Workshop on ICH M10

Input and comments from round tables

Primary matrix *vs* additional matrix

Moderators:

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Theme/question: How we define primary matrix ?

Comments:

Matrix with kinetic data: Matrix to define the exposure of the drug

PK characterisation: plasma/serum

We felt it was clear but not everybody could put it down in words

Recommendation/Action: Can a decision tree be useful?

Theme/question: Definition additional matrix ?

Comments:

Depending on the scope of use

What is not primary matrix

Recommendation: Call it additional matrix, not secondary matrix, as in the guidance

Action: CLARIFICATION REQUIRED

Theme/question:
What is the minimum requirement for additional matrix validation?
Are you clear on what is required to validate additional matrices?

Comments:
It depend on the context of use. Some rooms did not vote
Some rooms voted 50:50

Not clear, almost agreement to refer to the context of use

Action: AWARENESS AND FURTHER DISCUSSION

Theme/question: Stability required for additional matrices
What about stability ?

Comments:
Some doing stability for all additional matrices
Other refer to the context of use to decide

Recommendation: Discuss context of use

Action: AWARENESS AND DISCUSSION

Theme/question: Additional matrices you are you collecting but not analysing unless required ?

Comments:

Some says : analysed all sample described in a protocol

What about Gene therapy / Oligo / Ocular matrix

Some says collected if required after PK plasma data analysis

Some Pharma do that (At least 4 cases)

Action: AWARENESS