EMA - personal data / CCI documents workshop
14th July 2022

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Available guidance on deferrals not nuanced enough

Need for more clarity & predictability on principles to be applied by MS, guidance in writing

- Justifications are to be based on 'marketing authorisation status, pharmaceutical forms and routes of administration' – need for tangible examples of sufficient justifications
- How to ensure consistency between MS in its application? Need to ensure MS are consistent across trials for the same active substance, and category of trial

Redaction of documents

- CCI evolves over time, so level of redaction is dependant on length of deferral
- Documents are redacted and uploaded into the system before decision on duration of deferral timeline is known
- Need to reverse order, or otherwise need more predictability on what the likely deferral period will be at time when redacting
- How do we ensure that MS Assessment reports are deferred & redacted in line with sponsor's redactions / agreed deferral

CTIS RFI field redaction

- EMA built-in functionality allows a sponsor to provide responses in the CTIS field -or- by way of an attached document
- One EU Member States has requested that sponsor use RFI field rather than attachments, however the RFI field does not allow redactions.
- Sponsors should have the flexibility to choose how to provide responses to RFIs
  - Would like confirmation from EMA that uploading RFI response documents is equally as valid for responding to an RFI as populating a response in the free text field.