<<Insert Sponsor Ref; short study title; MVXX>>

Remote Pharmacy Monitoring Report & CAPA

For blinded studies include the following warning and add an 'unblinded report' watermark to the document.

**** WARNING ****

This is an unblinded report and contains information that must not be shared with blinded members of the research team.

Please take extra care when emailing this report and providing any additional/requested documents to ensure that blinded members of the research team are not included.

For this trial, the following people are unblinded:

- **Pharmacy staff**
- **Sponsor staff**
- **Specific Trial Staff/Research Nurse**

This report is to be used for Sponsor remote monitoring visits as per SOP S-1007 UoL, Sponsor Monitoring.

Completion of the report:

- Sponsor will complete ***Part A*** of the report prior to issuing to the study site.
- Pharmacy staff are to work through ***Part B*** of the report, confirming the presence of the listed documents in the site file and providing additional information/documents where required.
- The completed report and additional information/documents should be returned to Sponsor by the date stipulated in ***Part A***.
- Any report sections marked **NA** do not require completing and can be left blank.
- If there are specific documents missing from the site file indicate in the report and Sponsor will forward copies.
- All sponsor SOPs and associated documents can be accessed via our website.

Review and response:

- Sponsor will review the completed report and additional information/documents within 21 days of receipt. Findings will be detailed in the format of a 'Corrective Action Preventative Action' (CAPA) plan on ***Part C*** of the report.
- Findings from the monitoring visit will be categorised as 'Critical', 'Major' or 'Other' as per SOP S-1016 UoL, 'Procedure in the event of non-compliance in clinical research'.
- Sponsor will issue the CAPA on ***Part C*** of the report to the pharmacy contact.
- Pharmacy staff should address all findings, explaining what action(s) they will take in the first instance to correct the issue(s) and in the future to ensure that the issue(s) does not recur.
- Unless specified, site staff must return the completed CAPA to Sponsor within 28 days of issue. Sponsor will follow up the CAPA until completion/closure.

Part A should be completed by RGO. Text in blue should be actioned and deleted prior to issuing the report to the study team.

This report is designed to be adaptable to each study, sections headings can be marked not applicable and content deleted if they are not required to be completed.

Part A:

1.0 Visit information

1.1 Remote monitoring report details

Details required	Study specific information
Sponsor reference:	
Study title:	
Site name:	
Principal investigator:	
Site contact(s):	
Monitoring visit number & date:	
Monitoring visit type	☐ routine ☐ triggered
Date report issued:	
Report issued by:	
Date responses due:	

1.2 Overview of pharmacy monitoring visit

Add Sponsor comments including reason for visit, areas of concern or specific study details

Part B:

1.0 Pharmacy

1.1 Pharmacy documentation ☐ N/A

Are the following pharmacy documents present in the pharmacy site file? If any of these documents have been superseded provide the updated version and date of the new documents.

RGO to list details, dates and versions

Document	Version and date	Yes	No	N/A	Site comments:	Sponsor comments:
Pharmacy signature log	vx.x; date	☐	☐	☐		
Current approved protocol	vx.x; date	☐	☐	☐		
Current approved IB/SMPC	vx.x; date	☐	☐	☐		
Clinical trial synopsis	vx.x; date	☐	☐	☐		
Dispensing procedure	vx.x; date	☐	☐	☐		
Randomisation procedure	vx.x; date	☐	☐	☐		
Orders and receipts	vx.x; date	☐	☐	☐		
Returns and destruction	vx.x; date	☐	☐	☐		
Unblinding procedure	vx.x; date	☐	☐	☐		
Approved imp/placebo labels	vx.x; date	☐	☐	☐		
Pharmacy approved prescription template	vx.x; date	☐	☐	☐		
Temperature/Storage Monitoring						
Other, please specify						
Are all previous versions of the above listed documents present in the pharmacy file and marked as superseded?		☐	☐	☐		

1.2 Drug accountability ☐ N/A

Question	Yes	No	N/A	Site comments:	Sponsor comments:
Are the study drug accountability logs complete and up to date?	☐	☐	☐		
Confirm current stock balance including batch number and expiry date				IMP balance: IMP batch number: IMP expiry: Placebo balance: Placebo batch number: Placebo expiry:	
Does the stock on the shelf balance with the accountability log?	☐	☐	☐		
Does the stock on the shelf have an adequate expiry date to ensure stock will not expire whilst in use?	☐	☐	☐		
Is there a signed prescription on file for each participant dispensing visit?	☐	☐	☐		
Have there been any identified drug accountability issues?	☐	☐	☐		
Is there sufficient stock for the remainder of the study?	☐	☐	☐		

1.3 Temperature monitoring ☐ N/A

The IMP/placebo is to be stored at: *RGO to add temperature range*

Question	Yes	No	N/A	Site comments:	Sponsor comments:
Are records of temperature monitoring for the duration of the study present in the pharmacy site file?	☐	☐	☐		
Have there been any recorded temperature deviations?	☐	☐	☐	*If yes; provide further detail*	
Has any IMP/placebo been quarantined?	☐	☐	☐	*If yes; provide further detail*	
Are there complete records of fridge maintenance and calibration in the pharmacy site file?	☐	☐	☐		

1.4 Orders and receipts ☐ N/A

Question	Yes	No	N/A	Site comments:	Sponsor comments:
Are there records of IMP/placebo orders and receipts in the pharmacy file?	☐	☐	☐		
If temperature monitored; are there records of temperature monitoring during transit?	☐	☐	☐		
Have any temperature excursions been identified during transit?	☐	☐	☐	*If yes; provide further detail*	
Are there copies of QP release certificates on file for each batch of IMP/placebo received and dispensed during the study?	☐	☐	☐		

2.0 Remote drug reconciliation ☐ N/A

Complete the following table for all returned and quarantined IMP/placebo held in pharmacy.

Returns should be listed per participant per visit, ensuring all quarantined stock is marked as such.

Anonymised IMP/placebo accountability logs should be forwarded with this report. **Documents submitted must not contain participant identifiable information.**

RGO to add any study specific details

Participant ID number	Visit number and date	Batch number and expiry date	Quantity returned Mark (q) if quarantined stock	Specify: tablet / bottle / pen / other	Are the returns accurately recorded on accountability log	Sponsor Comments:	Pharmacy response:	Authorised for destruction (Y / N) (Sponsor to complete)
					☐ Yes ☐ No			☐ Yes <DATE>
					☐ Yes ☐ No			☐ Yes <DATE>
					☐ Yes ☐ No			☐ Yes <DATE>
					☐ Yes ☐ No			☐ Yes <DATE>
					☐ Yes ☐ No			☐ Yes <DATE>
					☐ Yes ☐ No			☐ Yes <DATE>
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					☐ Yes ☐ No			☐ Yes <DATE>
					☐ Yes ☐ No			☐ Yes <DATE>
					☐ Yes ☐ No			☐ Yes <DATE>
					☐ Yes ☐ No			☐ Yes <DATE>

3.0 Additional information ☐ N/A

Questions	Answer	Site comments	Sponsor comments
Is there any additional information you would like to provide?	☐ yes ☐ no		
Do you require any support from sponsor on any study related issues?	☐ yes ☐ no		
Please ensure you send the following documents with this report: RGO to add/delete as appropriate • Anonymised IMP/Placebo accountability logs			

****Please ensure you do not send any participant identifiable information with this report****

4.0 Signatures

Remote pharmacy monitoring report responses completed by:

Details	Completed by
Pharmacy staff name:	
Pharmacy staff role:	
Date:	

Part C:

1.0 Remote pharmacy monitoring response document ☐ N/A

Date response document issued:
Date response required:

No	Category	Finding	Immediate/Corrective Action	Preventative Action	Completed by Initials & Date
1					
2					
3					
4					
5					

2.0 Signatures

Remote pharmacy monitoring CAPA completed by:

Details	Completed by
Pharmacy staff name:	
Pharmacy staff role:	
Pharmacy staff signature:	
Date:	

Remote pharmacy monitoring report and CAPA reviewed and approved by PI:

Details	Approved by
PI name:	
PI signature:	
Date:	

Remote pharmacy monitoring report and CAPA closed by sponsor:

Details	Closed by
Sponsor name:	
Sponsor role:	
Sponsor signature:	
Date:	

Final Sponsor comments: