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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 the 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 or revised questions will be marked with 'New' or 'Rev' together with the relevant date.

This document must be read in conjunction with Policy 0070 ([Policy - Publication and access to clinical data \(2019 revision\) \(europa.eu\)](#)) and 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 the European Medicines Agency policy on the publication of clinical data](#)).

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## List of Acronyms

AE	Adverse Event
AnR	Anonymisation Report
BCP	Business Continuity Plan
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
DTD	Document Type Definition
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. Is the Agency re-starting Policy 0070?**

In December 2018 all Clinical Data Publication (CDP) activities were suspended due to the implementation of the EMA's business continuity plan (BCP). During the COVID-19 pandemic, CDP activities restarted with a scope restricted to the publication of clinical data submitted in support of regulatory procedures for COVID-19 medicines.

As part of the gradual restart of activities suspended or reduced due to the BCP, in September 2023 EMA will relaunch the publication of clinical data for centrally authorised products beyond the scope of COVID-19 medicines. The following applications will be subject to publication:

- Non-COVID-19 medicines: initial marketing authorisation applications (MAAs) for new active substances (NAS) that receive a positive or negative CHMP opinion in September 2023 and onwards. Withdrawn initial MAAs with a planned opinion date in September 2023 and onwards are also subject to publication.
- COVID-19 medicines: applications in line with the scope defined in Policy 0070 (initial MAAs, extensions of indication and line extensions).

## **1.2. When shall I submit my Redaction Proposal Document Package?**

Applicants/MAH(s) will receive a notification from the Agency to submit the Redaction Proposal Document Package as per the published [External guidance on the implementation of the European Medicines Agency policy on the publication of clinical data for medicinal products for human use](#). Applicants with an ongoing initial marketing authorization application for a new active substance with a planned CHMP opinion date from September 2023 onwards will receive a notification to submit a Redaction Proposal Document Package ≤90 days before the planned CHMP opinion date. This communication will include the list of expected documents (LED) and the procedure timetable for the submission. The timelines to provide the Agency with the Redaction Proposal Document Package are as follows:

- Initial MAAs: D181 to ≥30 days post-opinion
- Line extensions and extensions of indication (applicable to COVID-19 medicines only): ≤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

## **1.3. 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 the [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 whole CDP package will have to be re-submitted.

### **1.3.1. 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.

### **1.4. What do I need to do if my package(s) (Redaction Proposal/Final Redacted) passed the technical validation but is/are rejected during review process by EMA clinical data publication team?**

A CDP submission package will be rejected 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 18) and Table 2 (page 32) 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](#), including the required declaration text in the cover letter. The applicant/MAH is required to resubmit the entire package(s) within seven working days of receiving the 'Invalid letter from the EMA' to remain compliant with Policy 0070. Individual parts cannot be submitted separately to correct submission deficiencies.

### **1.5. 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 RPDP, and both the RPDP and the 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 CSR 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 addenda.

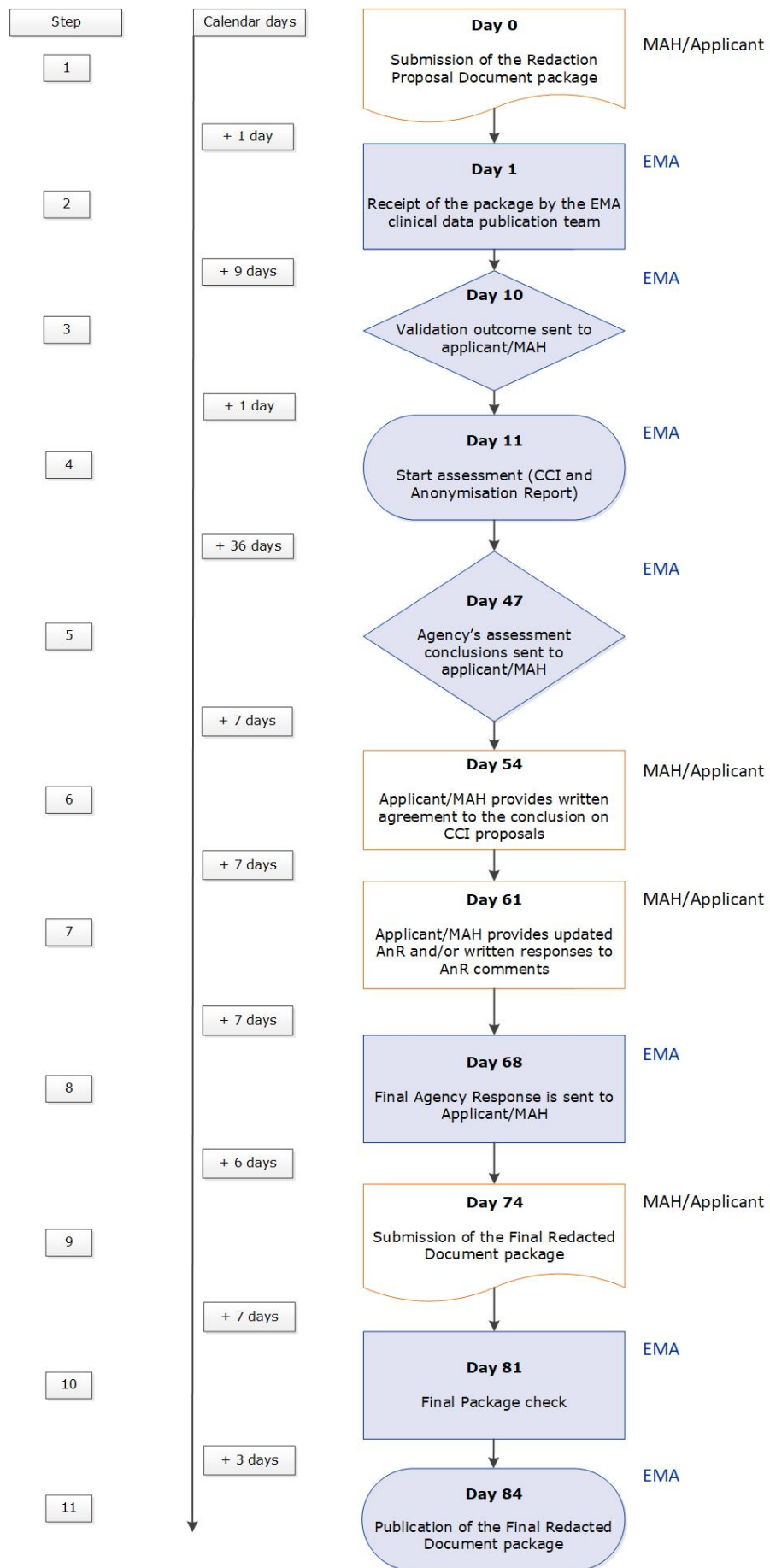
**1.6. How will the submission of clinical reports be handled? Is there any procedural timetable available?**

The procedure for publication of clinical reports will follow the procedural timetable from the moment the Redaction Proposal Document Package is submitted to the Agency (**Day 0**), regardless of the type of application (i.e., marketing authorization, line extension, extension of indication, withdrawn applications).

The timelines of the end-to-end process for the publication of clinical reports are up to 84 days, and the procedure terminates with the publication of the Final Redacted Document Package in the Clinical Data portal. MAHs are advised to start preparing the CDP package shortly after receiving the EMA invitation email in order to comply with the CDP procedural timelines.

The detailed end-to-end process for the publication of clinical reports will take place as shown on the next page.





Upon receipt of a technically valid package submission through the gateway, a dedicated Clinical Data Publication (CDP) team will be assigned to the procedure, and the consultation process starts (**Day 1**).

The Agency will initiate the validation of the submission content. The applicant/MAH may be asked to provide supplementary information in order to finalise the validation of the clinical data publication procedure (e.g., request clarification with regard to the CCI proposals). This stage will ensure that documents are correctly submitted and ready to be assessed by the Agency.

Once the clinical data publication procedure has been validated by the Agency, a validation outcome letter/email will be sent to the applicant/MAH (**Day 10**). In case of an unsuccessful (failed) validation, the Agency will reject the submitted package and the applicant/MAH will be asked to resubmit the revised Redaction Proposal Document Package within 7 days. Once the newly resubmitted package has been uploaded into the gateway (new eCTD sequence) and the procedure has been validated, the timetable will be restarted from **Day 0** and the revised package will be subject to a new content validation.

Following a successful validation, the Agency will start the assessment of the procedure. The CDP assessor will review the justifications submitted by the applicant/MAH regarding their proposed CCI redactions (**Day 10**). Documents submitted must have all proposed CCI redactions labelled, clearly indicating that the proposed redaction is requested on CCI grounds. Please see section 2.3 of this document, *How shall I label CCI redactions in the clinical reports?*. During the assessment, the Agency will initially review the justification tables submitted by the applicant/MAH to list proposed CCI redactions. The CCI proposed for redaction must be included in the relevant justification table providing the appropriate justification as to why the elements can be considered CCI. If further clarifications are needed, the applicant/MAH will be contacted. Whenever clarification is requested, it will be clearly indicated in the justification table and sent to the applicant/MAH (via Eudralink). If the applicant/MAH fails to submit the requested clarifications, the Agency will consider the initial justifications irrelevant or insufficient and consequently will reject the proposed redaction. Please see section 2.2 of this document, *How should I complete the Justification Table(s) for my proposed CCI redaction(s)?*. At the end of the assessment phase, the Agency will inform the applicant/MAH of its CCI conclusion for the entire set of clinical reports (**Day 47**). The outcome of the assessment (rejection, acceptance, or partial acceptance of the proposed CCI redactions) and its rationale will be clearly communicated and documented in the appropriate columns of the justification table/s.

The Agency will also review the Anonymisation Report to check whether the applicant/MAH has followed the anonymisation guidance and applied it consistently throughout the documents (**Day 10**). The submitted Anonymisation Report must describe the methodology of the anonymisation applied in each of the clinical reports in the Final Redacted Document Package. The report should also describe how the risk of re-identification has been measured and managed, or if the three criteria for anonymisation have been fulfilled. A template Anonymisation Report can be found in the guidance document Annex 1.2. At the end of the assessment phase, the Agency will transmit its comments on the Anonymisation Report, if any, to the applicant/MAH but will not formally adopt the Anonymisation Report (**Day 47**). If applicable, the applicant/MAH will revise the Anonymisation Report, taking into account the Agency's comments.

Once the outcome of the assessment of the CCI redactions has been received by the applicant/MAH, they are required to submit their agreement or disagreement with the Agency's redaction conclusion on CCI (**Day 54**).

If required, the applicant/MAH may also be asked to send a revised anonymisation report and/or written responses to the comments raised by EMA (**Day 61**). The Agency will review the documents

and conclude whether the comments have been addressed in a satisfactory manner by the applicant/MAH. The outcome of the review by EMA is sent to the applicant/MAH (**Day 68**).

In all cases, the applicant/MAH is required to submit the Final Redacted Document Package as a new sequence to the Agency for publication by **Day 74**. Failure to submit written agreement, disagreement or to submit the Final Redacted Document Package will result in the applicant/MAH being deemed non-compliant with the requirements of Phase 1 of Policy 0070, and thus a non-compliance notice to this effect will be published on the clinical data publication website.

Once the Final Redacted Document Package has been submitted by the applicant/MAH, the Agency will perform the final package check to make sure the comments raised by the Agency when reviewing the Redaction Proposal Document Package have been addressed in the documents submitted. The Agency will send a communication to the applicant/MAH to confirm whether the Final Redacted Document Package can be considered 'valid' or 'invalid'. If the package is considered valid, the Agency will inform the applicant/MAH of the publication date on the CDP Portal (**Day 81**).

The Final Redacted Document Package will be published by the Agency on its clinical data portal within 10 calendar days after the submission by the applicant/MAH through the gateway (**Day 84**). Prior to publication, the Agency will watermark each page of the clinical reports in the Final Redacted Document Package submitted by the applicant/MAH to emphasise the prohibition of their use for commercial purposes.

### ***1.7. 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.

### ***1.8. 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<sup>1</sup>. 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 phase 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

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<sup>1</sup> [pharm780\\_duplicates\\_en\\_0.pdf \(europa.eu\)](#)

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.

### **1.9. 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 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. In light of the resubmission of the regulatory procedure, the Agency will generally consider the postponement of the publication of the clinical data package for the withdrawn marketing application, on the understanding that the clinical data package will be published for the withdrawn product, once there is an outcome of the decision making process for the re-submitted regulatory application. In such cases, following the conclusion of the re-submitted application, the applicant is expected to submit two clinical packages for publication under Policy 0070; one package for the withdrawn application and one package for the re-submitted application.

### **1.10. 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 studies 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 described in section 3.3.1.8 "Technical requirements for the preparation of the Redaction Proposal version of the clinical reports" 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*<sup>2</sup>. In such cases, the applicant/MAH is expected to list the study titles that have already been published in the cover letter and declare if the level of anonymisation applied in the current CDP procedure is the same as, or different from, that applied in the previous procedure. Concerning commercially confidential information, as it can evolve over time, the redaction proposals will form the subject of another assessment by the Agency. A template cover letter for the Redaction Proposal Document Package can be found in Annexes 1.4 and 1.5 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*.

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

When a Marketing Authorisation Holder (the Transferor) submits an application to transfer a marketing authorisation to another company (the Transferee), responsibilities under Policy 0070 are transferred to the Transferee as of the date of notification of the amendment of the Commission Decision in relation to the transfer of the marketing authorisation based on Regulation (EC) No 2141/96 (the

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<sup>2</sup> [External guidance on the implementation of the European Medicines Agency policy on the publication of clinical data for medicinal products for human use | European Medicines Agency \(europa.eu\)](#)

transfer date). These include responsibility for clinical reports that were redacted by the Transferor and published by the Agency before the transfer date.

Should a transfer application be submitted to the Agency during the Policy 0070 process, the process will continue on the basis of the agreements, submissions and declarations made by the Transferor. From the transfer date onwards, the Agency will liaise with the Transferee for all remaining aspects of the Policy 0070 process for the product subject to the transfer.

In some cases the transfer date may occur after the Agency conclusion has been issued (to the Transferor) but before the Final Redacted Document Package has been submitted. In order to remain compliant with Policy 0070 in these cases, the Transferee must submit the Final Redacted Document Package in line with the Agency's conclusion issued to the Transferor. The Agency strongly encourages the Transferor and Transferee to exchange information on the agreements, submissions or declarations made between the Transferor and EMA under the scope of the Policy 0070 publication process.

### **1.12. Are interim study reports subject to publication?**

Yes, interim study reports are in principle subject to publication.

### **1.13. Are clinical results from ongoing blinded studies subject to publication?**

Yes, clinical results from ongoing blinded studies are subject to publication. In cases where the publication could have an impact on the conduct of the study in a blinded fashion, applicants/MAHs may propose additional redactions to protect from unmasking/unblinding. The implementation of additional redactions to protect from study unmasking/unblinding should be explained in the deviation sections of the Anonymisation Report.

### **1.14. Who should I contact if I have a question?**

The Clinical Data Publication Coordinator (CDPC) and Clinical Data Publication Manager (CDPM) will be assigned at the start of the procedure. These will be the primary contact points during that specific clinical data publication procedure, and their contact details will be mentioned in the Invitation Letter.

### **1.15. What if I have not yet received an Invitation Letter for my clinical data publication procedure?**

For any additional questions not addressed in the *External guidance on the implementation of the European Medicines Agency policy on the publication of clinical data for medicinal products for human use*<sup>3</sup> or in this document, please submit your question to the Agency 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 –".

### **1.16. May I request a preparatory meeting with the Agency?**

If you would like to have a preparatory meeting with the CDP team at EMA, please indicate so in the response to the invitation email. Please send us a list of all the questions you would like addressed at least 1 week in advance of the pre-submission meeting.

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<sup>3</sup> [External guidance on the implementation of the European Medicines Agency policy on the publication of clinical data for medicinal products for human use | European Medicines Agency \(europa.eu\)](#)

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

A clinical data package may be jointly reviewed and/or published by EMA and Health Canada. 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 Applicants/MAHs should communicate their request for a joint review as soon as possible after receipt of EMA's invitation email. EMA and Health Canada will jointly review the redaction proposals made by applicants/MAHs and will provide a joint list of comments to be addressed by the applicant/MAH prior to the submission of the Final Redacted Document Package.

To the extent that the same set of documents falls within the scope of both EMA and HC transparency initiatives, the same document package should be submitted for publication to both Agencies.

### **1.18. Are Generic and Biosimilar products subject to Policy 0070?**

Biosimilars and Generic products will be included in Step 2 of the relaunch of Policy 0070. This will be communicated well in advance.

## **2. Commercially Confidential Information (CCI) related questions**

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

Generally, the majority of the clinical information contained in clinical reports which fall under the scope of Policy 0070 should not be considered CCI. However, the Agency acknowledges that in limited circumstances clinical reports may contain information of a quality, non-clinical and general or administrative nature, some of which may potentially be considered CCI, and could, therefore, be subject to redaction prior to publication. Each individual CCI redaction proposed by the applicant/MAH will be scrutinised by the Agency in order to assess whether the definition of CCI applies.

Should the information proposed to be redacted be in the public domain or bear no innovative features, the Agency will not accept its redaction. In addition, if the applicant/MAH fails to provide sufficient and relevant justification, the proposed redactions will be rejected.

Section 3.2.3 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*<sup>4</sup> describes some additional examples of types of information which will not be accepted to be redacted as CCI. These examples reflect the most common redactions proposed by applicants/MAHs which are usually rejected by the Agency in the framework of a request for Access to Documents in accordance with Regulation (EC) No 1049/2001.

In order to achieve a high level of consistency in the redaction of CCI elements in the final redacted documents (and to decrease the administrative burden), the Agency has grouped the types of information that it does not consider to be CCI. (Please refer to Chapter 4 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*). The Agency foresees the use of the following five rejection codes

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<sup>4</sup> [External guidance on the implementation of the European Medicines Agency policy on the publication of clinical data for medicinal products for human use | European Medicines Agency \(europa.eu\)](https://www.ema.europa.eu/en/external-guidance-on-the-implementation-of-the-european-medicines-agency-policy-on-the-publication-of-clinical-data-for-medicinal-products-for-human-use)

that mirror the above considerations, and which at the end of the redaction consultation process, will be included in the justification table (if applicable), reflecting the Agency's final position:

- Information that is already in the public domain or publicly available – **Rejection code 01**
- Information that does not bear any innovative features – **Rejection code 02**
- Additional information the disclosure of which would be in the public interest – **Rejection code 03**
- Information lacking sufficient or relevant justification – **Rejection codes 04 and 05**

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

For each of the clinical reports submitted in which CCI redactions are proposed in the Redaction Proposal Document Package, applicant(s)/MAH(s) must complete a separate justification table in Word format. The Redaction proposals must be strictly limited to the information that is commercially confidential. Should there be no CCI identified in any of the documents submitted, then, completion of a justification table is not required, but this needs to be indicated by the applicant(s)/MAH(s) in the Cover Letter. In such cases, the Agency will understand that there are no proposed CCI redactions for any of the documents submitted 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 mentioned above, the Agency expects to receive a separate justification table for each submitted document as part of the CDP package. The applicant/MAH is 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<sup>5</sup>) 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. In addition, redaction 'in bulk' of whole pages or paragraphs will not be accepted unless properly justified.

Important note: The applicant/MAH should describe in detail the reasons why it considers the information proposed for redaction to be CCI.

Information on how to complete the different columns in the Justification Table(s) for proposed CCI redaction/s can be found below:

### **Column 1 (Page number(s))**

In column 1, the Applicant/MAH is expected to provide the page number of the relevant document, where the information that is proposed to be redacted is located. If exactly the same information can be found throughout the document and the Applicant/MAH has the same justification for the redaction of this element of information, EMA advises the Applicant/MAH to indicate all the page numbers in one row, instead of filling in a new line for each page where the information is mentioned.

### **Column 2 (Title of Section(s))**

In column 2, EMA expects the Applicant/MAH to indicate the appropriate section/s of the document where the proposed redaction can be found. If exactly the same information can be found throughout the document and the Applicant/MAH has the same justification for the redaction of this element of

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<sup>5</sup> [External guidance on the implementation of the European Medicines Agency policy on the publication of clinical data for medicinal products for human use | European Medicines Agency \(europa.eu\)](#)

information, EMA advises the Applicant/MAH to indicate all relevant sections in one row, instead of filling in a new line for each page and section.

### **Column 3 (Text proposed for redaction by Applicant/MAH)**

This column should contain the exact element proposed for redaction, copied verbatim from the document (e.g. word, numerical value, sentence or paragraph). If entire tables and figures are among the proposed redactions, EMA advises the Applicant/MAH to clearly identify in this column the table/figure number and its title. If for practical reasons the proposed redactions cannot be reflected verbatim in this column, this should be explained in an understandable manner. All the proposed redactions listed in the justification table should correspond to the text highlighted for redaction in the corresponding document.

Applicants/MAHs are strongly advised only to propose the redaction of word(s), figure(s), and pieces of text that, in their view, are considered Commercially Confidential Information (CCI). The Applicant/MAH should not propose the redaction of entire pages or entire sub-sections of a document.

### **Column 4 (Applicant/MAH to reference the section(s) of the Annex 3 of Policy 0070 on which the redaction is based)**

The Applicants/MAHs are advised to refer to Annex 3 of Policy 0070<sup>6</sup> to check which information contained in the clinical reports may be considered CCI and for guidance on how to build the justification for redaction.

### **Column 5 (Applicant/MAH to provide justification of CCI)**

In column 5, the Applicant/MAH should describe in detail the reasons why it considers that the information proposed to be redacted is commercially confidential. The Applicant/MAH should explain how the release of each and every element of information proposed for redaction will undermine the economic interest or competitive position of the owner of the information.

Applicants/MAHs are expected to submit a specific, relevant and appropriate justification corresponding to each and every element of information that is proposed for redaction.

In addition, it is highlighted that even if particular information is not in the public domain or publicly available, this information will only be considered commercially confidential if it is demonstrated that its disclosure may undermine the economic interest or competitive position of the owner of the information.

### **Columns 6 and 7 (EMA's assessment):**

The last two columns will capture the conclusion of EMA's assessment and the rationale behind it. The justification table containing the outcome of EMA's assessment will be sent to the Applicant/MAH.

For additional clarification on this topic please refer to section 4.2. of the External Guidance, *Completing the justification table*<sup>7</sup>.

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<sup>6</sup> [Policy - Publication and access to clinical data \(2019 revision\) \(europa.eu\)](https://european-council.europa.eu/media/eu-press/attachment/data/2019/04/16/12322_en.pdf)

<sup>7</sup> [External guidance on the implementation of the European Medicines Agency policy on the publication of clinical data for medicinal products for human use | European Medicines Agency \(europa.eu\)](https://www.ema.europa.eu/en/external-guidance/external-guidance-on-the-implementation-of-the-european-medicines-agency-policy-on-the-publication-of-clinical-data-for-medicinal-products-for-human-use)

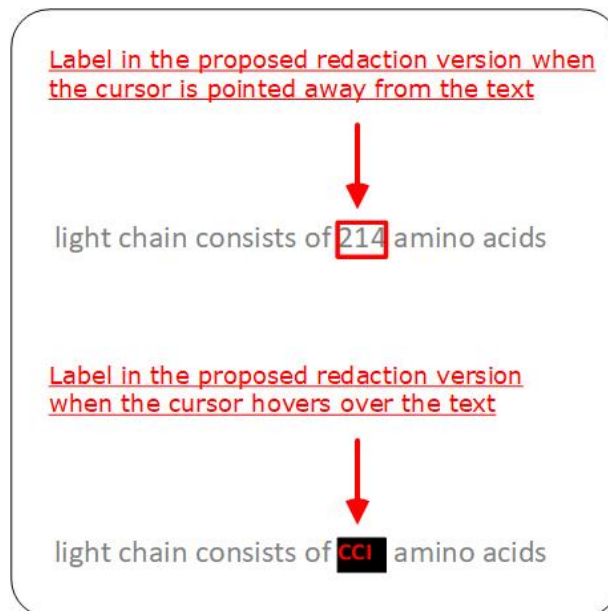


### **2.3. How shall I label CCI redactions in the clinical reports?**

In both the Redaction Proposal Document Package and the Final Redacted Document Package, applicants/MAHs are required to colour code the redactions proposed. The CCI redactions should have a black background with red overlay text, as follows:



For the Redaction Proposal Document Package the text proposed for redaction should be clearly identified as such (i.e. marked) and the text itself should be legible (read-through) as per the following example:



Please note that redactions must be clearly visible. Any agreed CCI redaction labels should be visible and irremovable together with the final redacted text.

### **2.4. 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 was not reached on the proposed CCI redaction(s), and the applicant/MAH decided 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 interim relief are filed with the General Court of the European Union in accordance with Article 263 of 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.

In an exceptional situation where an applicant/MAH does not submit a complete Redaction Proposal Document Package or a complete Final Redacted Document Package, the Agency will publish a noncompliance notice.

### ***2.5. 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.

## **3. Anonymisation (PPD)/Anonymisation Report related questions**

### ***3.1. 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.

### ***3.2. Do I have to use the Anonymisation Report (AnR) template provided by the Agency?***

Yes. Together, EMA and Health Canada have developed a structured field anonymisation report template. Applicants/MAHs are expected to use this template for all clinical data publication submissions, regardless of whether they are jointly submitting document packages to both Agencies, (EMA and Health Canada) or submitting document packages intended for publication on only one of the Agencies' clinical data publication portals. The template requires the applicants to address a number of questions which facilitate the description, in a clear and succinct manner, of the anonymisation strategy adopted for each individual document package as well as the data protection consideration taken into account by the applicants when deciding on the anonymisation strategy.

### ***3.3. How many Anonymisation Report templates do we have to submit in each document package? Do we have to prepare an individual Anonymisation Report for each and every clinical study report included in the document package?***

Only one overall Anonymisation Report has to be submitted describing the methodology of the anonymisation applied in the submitted clinical reports. The information included in the anonymisation report template must be aligned with the anonymisation strategy followed.

The Agency understands that in the same submission some CSRs present information from clinical trials where, due to various factors (number of recruitment sites, number of subjects, rarity of the disease), the applied level of anonymisation will be different. In this case, the different anonymisation strategies used for the same procedure must be properly explained in the Anonymisation Report template document, but under no circumstances should the applicant/MAH submit several different Anonymisation Reports.

### **3.4. If there are NO patient (direct or quasi) 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. The European Medicines Agency and Health Canada have developed a structured field anonymisation report template taking into account this scenario. If the document package submitted for publication does not contain any indirect identifiers, the applicant is expected to select the “No” answer to the first question included in the Anonymisation Report template, which reads as follows: A) Are there any indirect identifiers present within the clinical information package? This action will result in the collapse of all the subsequent sections of the Anonymisation Report Template which are not relevant, with the exception of section 6 Attestation, which needs to be signed off by the applicant.

Please note that the Anonymisation Report template published in Annex 1.2 of the clinical data publication guidance is no longer applicable.

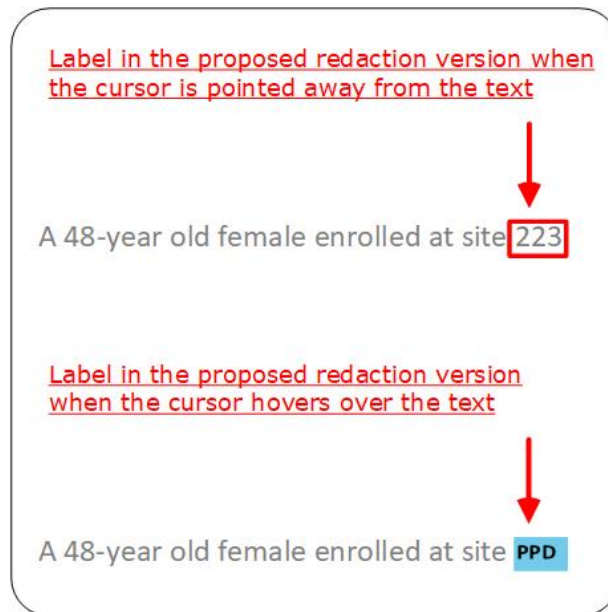
### **3.5. How shall I label PPD redactions in the clinical reports?**

If redaction is used as one of the anonymisation techniques, in both the Redaction Proposal Document Package and the Final Redacted Document Package, applicants/MAHs are required to highlight the proposed and final PPD redactions using the following colour code: blue background (pantone 291 C - corresponding to RGB colours 115, 203 and 235) with black overlay text reading “PPD”.

An example is provided below:



For the Redaction Proposal Document Package, the proposed PPD redactions should be clearly identified as such (i.e. marked) and the text itself should be legible (read-through) as per the following example:



For the Final Redacted Document Package the redactions must be clearly visible (using a blue rectangle as described above). Redacted text and the blue redaction box which covers the redacted text should be neither searchable nor subject to further editing.

### ***3.6. 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.

### ***3.7. Does the Agency issue a formal decision in relation to PPD redactions?***

The Agency does not formally assess the proposed PPD redactions 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 comments transmitted 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 in the Clinical Data Portal.

### **3.8. 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 a subject's identification. 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, but are not considered direct or quasi 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.

Taking into account the fact that data collected during the study is considered to have high scientific value, it is the Agency's position that applicants/MAHs should not redact patient narratives in full, without providing more comprehensive explanations (possibly with examples) to highlight how the release of such information on patient narratives can lead to the re-identification of an individual.

### **3.9. If I have individual patient data listings in the clinical reports (out of scope of phase I), how shall I remove these sections?**

All sections of the CSR body (sections 1 to 15 as per ICH E3) are subject to publication.

The Agency notes that the CSRs 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.

### **3.10. 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 CSRs via the public website of CTIS and publication under the Policy 0070 initiative are triggered by the same regulatory milestone (i.e., the completion of the marketing authorisation procedure) and therefore the same level of CCI redaction applied in the CSR published on Clinical Data Publication portal (under Policy 0070 initiative) should be applied in the CSR provided in CTIS.

From an anonymisation perspective, the same anonymisation principles and anonymisation techniques described in *Article 29 Data Protection Working Party Opinion on Anonymisation Techniques*<sup>8</sup> and further discussed in Chapter 3 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*<sup>9</sup> would apply regardless of whether the same Clinical Study Report (CSR) is published on the EMA clinical data publication portal or on the Clinical Trial Information System (CTIS)<sup>10</sup>.

For further guidance on protection of personal data and CCI while using CTIS please consult the Guidance document on how to approach the protection of personal data and commercially confidential information while using the Clinical Trials Information System (CTIS) Version 1.1.<sup>11</sup>

EMA acknowledges that further administrative guidance may be required in relation to the management of the publication of CSRs falling under the transparency requirements of both Policy 0070 and the Clinical Trial Regulation. EMA is planning to provide additional administrative guidance as part of future updates of this Question and Answer document as well as updates of the training materials and Q&As posted under the EMA "Clinical Trials Information System: training and support" landing page.

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<sup>8</sup> Opinion 05/2014 on Anonymisation Techniques, 0829/14/EN WP216, [https://ec.europa.eu/justice/article-29/documentation/opinion-recommendation/files/2014/wp216\\_en.pdf](https://ec.europa.eu/justice/article-29/documentation/opinion-recommendation/files/2014/wp216_en.pdf)

<sup>9</sup> [External Guidance on the implementation of Policy 0070 \(europa.eu\)](https://www.ema.europa.eu/en/documents/other/external-guidance-on-the-implementation-of-policy-0070-europa.eu) (Rev. 4)

<sup>10</sup> EMA Clinical Trials Information System: [Clinical Trials Information System: training and support | European Medicines Agency \(europa.eu\)](https://www.ema.europa.eu/en/documents/other/clinical-trials-information-system-training-and-support-europa.eu)

<sup>11</sup> <https://www.ema.europa.eu/en/documents/other/guidance-document-how-approach-protection-personal-data-commercially-confidential-information-while-.pdf>