EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Restart of Clinical Data Publication (CDP)
- Update on Transparency Activities -

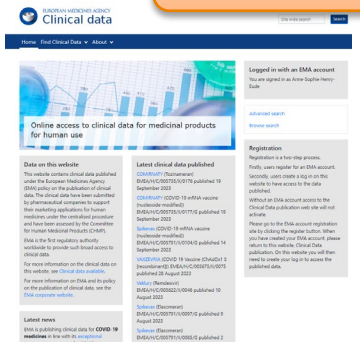
Silvia Garrido-Lestache
S-T-CDP
Documents Access and Publication/S-Div

What is CDP?

Clinical data supporting a MAA made public

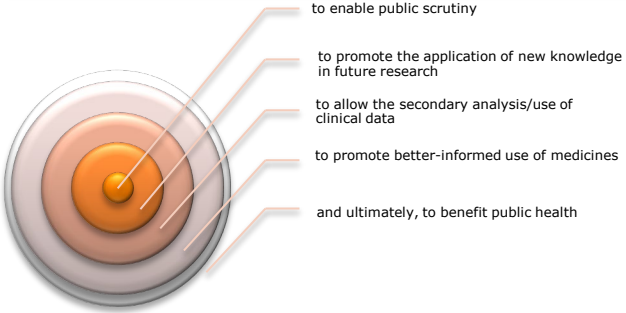
EMA first regulator to publish Clinical data

A portal* accessible to all



* https://clinicaldata.ema.europa.eu/web/cdp/

A tribute to transparency



Noël Wathion ’s legacy

CDP re-launch and 10 years anniversary of S-DP

Policy 0070 "CDP"

2014
Adoption by EMA MB of Policy 0070 on pro-active publication of Clinical Data

Oct 2016
First package published on the EMA CDP portal

Dec 2018
Suspension of publications due to Brexit BCP

Oct 2020
CDP as exceptional transparency measures for Covid-19 medicines

2022
EMA MB endorses relaunch of CDP activities

Sep 2023
Step 1 of Relaunch of CDP

Did you know…?
Zurampic (lesinurab) and **Kyrpolis (carfilzomib)** were the first human medicinal products for which clinical data were published by EMA

Did you know…?
Veklury (remdesivir) was the first COVID-19 medicine to have clinical data published in *EMA clinical data publication portal*

MB = Management Board
BCP = Business Continuity Plan

Experience from Covid Publications 2020-23

- Much wider scope includes new variants, boosters, Type II variations
- Interim study results published
- New tool to establish list of documents in scope
- Increased collaboration Health Canada - joint template
- Covid-19 and other public health emergencies publication continues

Clinical Data Publication Relaunch

In September 2023 EMA relaunched the publication of clinical data for centrally authorised products.

CDP Restart Step 1 (September CHMP 2023)

The following applications are subject to publication:

- COVID-19 medicines: applications in line with the scope defined in Policy 0070 (marketing authorisation applications [MAAs], extensions of indication and line extensions).
- Non-COVID-19 medicines: initial MAAs for **new active substances** that receive a positive or negative CHMP opinion in September 2023 and onwards. Withdrawn applications are also subject to publication.

CDP Restart Step 2

- Clinical data publication scope expanded to additional procedures/products - TBD

CHMP = EMA's Committee for Medicinal Products for Human Use

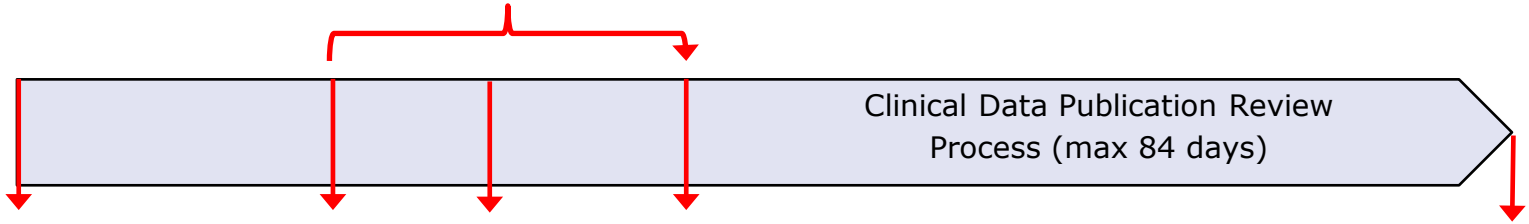
Restart of Policy 0070 in 2023

- Decision taken to **restart Policy 0070 see** here.
- Expected CHMP Opinions **new active substances from Sept 2023** onwards first phase
- **Invitation letters** being sent – detailed communication
- Build on gains and **experience with Covid products**
- Standardised **template for anonymisation report**
- Updated **guidance** in form of Q&A published
- IT tool to establish list of documents in scope

Q&A = Questions and Answers

Clinical data publication timeline (MAA)

Period for the submission of Redaction Proposal Document Package (D181 to 30 days after CHMP opinion)



Day 121: invitation email sent

D181

CHMP opinion

Deadline for Submission of Redaction Proposal Document Package (30 days after CHMP opinion, Clinical Data Publication process Day 0)

Publication deadline 120 days after CHMP opinion

CDP Guidance - Policy 0070 Webinar

- Webinar held 16 May 2023- Agenda and presentations published

https://www.ema.europa.eu/en/events/clinical-data-publication-policy-0070-re-launch-ema-webinar

- Covered scope, timelines, anonymisation report and Q&A document

CDP Guidance - Questions and answers document

- EMA has developed and updated version of the question-and-answer (Q&A) document to expand on issues addressed in the external guidance and in discussions with the applicants.
- It addresses a number of practical questions concerning procedural matters including timelines, commercially confidential information and the anonymisation process.
- It will be updated regularly to reflect any new guidance updates of Policy 0070 (New or revised questions are marked with ‘New’ or ‘Rev’ together with the relevant date).

New Anonymisation Report template EMA-Health Canada (HC)

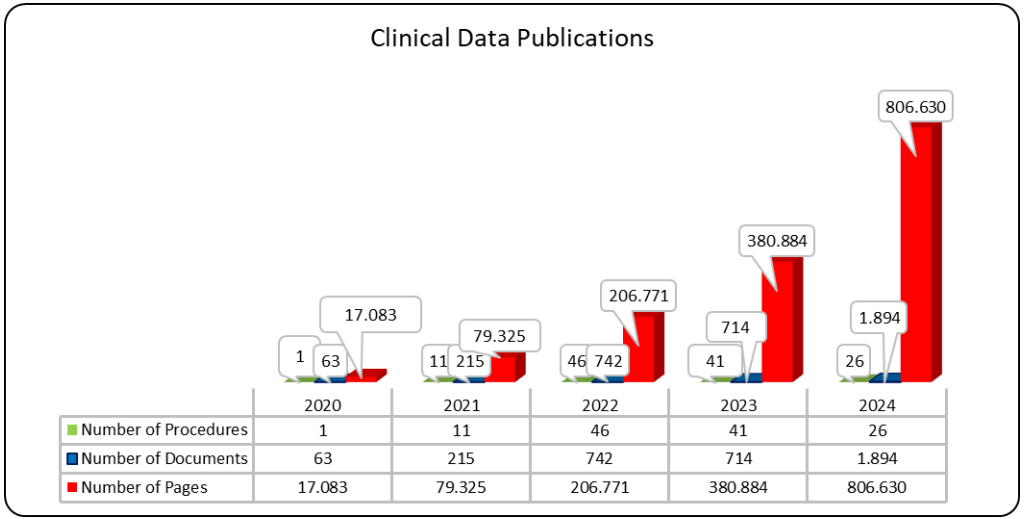
- **Mandatory to complete** – instructions prepared
- **Jointly prepared with HC** - applies to all procedures
- **Standardized layout** – general information on product, List identifiers, Methodology, Risk assessment, Data Utility, Deviations, Attestation
- **Form with structured fields** to complete – less free text
- Ensures **easier comparison** between anonymisation approaches
- **More consistent** information in all sections – guidance is provided
- To improve **review efficiency and reader understanding**

EMA-Health Canada (HC) collaboration

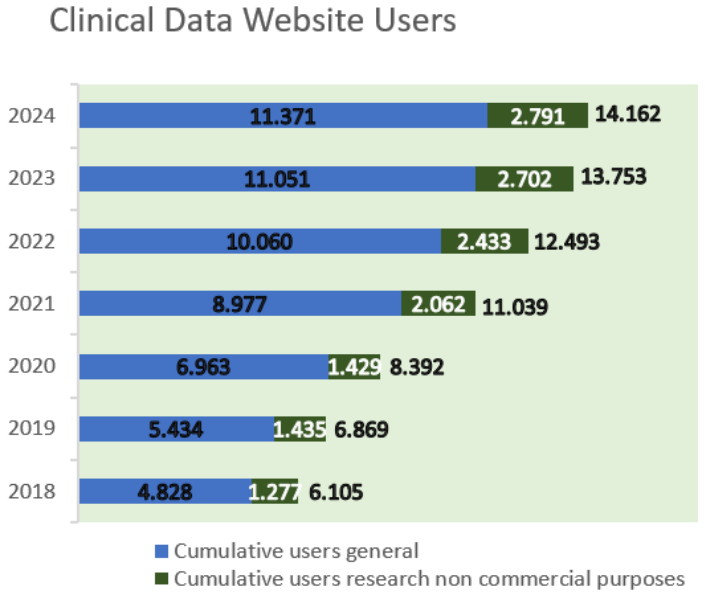
- Joint review and publication whenever possible (started with COVID-19 expanded to new pilot)
- Joint review list of documents in scope – scoping alignment
- Joint Anonymisation report (AnR) template form agreed; published May 2024 by EMA
- Ongoing work:
  - Accepting each other labels for redaction (CCI/CBI, PPD/PI)
  - Recognition of published packages
  - Trying to synchronise submission

CCI = Commercially Confidential Information
CBI = Confidential Business Information
PPD = Protected Personal Data
PI = Personal Information

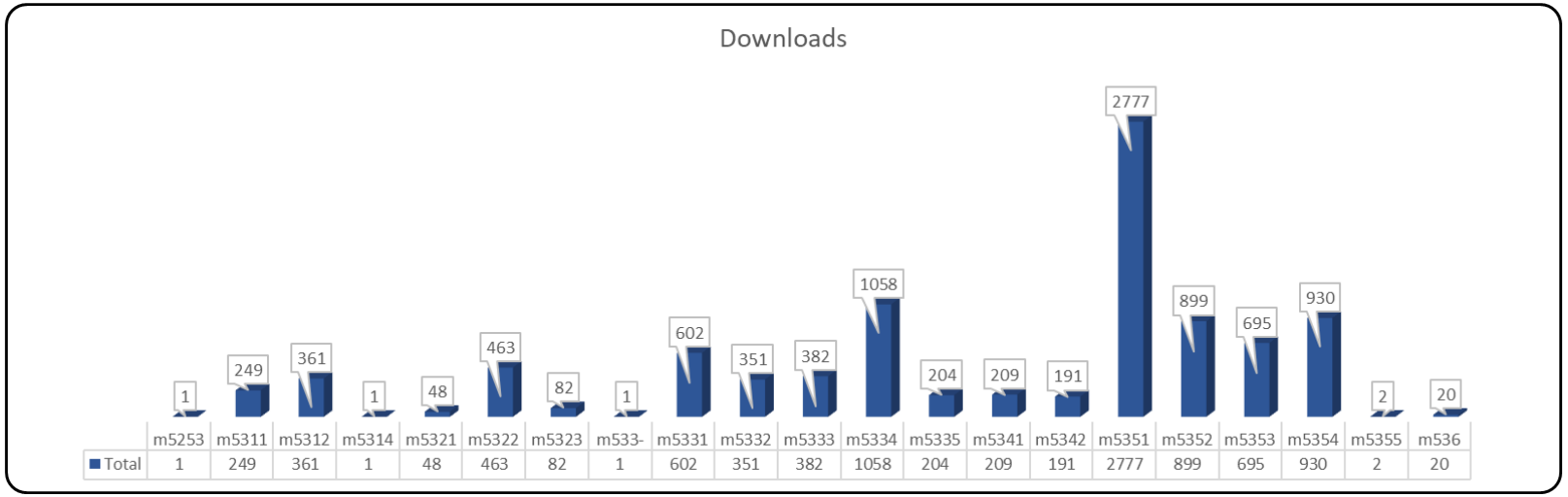
CDP data from 2020 to end of April 2024



	2020	2021	2022	2023	2024
Number of Procedures	1	11	46	41	26
Number of Documents	63	215	742	714	1.894
Number of Pages	17.083	79.325	206.771	380.884	806.630



DOWNLOADS FROM January-May 2024
MODULE 5 (Clinical)



	m5253	m5311	m5312	m5314	m5321	m5322	m5323	m533-	m5331	m5332	m5333	m5334	m5335	m5341	m5342	m5351	m5352	m5353	m5354	m5355	m536
Total	1	249	361	1	48	463	82	1	602	351	382	1058	204	209	191	2777	899	695	930	2	20

- Total of Downloads Module 5: 9.526
- Module 5.3.5.1, Study Reports of Controlled Clinical Studies Pertinent to the Claimed Indication, is the most downloaded.

CDP Relaunch – What are we looking at?

- Optimising anonymisation review process
- Optimising CDP process
- Optimising CDP portal – Survey launched link below

(https://ec.europa.eu/eusurvey/runner/ClinicalDataPublication_survey)

- Increasing collaboration with HC
- How to best manage legacy publications
- How to expand CDP scope
- Assess potential impact on Policy 0070

Any questions?

Further information

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Telephone +31 (0)88 781 6000
Send us a question Go to www.ema.europa.eu/contact

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