



Workshop on ICH M10

Input and comments from round tables

Round table: Scope Interpretation – Rare Matrix vs. Tissues

Moderators: Steve & Salvatore

14 November 2023 – Barcelona, Spain

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Comments:

- Discussion focused on tissues & “rare” fluids (e.g. CSF, tears, BAL, vitreous humor)
- Very uncommon where this is primary matrix
- As an “additional matrix” it is important to understand end use of the data
- Understood that we analyse tissue homogenate and not tissue
 - Recovery never known (in absence of radiolabel)
 - Stability can only be assessed in homogenate
- Cannot apply all elements of M10
- Use surrogate matrix for calibration standards where possible

Recommendation:

- Understand Context of Use
- Apply Scientific/fit for purpose validation

Action:

- Revisit EBF publications on Tissues (2014) and SV (2015) in the context of tissue analysis post M10