STANDARD OPERATING PROCEDURE 5:

HOW TO RESPOND TO THE MONITORING REPORT FROM THE CRO.

SOP 5: How to respond to the monitoring report from the CRO.

Who prepares the monitoring report by conducting monitoring for a given trial?

The Routine Monitoring will be conducted by the CRA/PM as per NCG CRO SOP in 2 approaches:

1) Remote Monitoring visit
2) On-site Monitoring visit

Process, time-points and how do you respond to monitoring?

Once after receiving the monitoring report the site PI/coordinator /designate should start working on the same by implementing the "corrective actions" and "preventive actions" as suggested by the CRA in the monitoring report.

Meanwhile, HCC Project Manager will prepare an excel sheet containing summary of findings for the site PI to enter their responses and share with the site.

within 1 week

Site should mention their response or the action taken in the column provided for each of the finding.

GLaD study_ Remote Monitoring Visit-02 Report (RMVR-02) for _ site name

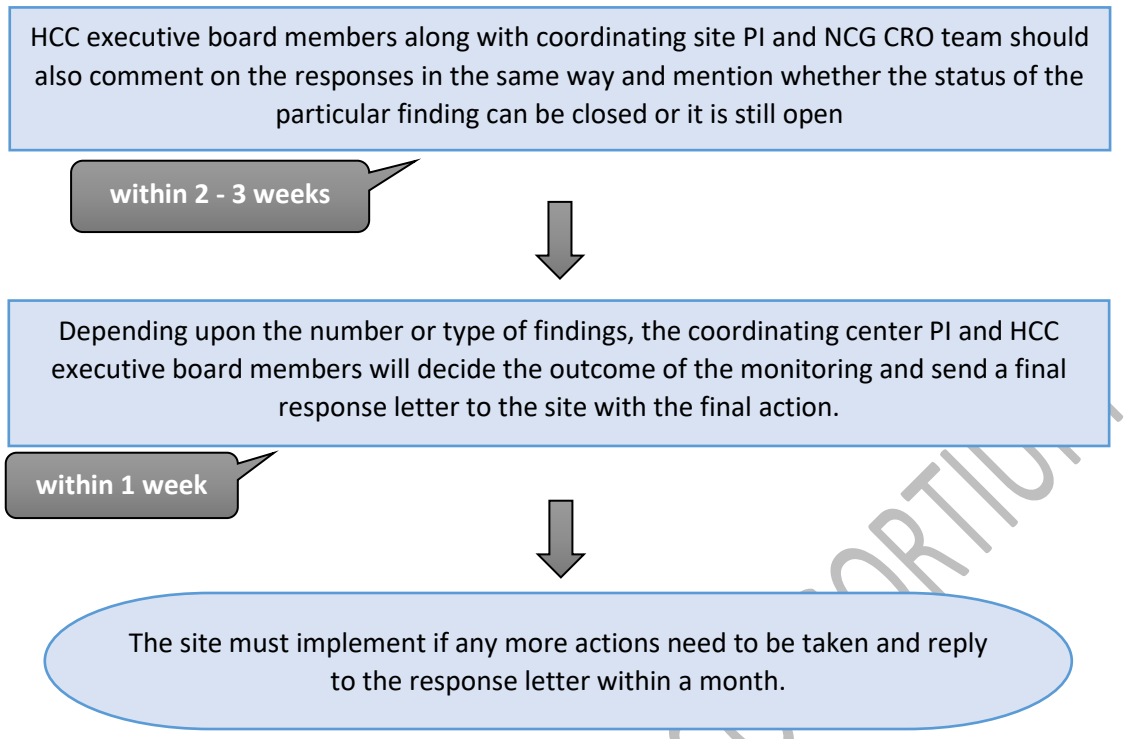
Summary of findings _ date of monitoring

From final report

Sr No	Findings	Action to be taken	Status	Response from site PI	Comments by Coordinating Center	Comments by NCG team	Status of the finding
1	xyz	abc	Open	xxx is the action taken for the finding			open/closed

Responses should be added and sent back to the coordinating site PI, HCC team & NCG team

within 2 - 3 weeks depending upon severity of findings



What could be the outcomes?

1. Continue the study
    - When there are just minor errors in the study conduct that can be rectified then and there.
2. Stop the study to repair the damages
    - When there are errors for which the site needs to report protocol deviations.
    - Major errors pertaining to informed consent processes where there occurs a need to re-consent the patients.
    - Requirement to amend the protocol and/or other documents.
    - IRB related issues.
3. Allow the study to continue with changes in parallel
    - Errors where there is some data missing in the eCRF, missing signature from PI, rectifying some dates and note-to-file that needs to be filed.
4. Stop the study site from continuing
    - When there occurs a major error pertaining to protocol violation.
    - This decision is to be taken by the HCC executive committee in consultation with the coordinating site and CRO.