EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

# Clinical data publication - next steps

Clinical Data Publication (Policy 0070) relaunch

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# Current and proposed Scope Policy 0070

**Current Step 1 (September 2023)**
New active substances and Covid transparency measures

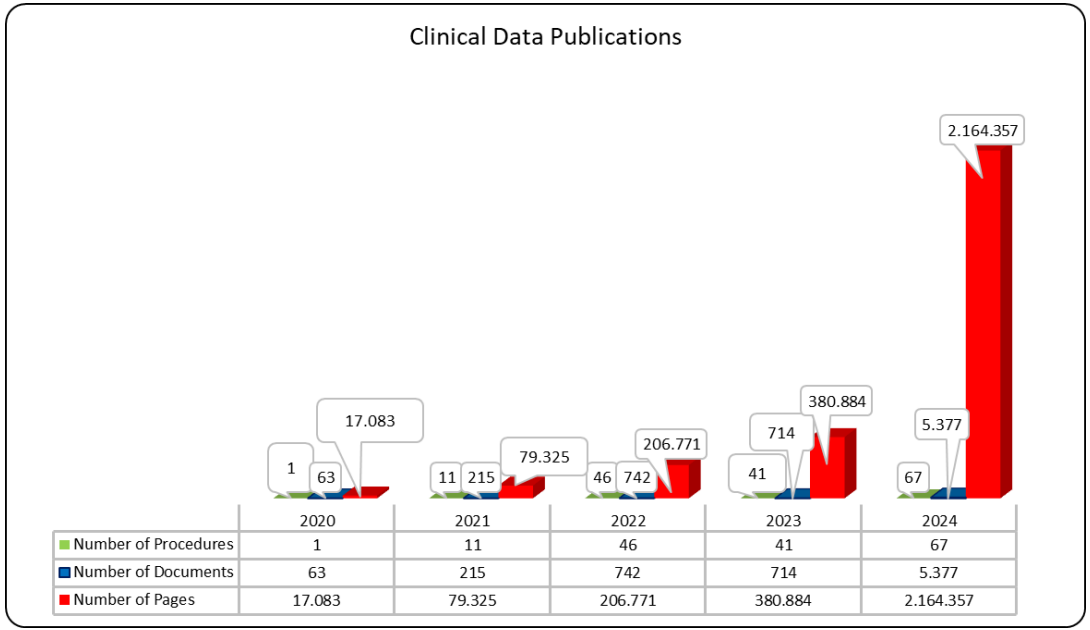
**Proposed Step 2**

All new MAAs including negative Opinions, withdrawn, and line extensions and major clinical Type II variations (extension of indications) from Q2 2025

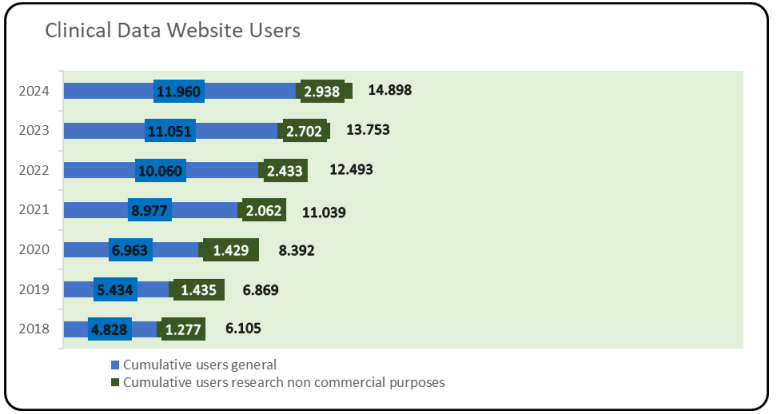
Exclude all biosimilars, hybrids and generics

Continue Covid procedures and any new public health emergencies that may arise

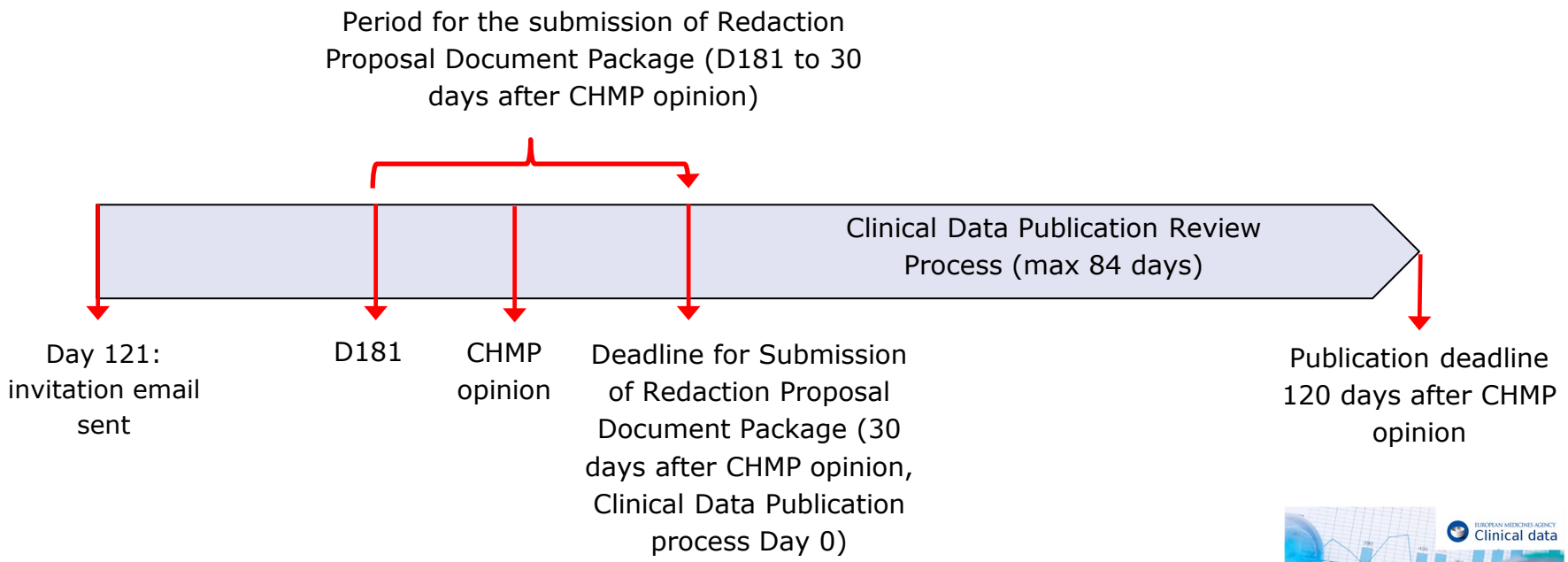
# CDP Data from 2020 to Oct 2024




| | 2020 | 2021 | 2022 | 2023 | 2024 |
|---|---|---|---|---|---|
| Number of Procedures | 1 | 11 | 46 | 41 | 67 |
| Number of Documents | 63 | 215 | 742 | 714 | 5.377 |
| Number of Pages | 17.083 | 79.325 | 206.771 | 380.884 | 2.164.357 |



# Clinical data publication timeline (iMAA and line extension applications)




# Updated Toolkit

- **External Guidance** - under review to publish early 2025
- Questions and answers **(Q/A)** document - published July 2023 – update in 2025
- EMA internal new **tracking tool** manage applications
- **Document identification system** developed in house - prepare list of documents in scope and provide with invitation letter
- **Invitation letter** – detailed procedural guidance – anonymisation template
- **Meetings** to assist preparation of packages – CCI - anonymisation strategy
- Collaboration with **Health Canada** align processes – workshare

# 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 interfere with the publication of clinical data packages related to the current regulatory procedures

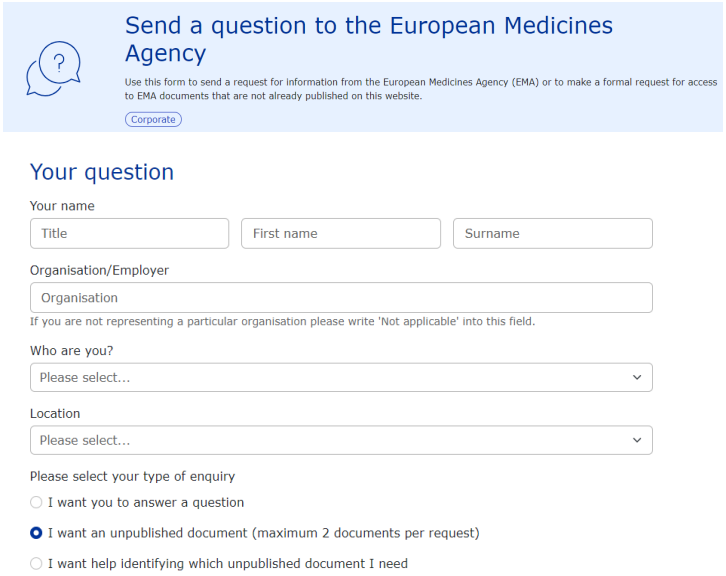
# EMA proposal for publication of legacy clinical data

**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)




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