EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Policy 0070 relaunch – what's new?

Clinical Data Publication (Policy 0070) relaunch - EMA webinar

Presented by Karen Quigley on 16 May 2023
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Some Background

Policy 0070 effective date 1 January 2015 for any new MAAs, and 1 July 2015 for extension of indication applications for centrally authorised medicinal products.

First clinical data published October 2016

Suspended December 2018 part of Business Continuity Plans

Agreed to gradually reinitiate policy (by EMA Management Board in December 2022)

Exceptional Covid transparency 2020 publications – ongoing

Policy 0070 aims unchanged however implement some procedural updates

Policy 0070 Covid-19 Clinical Data Publication in numbers

PUBLICATIONS COVID 2022:

46 PROCEDURES

742 DOCUMENTS

206,771 PAGES

WEB TRAFFIC 2022:

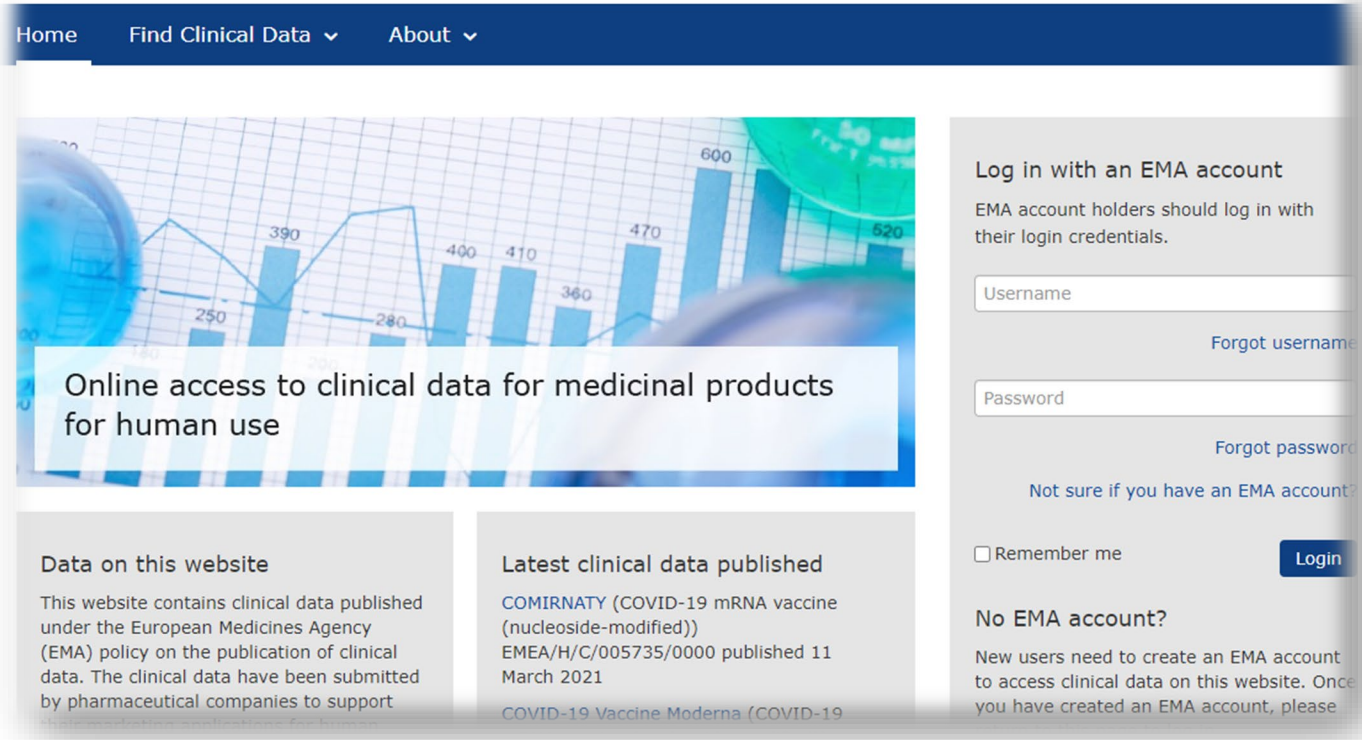
VIEWINGS: **23,996**

DOWNLOADS: **57,428**

USERS 2022:

TOTAL INCREASE OF **1,229**

(both general and research)



Scope of relaunch

Applies to new active substances from September 2023 CHMP

Includes negative and withdrawn products

Covid-19 and other public health emergency clinical data publication continues

No plan to request clinical data for products authorised during suspension of Policy 0070

Detailed specific invitation letters will be sent to request packages

Pre-submission meetings offered

Some changes to improve efficiency and continue work with Health Canada

What is new

Emphasis on early preparation of packages for submission – prior to Opinion

Targeted presubmission meetings specific to product

More guidance to be published

Updated cover letter to include checklist to ensure validation success

New anonymisation report template developed jointly with Health Canada

EMA drafts list of documents in scope – sends to MAH for agreement

Working with CTIS colleagues on PPD and CCI

Commercially Confidential Information (CCI)-Covid experience

- **46 procedures** published – 7 proposed CCI – 3 had CCI accepted
- Only 21 pages in total had any **CCI redactions = 0.01%**
- Not expect to see CCI in clinical documents for Policy 0070
- Rejections – already in public domain (including EPAR and SmPC) or insufficient justification provided - **avoid redacting entire paragraphs/pages**
- Accepted only 2.5 - 2.7.1 - protocol - detailed manufacturing / assay information / candidate products not further developed
- Detailed justification, precise, how it would undermine economic interest

Key Messages

Invitation letters will be sent if your product is in scope

Start to prepare package early prior to CHMP Opinion – in house or vendor chosen

Avail of presubmission meeting – product specific

Review any CCI proposed is not in public domain

Identify any out of scope sections and mark appropriately

Complete QC check prior to submission – all documents present

Contact EMA for any specific product issues

Any questions?

Join at

slido.com

#cdp1

https://app.sli.do/event/vTYquhyaJUqWrkHQrinZj9