Protection of personal data and CCI for documents uploaded to CTIS
EMA Workshop 14-July-2022

Session 1

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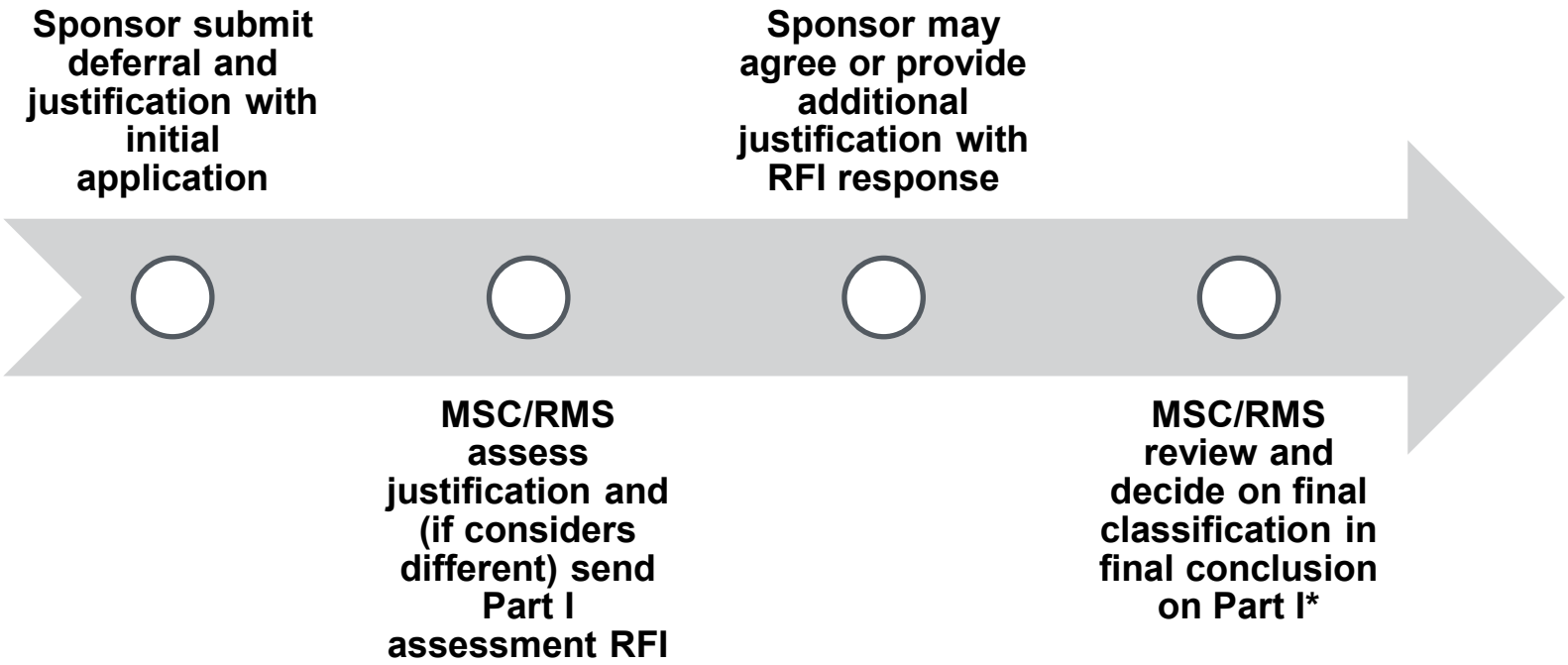
Deferrals are set at Initial Application



- MSC/RMS inform sponsor on deferral timing for their data / documents with the decision
- MSC for their Part II
- RMS for their Part II and for Part I
- The deferrals set at initial trial decision also apply to all subsequent applications throughout the trial life cycle

*Section 4.3.3 EMA/228383/2015 Endorsed "Appendix, on disclosure rules…"

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Publication Deferral is Trial Centric

Trial specific deferral of publication for same product documents (IB, IMPD-S&E) when used across trials

Different legal framework between trials, e.g. trial category, trial part of PIP or includes pediatric population, or trial under REGULATION (EU) 2022/123 (crisis preparedness trial)

Sponsor's **deferral justification may not be consistently accepted** by different MSC(s) across trials

Deferral periods individually triggered in each trial, e.g. initial trial application is "not authorized" or "early termination" the "end of trial" deferral timing immediately triggered

Publication triggered when CSR is submitted after **end of marketing authorization procedure** initial MA or variation or line extension in EU **in any procedure**

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Deferrals – Sponsor Data/Documents

Predictability that Member States do follow sponsor proposed deferral justification when trial category in line with the correct trial phase?

- e.g. reliability of justification for product documents used across trials
- Justification already accepted in another trial

When multiple IMPs/AxMPs used in trial, would the product requiring the most stringent confidentiality (e.g. test IMP) justify the overall deferral of product related data/documents?

- **Deferral timing of IB, IMPD-S&E per trial** not per each product

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Deferrals – MSC Data/Documents

Predictable criteria when Member States will a) follow, b) apply shorter, or c) apply no period of the sponsor proposed publication timepoint?

- RFI, Assessment reports, Conditions

Could MSC/RMS inform the sponsor of their envisaged publication timing already in their respective assessment reports rather than with their decision of the initial application (current CTIS behavior)?

- EMA/228383/2015 Endorsed "Appendix, on disclosure rules…", Section 4.3.3 : *The Member States will review and decide on the final classification of the trial in* ***the final conclusion on Part I*** *of the dossier.*

How do we ensure no CCI is disclosed in the final assessment report or decision supporting document, which is unaligned with sponsor's redaction / or publication timing of protocol or RFI response?

- Final assessment report includes large copy/paste information extracted from protocol, statistical analysis plan, and **full text of clinical and non-clinical RFI considerations / responses**

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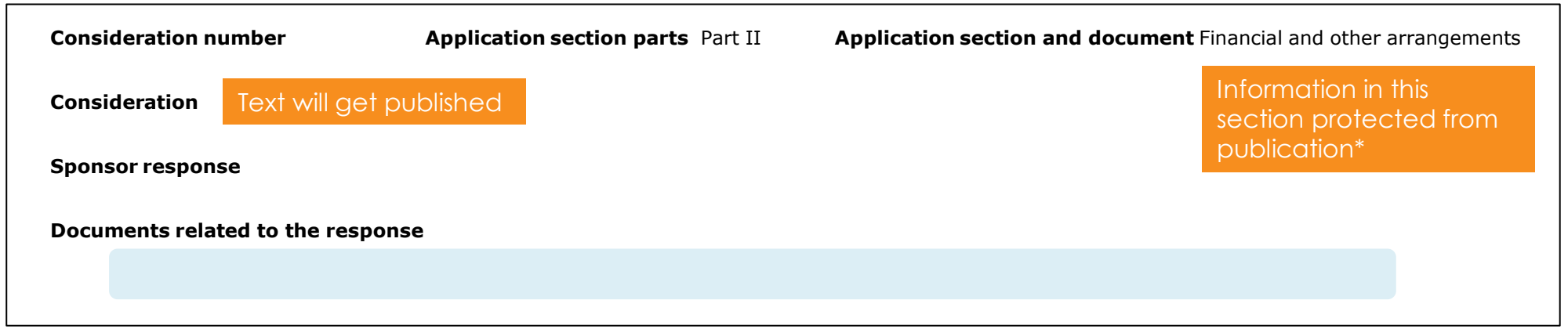
RFI text may refer to contents within protected Dossier Section



- RFI data fields cannot be redacted and will be subject to publication
- RFI consideration text may state information of a dossier section fully protected from publication while the related contents of the RFI consideration will be disclosed
- Short term solution needed, how MSC(s) describe information not appropriate to be disclosed (supporting doc?)
- Possible CTIS enhancement to protect these RFI's like Part I – Quality RFI's

*Exempt from publication according to section 4.8 EMA/228383/2015 Endorsed "Appendix, on disclosure rules…"

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