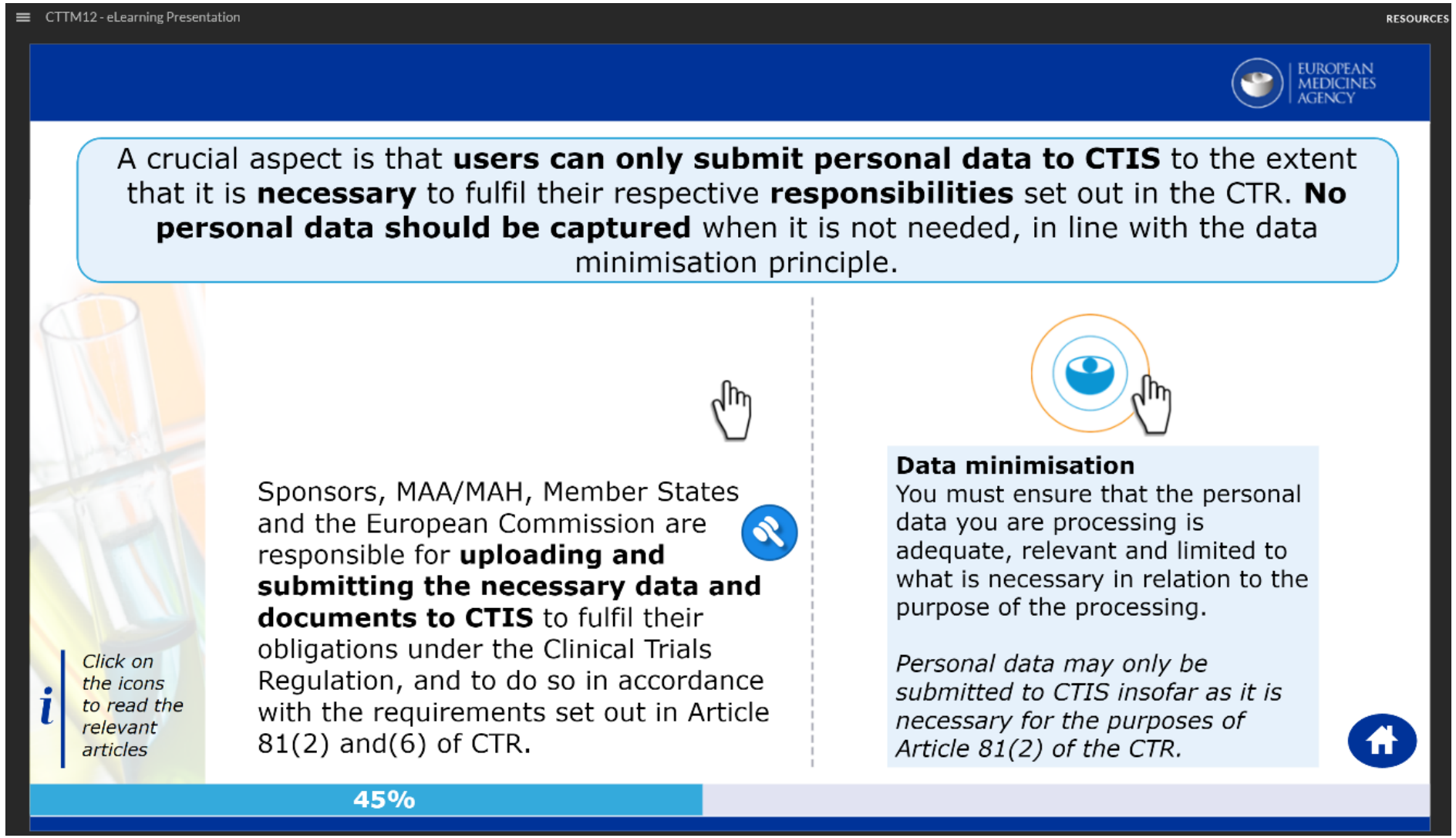
Protection of Personal Data and CCI for documents uploaded and published via CTIS:

Workshop on draft guidance – Personal Data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- Redaction of not for Publication Documents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



Personal Data & Article 81 (2) and (6)

Article 81

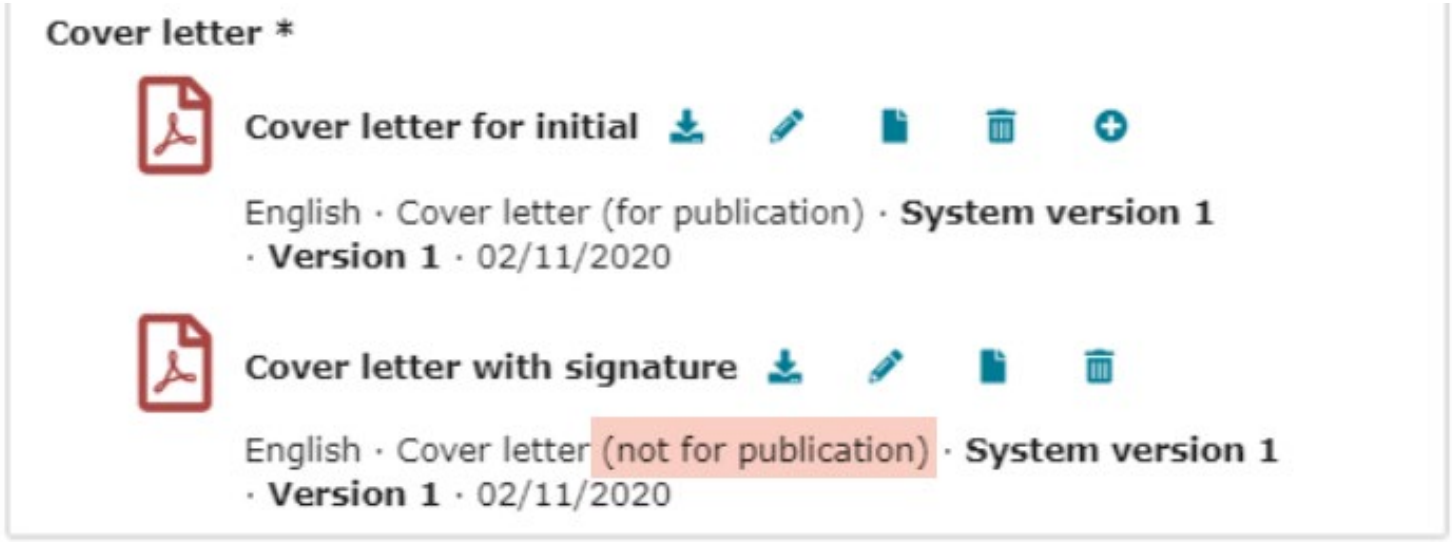
EU database

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Redaction of not for Publication Documents



- Redactions currently needed in some "not for publication" documents, to comply with Data Minimisation Principle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