

Monitoring Visit CAPA

Details required	Study specific information
Site name:	
Principal investigator:	
Site contact(s):	
Monitoring visit conducted by:	<insert name, role, contact details (email/phone number)>
Monitoring visit number & date:	
Monitoring visit type	<input type="checkbox"/> routine <input type="checkbox"/> triggered
Date report issued:	
Date responses due:	

This document should be reviewed in conjunction with the Monitoring Visit Report. Please to review the documents carefully and contact the Monitor if there are any inaccuracies or queries.

The CAPA should be **completed in full** to document immediate actions taken to correct the issue (**'corrective action'**) and then longer-term plans/process put in place to prevent the issue from re-occurring (**'preventative action'**). All actions will be followed-up until satisfactory resolution. Any actions that cannot be resolved will be documented in a Site File Note and signed by the PI, relevant site staff and the Monitor (if required).

For regulatory purposes we cannot accept partially completed CAPAs and appreciate your cooperation with this matter.

Unless otherwise specified, the site will have 28 calendar days to respond to the findings. If you are unable to complete an action(s) and/or complete all actions by the date specified, please contact the monitor to request an initial extension of 14 calendar days. Other response timelines may be agreed upon discussion with the Sponsor.

Failure to respond within by specified or agreed date and/or after reminder(s) will result in the non-compliance SOP S-1016 being implemented with a minimum of a major finding.

No.	Category	Detail of Finding	Immediate or Corrective Action taken	Preventative Action taken	Action(s) completed by (initial) and date of completion (or anticipated completion)	Monitor review/sign-off and date action completed

1.0 Signatures

Responses completed by:

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

Pharmacy Responses completed by: (Not Applicable)

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

Monitoring report and CAPA reviewed and approved by PI:

Details	Approved by
PI Name:	
PI Signature:	

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

Details	Approved by
Date:	

Monitoring report and CAPA closed by sponsor:

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

Final Sponsor comments: