



PASSIVE AUDIT REPORT, OCTOBER 2023, V1

Research Ethics
Committee



Final Version	Reason for Amendment	Effective Date
1	Developed and published for implementation	October 2023
	Administrative changes	March 2024

FORM FOR ANNUAL PASSIVE MONITORING OF AN APPROVED STUDY

PROGRESS REPORT

Please note SAHPRA Progress Reports are accepted. (SAHPRA, 2023)

Protocol Number:	
Protocol Title:	
1. Details of Applicant:	
2. Name of Applicant/Company:	
3. Contact Number:	
4. Cell Number:	
5. Email Address	
6. List of Trial Sites and Investigators:	
7. Expected Close Out of Study:	
8. Number of participants/patients in the trial per site	
9. Screened/Consented Patients:	
10. Randomised:	
11. Withdrawn and Reasons:	
12. Lost to Follow Up:	
13. Deaths:	
14. Applicant Comments on Progress to date:	
15. Summary Data:	

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		
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 recovered 2 still treated
Site 2: (name of site)		
Site 3: (name of site)		
Any safety issues of special concern outside South Africa		

- 2 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 SAMAREC

Critical and Major Protocol Violations	Resolution/Action taken
Site 1: (name of site)	
Site 2: (name of site)	
Site 3: (name of site)	
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)
Provide proof of current registration on South African National Clinical Trials Registry (SANCTR)	
3 Provide the summary of investigational product or device (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	



4	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
General Comments:		

Please email through to samarec@samedical.org

ACKNOWLEDGEMENTS:

SAHPRA. (2023, October 06). SAHPRA. Retrieved from SAHPRA: <http://www.sahpra.org.za>