SAHPRA
South African
Health Products
Regulatory Authority

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ADDENDUM 2: CONDUCTING REMOTE VIRTUAL GCP INSPECTIONS DURING EMERGENCIES/DISASTERS INCLUDING THE COVID- 19 PANDEMIC.

CHECKLIST FOR REMOTE VIRTUAL GCP INSPECTION

INFORMATION ABOUT THE REMOTE VIRTUAL GCP INSPECTION	
Name of Clinical Trial Site:	
Physical address of Clinical Trial Site:	
Contact details of Clinical Trial Site:	
Name of Applicant:	
Physical address of Applicant :	
Contact details of Applicant:	
Name of Sponsor:	
Physical address of Sponsor:	
Name and physical address of central laboratory:	
Principal Investigator:	
Sub / (Co) Investigator (s):	
Protocol number:	
Title of Clinical Trial:	
SAHPRA Trial ID:	
DOH Number:	
Stage of study:	☐ Before ☐ During ☐ After completion of trial
Purpose of inspection:	
Remote Virtual GCP Inspection Reference Number:	
Date(s) of inspection including all the inspection phases:	
Inspector (s)	

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<table>
<tr><th colspan="2">INFORMATION ABOUT THE REMOTE VIRTUAL GCP INSPECTION</th></tr>
<tr><td>Number of Participants reflected on the Participant Identification Code List:</td><td></td></tr>
<tr><td>Number of Participants reflected on the Participant Screening Log:</td><td></td></tr>
<tr><td>Screening date of first Participant at site:</td><td></td></tr>
<tr><td>Number of Participants reflected on the Participant Enrolment Log:</td><td></td></tr>
<tr><td>Randomization / Enrolment date of first Participant at site:</td><td></td></tr>
<tr><td>Number of participant who withdrew from the study.
(Reflect Participant number(s) and detail reason(s) for withdrawal)</td><td></td></tr>
<tr><td>Number of participants who completed the study:</td><td></td></tr>
<tr><td>Number of SAEs reported:
(Reflect Participant number(s) and detail SAE(s) according to the following guide:

<table><tr><td>Participant number</td><td>Description of event / Diagnosis</td><td>Relation to Investigational Product</td><td>Site awareness date of event</td><td>Date site reported event to Sponsor</td><td>Outcome</td></tr><tr><td></td><td></td><td></td><td></td><td></td><td></td></tr></table>
Where applicable, details of hospital admission and discharge should to be documented)</td><td></td></tr>
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Note: PHASE 1 – PHASE 3 whenever it appear in the document refers to the stage of the virtual GCP inspection as opposed to the phase of the clinical trial.

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Legend: ✓- YES X – NO	NR – NOT REVIEWED NA – NOT APPLICABLE

PHASE 1: VIRTUAL GCP INSPECTION			
ITEM NO.	**REQUIREMENT**	**✓/X/NR/NA**	**COMMENTS**
1.	**CLINICAL TRIAL SITE DECLARATION DOCUMENT, AND CONFIDENTIALITY AGREEMENT DOCUMENT**		
1.1	Is there a declaration by the Clinical Trial Site that all the information provided to the Regulator is accurate, authentic and that all documents supplied meet the standards of data integrity?		
1.2	Is a confidentiality agreement document between the Clinical Trial Site and the Regulator in existence and has been signed?		
2.	**NOTIFICATION LETTER AND PROPOSED INSPECTION PLAN**		
2.1	Has the inspection plan been sent in preparation for virtual meeting?		
2.2	Does the notification letter mention the suggested modes of virtual connection to be used between the Clinical Trial Site and the Regulator during the virtual interaction e.g. Microsoft Teams.		
2.3	Does the notification letter mention the availability of access to the Clinical Trial Site and Applicant electronic data systems?		
2.4	Has the Clinical Trial Site acknowledged the receipt of the notification letter and also confirm the mode of virtual connection they can engage in?		
2.5	Was the proposed inspection plan sent to the Clinical Trial Site following the notification letter?		
3.	**VIRTUAL OPENING MEETING**		
3.1	Is the virtual communication platform connected well on time? Is there adequate data to conduct the meeting?		
3.2	Are all the relevant staff present in the meeting e.g. Principal Investigator, Sub – investigator (s), Study Coordinator, Pharmacist, Laboratory Technologist, Study Nurse?		
3.3	Have the introductions and signing of the attendance register been completed? Has the		

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	Clinical Trial Site scanned back the attendance register after signing?		
3.4	Have the objectives and scope of the inspection been agreed upon?		
3.5	Has the brief presentation of the Clinical Trial Site background (NMT 10 minutes) been done?		
4.	**DISCUSSION ABOUT DOCUMENTS LISTED ON THE INSPECTION PLAN**		
4.1	Are the documents listed on the inspection plan all forwarded to the Regulator prior the virtual meeting?		
4.2	Are there any additional documents to the inspection plan list required?		
4.3	Has the Clinical Trial Site been made aware of documents required ?		
4.4	Has the Clinical Trial Site been told that the documents list is not exhaustive?		
5.	**CLOSING OF PHASE 1 (ACKNOWLEDGEMENT LETTER)**		
5.1	Have you agreed on time taken by the opening virtual meeting?		
5.2	Is the process going forward explained to the client?		
5.3	Has the closing time been captured on the register for the opening meeting?		

Billing for Phase 1: Virtual GCP Inspection

Total Number of Hours: [Hours and minutes]

Total Cost: R

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PHASE 2: DESKTOP INSPECTION/ REVIEW			
ITEM NO.	**REQUIREMENT**	**✓/X/NR/ NA**	**COMMENTS**
1.	**PERSONNEL**		
1.1	**ORGANOGRAM**		
1.1.1	Has the Clinical Trial Site current organogram been forwarded to the Regulator?		
1.1.2	Is the staff compliment relative to the scope of the work of the Clinical Trial Site?		
1.1.3	Are the reporting structures clearly defined?		
1.2	**TRAINING**		
1.2.1	Is the training SOP, program and specific training records been forwarded/ and is available to the Regulator?		
2.	**EQUIPMENT AND PREMISES**		
	Equipment Calibration Certification		
	Emergency Trolley Contents and Checklist		
3.	**DOCUMENTATION**		
3.1	**DOCUMENT CONTROL**		
3.1.1	Is there a procedure that describes how documentation is managed with regards to responsibilities such as: Approval, Review, Amendments, Revision, Signing Distribution, Withdrawal, Archiving, and Retention		

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4.	**CONTRACT AND AGREEMENTS (RSA GCP 3.2; 4.4; APPENDIX C 3.1.2; 3.1.4; 3.1.6; ICH E6(R2) 4.1, 5.6, 5.9, 8.2.2, 8.2.4, 8.2.6) (Trial specific)**		
4.1	Is a clinical trial agreement available?		
4.2	Is a confidentiality agreement signed between the sponsor and the investigator(s)?		
4.3	Is a signed and dated financial agreement between the sponsor and the Investigator available?		
4.4	Is an insurance certificate that covers the duration of the study available?		
4.5	Is a signed conflict of interest declaration available?		
5.	**RESPONSIBILITIES OF SPONSOR AND MONITOR (RSA GCP 4.1 - 4.23; ICH E6 (R2) 5.0 - 5.23)**		
5.1	Is documentation available to show that the sponsor conducted a pre-trial GCP site assessment?		
5.2	Is the study monitored as per monitoring plan?		
5.3	Is a site Initiation monitoring report available?		
6.	**INVESTIGATOR BROCHURE (RSA GCP APPENDIX C 3.1.1 & 3.2.1; ICH E6 (R2) 8.2.1, 8.3.1)**		
6.1	Is an investigator brochure and updates available on file with the date and version corresponding to that submitted to SAHPRA and ethics?		
7.	**REGULATORY APPROVALS (RSA GCP 1.6 & 4.1; ICH E6 (R2) 5.10)**		
7.1	Is a regulatory approval letter available for the conduct of the study at the site?		
7.2	Is the version number of protocols used in the study versus the version number of the approved protocol identical?		
7.3	Are regulatory approval letters available for new investigators?		
8.	**INDEPENDENT ETHICS COMMITTEE / INDEPENDENT REVIEW BOARD (RSA GCP 1.2.7, 2.2 & 8; ICH E6 (R2) 2.6, 3)**		

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8.1	Name of Ethics Committee: Is an Independent Ethics Committee / Independent Review Board (IRB) approval letter available for the conduct of the study at the site?		
8.2	Is the Ethics Committee composition ,current occupation of members, policies, or SOP of the Ethics Committee satisfactory?		
8.3	Are the agenda and attendance list of the IRB/ Ethics Committee meeting available?		
8.4	Does the ethics approval letter specify the version of the protocol and informed consent form approved?		
8.5	Are ethics approval letters available for new investigators?		
8.6	Did the IEC/IRB approve advertisements used for participant recruitment?		
9.	**INFORMED CONSENT (RSA P 1.2.8, 3.5;** **ICH E6 (R2) 2.9, 4.8)**		
9.1	Are the informed consent forms used approved by the IEC/IRB?		
9.2	Is a written SOP used to solicit informed consent?		
9.3	Do participants sign the consent forms before any study related procedure?		
9.4	Do all the participants receive a copy of the signed informed consent form?		
9.5	Do participants receive information regarding insurance?		
9.6	Is an assessment of understanding of the contents of the informed consent form done?		
9.7	Does the principal investigator or person designated by the principal investigator conduct the informed consent appropriately?		
9.8	Are participants given sufficient time to decide whether to participate in the study?		
10	**RESPONSIBILITIES OF THE INVESTIGATOR (S) (RSA GCP 3.1-3.15; ICH E6 (R2) 4.1 – 4.13)**		
10.1	Are updated CVs available?		
10.2	Is there a record of pre-trial training for all staff available?		
10.3	Are the signatures of the staff involved in the study recorded?		
10.4	Is there a participant identification code list available?		
10.5	Is there a participant screening log available?		

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10.6	Is there a participant enrolment log available?		
10.7	Does the investigator have a contingency plan for medical care in case of an emergency?		
10.8	Are significant trial related duties and functions delegated to qualified persons documented?		
10.9	Are all the inclusion criteria met by participants?		
10.10	Are none of the exclusion criteria met by participants?		
10.11	Are sixth monthly progress reports sent to the ethics committee?		
10.12	Are sixth monthly progress reports sent to the regulatory authority?		
10.14	Are all SAEs reported within the specified timelines to SAHPRA?		
10.15	Are all SAEs reported within the specified timelines to the sponsor?		
10.16	Are all serious adverse events reported within the specified timelines to the ethics committee?		
10.17	Is the investigator in control to ensure that the clinical trial is conducted in compliance with the protocol?		
10.18	Is informed consent conducted appropriately?		
10.19	Are adverse events and/or laboratory abnormalities identified in the protocol reported to the sponsor according to the reporting requirements.		
11	**INVESTIGATIONAL PRODUCT (RSA GCP 3.6; 4.14-4.16; ICH E6 (R2) 4.6, 5.13 – 5.14)**		
11.1	Are there shipping records of investigational product(s) from the sponsor to the investigator available?		
11.2	Are valid certificates of analyses (COA) for the study products available.		
11.3	Are instructions for handling of investigational product and trial related materials available?		
11.4	Are temperature control logs available?		
11.5	Does the labeling of the investigational products comply with Regulation 30 ?		
11.6	Is the dispensing of the investigational product done according to the protocol/SOP?		
11.7	Is dispensing done by a pharmacist or by a person with a dispensing license?		

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11.8	Is there proof that conditions as stated in the protocol have been maintained during shipment and storage of products?		
11.9	Is drug accountability done?		
11.10	Is documentation on disposal of investigational product available?		
12	**CLINICAL LABORATORY AND BIOLOGICAL SPECIMEN**		
12.1	Is an accreditation certificate available for the laboratory?		
12.2	Is an updated signed CV of the laboratory director available?		
12.3	Are normal values ranges for medical/laboratory/ technical procedures and /or tests and, wherever applicable their updates during the trial, available?		
12.4	Is a laboratory manual available?		
12.5	Are samples processed in accordance with the protocol and / or laboratory manual?		
12.6	Is the requisition number for a given participant sample reflected on the laboratory report consistent with that on the requisition form?		
13.	**RECORD KEEPING AND DATA HANDLING (RSA GCP 3.10, 4.8, 6; ICH E6 (R2) 4.9, 5.5)**		
13.1	Are records of key trial related procedures, e.g. eCRF, source documents (e.g. X-rays, serology printouts, diary cards etc), patient consent forms and SAE reports, complete and accurate?		
13.2	Is a signature sheet reflecting signatures and initials of all persons authorized to make entries and/or corrections on CRFs available?		
13.3	Does corrections to the CRF/eCRF comply with section 3.10 of RSA GCP ?		
13.4	Does each page of the case report form identify the participant and the study?		
13.5	Was there an SOP / manual for data entry corrections in the eCRF?		
13.6	Was the security of data protected in the eCRF?		
13.7	Are entries in the eCRFs / CRFs of participants included in the audit verifiable from source documents?		
Biling for Phase 2 : Desktop Review Inspection **Total Number of Hours = [Hours and minutes]** **Total Cost: R**			

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PHASE 3: REMOTE VIRTUAL INSPECTION THIS PHASE REQUIRES CONNECTION WITH AUDITEE TO FUTHER EVALUATE ADDITIONAL GxP AREAS IDENTIFIED IN PHASE 2			
ITEM NO.	**REQUIREMENT**	**✓/X/NR/NA**	**COMMENTS**
1.	**VIRTUAL REMOTE INSPECTION**		
1.1	Feedback phase 2		
1.2	Clarification / Disputes		
1.3	Additional evidence		
1.4	Closing meeting		
1.5	Define the process on the way forward		
1.6	Report writing		
1.7	Response review		
1.8	Fees		
Billing for Phase 3: Remote Virtual Inspection **Total Number of Hours = [Hours and minutes]** **Total Cost: R**			

INFORMATION ABOUT THE FOLLOW- UP PHYSICAL INSPECTION (should a need arises)	
Purpose of inspection:	
Inspection Reference Number:	
Date(s) of inspection of physical follow-up inspection:	
Inspector(s):	

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ABBREVIATIONS:

CRFs (Case Report Forms)

DOH: Department of Health

CRFs (Case Report Forms)

eCRFs (Electronic Case Report Forms)

GCP (Good Clinical Practice)

IB (Investigator's Brochure)

ICH: International Council for Harmonisation

IEC (Independent Ethics Committee)

IRB (Institutional Review Board)

NMT: Not More Than

SAEs (Serious Adverse Events)

SAHPRA (South African Health Products Regulatory Authority)

SOPs (Standard Operating Procedures)

Note:

1. **RSA GCP** whenever reflected in the document refers to ***Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants, Second Edition (2006);***
2. **ICH E6 (R2)** whenever reflected in the document refers to ***Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice E6 (R2)***