The Recurring Monitoring Issue Triage Sheet

Create a common description of one recurring monitoring issue before discussing additional oversight. Focus on the decision, accountable owner and evidence of follow-through instead of adding another status report.

For Study leaders examining an issue that keeps returning across monitoring cycles. Original planning tool - November 2026.

01 / Use this worksheet

Set aside fifteen minutes. Work on your own copy and choose one next step with a date. Mark unknowns honestly. Revisit the sheet in a week to compare the plan with what happened. Keep personal or confidential details in your own records.

Prepared by: _____ **Date:** _____

Review date: _____ **One person to involve:** _____

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02 / Describe the recurrence concretely

Write the issue as an observable event and link the relevant approved internal record. Note where and when it recurred without including participant identifiers in a public-facing document. Separate the current instance from a pattern that has actually been reviewed. Similar wording in two reports does not automatically establish the same cause or systemic failure.

Observed recurrence and internal evidence: _____

What still needs confirmation? _____

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03 / Locate the decision that remained open

Identify the decision required after the earlier finding: clarification, corrective action, escalation or another authorized step. Record who was expected to decide and by when. Distinguish work assigned from work verified as completed. If a decision was made, check whether the next person in the handoff received enough information to act on it.

Required decision, owner and due date: _____

Evidence the decision reached the next owner: _____

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04 / Check the information available for action

List the evidence the owner needed and what was actually supplied. Identify a missing document, unclear instruction or inconsistent status definition. Avoid assigning blame or declaring root cause before review. This sheet supports triage; any formal investigation, corrective action or regulatory reporting belongs within the study's authorized procedures and responsibilities.

Information needed versus available: _____

Question for the responsible function: _____

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05 / Agree what verified closure means

Describe the evidence that would show the agreed action was completed and whether the issue should be checked again. Name the reviewer and review window. A closed tracker field is an administrative state; it is not sufficient by itself to show the underlying issue was resolved or that recurrence risk has changed.

Closure evidence and reviewer: _____

Follow-up window or recurrence check: _____

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06 / Choose a bounded next conversation

Decide whether the immediate need is CRA capacity, study-level coordination or review of a defined oversight workflow. Bring the non-confidential pattern and ownership question to Lampgen if useful. A SIGNAL Managed Monitoring discussion concerns a separately scoped pilot; a worksheet does not authorize an operational intervention or imply a proven improvement in study outcomes.

Support question and responsible sponsor: _____

Next review date and decision to make: _____

A discussion aid, not a monitoring plan, root-cause determination or CAPA procedure. Use approved study governance. Keep patient information and confidential protocol details out of website inquiries.

NEXT STEP / Discuss the oversight question with Lampgen

https://lampgen-clinical.tlampley1.chatgpt.site/contact?purpose=signal-pilot#request