Research | Validation | Adoption

A Structured, Transparent Framework for Developer-Funded Validation Peer Review: Alignment with OECD GD 34 and Contemporary Data Integrity Expectations

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Background

Peer review is essential for regulatory confidence in toxicological methods, especially complex validation packages supporting non-animal and innovative technologies. Practical guidance for transparent, credible, and regulator-relevant peer review is limited, particularly when funded by method developers. Recent revisions to OECD Guidance Document 34 (GD 34) highlight increased expectations for data integrity, documentation quality, and traceability, elevating the importance of robust and transparent peer review processes.

Objectives:

- Present a practical roadmap for independent peer review of developer-funded validation packages
- Maintain scientific rigor, transparency, and regulatory relevance
- Emphasize process design, governance, and documentation to support robust scientific findings

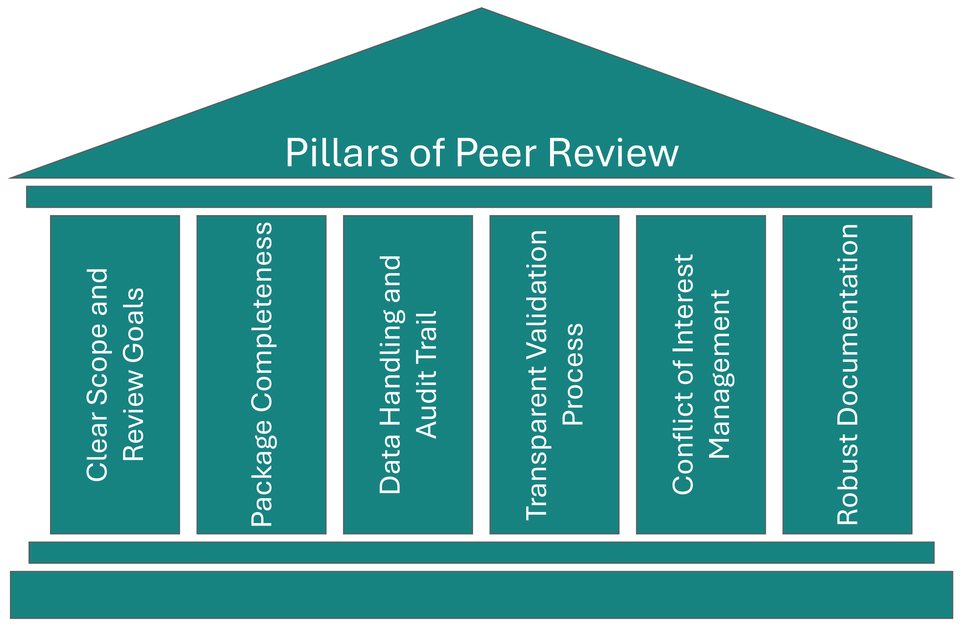


Figure 1- Key pillars of peer review to support a comprehensive, unbiased, transparent process

Scope Clarification and Review Goals

Prior to convening a peer review panel, the peer review management team, engaged by the method developer to act as a neutral third party, should define the scope and develop review goals for the peer review.

- Key Considerations:
  - Scope of the validation study and supporting data
    - Stage of method development
    - Validation aspects (reproducibility, transferability, relevance, predictive capacity)
  - Availability of data for review, Validation Project Plan, Validation Study Report (VSR) and standard operating procedure (SOP).
  - Drafting of review questions to meet the needs of the peer review panel

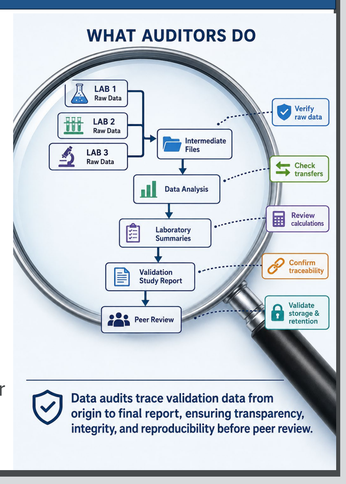
Data Handling and Audit Trail

Data audits provide objective evidence of the quality and integrity of data presented in the VSR. This ensures that peer review decisions are based on credible, traceable, and reproducible data.

Data audits evaluate:

- Authenticity of the data
- Traceability from raw data to VSR
- Reliability and consistency of data handling and analysis
- Data availability continuity

Data audits should be conducted by independent auditors, not peer reviewers, to maintain separation among the peer reviewers and method developer, who may be required to make modifications based on the audit. It is important to complete data audit activities before peer review begins so that discrepancies can be resolved.



Package Completeness

During the development of the peer review scope and goals, the validation package should be reviewed for completeness.

Items included in a package are dependent on the validation stage under review. At a minimum:

- Description and application of the method
- Definition of the scope of validation
- Study Design
- Identification of participating labs
- Training and transfer plans
- Chemical list
- SOP (and any edits)
- Data evaluation methods
- Raw data availability
- Results
- Quality control and quality assurance

Transparent Validation Process

The peer review panel and management team must have insight and documentation of the validation process to fully understand what decisions were made, why they were made, and how such decisions affected SOP, VSR, and other step changes within the validation study. Key features to note are:

- Records of Validation Management Team (VMT) meetings and discussions
  - Notes on discussion of reference chemical choices, methods updates, lab processes, data handling, etc.
- VSR updates (from final draft to published report)
  - Some may be at the request of the peer review panel, communicated through the peer review management team to the validation management team
- Full documentation of all edits to the SOPs

Transparent Conflict of Interest Process

Prior to assembling a peer review panel, conflict of interest (COI) and potential bias should be assessed for panel participants. Standard Declaration of Interest (DOI) forms address co-publications with the method developer, funding or co-funding, other efforts where the expert and method developer have collaborated, and potential competing interests. DOI reviews for identification of conflicts and the conduct of the peer review panel should be overseen by the management team.

Peer review panels funded by the method developer inherently introduce bias. Additional layers of agreement/transparency in the conduct of the panel, with external oversight, are necessary to minimize perceived and actual bias and conflict. These concerns and potential safeguards should be discussed and agreed upon before any funding transfers from the method developer to the peer reviewer. The management team should handle the entire process, including payment.

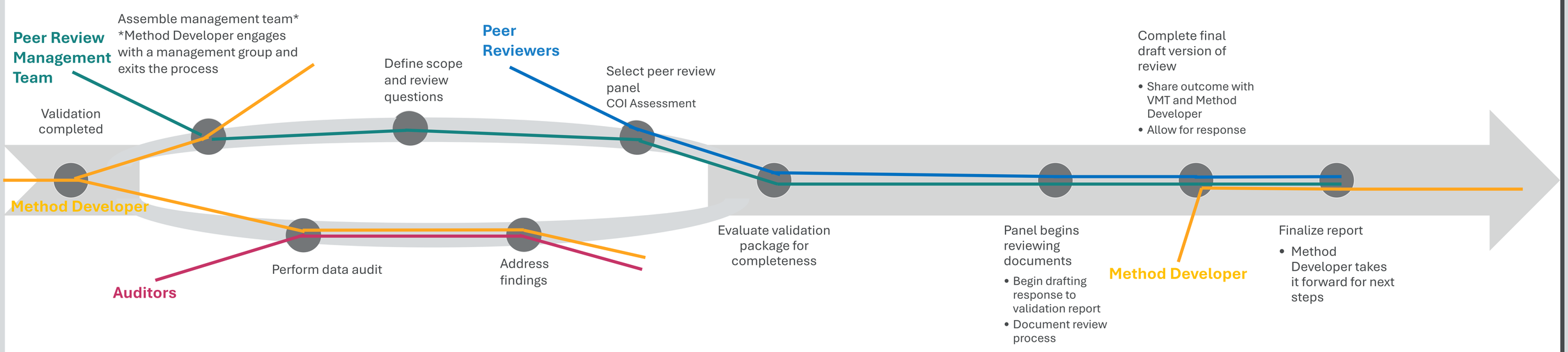
Documentation of Review Process

Before any meetings or documents are signed, the management team should establish methods to document all efforts by the peer review panel. Typically, a shared drive or other online resource is sufficient to store all documents and allows for collaboration between peer reviewers outside of meetings.

All meetings should be recorded, with summaries that cover all interactions. Any interactions between the peer review panel and the method developer or VMT should be documented and scheduled by the peer review management team. There should be no direct communication between the method developer and the peer review panel without the inclusion of the management team.

Following completion of the peer review, final versions of the validation report and peer review report and documentation of both processes should be made publicly available.

Peer Review Process



Discussion

Process and Governance

- Responsibility for data integrity lies with the validation management team and the method developer.
- The peer review panel relies on data reliability assurance.
  - Focus on data integrity, version control, and auditability
- The peer review framework enhances transparency, reproducibility, and alignment with GD 34 principles.
- Openness and transparency are required for successful method developer-funded peer review.

Conclusions

- Method developer-funded peer review is possible with appropriate guidance and documentation, while limiting implicit bias.
- Oversight by a third party is highly recommended.
- Oversight is necessary to support the increased need for validation and peer review.

References & Acknowledgments

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OECD (2018). Guidance Document on Good In Vitro Method Practices (GIVIMP). Series on Testing and Assessment. Paris, France, Organisation for Economic Co-operation and Development.

This project was supported by the Intramural Research Program (ES# 103386) at the National Institute of Environmental Health Sciences, National Institutes of Health (NIH), under contracts HHSN273201500010C (Inotiv, Inc.) and the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI), NIH, under contract GS-35F-393CA - 75N94025F00103 (General Dynamics Information Technology). GDIT staff provide technical support for ORIVA but do not represent NIH, DPCPSI, or the official positions of any federal agency. The findings and conclusions in this presentation are those of the author(s) and do not necessarily reflect the views of the NIH or the U.S. Department of Health and Human Services.

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Office of Research Innovation, Validation, and Application (ORIVA) Contract Support

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