# INSTRUCTIONS

1. This form is to be completed six-monthly from the date of approval of the clinical trial by the South African Health Products Regulatory Authority (SAHPRA).
2. The applicant/ sponsor must complete Parts A and B.
3. Part A is specifically for the study participants in South Africa. The Applicant must include the reporting period and the number of the progress report submission (e.g., 1 or 2).
4. Part B is an overall safety line listing for the study in South Africa (and any other issues of special concern outside South Africa) and includes all Serious Adverse Events (SAEs) and Suspected Unexpected Serious Adverse Reactions (SUSARS) for all participants in this study.

**NOTE:** Protocol Deviations must be reported separately, six-monthly to SAHPRA. Protocol deviations are not part of the report but should be submitted as a separate communication at the same time as this report.

1. The End of Study progress Report should include the summary of investigational product authorized for importation (initial and amendment), quantity imported, used and remaining (destroyed) at end of the study.

**NOTE:** The End of Study progress report should be submitted 30 days after completion or termination of a Clinical Trial (In exceptional cases justification should be provided in advance for submission more than 30 days and not exceed 60 days after Last Subject Last Visit).

# CLINICAL TRIAL SIX-MONTHLY PROGRESS REPORT

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| PART A: STUDY OVERVIEW SOUTH AFRICA  |
| **Progress Report No:** **Reporting Period:** |
| 1. SAHPRA Database tracking number
 |   |
| 1. Study Title
 |  |
| 1. Protocol number
 |  |
| 1. *Details of Sponsor / Applicant:*
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| * 1. Name of Sponsor
 |  |
| * 1. Name of Applicant
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| * 1. Contact Person
 |  |
| * + 1. Telephone number
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| * + 1. Fax number
 |  |
| * + 1. Cell-phone number
 |  |
| * + 1. E-mail address
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| 1. List of all active trial sites, address and Principal Investigators (PIs)
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| 1. *Trial Information:*
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| * 1. Date of approval of study
 |  |
| * 1. Treatment hold (if applicable) with reasons (start date and stop date of hold should be included)
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| * 1. Expected date of completion
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| 1. *Number of participants in the trial (per site), (this section should be accumulative):*
 |  |
| * 1. Screened (signed consent)
 |  |
| * 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

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| 1. Applicant/Sponsor comment on progress to date
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| 1. Summary Data Safety Monitoring Board or Safety Committee recommendations
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| PART B: OVERALL SAFETY LINE LISTING |
| 1. Safety Line Listing of all Serious Adverse Events (SAEs) and Suspected Unexpected Serious Adverse Reactions (SUSARS) for all participants per site in this study in South Africa

*Note: Detailed Site-specific Line listing may be submitted as an attachment (should not be accumulative) as per Safety Reporting guideline*  |
| **SAEs and SUSARS** | **Relationship to study medicine (investigator’s opinion)** | **Outcome(s)** |
| **Site 1: (name of site)**  |
| e.g. Pneumonitis (7 patients) | Possible (2)Probable (1)Definite (2)Unrelated (2)unknown (0) | 7 patients recovered2 still treated |
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| **Site 2: (name of site)** |
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| **Site 3: (name of site)** |
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| **Any safety issues of special concern outside South Africa** |
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| 1. Line Listing of all critical and major protocol violations at the site:

Protocol *Violation* is any change, divergence, or departure from the study design or procedures defined in the protocol that might significantly affect participants’ safety, and well-being and/or the reliability of the study data.Protocol *Deviation* is accidental or unintentional changes to, or non-compliance with the research protocol that does not increase risk or decrease benefit or does not have a significant effect on the participants, safety or well-being; and/or the reliability of the study data.***NOTE:*** *South African Site-specific Line Listing of all major protocol violations may be submitted as an attachment**Site specific Protocol Deviations must be reported separately to SAHPRA, six-monthly.*  |
| **Critical and Major Protocol Violations** | **Resolution/Action taken** |
| **Site 1: (name of site)** |
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| **Site 2: (name of site)** |
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| **Site 3: (name of site)** |
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| 1. National Principal Investigator comment on other major safety concerns (this should include information impacting on the risk-benefit profile, including changes in nature, severity or frequency of risk factors, *etc.*)
 | **(Provide detailed text here)** |
| 1. Provide proof of current registration on South African National Clinical Trials Registry (SANCTR)
 |  |
| * 1. DoH Number
 |  |
| * 1. Enclose transcript reflecting current information from SANCTR
 |  |
| 1. Provide the summary of investigational product (End of Study Progress Report):
* Authorized for importation
* Imported
* Used during the Clinical Trial
* Destroyed (include the destruction certificate(s)) and
* Quantity to be exported
 |  |
| 14.1 Overall comment on Investigational Product Reconciliation |  |
| 1. Planned date for provision of trial results to SAHPRA and SANCTR (applicable to final progress report)
 |  |
| We, the undersigned, agree that we have reviewed the above-mentioned report and is accurate. The trial is conducted according to the approved protocol, South African legal, ethical and regulatory requirements. In case of deviation or Violation those are reported accordingly.  |
| **Signature of National Principal Investigator** | **Date** |
| **Signature of Applicant/Sponsor** | **Date** |
| **FOR SAHPRA USE ONLY:****Comments:**

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**Action: Continue Trial**

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**Further information required from Applicant / Sponsor**

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**Refer to Clinical Trials Committee and / or Inspectorate****Reviewed by:** **Date:** **Signature:**  |

**UPDATE HISTORY**

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| --- | --- | --- |
| **Date**  | **Reason for Update**  | **Version & Publication**  |
| November 2017 | First version published for implementation | Version 1, January 2018 |
| May 2018 | Changes to sections 1, 4, 5, 6, Part A, Part B, including change from MCC to SAHPRA | Version 2, June 2018 |
| April 2020 | Administrative | Version 3, April 2020 |
| June 2022 | Addition of sections 13, 14 and 15 Document number changed from 6.27 to GLF-CEM-CT-06A | Version 4, June 2022 |
| September 2023 | Update to Instructions, Part A, sections 14 and 15Correction of document number from GLF-CEM-CT-06A to GLF-CEM-CT-01G | Version 5, September 2023 |