EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

# Guidance and new Question & Answer document

Clinical Data Publication (Policy 0070) relaunch - EMA webinar

Presented by Silvia Garrido-Lestache on 16 May 2023
Clinical Data Publication Senior Specialist, Documents Access and Publication

# Content


CDP Main Guidance documents


Updated Question & Answer document

Other ways to help you

# CDP Guidance documents

European Medicines Agency policy on publication of clinical data for medicinal products for human use – Policy 0070 (Oct 2016)


External guidance on the implementation of the European Medicines Agency policy on the publication of clinical data for medicinal products for human use – (v1.4 Oct 2018)


Questions and answers on the European Medicines Agency policy on publication of clinical data for medicinal products for human use - (Rev.2 old version Oct 2018/New version)

# CDP Guidance documents - External guidance document


The External Guidance on the implementation of Policy 0070 provides detailed guidance for pharmaceutical companies on the requirements to comply with its policy on the publication of clinical data. It gives further information on:

**Scope of the policy**

as regards clinical reports submitted as part of regulatory procedures, informed consent applications and duplicate marketing authorisations and definitions (chapter 1)

**Procedural aspects**

related to the submission of clinical reports (chapter 2)

**Anonymisation of clinical reports**

for the purpose of publication (chapter 3)

**Identification and redaction**

of commercially confidential information in clinical reports (chapter 4)

# CDP Guidance documents - Questions and answers document

EMA has developed an updated version of the question-and-answer (Q&A) document to expand on issues addressed in the external guidance and in discussions with applicants.

It addresses a number of practical questions concerning procedural matters including timelines, commercially confidential information and the anonymisation process.

It will be updated regularly to reflect any new guidance updates of Policy 0070 (New or revised questions are marked with 'New' or 'Rev' together with the relevant date).

# Question & Answer document

New version to include topics relevant to the 2023 relaunch of policy 0070

- Initial MAAs for new active substances only
- Different scope for Covid/Non-Covid procedures
- Policy 0070 Phase II–Individual Patient Data out of this version
- Anonymisation Template instead of Anonymisation report
- Timelines

# Question & Answer document

**5. How shall I submit my clinical data package to the Agency? Is there an acknowledgement of receipt provided?**

The Redaction Proposal Document Package and Final Redacted Document Package should be submitted via the eSubmission Gateway. For general guidance on eCTD see eCTD Guidance Document (eSubmission) for the Centralised Procedure.

The applicant/MAH will receive two automated replies upon individual submission of the packages. An automated Gateway MDN (Message Delivery Notification) message will be sent to the applicant/MAH acknowledging receipt of the transmission.

The applicant/MAH will also receive a pass/fail of the technical compliance check as per the current eCTD validation criteria for all submissions (the second automated reply). For failed submissions the error description can be found in the 'failure' acknowledgement (xml) and the submission has to be sent again.

# Question & Answer document

**2. How should I complete the Justification Table(s) for my proposed CCI redaction(s)?**

For the Redaction Proposal Document Package of each of the clinical reports in which CCI redactions are proposed, Applicant(s)/MAH(s) must complete a separate justification table in Word format. Should there be no CCI identified in the document, no justification table is required, but this needs to be indicated in the Cover Letter. In such cases the Agency will understand that there are no proposed CCI redactions and therefore will not check those clinical reports. Consequently, the corresponding Final Redacted Document Package will be published as provided by the applicant/MAH.

As a general principle, the Agency expects that each of the justification tables corresponds to one submitted document. The applicant/MAH is also not expected to propose information to be redacted that is already available in the public domain. Therefore, when completing the justification table, the applicant/MAH should confirm that all the necessary searches have been performed (see section 3.2.1 of Chapter 4) and the information proposed to be redacted as CCI is not in the public domain or publicly available, by ticking/checking the box at the top of the justification table.

# Question & Answer document

**6. Can I make reference to my company's proactive data sharing initiatives in the Anonymisation Report?**

During the initial operational start–up phase of Policy 0070 consent to link other data sharing portals in the Anonymisation Report was requested by several pharmaceutical companies. Whilst the Agency acknowledges that complimentary data sharing agreements undertaken by pharmaceutical companies exist, the aim of the Policy 0070 is to increase transparency on data underpinning the regulatory decision-making process and the scientific evaluation the CHMP based its opinion on. To avoid confusion resulting from disparities between the available platforms, such linking in the Anonymisation Report is not permitted.

# CDP web pages

- Clinical data publication

  Under ‘Support for industry’, relevant guidance and templates can be found (i.e.; Justification table to include CCI information, guidance,…)

- Clinical Data Portal

  Clinical Data published are a source of information (i.e; anonymization strategies used by different applicants, how documents have been anonymised by different applicants)

# Other ways to help you

Do you need help with anything?

- Any specific questions can be sent to the designated CDP team for the procedure (Assessor/Coordinator)
- Dedicated preparatory meeting with the Agency can be requested

# Questions?

Any specific questions can be sent to the designated CDP team for the procedure (Assessor/Coordinator)

**Prior to being contacted by EMA**

use the EMA webform* with "CDP-" to start the line with the subject of your enquiry

**Once you have received an invitation letter**

contact the CDP coordinator mentioned in the letter

* Send a question to the European Medicines Agency | European Medicines Agency (europa.eu)

# Any questions?

Join at

**slido.com**

**#cdp1**

https://app.sli.do/event/vTYquhyaJUqWrkHQrinZj9