EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Revised Scope and updated Toolkit

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

Presented by Karen Quigley on 14 November 2024
Head of Clinical Data Publication, Transparency Department, Stakeholders and Communication Division

Current and proposed Scope

Current Step 1

New active substances and Covid transparency measures

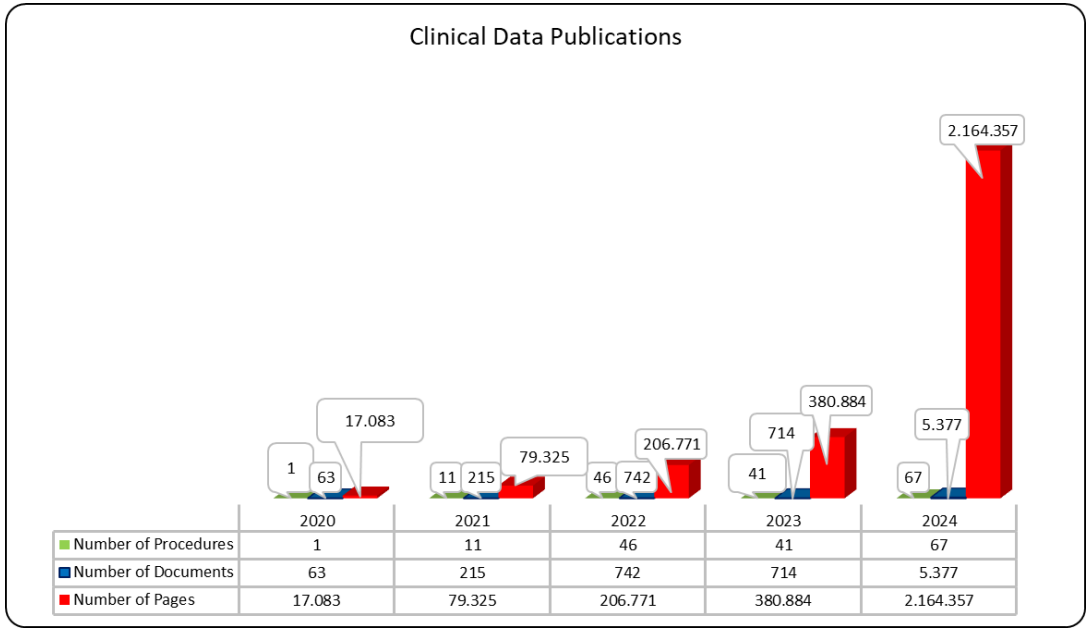
Proposed Step 2

All new MAAs including negative opinions, withdrawn applications, line extensions and major clinical Type II variations (extension of indications) from Q2 2025

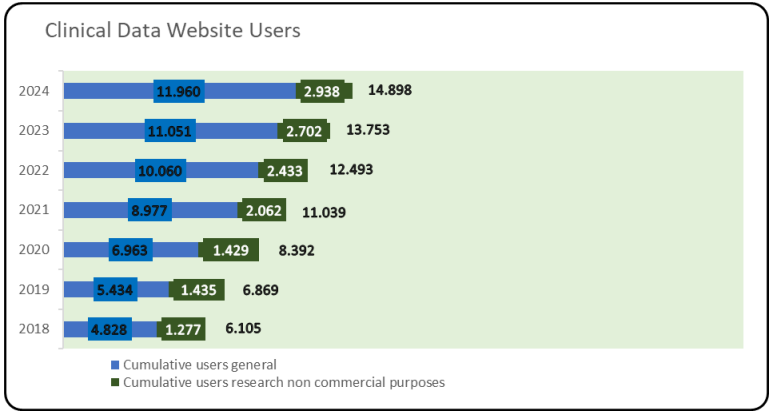
Exclude all biosimilars, hybrids and generics

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



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** to 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

Any questions?

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