EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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 updated and/or amended/deleted in the guidance (Version 1.5) is outlined in the table below, including the location within the document with a summary of the additional information provided.

1. Main changes

Chapter and Section reference	Summary of the change
Chapter 1:	Clarification has been provided on the current scope of Policy 0070 and adding reference to Regulation 123/2022 on public health emergencies requirements for transparency. Updating requirements on applications withdrawn that are to be re-submitted. Updated clarification on cross references to previously submitted studies not present in current dossier.
Chapter 2: • section 2.2.2 • section 2.3.1	Chapter 2 is no longer divided into three main sections. This change leads to an alteration of the section numbering in the current version and wording has been amended in the specific sections. Clarifications aimed on the publication scope of individual patient data listings contained within the body of the Clinical Study Report provided and on the possibility for applicants/MAHs to propose additional redactions to protect from study unblind (blinding redactions). High-level steps of the clinical data publication process added.

Chapter and Section reference	Summary of the change
• section 2.3.2	Additional guidance on the timelines and contents of the invitation sent to applicants (including a reference to the list of expected documents or LED serving as an agreed list for package validation), and to the possibility of merging/splitting documents to ease the submission when necessary.
• section 2.3.3	Schematic figures showing the clinical data publication review process steps added.
• section 2.3.3.1.2	Clarification on the amended timelines for the submission of Redaction Proposal Document packages depending on the regulatory procedures.
• section 2.3.3.1.3	Amendments to table 1 to reflect current requirements.
• section 2.3.3.1.4	Amendments to reflect the requirement to use the current anonymization report form template, and link to the form and instructions for completion added.
• section 2.3.3.1.6	Amendment of instructions for the naming of documents. Leaf titles take on the same naming as file names.
• section 2.4.3	Amendments to table 2 to reflect current requirements.
• section 2.4.11	Additional section related to the Final Package Check process step.
Chapter 3: • sections 3.1, 3.2 and 3.3	Including the relevant and updated references to the current EU data protection legislation as well as additional relevant pieces of guidance issued by data protection authorities and professional organisations active within the data protection space.
• section 3.3.3	Clarification aimed to underline that risk assessment is the preferred methodology to achieve anonymisation while preserving meaningful data utility.
• section 3.4.5	Additional guidance provided on which data variables to be retained or anonymised using transformation anonymisation techniques to maximise data utility.
• section 3.5.2	Clarification aimed to provide a common understanding of the concept of small population.
• section 3.7	A mandatory Anonymisation Report Form Template is provided along with completion instructions.
• section 3.8	Clarification on the fact that handwritten text in any shape of form should considered personal data and consequently it should not be disclosed.
• section 3.9	

Chapter and Section reference	Summary of the change
	New guidance on the implementation of temporary redaction of interim results of ongoing studies, still conducted in a blinded fashion at the time of publication.
Chapter 4:	Including the relevant and updated link references to the guidance documents mentioned in this chapter. Deletion of footnotes (links added beside name of the guidance document). Update of the Justification Table template deleting the column related to 'Applicant/MAH to reference the section(s) of the Annex 3 of Policy 0070 on which the redaction is based.'
Chapter 5: • Annexes	The annexes have been streamlined and updated to current templates. Obsolete templates have been deleted. Template letters have been updated to current versions. The current workflow is added. The current sample justification template is added. The current anonymisation report published on EMA corporate website and the old templates deleted. In addition to the checklist for the Redaction Proposal Document package, a new checklist for the Final Redacted Document package has been added.
Chapter 6 References	This chapter has been removed. References have all been updated and added to the individual relevant chapters.