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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'

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On 03 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 published on 12 April 2017 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: • Scope, page 7	Clarification has been provided on which clinical reports should be submitted for publication. All clinical study reports cross-referred to within a paediatric extension or modification of indication application submitted in the context of regulatory procedures not falling within the scope of Policy 0070 will be subject to publication. Where clinical study reports are cross-referred to within extension or modification of indication and line extension applications other than paediatric, only the pivotal clinical study reports submitted will be subject to publication.
Chapter 2: • Section 2.2, page 14	Clarification that **individual** patient data listings contained in CSR section 14.3.4 "Abnormal Laboratory Value Listing" can be considered out of scope of phase 1 of Policy 0070. Consequently, it is acceptable to have them removed from the clinical study reports prepared for publication. Individual patient data listings presented in other sections of the clinical study report (e.g. concerning PK and immunogenicity results,

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Chapter and Section reference	Summary of the change
	laboratory values, case narratives or protocol deviations) cannot be considered out of scope and should not be removed but anonymised.
Chapter 2: • Section 3.3.2.1.2 page 29	Validation stage In order to support applicants/MAHs with the preparation of the Redaction Proposal Document packages a new validation checklist is made available in annex 1.14.
Chapter 5: • Annex 1.12 page 91	In Annex 1.12 the column containing explanation - clarification on CTD format section 14.3.4 Abnormal Laboratory Value Listing (Each Patient) concerning modules/sections In and Out of scope of phase 1 of Policy 0070 has been updated to reflect clarification on individual patient listings considered out of scope.
Chapter 5: • Annex 1.13 page 95	Abbreviated Anonymisation Report template An anonymisation report template has been added for applications that do not contain patient identifiers.
Chapter 5: • Annex 1.14 page 97	A new Checklist for the "Redaction Proposal Document" package has been added. This checklist is to help applicants/MAH when submitting clinical data to comply with Policy 0070. This is not a submission requirement but simply an aid to ensure that both the applicant/MAH and the European Medicines Agency (EMA) are able to identify validation non-compliance at an early stage.

2. Minor changes

Chapter and Section reference	Summary of the change
Chapter 2: • section 3.2 page 15	Article 58 timeline for submission of documents has been added to the table
Chapter 2: • section 3.3.1.6 page 18 • section 3.3.1.7 page 20	File naming convention The leaf title for module 1 anonymisation report has been moved from the end of the section to first item File name template for pdf file for module 1 added to this section as first item
Chapter 2: • section 3.3.1.8 page 25	Clarification that the out of scope sections must clearly indicate which pages and information has been removed.
Chapter 5: • Annexes 1.4 page 71	Editorial improvements to Template cover letter text "Redaction Proposal Document" package where a CHMP opinion has been

Chapter and Section reference	Summary of the change
	adopted.
Chapter 5: • Annexes 1.5 page 73	Editorial improvements to Template cover letter text "Redaction Proposal Document" package where an application has been withdrawn.