

Peer Review for Validation Studies - Building Confidence and Transparency into a New Validation Paradigm

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Conducting a peer review of a validation study is a key step toward both gaining regulatory acceptance and development of an OECD test guideline. Historically, peer review panels have been convened under the purview of the various national validation organizations following a comprehensive, multi-laboratory validation study that is typically managed by the same validation organization. However, OECD has called for external support for validation studies, and suggested that validation studies and subsequent peer review be funded by test method developers. This suggestion introduces a plethora of questions and concerns about how the validation and peer review can be conducted in a sufficiently transparent manner, without concern of conflicts of interest that may bias the outcome. In this talk, we will consider as a case study a recently conducted peer review panel that was supported by the test method developer. We will discuss the steps taken by the peer review panel to ensure independence from the test method developer to foster a transparent and unbiased process. We also discuss how we confirmed that data and supporting documentation submission packets were complete and correct. The presentation will summarize lessons learned throughout the process. A discussion following the presentation will allow the audience to provide feedback on what was done and share ideas/suggestions on further improvements. This project was funded with federal funds from the NIEHS, NIH under Contract No. HHSN273201500010C.