



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Event Summary: Workshop on the guidance on the protection of personal data and commercially confidential information (CCI) in documents submitted or uploaded via CTIS – 14 July 2022

Background and objectives

A draft guidance document on how to approach the protection of personal data and commercially confidential information (CCI) in documents uploaded and published in the Clinical Trials Information System (CTIS) was made available for consultation on the EMA Corporate website: [Draft Guidance document on protection of personal data and commercially confidential information \(CCI\) in CTIS \(europa.eu\)](#)

On 14 July 2022, EMA hosted a dedicated workshop on the draft guidance, in order to share experience on the use of CTIS and initiate a discussion towards a common understanding and expectations on the protection of personal data and CCI while using the new system.

The workshop addressed three main topics, covering both Member States and sponsors' perspectives:

- experience with the use of CTIS, including deferrals
- protection of personal data: pseudonymisation, anonymisation, principle of minimisation
- protection of CCI

Participation to the workshop was by invitation only.

A summary of the major points discussed during the event is presented below, please refer to the presentations for more information.

Session 1: Relevant CTIS Functionalities

The session focused on CTIS functionalities implemented to allow users to protect personal data and commercially confidential information while using the new system. Transparency requirements on publication are mandated in the Clinical Trials Regulation (EU) No 536/2014, Article 81(4).

CTIS Users can upload a version of documents 'for publication' and one 'not for publication' to protect personal data and CCI. Deferral mechanisms have been introduced in the system to reduce the burden of redaction of CCI, by delaying instead the publication of data and documents.

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The following major points were raised during the session:

- An harmonised approach and predictability in Member States' assessment on the use of deferrals is important. This includes both the indication of acceptance of sponsors' proposed timelines for deferrals, as well as a consistent approach from the Member States to delay the publication of their Requests for Information (RFIs)/documents in line with sponsors' timelines, as applicable.
- On this respect, it was confirmed to sponsors that the Reference Member State (RMS)/Member State Concerned (MSC) will look at the deferral category rather than the proposed deferral duration period and will, probably, not challenge the duration of requested deferral. *Case by case assessment should also be considered in this respect.*
- It was also mentioned that most likely MSCs will apply the same deferrals timelines for the documents of their concern, i.e. assessment reports, and RFI, in line with sponsors' timelines.
- Sponsors raised concerns on the limited time available to produce documents suitable for publication when updating documents in response to an RFI and the fact that CCI can be included not only in documents but also in structured data.
- Deferrals are applied per trial application submitted to different MSCs. Consistency on the use of deferrals across MSCs when the same active substance is used in different trials is preferred. In this case, however, the specifics of the trial, such as if it is related to a public health emergency, population age and group, should also be considered and different deferrals rules may apply. For example, for trials conducted in case of a public health emergency, clinical trial data should be published in line with Article 7 of Regulation 123/2022.
- It was noted that limited time has passed since the application of the Clinical Trials Regulation (CTR) that introduces a new way of working for both Sponsors and Authorities. It is important to have further opportunities for discussion in the future, once more practical experience has been gained.

Session 2: Data protection

The session focused on protection of personal data. In this respect, it is important to differentiate between personal data of trial participants and other personal data (sponsor staff, QP for GMP declaration, sponsor legal representatives, principal investigators, etc.) that can be provided in CTIS.

- Protection of personal data is a joint responsibility for MSs and sponsors in line with the published [Joint controllership arrangement](#)
- Personal data should also be treated in line with the [Q&A on the joint controllership arrangement](#)
- Regarding the anonymisation techniques, it was clarified they would depend on the personal data at stake. While redaction could be a suitable solution for direct identifiers (i.e. names and surnames available in the documents), other techniques should be considered when data utility should be retained (for example to protect personal data of trial participants in trial results). The choice of anonymisation technique is up to sponsors.
- In response to a question on the impact of CTIS transparency requirements on patient consent information, forms, and rights (i.e. withdrawal of consent over time), EMA advised consulting the [Question and Answers on the interplay between the Clinical Trials Regulation and the General Data Protection Regulation](#).

According to above document, 'patient consent information, forms, and consent rights' regarding participation in a clinical trial and consent regarding the processing of personal data should be considered separately. The transparency requirements of CTIS appear relevant as regards information to be provided about the personal data processing.

- Sponsors raised the point that personal data should be provided in CTIS according to the principles of **minimisation** defined in the GDPR/EUDPR, so personal data should be provided to CTIS only when necessary, in line with requirements of Article 81 (6) referring to 81(2) of the CTR. However, clarity is lacking on which type of personal data are to be provided in the documents submitted to the authorities, e.g. names of investigators, study staff, DMSB composition, etc. This point will be further discussed within the EU regulatory network.
- Regarding signatures, reference was made to the latest version of Q&A published in EudraLex volume 10, [question 1.4 point 8](#) clarifying that the CTR does not require documents to be signed and signatures of documents should only be provided in case of clear Legal requirements in the Member States.
- It might be good to differentiate between the document to be submitted in CTIS vs the (signed) documents included in the clinical trial master file.
- Point for further discussion: an harmonised approach for content of part I documentation (e.g. names of DSMB charter), and part II documents (e.g. principal investigators versus sub-investigators) would be welcome. Ethics Committees should be part of this discussion.
- Users should be mindful that personal data in CTIS free text box cannot be redacted.

Session 3: Commercially Confidential Information (CCI)

The session focused on protection of commercially confidential information. The principles described in the guidance were presented, including the elements that may or may not be considered CCI.

- Sponsors requested clarification on the best way to indicate what is considered CCI in data and documents submitted in CTIS. It should be considered whether it would be appropriate to list CCI elements in the cover letter, or mark them as such in the document version 'not for publication', so that this can be taken into account by the Members States when preparing their documents, such as assessment reports.
- Reference was made to the fact that CCI can be protected via redaction of the documents or via the use of deferrals in the system. It was noted that [Q&A 6.5 of the document published in EudraLex](#) refers to the possibility to redact the documents and publish at the time of decision rather than use deferrals.
- The use of free text/structured data should also be considered as it cannot be redacted. Member States and sponsors should be mindful of what is already published via the system or, on the contrary, considered CCI when using CTIS.

Next steps

EMA will:

- Consider the feedback provided during the workshop as part of the revision of the guidance document, as well as the feedback provided during the public consultation
- Continue the discussion on major points in dedicated fora, as applicable
- Continue to engage with key-players on the topic