



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA - HC Collaboration

Review & Publication of Clinical Data Packages

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

Presented by Radu Popescu on 14 November 2024
Clinical Data Publication Manager, Transparency Department, Stakeholders and Communication Division

An agency of the European Union





EMA-HC collaboration on publication of clinical reports

- The same clinical reports in scope for publication – 2.5, 2.7.1 – 2.7.4 & CSRs
- The same publication timelines – 120 days post regulatory outcome
- Joint Anonymisation Report Template & Instructions
- Alignment on out of scope documents / information
- Acceptance of the redaction overlay text specific for the other jurisdiction
- Pilot on single review of redaction proposal packages



Proposed Areas of Collaboration (1/2)

- Monitoring the regulatory procedure pipelines in both jurisdictions
 - Regular exchange of information between the two agencies
- Identification of procedures suitable for single review
 - Applicant's agreement requested
 - One agency taking the lead of the review
- Establishing the list of documents (LED) for publication (for single review procedures)
 - LEDs in both jurisdictions agreed with the applicant



Proposed Areas of Collaboration (2/2)

- Single review of the CCI proposals and anonymisation implementation
 - One single submission of the redaction proposal package to the lead agency
 - One single outcome sent to the applicant
 - Non-lead agency consulted on specific matters
 - Non-overlapping documents submitted for review to non-lead agency prior to publication
 - Applicants can request single review
- Package publication
 - Publication synchronisation in both jurisdictions (if possible, for joint review)
 - Recognition of already published packages in the other jurisdiction
 - A separate final redacted package submitted to each agency (for all packages)



Procedural Selection Criteria for Single Review

- Marketing authorisation application submitted in both jurisdictions
- Up to 6-month difference between the regulatory procedural outcomes in the two jurisdictions
- More than 70% overlap between the content of the packages to be published in the two jurisdictions



EMA-HC Collaboration Benefits

- Single review packages
 - ✓ Applicants can start preparing the packages for both jurisdictions simultaneously
 - ✓ One redaction proposal package prepared and submitted to lead agency
 - ✓ One outcome applicable for both jurisdictions
 - ✓ Only non-overlapping documents submitted for review to non-lead agency
- Packages already published in one jurisdiction
 - ✓ No redaction proposal package submission in the other jurisdiction
 - ✓ Only non-overlapping documents submitted for review in the other jurisdiction



Any questions?

Join at
slido.com
#2883 085

 Passcode: **zjc1xf**



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