



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Clinical data publication overview process and timelines

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

Presented by Silvia Garrido-Lestache on 14 November 2024

Clinical Data Publication Senior Specialist, Transparency Department, Stakeholders and Communication Division

An agency of the European Union





Overview



Clinical data publication dates



Submission of Redaction Proposal Document Packages



Invitation email



Overview of timelines for different types of applications



Clinical data publication review process



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- For withdrawn applications and applications under Article 58 of Regulation (EC) No 726/2004 the publication of the redacted/anonymised clinical reports will take place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- For withdrawn applications and applications under article 58 of Regulation (EC) No 726/2004 the publication of the redacted/anonymised documents will take place within **150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 authorisation 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 $\leq$ **30 days pre-opinion and ≤ 10 days post-opinion**.
- For withdrawn applications, applicants/MAHs must submit their Redaction Proposal Document package $\leq$ **30 days post-receipt of the withdrawal letter by EMA**.
- For Article 58 applications, applicants must submit their Redaction Proposal Document package $\leq$ **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**



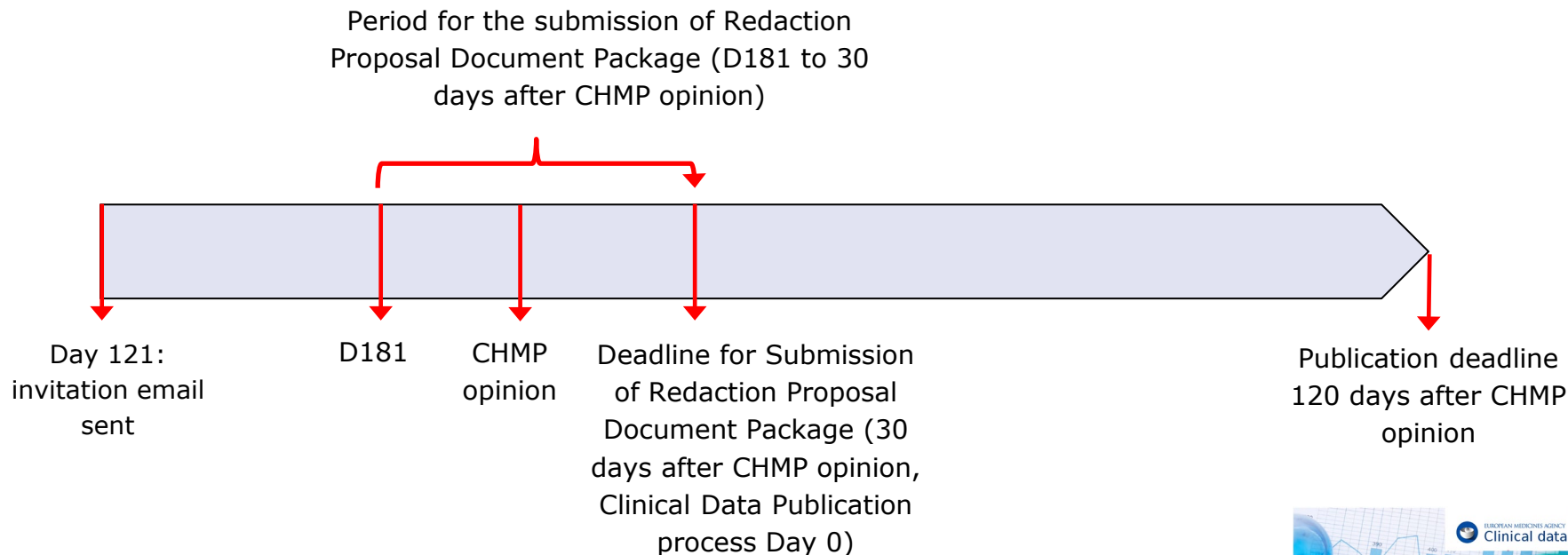
Clinical data publication procedural steps: invitation email

Applicants with ongoing selected procedures with a planned CHMP opinion date from Q2 2025 onwards will receive an invitation email

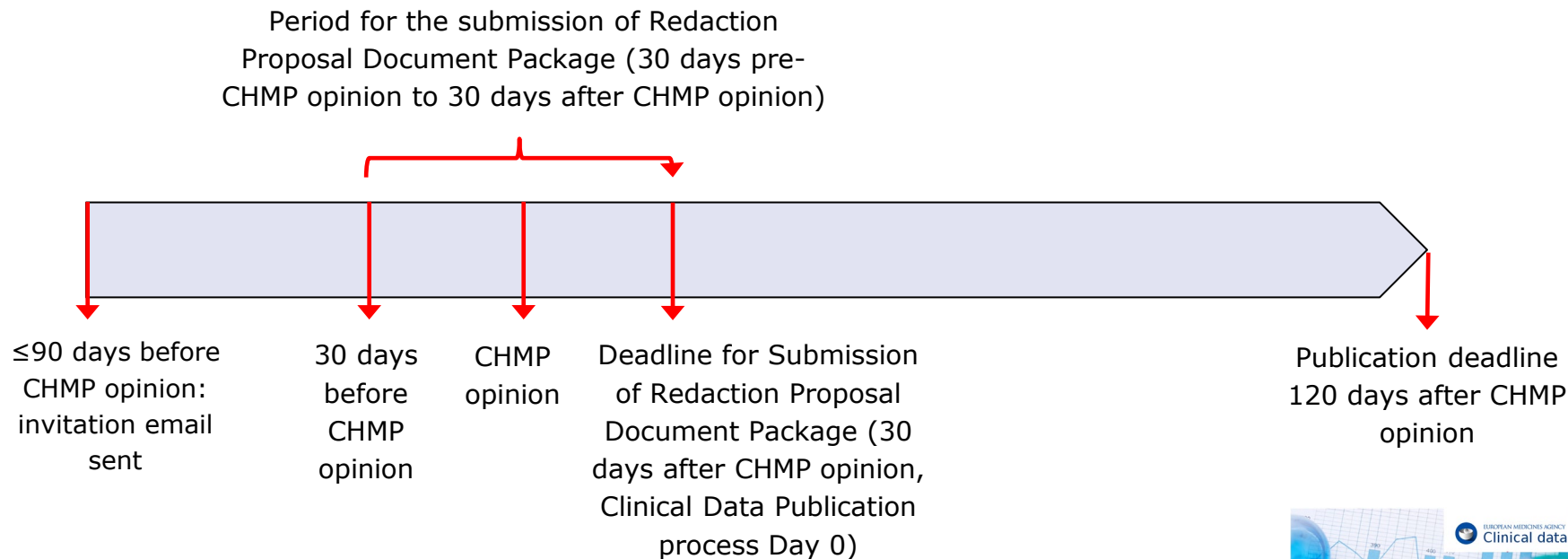
The following documents will be attached to the invitation email:

- Updated Q&A
- Draft list of documents (LED) considered in scope for publication, for agreement within 2 weeks after receipt of the invitation email
- Submission checklist
- Anonymisation Report template

Clinical data publication timeline (iMAA and line extension applications)

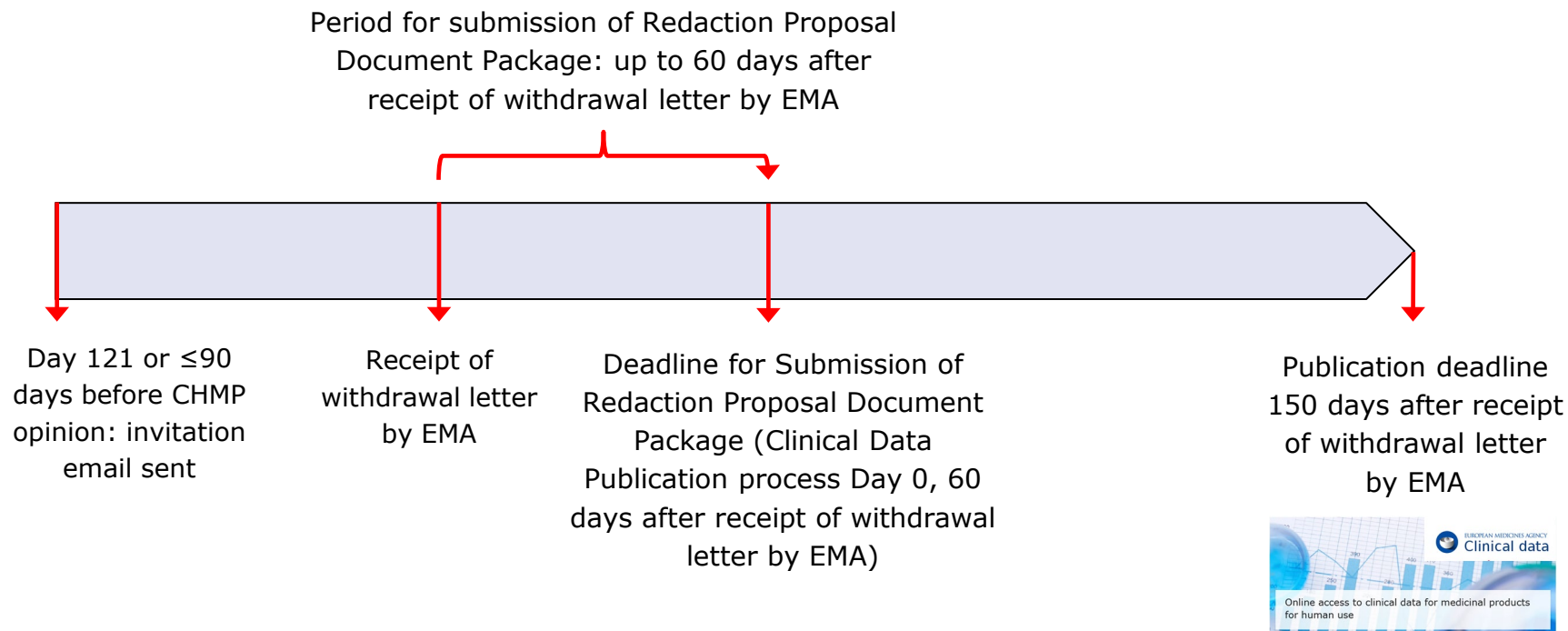


Clinical data publication timeline (extension of indication applications)



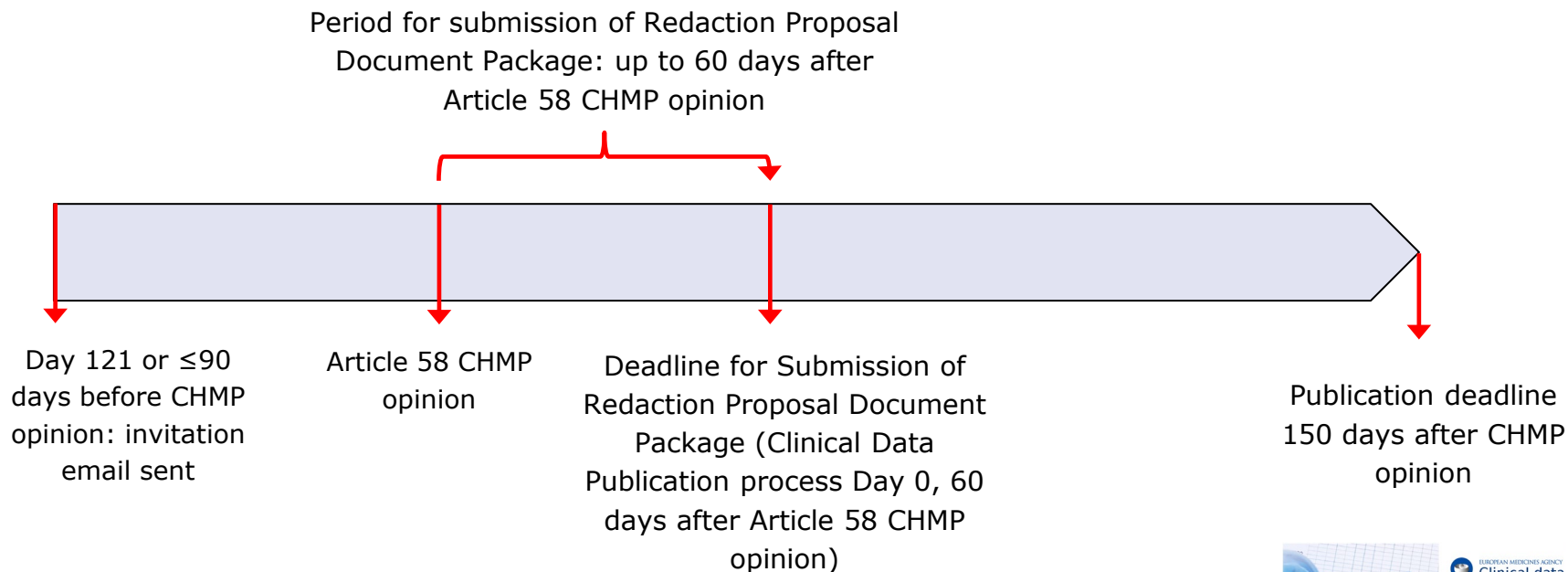


Clinical data publication timeline (withdrawn applications)



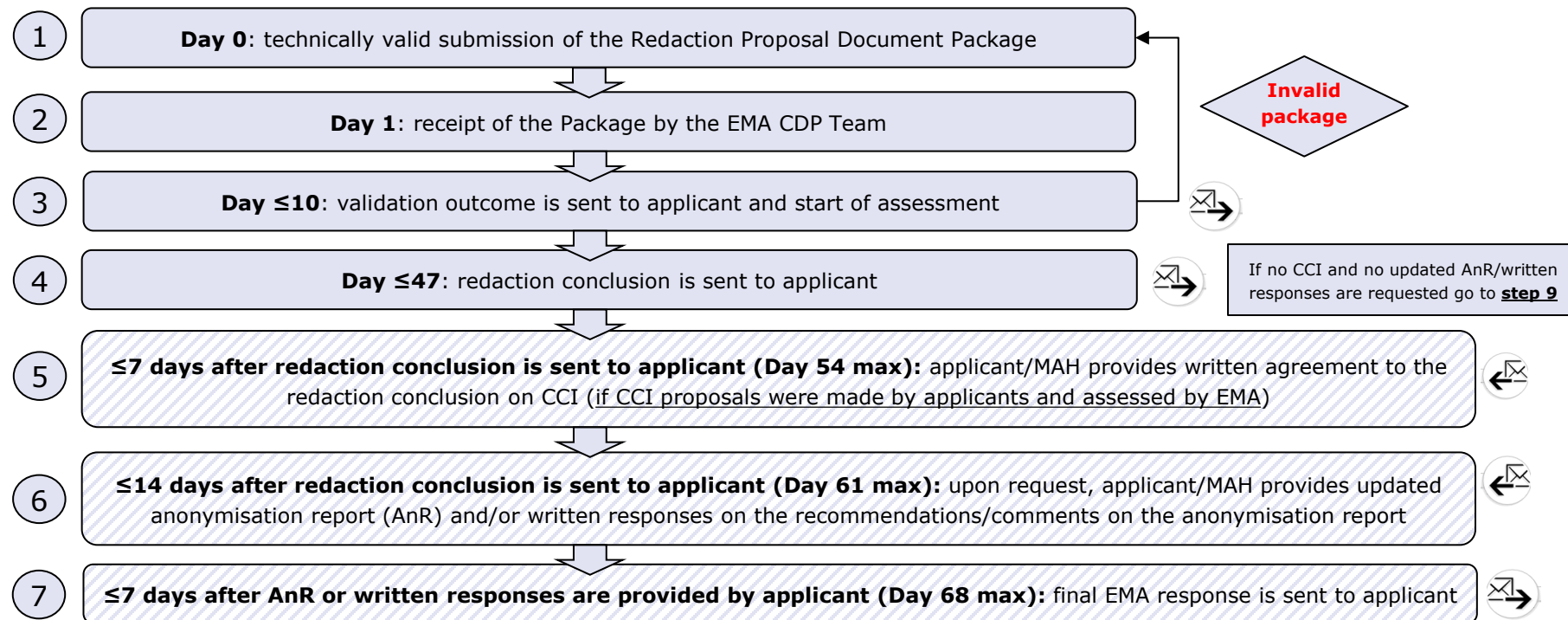


Clinical data publication timeline (Article 58 applications)

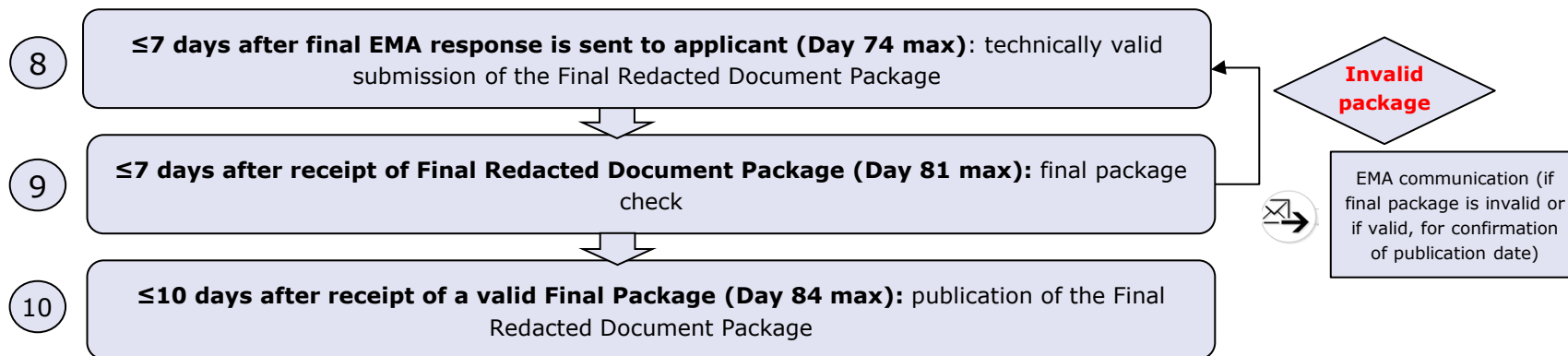




Clinical data publication review process steps (1): redaction proposal document package



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





Any questions?

Join at
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#2883 085

 Passcode: **zjc1xf**



<https://app.sli.do/event/eQXpoY4Tkyb5mVkMMDnuK1>