STANDARD OPERATING PROCEDURE 4: MONITORING THE TRIAL.

SOP 4: Monitoring the trial.

Routine monitoring will be conducted by the CRA/P-In of CRO in two approaches:

1. Remote Monitoring
2. Routine On-site Monitoring

Time Points for monitoring

1. Remote Monitoring
    a. After first enrollment
    b. Once in 3 months (it may vary depending upon the nature of the protocol and findings from previous monitoring)
    c. After last enrollment
    d. During follow-up period: Once in 6 months / a year (based on the protocol)

2. Routine On-site Monitoring

Sr No	Time point	Duration
1	After first enrollment	Within 2-3 weeks
2	After last enrollment	Within 2-3 months
3	During follow-up period	Once in 6 months / a year (based on the protocol)

Documents that will be reviewed during monitoring (Remote & Routine On-site):

1. Informed consent forms and informed consent narratives, updated/current version of protocol, ICF and CRF
2. Eligibility criteria from source documents
3. Efficacy variables from lab reports & source documents
4. Lab investigation reports
5. Any AE's & SAE's occurred at the site from SAE forms and source documents
6. eCRF
7. Prescription or entries in Patient Diary card or Source notes/EMR to check if any prohibition medications were given
8. Drug inventory log, drug dispensing log and any other study specific log
9. Reimbursement log of tests that are not part of standard of care
10. Review of Investigator site file
11. IEC communication, status reports and other submissions (for amendments in protocol, ICF SAE)

Process and time-points for monitoring:

Site PI should inform the PI of the coordinating center and the CRO when the criteria for a monitoring visit is met / CRO can conduct a for-cause monitoring

within 1 week

The site CRC will be contacted via email by the CRA/ PM/ NCG team to set-up a date for conducting monitoring

within 1 -2 weeks

If the monitoring is to be conducted remotely, a Zoom video call or Microsoft Teams video call will be set up once after confirming the date of monitoring. This will be conducted between the site CRC and the CRA.

Monitoring process will happen once after the site was contacted for monitoring date

within 1 week

Immediately after the monitoring, the CRA would email an initial summary of the finding to the site PI of the monitoring

within 24 – 48 hours

Response to the email should be sent
The coordinating center/HCC must confirm incase the study needs to be halted

within a day or two

The CRA would prepare the detailed monitoring report of the visit and forward it to the Project Manager, NCG CRO for review & approval

within 10 working days

The NCG Project Manager would review the report and revert back to the CRA with his/her comments

within 10 - 12 working days

After finalization, the CRA should send the final detailed monitoring report through an email to the Principal Investigator of that site keeping the Sponsor-Principal Investigator, NCG CRO P-In and HCC Project Manager in cc list

within 5 - 7 working days

Following points are applicable for all visits:

- A confirmation email will be sent to the site(s) 2 weeks prior to monitoring by CRA (exception for any urgent matters).
- An exit meeting of 15-20 minutes would be held between CRA and PI/study team after every On-site visit to thank the site for the visit and also to discuss the recruitment, any outstanding issues as well as critical observations and appropriate corrective actions identified during the monitoring visit.
- Signing of the monitoring visit log.
- Summary of findings will be shared with the site via email within a week.
- Final report of the monitoring will be shared within 3 - 4 weeks of monitoring.
- Sites should respond to the monitoring report by implementing the suggested corrective action within 3 – 4 weeks.