

**FOUR WEEKLY PROGRESS REPORT TEMPLATE**

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| **PART 1: ADMINISTRATIVE**  *(Blocks will expand to contain the information required, no extra references or pages should be added)* | |
| Ethics Reference Number: |  |
| Study Title: |  |
| Phase of trial: |  |
| Protocol/Project/Study Number: |  |
| Approved Version/No. and Date: |  |
| Amended Version/No. and Date (if applicable): |  |
| Health product being studied: |  |
| Date of SAHPRA approval: |  |
| Funder (if applicable) |  |
| Sponsor: |  |
| Applicant: |  |
| Person making report: |  |
| Address: |  |
| Cell No.: |  |
| E-mail address: |  |
| Date of Report: |  |

1. Due to the very high risks associated with Phase 1, especially First-in-Human studies, it has become necessary for the Wits HREC (Medical) to introduce more frequent reporting and monitoring.

2. This form is to be completed four-weekly from the date of first patient screened.

3. This form does not replace the required six-monthly Progress Report Form for clinical trials.

**PART A:**

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| 1. *Study Information (as applicable):* |  |
| * 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 approved by Wits HREC (Medical):* |  |
| * 1. Pre-screened |  |
| * 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 Withdrawn from treatment (continue in follow up) with reasons |  |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 Withdrawn from study (early termination) with reasons |  |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: SAFETY LINE LISTING**

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| **SERIOUS ADVERSE EVENTS** | **Treatment of SAE** | **Outcome(s)** |
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**PART C: OTHER AREAS OF CONCERN WITH REGARD TO SAFETY, QUALITY, EFFICACY AND/OR FUTILITY**

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| I hereby certify that, to the best of my knowledge, the provided information is true and accurate | |
| Applicant/Principal Investigator:  Signature:  ………………………………………………… | Date  ……………………………………. |