINICAL TRIAL TWO-WEEKLY ABRIDGED PROGRESS REPORT

# PART A: STUDY OVERVIEW SOUTH AFRICA

|  |  |
| --- | --- |
| 1. SAHPRA Database tracking number
 |  |
| 1. Study Title
 |  |
| 1. Protocol number
 |  |
| 1. *Details of Sponsor / Applicant:*
 |  |
| * 1. Name of Sponsor
 |  |
| * 1. Name of Applicant
 |  |
| * 1. Contact Person
 |  |
| * + 1. Telephone number
 |  |
| * + 1. Cell-phone number
 |  |
| * + 1. E-mail address
 |  |
| 1. *Trial Information:*
 |  |
| * 1. Date of SAHPRA approval of study
 |  |
| * 1. List of Local Ethics Committees Review and date of their approval / non approval of study
 |  |
| * 1. Treatment hold (if applicable) with reasons (start date and stop date of hold should be included)
 |  |
| 1. *Number of participants in the trial (per site), (this section should be accumulative):*
 |  |
| * 1. Screened (signed consent)
 |  |
| * 1. Screening failure (with reasons)
 |  |
| * 1. Randomised
 |  |
| * 1. Withdrawn from treatment (continue in follow up) with reasons
 |  |
| * 1. Withdrawn from study (early termination) with reasons
 |  |
| * 1. Study completed
 |  |
| * 1. Lost to follow-up
 |  |
| * 1. Deaths
 |  |
| 1. Summary of any new Data Safety Monitoring Board or Safety Committee recommendations since last report
 |  |

# PART B: OVERALL SAFETY LINE LISTING

|  |  |  |
| --- | --- | --- |
| **SUSARS AND/OR SERIOUS ADR** | **Indicate whether Local/International** | **Outcome(s)** |
| e.g. Pneumonitis (7 patients) |  | 7 patients recovered2 still treated |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

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| --- |
|  |
| **Signature of National Principal Investigator** | **Date** |
| **Signature of Applicant/Sponsor** | **Date** |

