

# Improving Your Quality Toolbox with Quality Metrics

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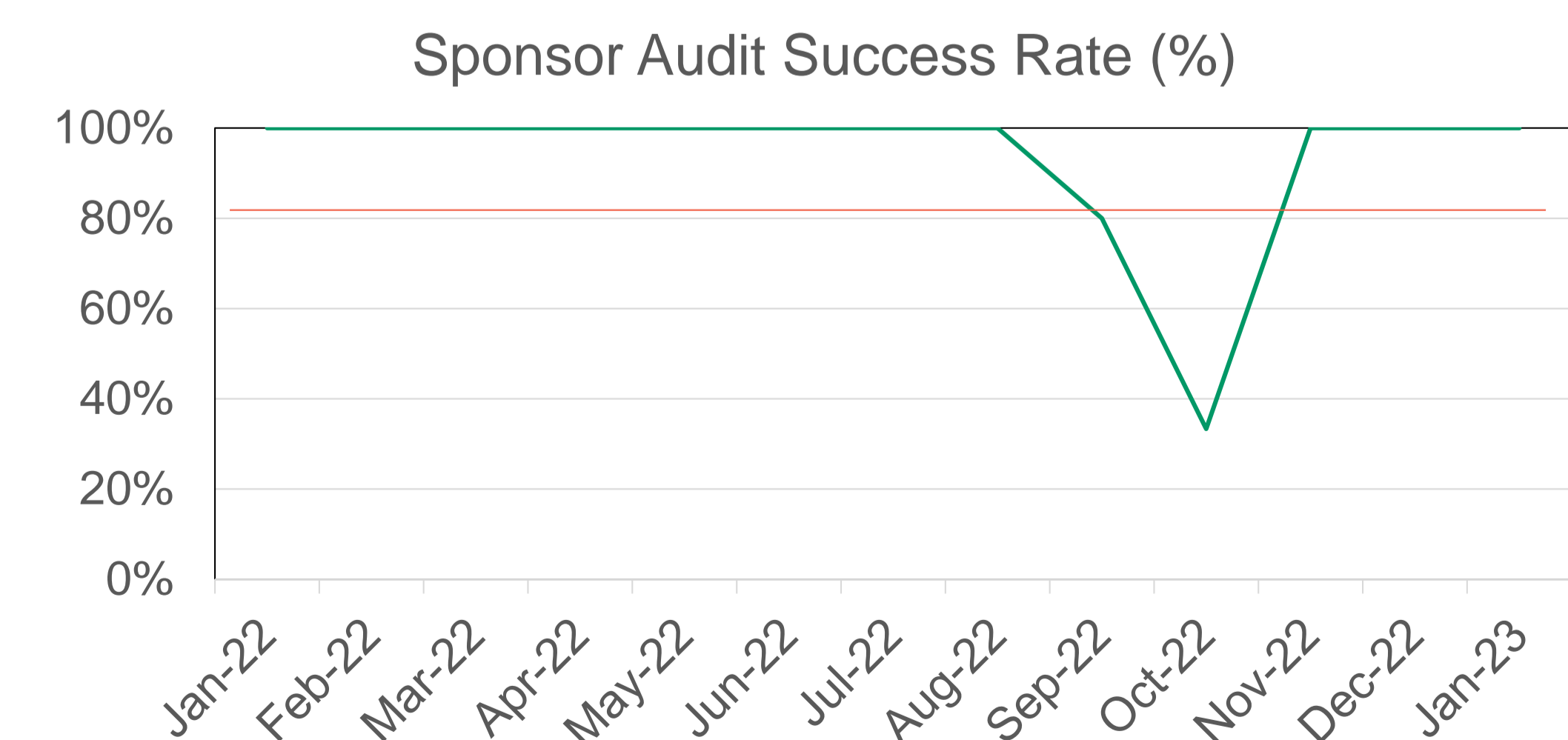


## ABSTRACT

Monitoring the quality program of your facility can help management identify areas of improvement, to reduce process failure and help identify recurrent issues. Collation and analysis of procedural deviations and Quality Assurance (QA) findings (i.e., Quality Metrics) can be a valuable tool to support management's culture of quality. Quality Metrics can provide valuable analysis to the quality of data collection, reporting, animal welfare program, method testing, or product release. Ensuring site-wide acquisition of the quality indicators by management and stakeholders is the key in establishing a robust and effective quality metrics monitoring program. Along with the support from the stakeholders, the quality management system acquiring the data must be intuitive to ensure adoption by all site personnel to support, monitor, and maintain continuous improvements in the organization. The sustainability of the program depends on the review of the metrics and monitoring the effectiveness of the process changes in reducing failure recurrence. The Quality Metrics program must be evaluated periodically to ensure that it accurately identifies areas of improvement and mitigates risks. Adopting a Quality Metrics program is a key tool for management to mitigate risk and drive continuous quality improvement.

## WHY ARE METRICS VALUABLE?

Metrics are measures of quantitative assessment commonly used for assessing, comparing, and tracking performance or production<sup>1</sup>. Metrics can be collected through standard quality management system (QMS) processes, such as audits, deviations, corrective and preventive actions (CAPAs), and sponsor or regulatory feedback. A QMS provides an abundance of valuable information; however, it is what you do with that information that is key. Extracting the information from a facility's QMS can assist in a facility's ability to identify process gaps, compliance risks, inefficiencies and gauge product quality. Showcasing the benefits that a facility can glean from metrics to management and stakeholders is imperative to obtaining buy-in and support.



Goal = Success rate of 80% or higher

### Case Study—Were all Study Deviations Approved in a Timely Manner?

The QA team was to monitor studies to determine if deviations were approved by the Study Director in a timely manner. This metric was monitored for 3 months, and the data showed that deviations were not being approved in a timely manner. Looking into the data to confirm that this indeed was the case, it was determined that there was no specified timeframe for the approval of deviations. Therefore, the auditor conducting the audit had to determine if the deviation was approved in a manner based on his/her interpretation of the question.

This subjectivity caused the metric data to be unreliable because there was too much bias in the data. Therefore, subjectivity should have been minimized first before using this metric to determine if the deviation approval process was working.

## CREATING A QUALITY METRIC PROGRAM

Data collected to produce metrics must be meaningful and fact-based to gauge a facility's level of quality and compliance. Removing as much subjectivity from the data is important because the data used for trending metrics must be objective.

### Sources of data

#### QA Observations

- What is the validity rate of the observations?
- Do most observations yield change or correction?

#### Deviations/CAPAs

- Are the deviations categorized to map to specific SOPs, processes, or protocol requirements?
- Are deviations generated or tracked in a manner that can yield metric data collection?

#### Sponsor and Regulatory Observations

- Are the observations collated to yield the ability to look across sponsor audits?
- Is there the ability to track trends from sponsor audits?

Collecting data can be performed in several ways, such as asking a series of Yes/No questions, counting number of pass or fails, or trending a count of events. This allows a facility to transform qualitative data into a quantitative measure of success.

### Examples

- Count of CAPAs initiated
- Count of major deviations
- Count of major audit observations
- Count of reports that do not meet an acceptable quality level
- Count of processes that do not meet an acceptable compliance rate

## Key Points to Consider

- Sample set (n) is critical.
  - If the sample set is too low, the metric could lead to a false conclusion.
- Metrics are pulled from a sample set of data; therefore, they need to be treated as signals or indicators.
  - While the sample set will support how strong the signal may be, it is still only a sample set of data.
- How subjective of a question is asked to collect the data.
  - If the question is too subjective, it can lead to differing responses. One auditor can answer the question as non-compliant, and another auditor can answer the question under the same conditions as compliant.
- How meaningful are the data to management, to the compliance, and to the quality.
  - Collecting data that have no impact on the site, product, compliance, and business is not meaningful.

## Presenting the data

Once it has been determined how to collect meaningful data, the next steps are to develop the plan to ensure that the data are presented in a format that is easily understood and summarize the data in a succinct and actionable manner. There are a few ways to use metrics as the tool to tell a story. For example, it could be tracking data to show a trend or using data to show that processes are in control and compliant. The criteria for which level of compliance or quality are determined is a major part of using data to tell a story.

Communication of the metrics can be done in a few different ways:

- Emailing results to management and stakeholders at a pre-defined frequency
- Meeting with management and stakeholders at a pre-defined frequency to discuss the outcome of the metrics
- Meeting with just management or just one member of management at a pre-defined frequency

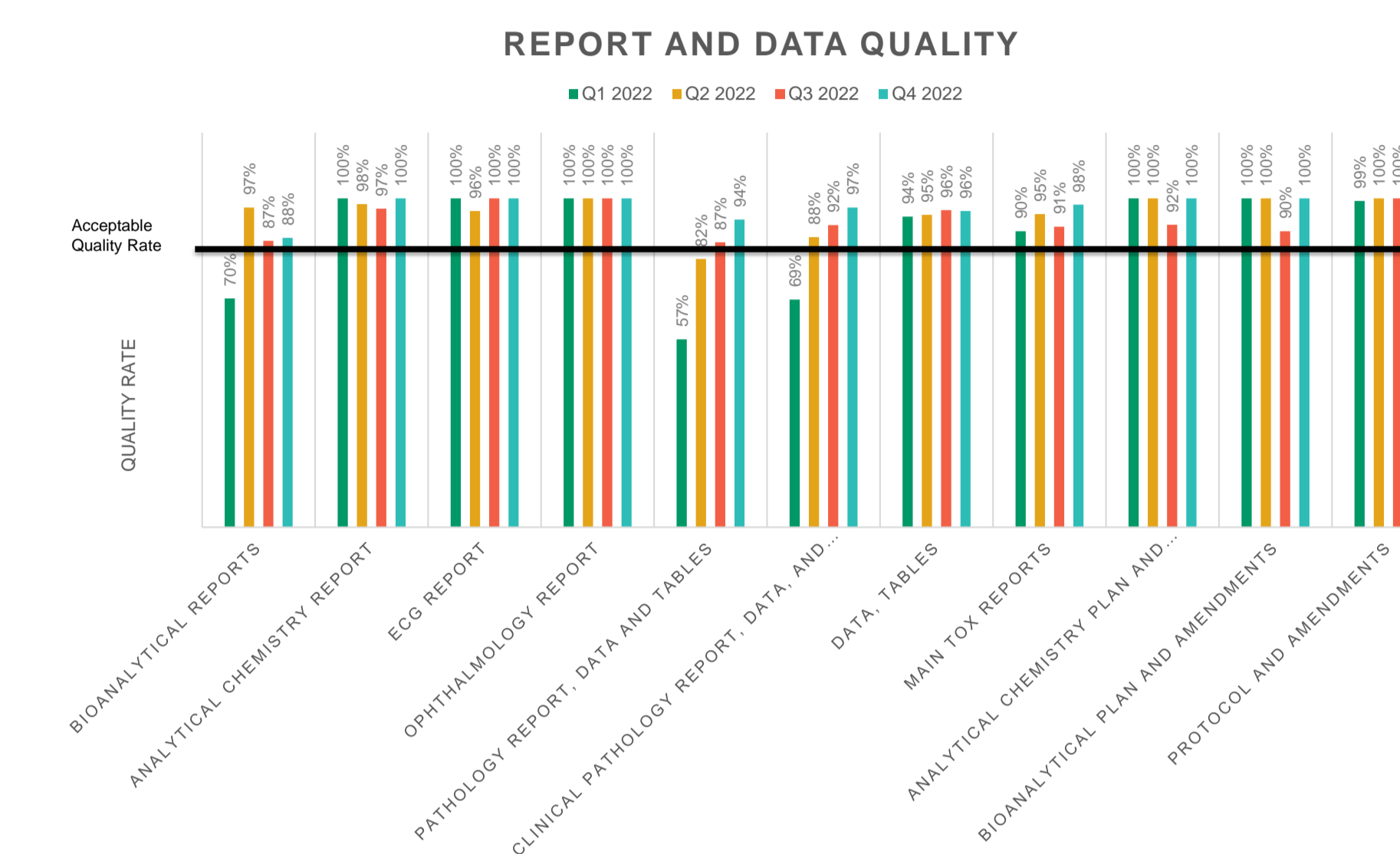
In all three communication scenarios, it is important to allow management and stakeholders the opportunity to review the data and ask any questions.

### Case Study—Was QC Performed on Time?

Data were pulled from audit observations for the previous 3 months where auditors cited that QC was not being performed on time.

Data showed that QA observed that over the course of 3 months, 30 studies were audited, and there were 7 instances where the QC was not performed on time.

Therefore, it showed that there was a 77% compliance rate for performing QC on time.



## PROGRAM MAINTENANCE

Maintaining a Quality Metrics program takes diligence and flexibility. The effectiveness of the program should be monitored to ensure that it is useful and continuing to improve the quality culture.

### Diligence

There must be an owner of the program that monitors its effectiveness. It takes time and effort to review all incoming data that are used to produce the metrics. It is critical that the data used are valuable and reliable.

### Flexibility

The Quality Metrics program must be designed to be flexible. It must be able to adapt to the trends of the facility and industry. If a trend is developing in the facility, the Quality Metrics program should be able to adapt to collect data on the trend. Feedback from management and stakeholders must be taken into account when monitoring the program. It is important that the Quality Metrics program is still a useful tool, therefore, changes will need to be made to the program based on feedback to ensure the program's usefulness to management and stakeholders.

## CONCLUSION

Metrics can be a powerful tool that a facility can use to determine quality, compliance, effectiveness, and efficiencies. The quality culture of the facility can be enhanced by implementing a Quality Metrics program. Reviewing QA audits, deviations, CAPAs, sponsor audits, and regulatory audits can help management determine how its facility is functioning on a quality and compliance level. It can help determine if additional resources are needed or if process improvements are warranted. With the buy-in of management and stakeholders, and reliable data, a Quality Metrics program can be a key tool in a site's quality management system.

**Disclosures:** Data used in case studies and graphs are for illustration purposes only and not true representation of Altasciences' Quality Metrics.

**Reference:** <sup>1</sup>Julie Young (2023 February 02) Investopedia  
<https://www.investopedia.com/terms/m/metrics.asp>