

Model qualification and relief from regulatory review** :

Illustrative* table based on draft ICH M15 Guideline

*does not represent ICH M15 group consensus

Question of Interest	Model provides Primary Evidence	Model provides Primary Evidence	Model provides Primary Evidence
Context of Use	Uses Non-Qualified Model	Within Qualified Model Scope Using Qualified Platform	Within Qualified Model Scope Using Alternative Platform
Model Impact	High (not regulatory standard)	Low (Regulatory Standard)	Low (Regulatory Standard)
Model Influence	High	High	High
Consequence of wrong Decision	Case Specific	Case Specific	Case Specific
Model Risk	Case Specific	Case Specific	Case Specific
Appropriateness of planned use	To be aligned	**Accepted	** To be aligned but there is regulatory precedence with platform model
Applicability to specific Question of Interest	To be aligned	**Focused on Additional Data and Associated Model Validation	** To be aligned but there is regulatory precedence with platform model
Model Evaluation & Technical Criteria	To be aligned	**Informed by Qualification Opinion but also Case Specific	To be aligned