

## Main points





- 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 Application section parts Part I - Clinical Application section and document Protocol
-IN-006-06

Consideration

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

Sponsor response

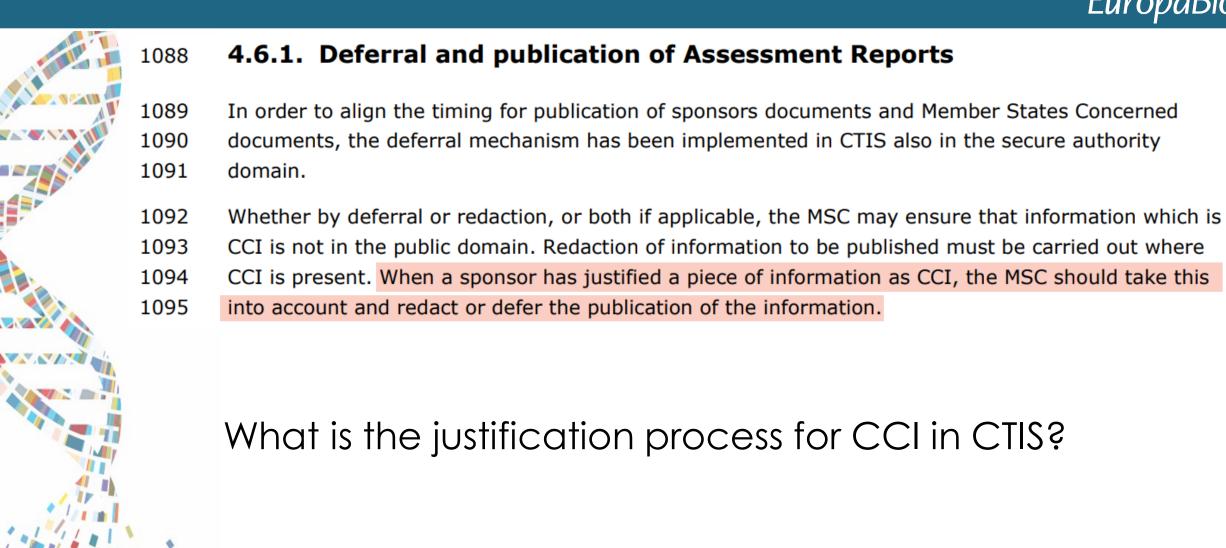
Documents related to the response

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.

## Company Confidential Information - CCI





## Protection of CCI in Authority Workspace





 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?