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Workshop on ICH M10

Input and comments from round tables
L03 – Surrogate/rare/preclinical matrix for LBA

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Theme/question:
Definition of rare matrix… is this clear for everybody?

Comments:

- Availability of the matrix (in stock…)
- Partially cost (but not a argument for the agencies)
- Rare matrix definition is not 3R driven

Recommendation: use surrogate matrix in a pragmatic way

e.g: synthetic CSF with additives if needed. Surrogate matrix should be close to original matrix (for AH -> buffer plus additives)

Theme/question:
How and when to use surrogate matrix

Comments:

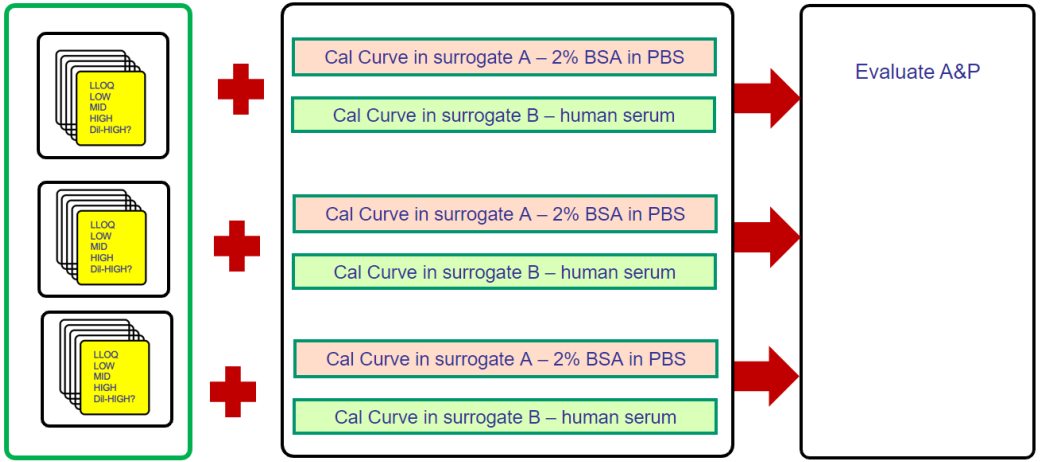
- Early on in first development … Start with surrogate

But:

- Proof that it provides the same results and is a true surrogate?
- Run comparison between surrogate and original matrix
  - During development/validation: QC, selectivity, dil. linearity in both matrices are mandatory

Routine sample analysis: participants felt uncomfortable to use only surrogate matrix for QC. Calibration curve and sample dilution surrogate can be used

Bu: Experimental plan reducing preclinical matrix



- Experimental proposal provided in word doc
- QCs in original matrix, calibrators in two different surrogates
- VHQC and limits optional.
- Surr B could be human or alternative (e.g. horse)
- No restriction on platform
- Total Assay formats