



Workshop on ICH M10

Input and comments from round tables

Pivotal Studies Definition

Moderators:

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Theme/question: Defining Pivotal Studies Definition – Do you understand ‘pivotal study’?

Comments:

- Not only the definition of “pivotal study” itself seems to be very controversial, also the decision which study is a pivotal study is the sticking point
- ICH M10 clearly (?) states which studies require ISR from a regulatory point of view, but pivotal study in the context of ISR seems to cause confusion
- People tend to do more than needed (apply ISR assessment to each study) not only because of the lack of understanding which studies are ‘pivotal’ but also because of the fear to miss something
- Risk-based approaches are barely implemented, because ISR assessment is ‘an easy exercise and avoids questions of agencies, so why not do it?’
- Definition of pivotal study is not crucial at all if we ‘just always assess ISR’, ISR assessment should always be done during studies that create pivotal data

Recommendation:

Don’t raise the bar!