


# Protection of Personal Data and CCI for documents uploaded and published via CTIS:

## Workshop on draft guidance - CCI 14 July 2022



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- RFIs from Authority that contain CCI
  - Sponsor Justifications of Redactions
  - Protection of CCI by Member States



# Request for Information (RFIs) from Authorities

## Evaluation

**Consideration number** RFI-CT-2022-5  
-IN-006-06

**Application section parts** Part I - Clinical

**Application section and document** Protocol

**Consideration**

This Free Text Field entered by the Member State can contain CCI

**Sponsor response**

**Documents related to the response**

No document available

- By the time of an RFI, the sponsor has already applied CCI to documents in the Clinical Trial Application.
- Any CCI data in the RFI response would be made public, without the possibility to redact.




## 1088 **4.6.1. Deferral and publication of Assessment Reports**

1089 In order to align the timing for publication of sponsors documents and Member States Concerned  
1090 documents, the deferral mechanism has been implemented in CTIS also in the secure authority  
1091 domain.

1092 Whether by deferral or redaction, or both if applicable, the MSC may ensure that information which is  
1093 CCI is not in the public domain. Redaction of information to be published must be carried out where  
1094 CCI is present. When a sponsor has justified a piece of information as CCI, the MSC should take this  
1095 into account and redact or defer the publication of the information.

What is the justification process for CCI in CTIS?



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- Authorities appear to need a list of what the Sponsor considers CCI as part of the Initial Clinical Trial Application. Without this, it is unclear how CCI redactions would be maintained in CTIS.
  - If a CCI list is provided in CTIS, where would this information be provided?