Break-out session 2:

New strategies for streamlining clinical trial review and approval processes

Presented by Monique Al on 11 09 2024
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Key Topics

- Change protocol only applicable for EU region, EU specific addendum allowed?
- Protocol update during assessment phase. Also allowed to implement other changes (non-SM). More helpful to have a complete protocol
- Aligning MSs - Separate part I more from part II? Finalise part I together and then finalise step 2
- Timelines: reducing timelines for simple SMs
- SM part I and part II – simplifications to prevent blocking submit SMs
- More coordination on consolidated considerations to reduce the number of considerations on RFI. Role of RMS vs role of MSC .
- Communication outside CTIS system about clarifications RFI.
- Working outside CTIS – how to bring this back into CTIS.
- Part II RFI – diversity, inconsistency in questions depending on who is the selected MREC. Are there harmonisation actions foreseen?
- Part II conclusion early and not able to re-open. Not close part II before part I conclusion.
- Coordination between part I and part II – the how issue will resolved. When is important as well.

- Substantial modification to align part I and part II. Expedited approval for these kind of SMs.
- CT authorised with conditions has increased. Use of non-SM (81.9 non-SM or other non-SM) or expedited assessment not to delay start of CT
- Risk based approach if documents already approved by other MS. For instance, IBs. Or in case of additional MS.
- More clarity on conditions – also with respect to specific MS conditions. And could the latter be assessed expedited.
- Have an overview of the conditions in CTIS
- Less restrictive procedure of adding MSs during ongoing SM part I.
- SM to fulfill conditions. Conditions are not always related to patient safety, science. Many times, more administrative (statistical plan). Please be explicit on which conditions should delay start CT or not.
- Low intervention clinical trials – more liberal interpretation of scope LICT. And a risk-based approach in assessment. Incentive for more TOS trials?
- Transparancy on which MS are addressing the part I consideration for strategic reasons (also in RMS selection)
- Mimic centralised procedure authorisation application –
- RMS negative conclusion part I – MSC cannot opt-out . Decision taken by majority?
- Contacting RMS for clarity and then RMS refers to MS who raise the consideration. For MS specific considerations, please mention name MS.