

Measurement for Individual Study Teams: Leverage Plan–Do-Check-Act Approach

PLAN:

- The study team should proactively identify appropriate measures that will enable oversight of quality performance during study conduct; however, consideration should be given to unanticipated issues that may arise, or the combination of metrics that indicate issues around which action is needed.
- Measures should be aligned with critical to quality factors (i.e. critical data and processes) and/or key risks to quality for the study.
- Some measures may be study specific while others may be common across many/all studies.
- For each measure the study team should define the review frequency, establish rational thresholds and have a process in place for escalation as needed.
- These thresholds define the level of quality performance variability that will be tolerated for each measure.
- Much care and consideration should be taken when setting thresholds for these quality measures. Normal variability in measure performance should be understood before a threshold is established. Statistical methods may be utilized. Setting thresholds too high may result in frequent and unproductive efforts to remediate measure performance while setting thresholds too low may allow poor quality performance to go unchecked.
- Metrics are one way of measuring quality, but do not replace others ways to identify errors that matter, or other issues that require attention.

DO

- Quality metrics will be reviewed periodically throughout study execution.

CHECK

- Oversight of quality measures/key risk indicators should take place on an ongoing basis per the frequency that was prospectively defined.
- Evaluate metrics on an ongoing basis also, and adjust as needed. Evaluate if metrics are measuring things that don't matter, or if important metrics are not being evaluated.

ACT

- A metric deviation beyond such threshold (during study conduct) must trigger a response to investigate the issue, understand the cause, and to take appropriate steps to correct.
- Corrective actions should be targeted to directly address the nature and scope of the identified cause(s).
- Oversight of these measures and remediation of issues identified should be documented.
- In some cases, oversight may reveal new risks that were not previously anticipated. These new risks should be added to the risk management plan.