



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Legacy procedures – EMA proposal

Clinical Data Publication (Policy 0070) – Step 2 – EMA webinar

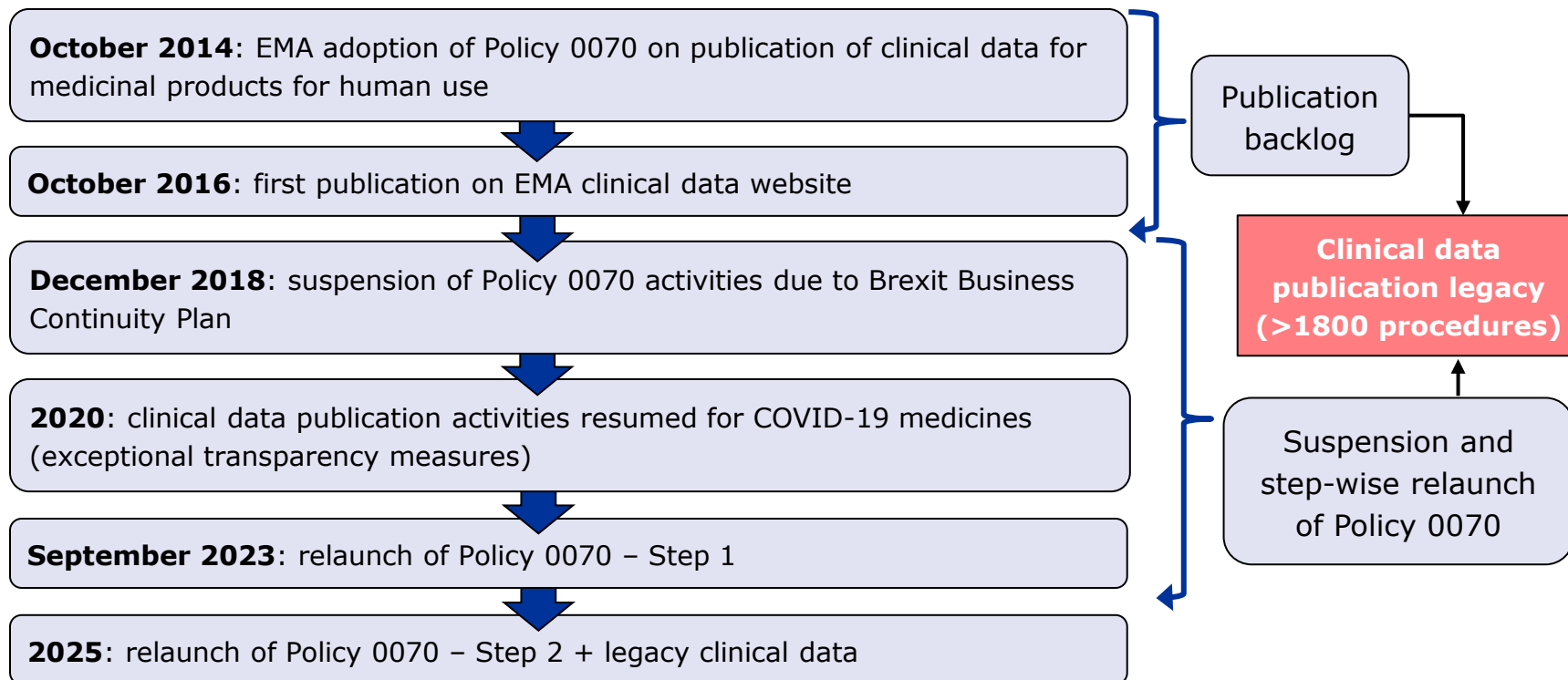
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Legacy clinical data - overview



EMA proposal for the publication of legacy clinical data

In view of the significant volume of clinical data publication legacy procedures, careful consideration has been given to how they should be handled as part of Step 2 of Policy 0070 relaunch

Main aspects considered:

- Balance between EMA's duties on clinical data transparency and resource management
- Sustainability of the cooperation of marketing authorisation applicants and holders to achieve compliance with Policy 0070
- Providing an adequate and timely response to public interest on clinical data
- Not interfering with the publication of clinical data packages related to the current regulatory procedures

EMA proposal for publication of legacy clinical data

Option 1: processing the legacy in chronological order or by a priority list

- May not respond to the interest of the public in a timely manner
- Resource intensive
- Priority list: criteria may not satisfy all stakeholders

Option 2: publication upon request (access-to-documents)

- Responds to the interest of the public
- Resource compatible
- Processed in chronological order/repetitive interest of request received (still TBD)

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If you are not representing a particular organisation please write 'Not applicable' into this field.

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Please select your type of enquiry

☐ I want you to answer a question

☒ I want an unpublished document (maximum 2 documents per request)

☐ I want help identifying which unpublished document I need

Option 2: Access-to-documents requests related to legacy clinical data will trigger a clinical data publication procedure

Any questions?

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