15 October 2018
EMA/482146/2018
European Medicines Agency

Summary of changes to the 'External guidance on the implementation of the European Medicines Agency policy on the publication of clinical data for medicinal products for human use'

On 3 March 2016, the European Medicines Agency published 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). Additional information that has been included in the guidance (Version 1.4) is outlined in the table below, including the location within the document with a summary of the additional information provided.

1. Major changes

Chapter and Section reference	Summary of the change
Chapter 1: • section 2, page 7	Clarification has been provided on the publication of withdrawn applications in cases where the application has been re-submitted or has an agreed re-submission date: *"However, in case of withdrawn applications where there is a confirmed re-submission date (e.g. CHMP eligibility letter) or re-submission of the application has already taken place, it is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 re-submission of the regulatory procedure, the Agency will generally consider the postponement of the publication of the clinical data package for the withdrawn marketing application, with the understanding that the clinical data package will be published for the withdrawn product, once there is an outcome of the decision making process for the re-submitted regulatory application.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the applicant is expected to submit two clinical packages for publication under Policy 0070; one package for the withdrawn application and one package for the re-submitted application."*

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Chapter and Section reference	Summary of the change
Chapter 2: • section 2.2, page 14	Clarification added on the publication of clinical studies where the main period/phase of a clinical study is still on-going at the time of publication: *"Exceptionally, in cases where the main period/phase of a clinical study is still on-going at the time of publication, this specific study will not be subject to publication until the last subject completes the study (i.e. Last Patient, Last Visit completed). In such cases, the applicant/MAH will be asked to provide a statement for publication where they commit to submit the study once completed. The other clinical documents that were considered during the evaluation and formed part of the decision-making process remain subject to publication."*
Chapter 2: • section 3.3, page 16 also throughout sections 3.3.1., 3.3.2., 3.3.3., and 3.3.4., as needed Chapter 5: • annex 1.9, page 83	Timetable of the main steps of the end-to-end process for the publication of clinical reports added: *"The main steps of the end-to-end process for the publication of clinical reports are listed below (and described in the following sections):* ***Day 0** – Submission of the Redaction Proposal Document package by the applicant/MAH* ***Day 1** – Receipt of the Redaction Proposal Document package by the EMA clinical data publication team* ***Day 10** – Validation outcome is sent to applicant/MAH* ***Day 47** – Redaction conclusion (including conclusion on the CCI assessment and recommendations/comments on the anonymisation report) is sent to applicant/MAH* ***Day 54** – Applicant/MAH provides written agreement to the redaction conclusion on CCI* ***Day 61** – Upon request, applicant/MAH provides updated anonymisation report and/or written responses on the recommendations/comments on the anonymisation report* ***Day 74** – Submission of the Final Redacted Document package by the applicant/MAH* ***Day 84** – Publication of the Final Redacted Document package"*
Chapter 2: • section 3.3.2.1., page 30 Chapter 5:	Addition of wording to reflect the review of the anonymisation report that takes place during the consultation phase.

Chapter and Section reference	Summary of the change
• annex 1.11., page 85	
Chapter 2: • section 3.3.2.2., page 31 and section 3.3.3.2., page 32	Addition of wording on the potential need to submit an updated anonymisation report and/or written responses to the comments transmitted by EMA on the anonymisation report before the submission of the Final Redacted Document package: *"During the consultation phase, in parallel with the assessment of CCI, EMA will also review the anonymisation report to check whether the applicant/MAH followed the anonymisation guidance and applied it consistently throughout the documents. EMA will transmit its comments (by **Day 47**), if any, to the applicant/MAH but does not formally adopt the anonymisation report. If required, the applicant/MAH will be asked to send a revised anonymisation report and/or written responses to the comments transmitted by EMA (by **Day 61**). The Agency will review the documents and conclude on whether the comments have been addressed in a satisfactory manner. The outcome of the final review will be communicated to the applicant/MAH within 7 calendar days from the date of receipt of the revised report and/or the response document."* *"If required, the applicant/MAH will be asked to send a revised anonymisation report and/or written responses to the comments transmitted by EMA by **Day 61**."*
Chapter 2: • section 3.3.3.3., page 33	Wording added flagging the availability of a checklist to assist applicants/MAHs with the preparation of the Final Redacted Document package: *"In order to support applicants/MAHs with the preparation of the Final Redacted Document packages, a validation checklist is made available in annex 1.14. Please note that this checklist should be seen as an additional tool meant to improve the quality of the submitted packages and should not be included in the submitted document packages."*
Chapter 5: • annex 1.4., page 74 and annex 1.5., page 77	Inclusion of template paragraphs and use instructions within the cover letter regarding studies already published previously under Policy 0070.

Chapter and Section reference	Summary of the change
Chapter 5: • annex 1.14, page 103	In addition to the checklist for the Redaction Proposal Document package, a new checklist for the Final Redacted Document package has been added.

2. Minor changes

Chapter and Section reference	Summary of the change
Chapter 2: • section 3.3.1.8., page 26	Clarification added on the labelling requirements of information considered to be out of scope of phase 1 of Policy 0070: *"A blank page with overlay text is only required for pages that have been removed from a consecutively numbered single PDF, i.e. it is not required when multiple files are merged into a single PDF document.* *Out of scope sections can either be removed in the Redaction Proposal Document package or only in the Final Redacted Document package. If pages are not removed until the Final Redacted Document package, each page to be deleted should indicate the removal as out of scope of phase 1 of Policy 0070 e.g. in the form of watermark or overlay text within the Redaction Proposal Document package."*
Chapter 5: • annex 1.4., page 74 and annex 1.5., page 77	Editorial changes to comply with the above clarification that was added for the labelling requirements of out of scope sections: *"This is only applicable in cases where the clinical report body and the Appendices are submitted as a single pdf document with consecutive page numbering across body and Appendices"*
Chapter 5: • annex 1.14, page 101	Editorial changes to comply with the addition of the new checklist for the Final Redacted Document package in annex 1.14
Chapter 5: • annex 1.15, page 104	Deletion of the column "Page Number" from the template table for listing the out of scope sections