Implementing Quality Management Processes to Assure Data Quality

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BACKGROUND

- Processes to protect data integrity and reliability are paramount to support patient safety and product quality. However, the "controls for data integrity do not necessarily guarantee the quality of the data generated," as recently recognized by the UK Medicines & Healthcare Products Regulatory Agency (MHRA) in its 'GxP' Data Integrity Guidance and Definitions.[1]
- Implementing a quality management process aligned with the Plan-Do-Study-Act (PDSA)[2] framework and incorporating a control strategy that holds staff accountable for data quality at critical document deliverable stages is essential to assure data quality in research output.
- There is a potential in organizations that have a quality review process to also have deviations to that process related to:
  - Process form control and usage
  - Training on the quality review process
  - Ensuring the timely acquisition of required form signatures

OBJECTIVE

- To explore the implementation of a quality management control strategy and its potential impact to assure data quality in research output.
- To discuss the potential post-implementation monitoring and performance indicators that can be used to assess impact and risk associated with the data quality review process.

METHODS

- The control strategy implementation includes three layers of a data quality control procedure that, when applied operationally to document deliverables:
  - Confirm the accuracy of data, information, and analysis
  - Verify the validity of the scientific content and interpretation
  - Ensure that appearance and writing (when applicable) meet internal quality standards
- The integration of a controlled quality review checklist in the procedural workflow requires independent data review signatures prior to the deliverable release:
  - Peer quality control (QC) review ensures data are accurate and interpretations are valid
  - A team member (senior reviewer) responsible for a review ensures technical content is accurate and interpretations are valid
  - A team member (editor) responsible for a review ensures spelling, grammar, punctuation, clarity, consistency, and formatting are accurate
- Evaluate how compliance with the data quality management process could be monitored through internal process audits, client project audits, and management review of performance indicators.
- Study results from this PDSA iteration will apply as lessons learned to strengthen the process performance within the quality management system.

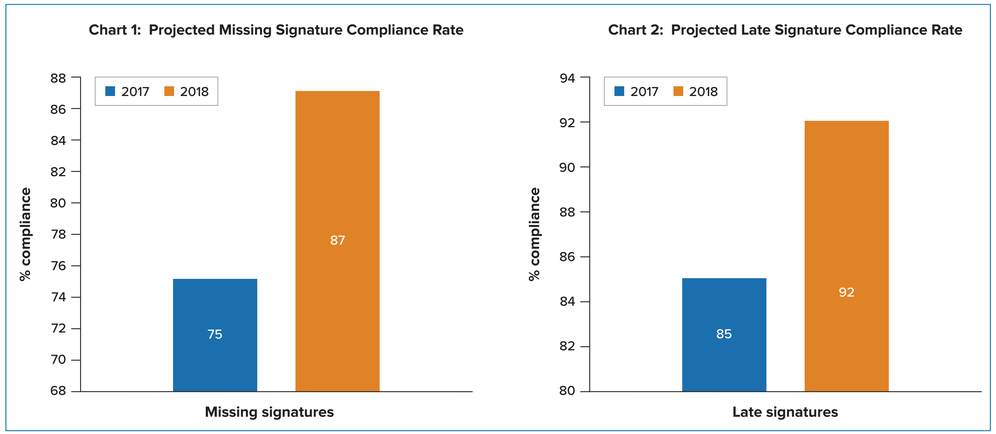
RESULTS

- By evaluating this process and projecting impact, it was expected that quality review deviations would decrease significantly over a 2-year period with a direct correlation to the following improvement factors:
  - Implementation of a quality review checklist available to all project teams
  - Training on the quality review process and related forms
  - Implementation of an e-signature tool to facilitate the timely acquisition of form signatures
- Important factors in the evaluation of post-implementation data included:
  - A consistent internal audit approach such as:
    - Annual internal process audits of the quality review process
    - Calibrating the audit team approach to scope and document review to provide longitudinal data trending across observation categories and standard operating procedure (SOP) deviation reporting
  - Consideration of reporting factors and the effect on data analysis:
    - Reporting distinctions between contemporaneous and retroactive quality review SOP deviations
    - Reporting distinctions between self-reported deviations and those driven by internal process auditing
    - The implementation of an electronic signature tool for quality review signature documentation
  - Consideration of training as a solution to improve compliance.

Figure 1. Control Strategy PDSA

Figure 2. Quality Review Progression Workflow

Figure 3. Projected Quality Review Checklist Signature Compliance Rates With E-signature Implementation



Note: Data shown are not real.

DISCUSSION

- Achieving high-quality research output and professionally consistent performance requires commitment to continual improvement. Projection of 2-year data revealed questions that would require attention as the control strategy evolves into the next PDSA iteration.
  - Question: Does the quality review process need refinement based on the projections and demonstration analysis?
    - Continuous improvement efforts will focus on procedural compliance and other approaches to quality-related training. Data trending on corrective and preventive actions, root cause analysis, and contemporaneous deviation reporting will be included toward the next PDSA iteration as the organization moves forward with additional compliance data.
  - Question: What may cause variation in reported SOP deviations?
    - Unplanned deviations could be correlated to corrective and preventive actions initiated by internal process audits and the corresponding audit outcome requirements.
    - Such a trend of unreported deviations captured by the internal audit process could raise additional questions regarding contemporaneous self-reporting and procedure comprehension.
  - Question: What could cause variation in the quality review internal process audit results?
    - The number of contracted document deliverables often varies by project. This may impact the project audit sample if selected according to operational group project volume.
    - Misfiled document evidence could impact this audit result.

CONCLUSIONS

- Utilizing a well-regarded performance improvement tool could produce an opportunity to establish baseline data quality control at critical document deliverable stages. Although there is projected generalized compliance, the necessity of compliance monitoring through strategic internal process audits and defined indicators was evident.
- Despite implementing an electronic signature tool and defined process, deviations may still occur. Although fewer deviations were expected to occur within the established process, it may be difficult to assess the total number of deviations due to factors identified such as self-reporting and consistency of internal process audits.
- Minimizing selective reporting and decreasing planned and unplanned deviations will be addressed by establishing a focus group to provide input on the quality review process, evaluating training as a solution to improve compliance, and conducting unannounced internal audits to assess real-time procedural compliance.

REFERENCES

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2. Deming WE. Plan-Do-Study-Act (PDSA). Available at: https://deming.org/explore/p-d-s-a. Accessed 21 March 2019.

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