

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

Workshop on draft guidance – Personal Data
14 July 2022


Main points

- Data Minimization
- Article 81 (2) and (6)
- Redaction of not for Publication Documents




Data Minimisation Principle


CTTM12 - eLearning Presentation RESOURCES


 EUROPEAN MEDICINES AGENCY

A crucial aspect is that **users can only submit personal data to CTIS** to the extent that it is **necessary** to fulfil their respective **responsibilities** set out in the CTR. **No personal data should be captured** when it is not needed, in line with the data minimisation principle.




Sponsors, MAA/MAH, Member States and the European Commission are responsible for **uploading and submitting the necessary data and documents to CTIS** to fulfil their obligations under the Clinical Trials Regulation, and to do so in accordance with the requirements set out in Article 81(2) and(6) of CTR.





Data minimisation
You must ensure that the personal data you are processing is adequate, relevant and limited to what is necessary in relation to the purpose of the processing.

Personal data may only be submitted to CTIS insofar as it is necessary for the purposes of Article 81(2) of the CTR.



Click on the icons to read the relevant articles

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Article 81

EU database

2. The EU database shall be established to enable cooperation between the competent authorities of the Member States concerned to the extent that it is necessary for the application of this Regulation and to search for specific clinical trials. It shall also facilitate the communication between sponsors and Member States concerned and enable sponsors to refer to previous submissions of an application for authorisation of a clinical trial or a substantial modification. It shall also enable citizens of the Union to have access to clinical information about medicinal products. To this end all data held in the EU database shall be in an easily searchable format, all related data shall be grouped together by way of the EU trial number, and hyperlinks shall be provided to link together related data and documents held on the EU database and other databases managed by the Agency.
6. The EU database shall contain personal data only insofar as this is necessary for the purposes of paragraph 2.

- Sponsors following the Data Minimisation principle do not yet know what Personal Data is necessary to include in CTIS.

Redaction of not for Publication Documents

Cover letter *



Cover letter for initial



English · Cover letter (for publication) · **System version 1**
· **Version 1** · 02/11/2020



Cover letter with signature



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- Redactions currently needed in some “not for publication” documents, to comply with Data Minimisation Principle
- Working towards authoring documents without unnecessary personal data