Paper PP13

Oversight of Vendor Deliverables: A Layered Approach for Statistical Programming

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ABSTRACT

Effective oversight of vendor deliverables in clinical trials is critical for every sponsor to ensure compliance with regulatory standards, maintain data integrity, and quality. We developed a structured and layered approach for reviewing statistical programming outputs, designed to minimize risk, enhance quality, and optimize resource utilization. The framework comprises three levels of oversight—initial automated verification, semi-automated detailed review, and optional focused review for high-risk studies. By integrating automation and continuous improvement principles, this approach supports early error detection, systematic verification, and adaptability across diverse study contexts.

INTRODUCTION

In alignment with the ICH E6(R2) Good Clinical Practice and ICH E9 Statistical Principles for Clinical Trials, sponsors must safeguard data integrity and implement robust quality management processes [1] [2]. Sponsors of clinical trials retain ultimate accountability for regulatory compliance, even when tasks are delegated to Contract Research Organizations (CROs) or vendors. Oversight of statistical programming deliverables is a crucial component of these responsibilities, requiring systematic procedures to detect inconsistencies early and to ensure outputs meet regulatory and industry standards. This oversight becomes even more complex when coordinating multiple vendors across different study phases. Additionally, ensuring that programmers dedicate the ideal amount of time to manage vendor deliverables present its own challenge.

LAYERED OVERSIGHT FRAMEWORK

Vendors and CROs generally conclude their responsibilities once they have conducted specific study-related activities and delivered the agreed study package. The sponsor's responsibilities, however, continue well beyond that point. Oversight obligations extend throughout the lifecycle of the investigational product, from trial conduct and reporting to regulatory submission and eventual post-approval obligations.

We propose an oversight model that includes automation solutions to reduce the risk of missing critical checks to identify the issues at early stage. We propose an oversight model that includes automation solutions to reduce the risk of missing critical checks to identify the issues at an early stage. The model comprises three distinct layers that not only facilitate early detection and communication of issues but also optimize resource allocation. It ultimately leads to a more efficient oversight process by preventing the spread of errors and reducing unnecessary expenditures on oversight and resources in later stages. The model aspires to evolve toward a Continuous Integration/Continuous Deployment (CI/CD) model, incorporating lessons learned into automated checks and reducing manual effort over time.

The layers are checked consecutively, and the process ends when a deliverable does not pass a given layer check. If a layer check fails, comments are sent to the vendor or CRO, and updates are required before the deliverable is resubmitted and the failed check is restarted. When a layer check passes, we proceed to the next layer until all layers have been checked.

The proposed oversight model consists of three distinct layers. A schematic overview the process can be found in Figure 1.

Layer 0: Initial Verification (Fully Automated)

The first layer, called Layer 0 as it is a fully automated process with no or minimum human expertise involved, is executed once the delivery is received by the sponsor. This includes checking whether all expected components are received, validating basic data formats and structures, and assessing documentation completeness.

Layer 1: Detailed Review (Semi-automated)

Layer 1 is the first layer that requires human expertise, rather than relying solely on automated checks due to study dependency checks. In this layer, several technical and analytical components undergo comprehensive examination. Key checks include adherence to sponsor and industry standards, assessment of submission readiness of artifacts, and verification of critical variables (e.g., N counts, flags such as FASFL and SASFL) against the Statistical Analysis Plan (SAP) or Clinical Study Protocol (CSP).

Layer 2: Focused Review (Optional)

This final layer is optional and is performed only for critical studies. It provides a focused review that is narrower in scope and concentrates on components requiring additional scrutiny due to complexity and/or risk. The depth and scope are tailored to study-specific needs, and all vendor responses to comments are tracked and resolved. Most checks in this layer are non-automated and therefore require human expertise.

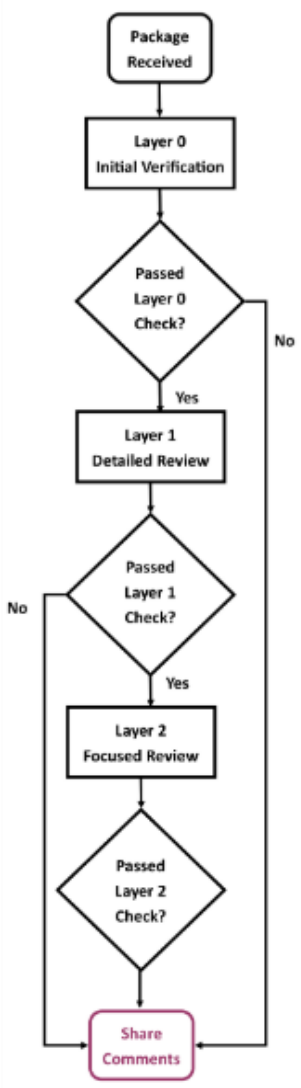

Figure 1. Flowchart of the layered oversight process for vendor deliverables, from package receipt to focused review and vendor feedback loop. CI/CD aspiration emphasizes continuous automation and learning.

DISCUSSION

The layered approach offers four major advantages. The first is the systematic verification: by breaking down the review process into distinct layers, each within a specific focus, organizations can systematically verify every aspect of their deliverables. This ensures thoroughness and minimizes the risk of overlooking critical details. The second advantage is early error detection: automated checks at Layer 0 prevent error propagation into downstream analyses, saving time and resources in later review stages. The third advantage is flexibility and adaptability: the framework adapts to diverse study requirements and risk profiles, and it can also be adjusted based on study learnings by enabling teams to enhance or streamline the process over time. The fourth and last advantage is the quality enhancement: early issue resolution and traceable feedback loops improve the reliability and submission readiness of outputs. Leveraging automation and iterative refinement enables sponsors to meet regulatory obligations efficiently while scaling oversight across studies and vendors, thereby reducing operational risk.

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CONCLUSION

A layered oversight strategy for vendor deliverables strengthens compliance, ensures data integrity, and optimizes resources in clinical trials at each stage. It is a continuously evolving process that adds new checks and expands automation as much as possible to perform them in minimum time. Future developments should also prioritize the integration of CI/CD principles and the standardization of check libraries to achieve near-real-time quality assurance across programs.

REFERENCES

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