EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Key aspects related to the submission of clinical reports for the purpose of publication in accordance with EMA Policy 0070

Follow-up stakeholder meeting on the implementation of EMA policy 0070

Presented by Frances Nuttall (Senior Policy Adviser)
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Types of documents/sections of documents considered not to fall within the scope of policy 0070 (1/4)

- In the CTD locations within the policy's scope there may be additional documents other than clinical overviews, clinical summaries and Clinical Study Reports submitted by the Applicants/MAHs. The EMA would like to clarify the types of documents that are subject to publication

- CTD section 2.7 may contain apart from the standard clinical summaries, additional documents such as Integrated Summary of Safety (US) and Integrated Summary of Efficacy (US). The EMA confirms that these documents are considered clinical summaries and therefore they are subject to publication

Types of documents/sections of documents considered not to fall within the scope of policy 0070 (2/4)

- CTD section 5.3 may contain, apart from the Clinical Study Reports, additional documents such as Reports of supportive studies not involving human subjects and PSURs/PBERs. These types of documents are not Clinical Study Reports and they are not considered subject to publication

- CTD section 5.3 may also contain Reports of Analyses of Data from More than One Study (meta-analyses and pooled analyses). These reports are considered Clinical Study Reports and they are subject to publication

- The EMA emphasizes that all sections of the clinical reports falling within the scope of the Policy are subject to publication

Types of documents/sections of documents considered not to fall within the scope of policy 0070 (3/4)

- In particular, all appendixes (as per ICH M4) of the clinical overview and clinical summaries and all sections of the Clinical Study Reports up to and including section 15 (as per ICH E3) are subject to publication

- The EMA notes that under ICH E3, the Clinical Study Reports are expected to contain individual patient data listings even within the body of the report. In particular, these listings are contained in section 14.3.4 Abnormal Laboratory Value Listing (Per Patient/per Visit). The EMA considers that such listings fall outside the scope of Phase 1 of the policy. It would be acceptable to remove them from the Clinical Study Reports prepared for publication. It is not expected that the removal of this data would affect in a significant way the understanding of the findings and data utility of the published clinical report since the clinical relevant findings are revealed in section 12.4.2.3 Individual Clinically Significant Abnormalities, which section is subject to publication

Types of documents/sections of documents considered not to fall within the scope of policy 0070 (4/4)

- Case narratives should not be redacted in full regardless of their location within the clinical reports (body of the report or listings). They should be instead anonymised

- Patient level data referred to in the free-text should not be redacted in full but instead anonymised

- External guidance on the anonymisation of clinical reports for the purpose of publication in accordance with Policy 0700 should be followed

Process for the submission of clinical reports (1/7)

- There are de facto 4 sub processes:
  - Submission of redaction proposal version process
  - Redaction consultation process
  - Submission of the final redacted version process
  - Publication process

Process for the submission of clinical reports (2/7)

- Applicants/MAHs are required to submit two packages:
  - a Redaction Proposal Document Package and
  - a Final redacted Document Package

- Redaction Proposal Document Package:
  - The Redaction Proposal version is an initial version of the clinical reports for publication in which proposal redactions are marked
  - Cover letter including the declaration confirming that the clinical reports submitted for scientific evaluation are the same as that submitted for publication, except for the proposed redactions
  - A list of documents submitted, annexed to the cover letter
  - Table of contents for each module
  - A completed set of justification tables (CCI redactions only) detailing all proposed redactions for each redacted document

Process for the submission of clinical reports (3/7)

- Redaction Proposal Document Package (cont'd):
  - Files uploaded to the Redaction Proposal eCTD sequence should be named in line with existing naming conventions. The mandatory 'submission description' field for the files uploaded to the relevant sequence will also need to be populated. In respect of the individual documents within each file, the file name components are:
    - 1. Product name: Trade name
    - 2. Procedure number: EMEA/H/C/xxxxxx/xx/xxxx
    - 3. CTD Location
    - 4. Type of document

    Taking the above elements together, the submitted documents must be named as follows:

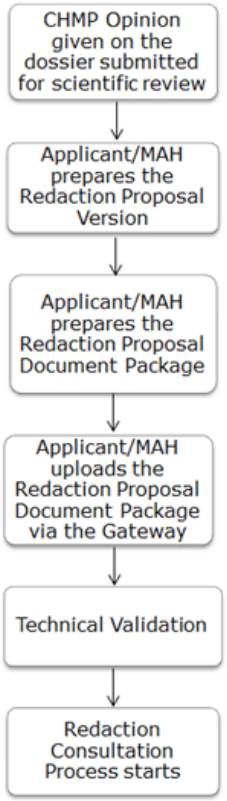
    1 2 3 4
    - Trade name_ EMEA/H/C/xxxxxx/xx/xxxx_ Module 2.5_ Clinical Overview

Process for the submission of clinical reports (4/7)

- On receipt of the redaction proposal version, the EMA initiates a redaction consultation process. Following the assessment the Agency will communicate its final conclusion to the company
- The redaction consultation consists of three different stages that are:
  - Internal receipt and distribution
  - Validation
  - Assessment of CCI

Process for the submission of clinical reports (5/7)

Redaction Proposal Version Process Flowchart:



Process for the submission of clinical reports (6/7)

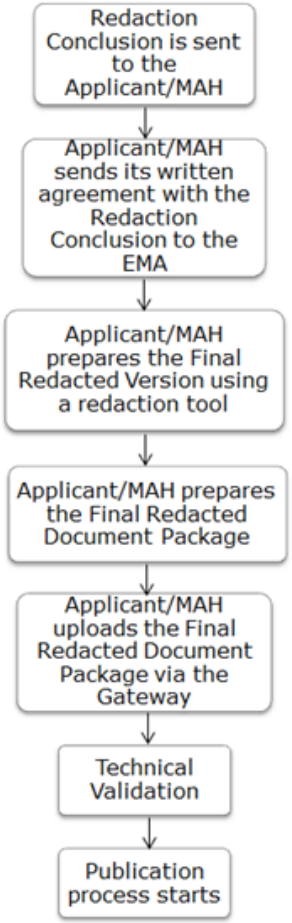
- Final redacted Document Package:
  - The Final Redacted version is the final version of the clinical reports for publication in which redactions have been carried out by the Applicant/MAH using a redaction tool
  - Cover letter together with a list of documents submitted annexed to this letter
  - Table of Contents for each Module
  - Anonymisation report

Process for the submission of clinical reports (7/7)

The Final Redacted version output from the redaction tool must adhere to the following requirements:

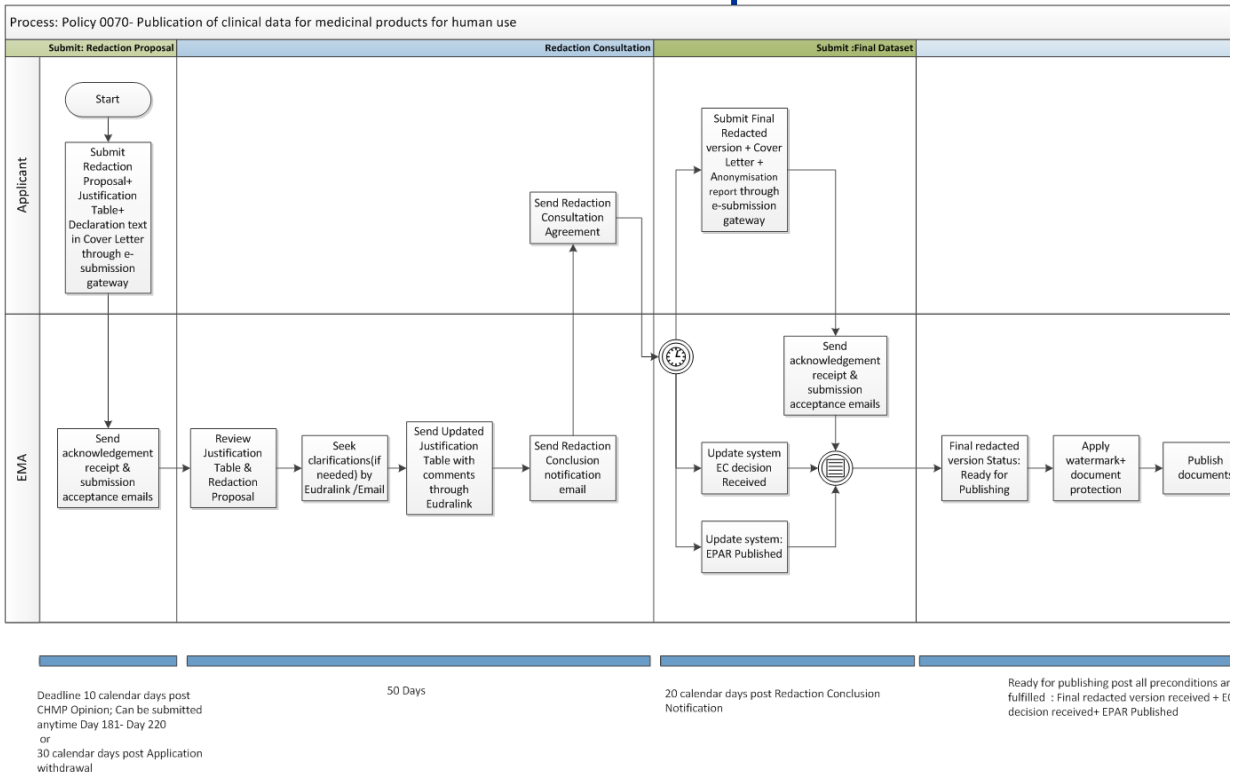
- The file format of the documents must be in PDF format. [Supported PDF formats are ISO 32000-1 (PDF 1.7), ISO 19005 (PDF/A), ISO 14289 (PDF/UA)]
- The size of the PDF files should not exceed 100 Mbyte each
- The PDF files must not be password protected, as EMA will add a watermark to every page
- The un-redacted text only must be text-searchable. Redacted text and the redaction box should neither be searchable nor subject to further editing
- Redactions must be clearly visible (typically using a black rectangle)
- Any redaction agreed codes, e.g. CCI and PPD) should be visible and irremovable together with the redacted text
- The Final Redacted Version of documents in colour should also be in colour

Final Redacted Process Flowchart:



Process for the submission of clinical reports

Illustration of key components in the process from the point of submission by an Applicant/MAH to the point of publication



Thank you for your attention

Further information

[Insert relevant information sources or contact details as applicable.]

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