EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Clinical data publication procedural timelines

Clinical Data Publication (Policy 0070) relaunch - EMA webinar

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Overview

Clinical data publication dates

Submission of Redaction Proposal Document Packages

Invitation email

Overview of timelines for different types of applications

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Clinical data publication dates

Policy 0070

- For initial marketing authorisation applications, extension of indication applications and line extension applications, EMA will publish the redacted/anonymised clinical reports **within 60 days of the issuance of the Commission Decision**.
- For withdrawn applications and applications under Article 58 of Regulation (EC) No 726/2004 the publication of the redacted/anonymised clinical reports will take place **within 150 days after the receipt of the withdrawal letter by EMA or adoption of the CHMP opinion, respectively.**

CDP restart Step 1

- For initial marketing authorisation applications, extension of indication applications and line extension applications, EMA will publish the redacted/anonymised clinical reports within **120 days after CHMP opinion.**
- For withdrawn applications and applications under article 58 of Regulation (EC) No 726/2004 the publication of the redacted/anonymised documents will take place within **150 days after receipt of withdrawal letter by EMA or after CHMP opinion, respectively.**

Clinical data publication procedural steps: submission of Redaction Proposal Document Packages

External Guidance on Policy 0070

- For initial marketing authorization applications and line extension applications, applicants/MAHs must submit their Redaction Proposal Document package **between day 181 and day 220 of the procedure** (≤30 days pre-opinion and ≤10 days post-opinion).
- For extension of indication applications, applicants/MAHs must submit their Redaction Proposal Document package **≤ 30 days pre-opinion and ≤ 10 days post-opinion**.
- For withdrawn applications, applicants/MAHs must submit their Redaction Proposal Document package **≤ 30 days post-receipt of the withdrawal letter by EMA**.
- For Article 58 applications, applicants must submit their Redaction Proposal Document package **≤ 30 days post-CHMP opinion**.

CDP restart Step 1

- For initial marketing authorisation applications and line extension applications, applicants must submit their Redaction Proposal between D181 and **≤30 days post-opinion**
- For extension of indication applications, applicants must submit their Redaction Proposal between ≤30 days pre-opinion **and ≤30 days post-opinion**
- For withdrawn applications, applicants must submit their Redaction Proposal Document Package **≤60 days post-receipt of the withdrawal letter by EMA**
- For Article 58 applications, applicants must submit their Redaction Proposal Document Package **≤60 days post-opinion**

Clinical data publication procedural steps: invitation email

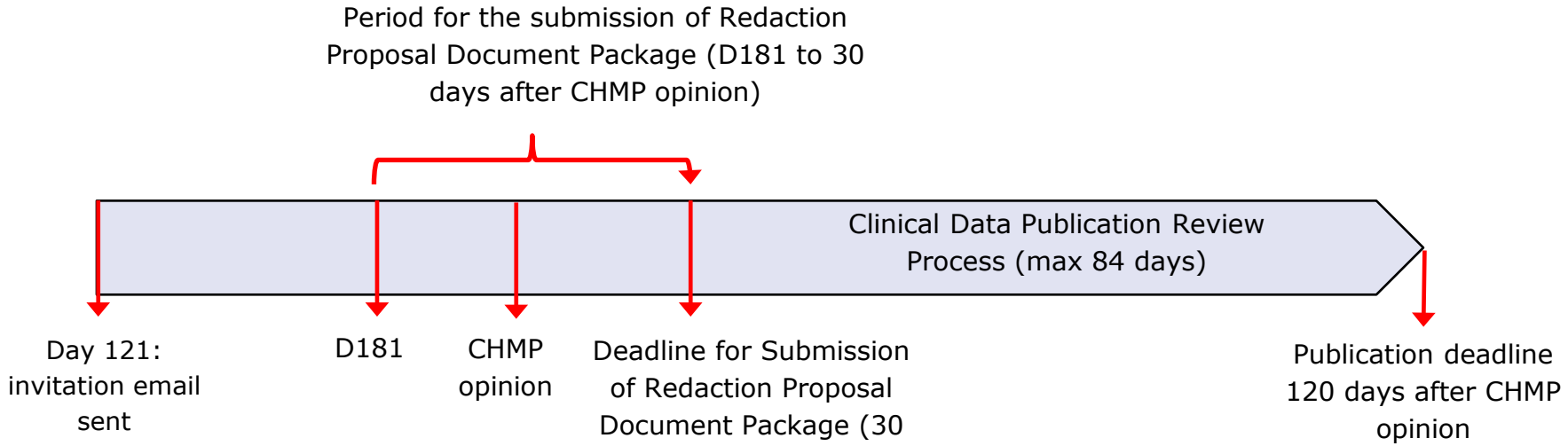
Applicants with ongoing **initial marketing authorisation (new active substances) and/or line extension applications (COVID-19 medicines only)** with a planned CHMP opinion date in September 2023 and onwards will receive an invitation email by **procedure Day 121**

Applicants with ongoing **extension of indication applications (COVID-19 medicines only)** with a planned CHMP outcome date in September 2023 and onwards will receive an invitation email **≤90 days pre-CHMP outcome**

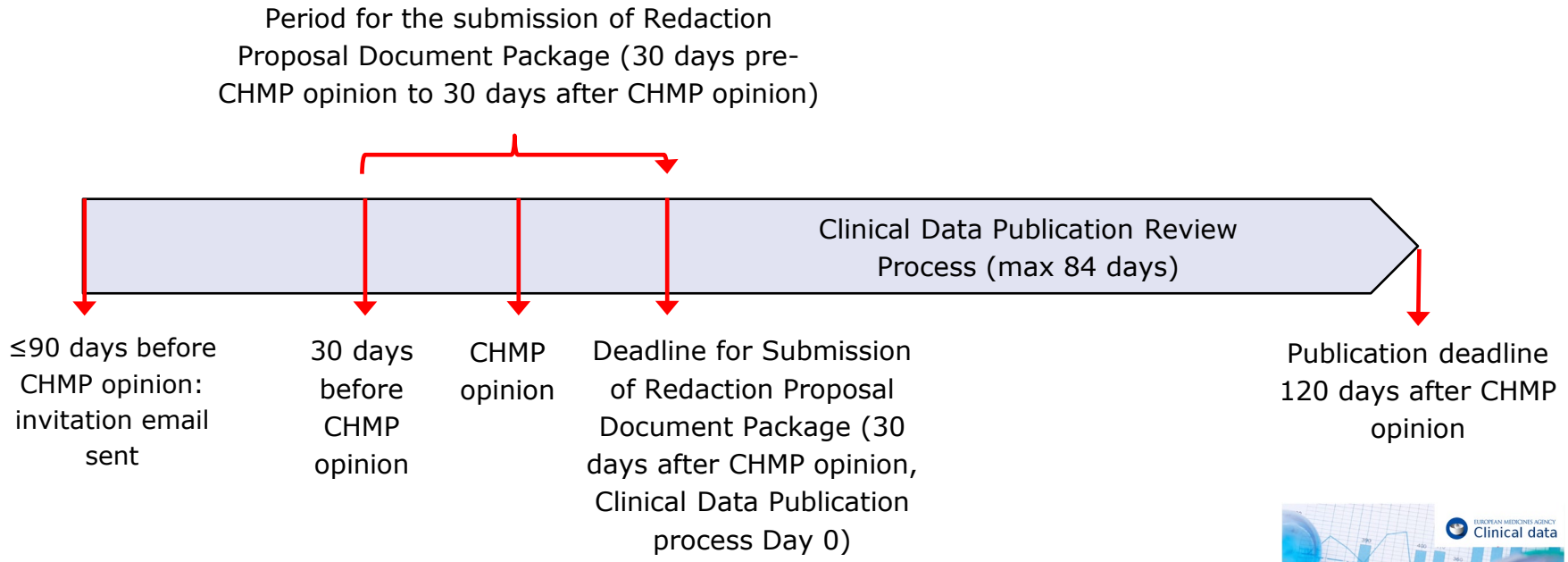
The following documents will be attached to the invitation email:

- Updated Q&A
- Draft list of documents in scope for publication, for agreement within 2 weeks after receipt of the invitation email
- Submission checklist

Clinical data publication timeline (iMAA and line extension applications)

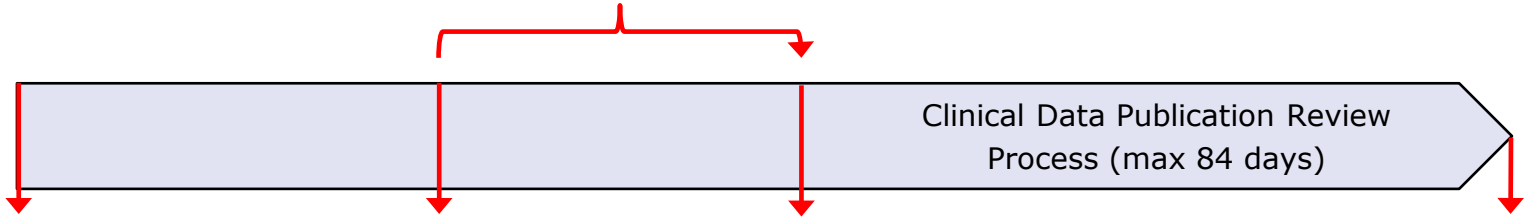


Clinical data publication timeline (extension of indication applications)



Clinical data publication timeline (withdrawn applications)

Period for submission of Redaction Proposal Document Package: up to 60 days after receipt of withdrawal letter by EMA



Day 121 or ≤90 days before CHMP opinion: invitation email sent

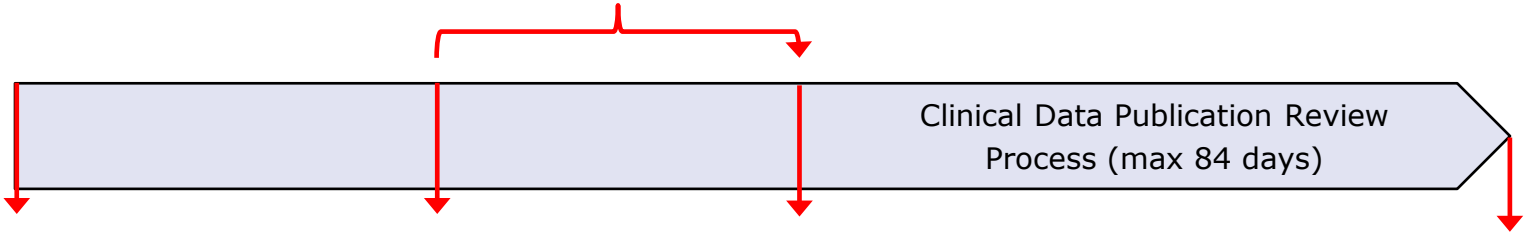
Receipt of withdrawal letter by EMA

Deadline for Submission of Redaction Proposal Document Package (Clinical Data Publication process Day 0, 60 days after receipt of withdrawal letter by EMA)

Publication deadline 150 days after receipt of withdrawal letter by EMA

Clinical data publication timeline (Article 58 applications)

Period for submission of Redaction Proposal Document Package: up to 60 days after Article 58 CHMP opinion



Day 121 or ≤90 days before CHMP opinion: invitation email sent

Article 58 CHMP opinion

Deadline for Submission of Redaction Proposal Document Package (Clinical Data Publication process Day 0, 60 days after Article 58 CHMP opinion)

Publication deadline 150 days after CHMP opinion

Clinical data publication review process steps (1): redaction proposal document package

1. **Day 0**: technically valid submission of the Redaction Proposal Document Package
2. **Day 1**: receipt of the Package by the EMA CDP Team
3. **Day ≤10**: validation outcome is sent to applicant and start of assessment
4. **Day ≤47**: redaction conclusion is sent to applicant
5. **≤7 days after redaction conclusion is sent to applicant (Day 54 max):** applicant/MAH provides written agreement to the redaction conclusion on CCI (if CCI proposals were made by applicants and assessed by EMA)
6. **≤14 days after redaction conclusion is sent to applicant (Day 61 max):** upon request, applicant/MAH provides updated anonymisation report (AnR) and/or written responses on the recommendations/comments on the anonymisation report
7. **≤7 days after AnR or written responses are provided by applicant (Day 68 max):** final EMA response is sent to applicant

Invalid package

If no CCI and no updated AnR/written responses are requested go to **step 8**

Clinical Data Publication procedural timelines

Clinical data publication review process steps (2): Final Redacted Document Package

8 **≤7 days after final EMA response is sent to applicant (Day 74 max)**: technically valid submission of the Final Redacted Document Package

9 **≤7 days after receipt of Final Redacted Document Package (Day 81 max):** final package check

10 **≤10 days after receipt of a valid Final Package (Day 84 max):** publication of the Final Redacted Document Package

Invalid package

EMA communication (if final package is invalid or if valid, for confirmation of publication date)

Any questions?

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#cdp1

https://app.sli.do/event/vTYquhyaJUqWrkHQrinZj9