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SCIENCE MEDICINES HEALTH

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European Medicines Agency

Clinical Data Publication (CDP)

Questions and Answers (Q&As) on the External Guidance on the implementation of the European Medicines Agency policy on the publication of clinical data for medicinal products for human use (Policy 0070)

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Executive Summary

The aim of this document is to provide Applicants/MAHs with information they need to navigate the CDP process - to identify, redact/anonymise and submit documents -.

The document addresses key questions on the CDP process and provides a compilation of, and references to, relevant guidance, recommendations and supportive documentation to facilitate the submission of documents in the context of CDP.

The document will be revised regularly as more information becomes available. New questions will be marked with *'New'* and some of the existing ones have been updated.

This document must be read in conjunction with Policy 0070 (Policy - Publication and access to clinical data (2019 revision) (europa.eu)) and the latest version of the external guidance on the implementation of the European Medicines Agency policy on the publication of clinical data for medicinal products for human use External Guidance on the implementation of Policy 0070 (v1.5).

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List of Acronyms

AE	Adverse Event
AnR	Anonymisation Report
CCI	Commercially Confidential Information
CDP	Clinical Data Publication
CHMP	Committee Human Medicinal Products
CDPC	Clinical Data Publication Coordinator
CDPM	Clinical Data Publication Manager
CSR	Clinical Study Report
CTIS	Clinical Trials Information System
CTR	Clinical Trials Regulation No. 536/2014
eCTD	electronic Common Technical Document
EMA	European Medicines Agency
EU	European Union
FRDP	Final Redacted Document Package
HC	Health Canada
ICH	International Council for Harmonisation
ISH	International Standards on Harmonisation
LED	List of Expected Documents
MAA(s)	Marketing Authorisation Application(s)
MDN	Message Delivery Notification
MAH	Marketing Authorisation Holder
NAS	New Active Substance
PPD	Protected Personal Data
RPDP	Redaction Proposal Document Package
SAE	Serious Adverse Event

1. Procedural related questions

1.1. Which procedures are in Scope of Policy 0070?

Since CHMP Opinions in May 2025, EMA initiated Step 2 with wider scope. All new initial MAAs, line extensions and major clinical Type II variations (extension of indications) are now included in the scope of Policy 0070. The EMA management board confirmed in December 2024 that biosimilar, hybrid and generic products are excluded from publication under Policy 0070. The Agency will also publish clinical data for any new health emergency that may arise outlined in article 17 of Regulation 123/2022.

1.2. When should I receive updated list of expected documents (LEDs) from EMA? - New

The Agency sends a preliminary list of expected documents (LED) to the applicant/MAH with the invitation email. The applicant/MAH is expected to review the list of expected documents (LED) thoroughly and agree with the list of documents included in the preliminary (LED) within 14 calendar days. In the case that the applicant/MAH has comments on the list of expected documents (LED), then this should be clearly indicated in the response to the invitation e-mail. The applicant/MAH's feed-back should be as specific as possible highlighting which documents or sections within documents (including page numbers) are considered to be out of the scope and providing a justification as to why they should be removed from the document package. The Agency will then review the proposals made and provide a response.

If the agreement on the preliminary list of expected documents (LED) is reached and additional clinical documents are submitted later on during the next stages of the regulatory procedure (e.g. responses to D120 LoQ, responses to D180 LoOI or closing sequence) the applicant/MAH should seek the Agency's agreement on whether the additional submitted clinical documents would be deemed falling under the scope of Policy 0070. The Agency will review those documents and if deemed in scope of Policy 0070 will amend the list of expected documents (LED) accordingly:

- Retain only the latest version of documents that are replacing previous versions which currently are considered outdated (e.g. clinical overview, clinical summaries, the latest interim clinical study reports)
- Include any additional documents submitted as 'new'.

The final agreed updated list of expected documents (LED) will be shared with the Applicant/MAH via email. Applicants/MAHs are strongly encouraged to inform the EMA Clinical Data Publication contact points of any new eCTD sequences that may include clinical documents in scope of Policy 0070 at any time during the regulatory review.

1.3. When shall I submit my Redaction Proposal Document Package?

The timelines to provide the Agency with the Redaction Proposal Document Package are as follows:

- Initial MAAs and Line extensions applications: D181 to ≤30 days post-opinion
- Extensions of indication: ≤30 days pre-opinion to ≥30 days post-opinion
- Withdrawn applications: ≤60 days post-receipt of withdrawal letter by EMA
- Article 58 applications: ≤60 days post-opinion

1.4. 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 (please refer to sections 4.9 and 4.10 of the User guide to XML delivery file creation on eSubmission website). The applicant/MAH must create a separate eCTD sequence with the relevant submission type containing the redacted/anonymised clinical reports as a separate data set (using eCTD operator *'new'*). Additionally, the clinical reports submitted must not be linked to any previously submitted documentation for the purpose of the scientific evaluation of a medicinal product or if the redaction or final packages are resubmitted.

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 whole CDP package will have to be re-submitted.

1.5. Can the Agency confirm that all eCTD sequences related to CDP are part of the lifecycle procedure sequences? - New

Yes, the CDP related eCTD submission or resubmission of the Redaction Proposal Document Package and the Final Redacted Document Package falls under the same eCTD lifecycle of the initial MAA, line extension application or extension of indication application as applicable.

1.6. What do I need to do if my package(s) (Redaction Proposal/Final Redacted) is/are rejected upon submission?

A submission of the CDP package(s) can be rejected during technical validation. Technical validation refers to the automated tool validation carried out on an eCTD submission by checking the document type definition (DTD) and technical components of the submission. Where an error is found during the technical validation, the submission will not be loaded into the review system and a replacement sequence 0000 (or sequence as appropriate) will be requested from the applicant/MAH by EMA.

1.7. What do I need to do if my package(s) (Redaction Proposal/Final Redacted) passed the technical validation but is/are rendered invalid following the review carried out by EMA clinical data publication team?

A CDP package will be considered invalid if any of the documents in the Redaction Proposal Document Package and/or Final Redacted Document Package are not submitted, as respectively set out in Table 1 (page 16) and Table 2 (page 27) of the External Guidance on the implementation of Policy 0070 (v1.5), including the required declaration text in the cover letter. The applicant/MAH is required to resubmit the entire package(s) within seven calendar days of receiving the *'Invalid letter from the EMA'* to remain compliant with Policy 0070. Individual documents are not accepted as separate submissions to correct identified deficiencies.

1.8. For the eCTD submission of the Redaction Proposal Document Package and the Final Redacted Document Package. Could the Agency confirm how

the Redaction Proposal and the Final Redacted Document Package should be distinguished? - New

When creating the XML delivery file via the eSubmission Gateway the applicant/MAH needs to distinguish between the Redaction Proposal Document Package and the Final Redacted Document Package by selecting the correct *'Submission type'* (please refer to sections 4.9 and 4.10 of the User guide to XML delivery file creation on eSubmission website). The same applies in case of resubmissions of redaction or final packages.

1.9. May the MAH propose merging or splitting the documents to be submitted for publication?

The Applicants/MAHs may propose merging or splitting documents during the review of the List of Expected Documents provided by EMA. The Applicant/MAH's proposals should be justified and will be considered by EMA on a case-by-case basis. Any amendment to the documents included in the LED should be agreed upon before the submission of the Redaction Proposal Document Package (RPDP), and both the Redaction Proposal Document Package (RPDP) and the Final Redacted Document Package (FRDP) should contain the same documents.

Examples of proposals that may be accepted are the following:

- Merging different versions of the Clinical Study Protocol or the Statistical Analysis Plan for the same clinical study in one single document.
- Merging several documents containing case narratives reported within the same clinical study in one single document.
- Splitting a lengthy Clinical Study Reports annex in several separate documents due to technical constraints related to anonymisation or document management/submission.

Examples of proposals that may not be accepted are:

- Merging parts of different Clinical Study Reports into one document.
- Merging Clinical Overview/Clinical Summaries and addendum.

1.10. How will the submission of clinical reports be handled? Is there any procedural timetable available?

Please refer to the chapter 2 in the External Guidance on the implementation of Policy 0070 (v1.5).

1.11. What are the CDP timelines for an initial MAA evaluated under accelerated assessment procedure? - New

In the case of marketing application evaluated under accelerated assessment, the invitation email and preliminary list of expected documents (LED) are sent to the Applicant/MAH by procedure day 91. The applicable timelines for the submission of the redaction proposal document package and the publication of the final redacted document package are the same as for a standard marketing authorisation application (MAA) (30 days prior to CHMP Opinion to 30 days post opinion and within 120 days post CHMP Opinion respectively).

1.12. When do I need to submit the Redacted Proposal Document Package if my MAA goes for re-examination? - New

If the procedure goes for re-examination, the timetable will be adjusted accordingly. The redacted proposal document package can be submitted to EMA for review as soon as possible but not later than 30 days after the CHMP Opinion on re-examination.

1.13. If there were no comments resulting from the Agency's assessment, do I still have to submit the Final Redacted Document Package?

Yes, the applicant/MAH is required to submit the Final Redacted Document Package as a new sequence to the Agency for publication. The naming conventions of the clinical reports included in the Final Redacted Document Package must be the same as those used for the Redaction Proposal Document Package. In the cover letter submitted to the Agency for the Final Redacted Document Package, the applicant/MAH should provide the declaration stating that the clinical reports submitted for publication are the same as those submitted for scientific review.

1.14. What do I need to know if I have a duplicate marketing authorisation under the scope of Policy 0070?

When submitting duplicate marketing authorisation applications, the Agency understands that the clinical reports included in such submissions are identical to the ones submitted in the application of the original medicinal product.

However, duplicate submissions might contain differences in certain data, such as different salt, excipient or manufacturing sites. If these changes affect the content of the clinical reports submitted for publication, the applicant/MAH is required to flag such differences at the beginning of the procedure; they will then be assessed by the Agency on a case-by-case basis.

Where the clinical reports submitted for the original and duplicate medicinal products are identical, the Agency will only initiate one consultation process based on one Redaction Proposal Document Package, submitted for the original product. At the end of this consultation process the Agency will send out the conclusion which will be equally valid for the duplicate medicinal product. A statement should be included in the cover letter of the duplicate Final Redacted Document Package confirming that the Final Redacted Document Package submitted for the duplicate is identical to the Final Redacted Document Package of the original medicinal product.

Therefore, for identical duplicate medicinal products the Agency accepts that the Redaction Proposal Document Package is only submitted once for the original product but still requires the submission of two stand-alone Final Redacted Document Packages, one for the original and the other for the duplicate medicinal product, as separate publications are needed.

1.15. What if my withdrawn application has been re-submitted for evaluation under the centralised procedure?

Clinical reports contained in applications where the applicant has notified EMA of the withdrawal of the marketing authorisation application (MAA) are also published under Policy 0070. However, in cases of withdrawn applications where there is a confirmed re-submission date (e.g. CHMP eligibility letter) or where re-submission of the application has already taken place, it is possible to request a delay in publication under Policy 0070. The clinical data package will not then be published for the withdrawn product, provided there is an outcome of the decision making process for the re-submitted application.

In such cases, following the conclusion of the re-submitted application, the applicant is expected to submit the clinical package for publication under Policy 0070.

1.16. Some of the clinical reports in my Redaction Proposal Document Package have already been published previously under Policy 0070. Do I need to re-submit them?

When some or all of the clinical documents comprising the Redaction Proposal Document Package have already been published under Policy 0070, the applicant/MAH is expected to re-submit them as per the standard procedure. In such cases, the applicant/MAH is expected to list the documents that have already been published in the cover letter and declare if the level of anonymisation applied in the documents to be published under the current CDP procedure is the same as, or different from, that applied in the already published documents. Concerning commercially confidential information, as it can evolve over time, the redaction proposals will form the subject of another assessment by the Agency.

1.17. If I transfer a Marketing Authorisation to another company, what are my responsibilities under Policy 0070?

Please refer to the section 2.5 in the External Guidance on the implementation of Policy 0070 (v1.5).

1.18. Are interim study reports subject to publication?

Interim study reports are in principle subject to publication. Please consult section 3.7 of the External Guidance on the implementation of Policy 0070 (v1.5).

1.19. Are clinical results from ongoing blinded studies subject to publication?

Information on how to handle the publication of interim results of clinical studies conducted in a blinded fashion at the time of publication can be found in section 3.7 of the External Guidance on the implementation of Policy 0070 (v1.5).

1.20. Who should I contact if I have a question?

The primary CDP contacts (Clinical Data Publication Coordinator (CDPC) and Clinical Data Publication Manager (CDPM) will be assigned to a specific product/procedure at the start of the procedure and their contact details will be mentioned in the invitation email. In case of questions, the Applicant/MAH should contact them directly.

1.21. What if I have not yet received an invitation email for my clinical data publication procedure?

Please submit any CDP related query including concerning your invitation email using the web form (Send a question to the European Medicines Agency) available on the corporate website. When filling in the field *"What is the subject of your enquiry?"* please start by adding the reference *"CDP".*

1.22. May I request more than one pre submission meeting with the Agency? - New

The Agency offers to all the applicants/MAHs the opportunity to have a pre-submission meeting. This is included in the invitation email. The applicant/MAH may have questions on any aspects of the CDP process prior and after the pre-submission meeting. The Agency emphasizes that in cases where email or Eudralink communications are not sufficient to resolve applicant/MAH's questions it may be beneficial for both parties to request a second pre-submission meeting/call.

At any stage during the CDP process, the Clinical Data Publication contact points can be reached by e-mail, Eudralink or phone to seek clarifications, where needed.

1.23. How can the Agency support the applicants/MAHs to prepare for a seamless submission and review process of CDP document packages? - New

The Agency offers the possibility of having CDP pre-submission meetings to address specific questions that the MAH might have regarding any aspect of the CDP process. These may include aspects related to the scoping of documents, anonymisation methodologies, preliminary discussions on CCI proposals or submission via the Gateway (e.g. naming of documents).

In addition, the Applicant/MAH might submit samples of anonymised documents (e.g. some pages of the study participants' narratives) via EUDRALINK ahead of the actual CDP submission to provide the Agency with some insight on the implementation of the anonymisation methodology to be applied in documents.

The applicant/MAH may submit via EUDRALINK samples of documents highlighting the proposed CCI details along with the appropriate justifications (documented in duly completed Justification Tables) to get an indication on the likely outcome of the assessment of their CCI proposals (CCI pre-submission advice). This can be particularly useful in cases where the same details of CCI are proposed in multiple documents. This review will allow the applicant/MAH to understand the Agency's position on the draft proposals and avoid preparing multiple JT if it is not necessary.

CCI proposals will still be formally reviewed once the complete document package is submitted for review and the final EMA conclusion on CCI redaction proposals will be provided with the redaction conclusion letter.

In addition, the Agency recommends reaching an agreement on CCI proposals prior to the submission of the redaction proposal document package to speed up the Agency's review process (advance CCI submission).

1.24. Can I prepare and submit one joint Clinical Data Publication package to both EMA and Health Canada for review and publication?

The Agency in collaboration with Health Canada has initiated a pilot workshare for the publication of clinical data. To avoid duplication of reviews, only one Agency will conduct the review of the clinical data package. Subsequently, the clinical data package is published by both Agencies. This approach may be considered for regulatory procedures assessed in parallel by both Agencies for which there is a significant overlap in the list of documents in scope for publication.

The applicant/MAH will be notified well in advance which of the two Agencies will conduct the review. Once the review is finalised by either EMA or Health Canada, the applicant/MAH is expected to submit jurisdiction tailored Final Redacted Document Packages to both Agencies. Each of the document

packages will contain all identical documents submitted for regulatory review in both jurisdictions, plus any additional clinical documents relevant only for the jurisdiction the document package is submitted and published. No renaming or relabelling of documents will be requested for documents already published in one jurisdiction.

In case CCI redactions other than those assessed by the Agency performing the review are proposed by the applicant/MAH in the additional jurisdiction specific clinical documents, these will be reviewed independently by the other Agency prior to publication.

2. Anonymisation (PPD)/Anonymisation Report related questions

2.1. Who does the Agency consider to be the target audience for the anonymised clinical data reports?

The target audience should be considered to be the broadest possible spectrum (i.e; patient, doctor, academic/researcher, curious/lay person, journalist, pharma industry etc.). It is assumed that all categories of users have one common requirement: to have access to data that is informative. Therefore, the highest level of data utility is one of the aims that should be taken into account when deciding on the anonymisation strategy.

2.2. Is the Anonymisation Report (AnR) template provided by the Agency mandatory? Do I prepare individual Anonymisation Reports for each and every clinical study report included in the document package?

EMA CDP and Health Canada PRCI have developed in close collaboration a structured field anonymisation report template. Applicants/MAHs are expected to use this template for all clinical data publication submissions, regardless of whether the same document package is submitted to both Agencies (i.e EMA and Health Canada) or only to one Agency.

Only one Anonymisation Report (to download it please see Guidance and templates) should be prepared for each document package. However, within the same document package some Clinical Study Reports (CSRs) may require, due to various factors (number of recruitment sites, number of subjects, rarity of the disease), different levels of anonymisation. In such scenario, the different anonymisation strategies used for the clinical documents part of the same document package must be properly reflected in the Anonymisation Report, but under no circumstances should the applicant/MAH prepare several separate Anonymisation Reports.

2.3. If there are NO patient (direct or indirect) identifiers in the clinical reports, do I need to complete and submit an Anonymisation Report?

Yes, you do still need to submit an Anonymisation Report. For specific completion instructions please consult section *"A) Are there any indirect identifiers present within the clinical information package?"* included in the published Anonymisation Report Form Instructions.

2.4. How shall I label PPD redactions in the clinical reports?

Please refer to section "*2.3.3.1.7. Technical requirements for the preparation of the Redaction Proposal version of the clinical reports*" of the External Guidance on the implementation of Policy 0070 (v1.5).

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

The Agency acknowledges that complementary data-sharing agreements undertaken by pharmaceutical companies exist. The aim of Policy 0070 is to increase transparency on data underpinning the regulatory decision-making process and the scientific evaluation on which the CHMP based its opinion. To avoid confusion resulting from disparities between the available platforms, links to such platforms in the Anonymisation Report is not permitted in the Anonymisation Report.

2.6. Does the Agency issue a formal decision in relation to the anonymisation strategy employed by the applicant/MAH and its implementation across the clinical data package?

The Agency does not formally endorse the level of anonymisation applied in the document or the anonymisation approach followed by the Applicant(s)/MAH(s). However, the Agency will review the Anonymisation Report to check whether the applicant/MAH followed the principles laid down in the anonymisation guidance and whether the anonymisation approach was applied consistently throughout the clinical reports submitted.

The Agency will share its comments (which might include some points for clarification), if any, with the applicant/MAH but does not formally adopt the Anonymisation Report. The applicant/MAH is expected to revise the Anonymisation Report taking the Agency's comments into account.

If required, the applicant/MAH will be asked to send a revised anonymisation report and/or written responses to the points raised by the Agency. The Agency will review the documents and conclude whether the comments issued have been satisfactorily addressed by the applicant/MAH. The outcome of the final review will be communicated to the applicant/MAH within 7 calendar days of the date of receipt of the revised report and/or the response document provided by the MAH.

The revised version of the Anonymisation Report must be submitted as part of the Final Redacted Document Package along with the anonymised clinical reports. The Anonymisation Report and the clinical reports will subsequently be published on the Clinical Data Portal.

2.7. Can the Agency clarify the format in which the outcome of the assessment of the AnR will be provided? - New

The Agency will review how the anonymization approach followed by the MAH to protect PPD details is implemented in clinical documents and how the strategy is captured in the AnR.

The Agency's observations related to the anonymisation strategy and its implementation across the document package will be provided in a separate word document named *'Responses to AnR comments'*. The applicant/MAH is expected to reply to each and all of the Agency's observations. The Agency will review the responses provided by the applicant/MAH and confirm whether the responses are satisfactory.

2.8. Can patient narratives be removed from the clinical study reports?

It is the Agency's position that case narratives should not be removed or redacted in full, regardless of their location in the clinical study reports (body of the report or listings). Case narratives should instead be anonymised. The Agency cannot accept the redaction of the entire case narratives by default (as a rule). If, exceptionally, the entire case narrative needs to be redacted to ensure anonymisation, i.e. all identifiers (direct and indirect) need to be redacted in the clinical report(s), the

applicant/MAH must clearly justify this in the Anonymisation Report (in Section 4 *"Data utility considerations"*) and explain (in section 5 *"Deviations"*) why they are compromising data utility in order to protect subject/patient reidentification. Hence, applicants/MAHs should discuss the impact on data utility, particularly where case narratives have been extensively redacted to protect the study participants' privacy. The protection of personal data of individuals while still ensuring the best possible data utility is essential. Release of adverse events and serious adverse event terms in both narratives and summary tables is thus the default.

Surrounding identifiers that are not relevant for efficacy and safety considerations may be selectively protected in narratives in order to retain AE/SAE terms and relevant identifiers.

Of note, there are additional elements that are present in the narratives, which are not considered direct or indirect identifiers that could be released without increasing the risk of re-identification, such as information on medical procedures performed as per protocol and/or standard of care. Additionally, other elements such as laboratory values and/or common adverse events that do not fall into the category of directly identifying events could also be released with no strong impact on the risk of re-identification. In general, such information is likely to be unknown even to the patients included in the clinical study.

2.9. If I have individual patient data listings in the clinical reports, how shall I remove these sections?

All sections of the Clinical Study Report body (sections 1 to 15 as per ICH E3) are subject to publication. The Agency notes that the Clinical Study Reports (CSR) may contain individual patient data listings within the body of the report. In particular, as per ICH E3, these individual patient data listings are most likely to be found in section 14.3.4 *"Abnormal Laboratory Value Listing".*

Therefore, individual patient data listings contained in (CSR) section 14.3.4 *"Abnormal Laboratory Value Listing"* can be considered out of scope. Consequently, it is acceptable to have them removed from the clinical study reports prepared for publication. If ICH E3 format is not followed for a particular CSR, the individual patient data listings included in the corresponding section presenting "Abnormal Laboratory Values" may be considered out of scope and removed from the clinical study report.

Nevertheless, individual patient data listings (other than abnormal laboratory value listings) presented in other sections of the body of the clinical study report (e.g. concerning PK and immunogenicity results, laboratory values, case narratives or protocol deviations) cannot be considered out of scope and should not be removed. They should instead be anonymised.

It is important to note that data presented as aggregated patient data listings within section 14.3.4 *"Abnormal Laboratory Value Listing"* should NOT be removed.

2.10. Are the requirements for publication of the same Clinical Study Report under Policy 0070 and Clinical Trial Regulation aligned?

The submission and corresponding publication of Clinical Study Reports (CSR) via CTIS and publication under Policy 0070 initiative are triggered by the same regulatory milestone (i.e., the completion of the marketing authorisation procedure) and therefore the same redactions applied in the Clinical Study Report (CSR) published on Clinical Data Publication portal (under Policy 0070 initiative) should be applied in the Clinical Study Report (CSR) provided in CTIS.

EMA is finalising further administrative guidance to be published by the CTIS team in their Q&A document in Q3 of 2025. The aim in the management of the publication of CSRs falling both under the transparency requirements of Policy 0070 and the Clinical Trial Regulation is to avoid duplication.

Therefore, CSRs that are subject to Policy 0070 will be published as usual on the Policy 0070 portal following the normal review of the redaction proposal package. Any CSR prepared for Policy 0070 where the same CSR is also due to be posted to CTIS will not need to be prepared twice but the version for Policy 0070 will suffice for the requirements of CTIS. EMA will provide administrative guidance on how this will be implemented in CTIS, as part of the Q&As posted under the EMA *"Clinical Trials Information System: training and support"* landing page (expected in Q3 2025).

3. Commercially Confidential Information (CCI) related questions

3.1. I am preparing CCI justifications in the clinical reports; what does the Agency not consider to be CCI?

Please refer to section 4.3.2 of the External Guidance on the implementation of Policy 0070 (v1.5)

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

Please refer to section 4.4.2 of the External Guidance on the implementation of Policy 0070 (v1.5)

3.3. How shall I label CCI redactions in the clinical reports?

Please refer to section 2.3.3.1.7. Technical requirements for the preparation of the Redaction Proposal version of the clinical reports of the External Guidance on the implementation of Policy 0070 (v1.5)

3.4. What if I disagree with the Agency's assessment outcome on the proposed CCI redactions?

A situation may arise where an agreement between the applicant/MAH and the Agency is not reached on the proposed CCI redaction(s), and the applicant/MAH decides to apply for interim relief against the Agency's decision to publish the documents without accepting the redactions which are still controversial. In this case, the applicant/MAH will submit a partial Final Redacted Document Package, whereby the clinical reports would be redacted according to the applicant's/MAH's views. The applicant/MAH will confirm, in the text of the cover letter, which disputed redactions (page, line) have been made in the documents.

Please note that applications for annulment of the Agency's decisions and the related application for the Treaty of the European Union and the Rules of Procedure of the General Court. The related deadlines and time limits are set therein.

In the event that interim relief is sought against the Agency's decision, the Agency will publish a partial Final Redacted Version of the clinical reports. When a final decision on the interim relief proceedings is issued, the applicant/MAH shall submit a Final Redacted Document Package in accordance with the indications from the Court of Justice of the European Union. The Agency will withdraw from its corporate website the partial Final Redacted Document Package previously published. The Agency will then publish the Final Redacted Document Package.

3.5. Will the Agency's CCI assessment conclusions (if any) be published?

The outcome of the Agency's assessment on the proposed CCI redaction/s is not published on the Clinical Data Portal. Therefore, Applicants/MAHs are requested not to include the assessed justification tables in the Final Redacted Document Package submission.