

Oversight of vendor deliverables- A Layered approach

To enable consistent and automated oversight, minimizing the risk of overlooking critical issues

Author: Pramod Chittam – Pramod.Chittam@astrazeneca.com
 Co-Author: Camille Raets – Camille.Raets@astrazeneca.com



Why

In accordance with ICH E6 (R2) Good Clinical Practice (GCP) and ICH E9 Statistical Principles for Clinical Trials:

- Ultimate Accountability:**
 Sponsors retain responsibility for regulatory compliance, even when tasks are delegated to CROs or vendors.
- Safeguarding Data Integrity:**
 Sponsors must ensure high data quality and research integrity throughout the study.
- Quality Management:**
 Implementation of robust quality assurance and control processes, including monitoring, auditing, and risk management for all delegated tasks.
- Oversight of Statistical Processes:**
 Sponsors are responsible for reviewing statistical programming, data analysis, and reporting, and ensuring all outputs meet regulatory standards.
- Effective Vendor Oversight:**
 Managing deliverables across multiple vendors demands systematic oversight—including clear procedures for early detection of inconsistencies and assignment of dedicated personnel.

How

- Layered oversight approach** enables systematic review of deliverables and reduces errors through targeted automation.
- Benefits:** Maintains data reliability, reduces the risk of missing critical issues, optimizes resource use, and supports sponsor accountability throughout all study phases.

What

The structured, layered approach offers several advantages while reviewing statistical programming deliverables:

- Systematic verification:** Distinct review layers ensure thorough and reliable assessment of every aspect of their deliverables.
- Early error detection:** Identifying and addressing issues at the earliest possible stage (Layer 0) prevents the propagation of errors, saving time and resources in later review stages.
- Flexible and adaptable:** The structure allows for adjustments based on study needs or lessons learned, enabling teams to enhance or streamline the process over time.
- Quality enhancement:** Layered checks support early issue resolution, improving the overall quality and reliability of statistical programming deliverables.

Oversight checks are categorised into three layers that serve as gates for oversight:

Layer 0: Initial Verification – Fully automated

The checklist of automation solutions for effortless checks.

Layer 0 examples:

- Are all expected components received?
- Are the basic data formats and the structure, correct?
- Review overall completeness and appropriateness of documentation

Layer 1: Detailed review - Semi automated

Comprehensive examination of the technical and analytical components of the deliverables.

Layer 1 examples:

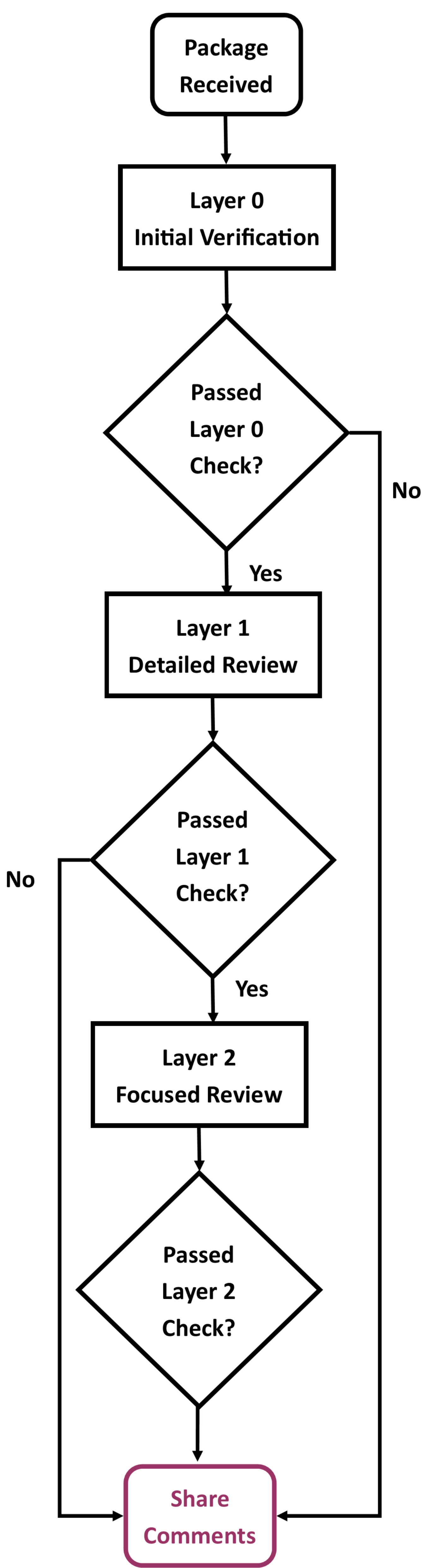
- Ensure AZ standards and industry Standards are followed.
- Applicable artifacts are submission ready.
- Ensure N counts and basic flag (e.g. FASFL, SASFL) variables are as per SAP/CSP.

Layer 2: Focused review

Optional, only required for critical studies. Highest level of oversight and is determined by the content and context of each study.

- Narrower in scope
- Concentrated on components that may require additional scrutiny or are considered substantial risk.
- Adjust the depth and focus of the review based on specific study needs and complexity.

Communicate all the comments to vendor. Ensure all comments are addressed by vendor.



Aspiration-CI/CD

Oversight of vendor deliverables should be a continues evolving process of adding new checks and automizing as many check as possible to perform the checks with minimum time.

- Lessons learnt and new findings are transformed into checks.
- Perform checks
 - Based on the study design
 - Vendor
 - With minimum time and effort