Getting ready for the EMA Policy 0070 – Clinical Data Publication – Relaunch

Policy 0070 was developed by the EMA. It became effective January 1st, 2015, and applies to centrally authorised medicinal products. The Policy was suspended in December 2018 because of the relocation of EMA from London (UK) to Amsterdam (the Netherlands). After some delay, mainly due to the COVID-19 pandemic, EMA is now relaunching Policy 0070 as of September 2023.

What is Policy 0070 about?

There is growing demand from stakeholders and the public for additional transparency on medicinal products. Therefore, EMA aims to publish clinical data submitted by pharmaceutical companies that support their marketing authorisation application (MAA), while also ensuring protection of patient privacy and commercially sensitive information.

The clinical data published include the Clinical Overview & Summaries, the Clinical Study Reports & appendices.

Important: Policy 0070 applies to all clinical data submitted to EMA, regardless of the outcome of the regulatory procedure. Hence, it includes rejected and withdrawn applications too.

Redaction of Clinical Data

EMA will not publish clinical data without consulting with the applicant first. The applicant needs to supply EMA with the redacted clinical data set. EMA reviews the company's redaction proposals and provides recommendations. The company then submits the revised documents in line with EMA's recommendations and the Agency publishes the final version.

The applicant may redact clinical data documents for two reasons:

- Protected Personal Data (= PPD): Personal data should not be visible. This means that any information relating to an identified or identifiable natural person should be anonymised. This should be justified in the Anonymisation Report (AnR).
- Commercial Confidential Information (= CCI): If the applicant qualifies information as CCI, this needs to be suitably justified in the CCI Justification Table. Please note that public information cannot be categorised as CCI.

Policy 0070 relaunch: What's New?

Although Policy 0070 remains mostly unchanged compared to 2015, there have been several updates.

Procedural updates – Relaunch in two steps:

Step 1 applies to new active substances that receive an opinion from the Committee for Medicinal Products for Human Use (CHMP) from September 2023, as well as products that will receive a negative CHMP opinion or products for which the application is withdrawn. Important: there is no plan to request clinical data for products authorised during suspension of Policy 0070.

Step 2 covers the full scope of Policy 0070 (including biosimilars, generics, Article 58 applications, extension of indications, and line extensions) and is planned in the course of the year 2024. More information will follow in due time.

Practical updates:

- EMA has updated Q&As document on the External Guidance on Policy 0070 (July 2023).
- Invitation Letters to request Redaction Proposal Document Package (RPDP).
- Pre-submission meetings are offered.
- Updated cover letter to include checklist to ensure validation success.
- Amended justification table template: Applicants to confirm they reviewed that the proposed CCI is not in the public domain or publicly available.
- Updated Anonymisation Report (AnR) template in structured fields format.

When to submit during the Centralised Procedure?

Applicants with an ongoing initial marketing authorisation applications (MAA) for a new active substance with a planned CHMP Opinion date from September 2023 onwards will receive an invitation letter from EMA to submit a RPDP ≤ 90 days before the planned CHMP opinion date.
For initial MAAs, the timeline to provide EMA with the RPDP is Day 181 to ≥ 30 days post-opinion. For other kind of applications, please see EMA Q&A guidance document.

The Redaction Consultation (Clinical Data Publication review) process

The main steps of the end-to-end process for the publication of clinical data documents are:

Time	Step
Day 0	Submission of Redaction Proposal Document Package (RPDP) by the applicant
Day 1	Receipt of RPDP by EMA clinical data publication team
Day 10	Validation outcome send to the applicant
Day 47	Redaction conclusion (including conclusion CCI assessment and recommendations/comments anonymisation report) is sent to the applicant
Day 54	Applicant provides written agreement on Agency's redaction conclusion on CCI
Day 61	Upon request, applicant provides updated anonymisation report and/or written responses on the recommendations/comments on the anonymisation report
Day 74	Submission of Final Redacted Document Package (FRDP) by the applicant
Day 84	Publication of FRDP

What needs to be submitted?

The Redaction Proposal Document Package should contain:

	Item
1	Cover letter
2	List of documents submitted, annexed to the cover letter
3	Clinical overview (Module 2.5) - supplement/amendment/appendix
4	Clinical summary (Module 2.7.1. - 2.7.4.) - supplement/amendment/appendix
5	Clinical study report - body (Module 5.3)
6	Clinical study report - Appendices (Module 5.3) 16.1.1 protocol and protocol amendments 16.1.2 sample case report form 16.1.9 documentation of statistical methods
7	Set of justification tables (CCI redactions only) detailing all proposed redactions for each document
8	Anonymisation Report - Structured fields template will be available soon

After consultation with EMA and possible updating of the documents, the Final Redaction Document Package is submitted (see Redaction Consultation process, Day 74). Items 3, 4, 5, 6, and 8 will be published (see the items coloured in yellow in the Table above).

Where is clinical data published?

EMA Clinical Data Portal: https://clinicaldata.ema.europa.eu/web/cdp/home.

Zwiers Regulatory Consultancy recommendations

Start in time: The Clinical Data Publication review process runs in parallel with the Centralised Procedure and can pose an extra burden. To avoid delays during pending procedures, we recommend to review the list of documents in EMA's Invitation Letter, to start preparing the package already and to decide on the anonymisation approach, and whether this will be done in-house or will be outsourced.

Alternatively, you can pro-actively apply the CCI and PDD requirements and principles already during the writing of the CSRs, including appendices and the Clinical Overview and Summary. It means you are already prepared at the start of the Centralised Procedure.

The PPD/Anonymisation is the bulk of the work as all the documents defined by the EMA for clinical data publication need to be reviewed for PPD. It is necessary to perform a thorough quality check to ensure the risks of patient reidentification are being suitably mitigated while still allowing for optimal data utility for the users of the published clinical data documents. This strategy needs to be sufficiently described in the Anonymisation Report. Reserve enough time to do this task.

CCI justification is critical: Ensure that any CCI proposed is not already in public domain. Proposed CCI claims need to be very detailed, relevant, and specific and the justification needs to indicate how it would undermine your economic interest for each redaction proposal. A justification that an information is considered CCI in documents already published on CTIS (Clinical Trials Information System) is not sufficient. As per CCI Covid clinical data publication experience so far, the percentage of CCI within the documents has been very small: 0.01 %.

How can Zwiers Regulatory Consultancy support you?

We have experience with the Redaction Consultation process from start to finish and can support you as needed. If you want us to take care of the complete Policy 0070 process, we can. We have experienced teams of medical writers and regulatory experts that write clinical data documents with Policy 0070 in mind.