10th Meeting of the Industry Stakeholder Platform

Transparency - Clinical Data – Policy 0070

Presented by Karen Quigley on 27 June 2023
Clinical Data Publication

Disclaimer

The presenter does not have any conflict of interests.

Transparency in 2023

- Strategic focus area of EMA – EPARs, RMPs..
- Clinical Data for **Covid-19** products ongoing
- Restart **Clinical Data Policy 0070** for new MAAs September 2023
- **CTIS** first anniversary now mandatory – overlap with Policy 0070

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

Experience from Covid Publications 2020-23

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

Public Health Emergencies -Art 17 Regulation (EU) 2022/123

Article 17

Public information regarding clinical trials and marketing authorisation decisions

1. For the duration of a public health emergency, the sponsors of clinical trials conducted in the Union shall, in particular, make the following information publicly available through the EU portal and EU database established respectively by Articles 80 and 81 of Regulation (EU) No 536/2014:

(a) the clinical trial protocol, at the start of each trial for all trials authorised under Regulation (EU) No 536/2014 that examine medicinal products which have the potential to address the public health emergency;

(b) the summary of the results, within a timeline set by the Agency that is shorter than the timeline laid down in Article 37 of Regulation (EU) No 536/2014.

2. Where a medicinal product of relevance to the public health emergency receives a marketing authorisation, the Agency shall publish, in particular:

(a) the product information with details of the conditions of use at the time of the marketing authorisation;

(b) the European Public Assessment Reports as soon as possible and, where possible, within seven days of the marketing authorisation;

(c) the clinical data submitted to the Agency in support of the application, where possible within two months of the marketing authorisation by the Commission;

(d) the entire risk management plan referred to in Article 1, point 28c, of Directive 2001/83/EC, and any updated versions thereof.

For the purposes of the first subparagraph, point (c), the Agency shall anonymise all personal data and redact commercially confidential information.

Covid-19 CDP - Commercially Confidential Information (CCI)

- **46 procedures** published 2022– 7 proposed CCI – 3 had CCI accepted
- **CCI redactions = 0.01% (same as CDP annual report 2018)**
- 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**
- One **Justification table** per document
- Detailed justification, precise, how it would undermine economic interest

CTIS one year on

- **Article 81(4) of CTR outlines the level of transparency in CTIS**

*"The **EU database shall be publicly accessible unless**, for all or part of the data and information contained therein, confidentiality is justified*

- **Uploaded documents in CTIS – at same time**
  - Document version 'not for publication' which is the full, comprehensive version of the document for scientific/regulatory evaluation and
  - Document version 'for publication' without CCI and personal data
- **Published information once decision on CT made**
  - Structured data (e.g. name of principal investigator and study site name)
  - Clinical Trial Application documents (e.g. ICF, IB, study protocol)
  - Study results (e.g. clinical study reports)

CT updates

- Draft guidance on transparency aspects first published 8/04/2022: interim update 3 May 23 https://www.ema.europa.eu/en/documents/other/interim-guidance-document-how-approach-protection-personal-data-commercially-confidential_en.pdf
- EMA working closely with NCAs on comments received – update due CCI
- EMA monitoring any overlap of Policy 0070 and CTIS publication of CSRs to avoid duplication – joint guidance in form Q/A in preparation
- Bitesize talks ongoing – opportunity ask questions

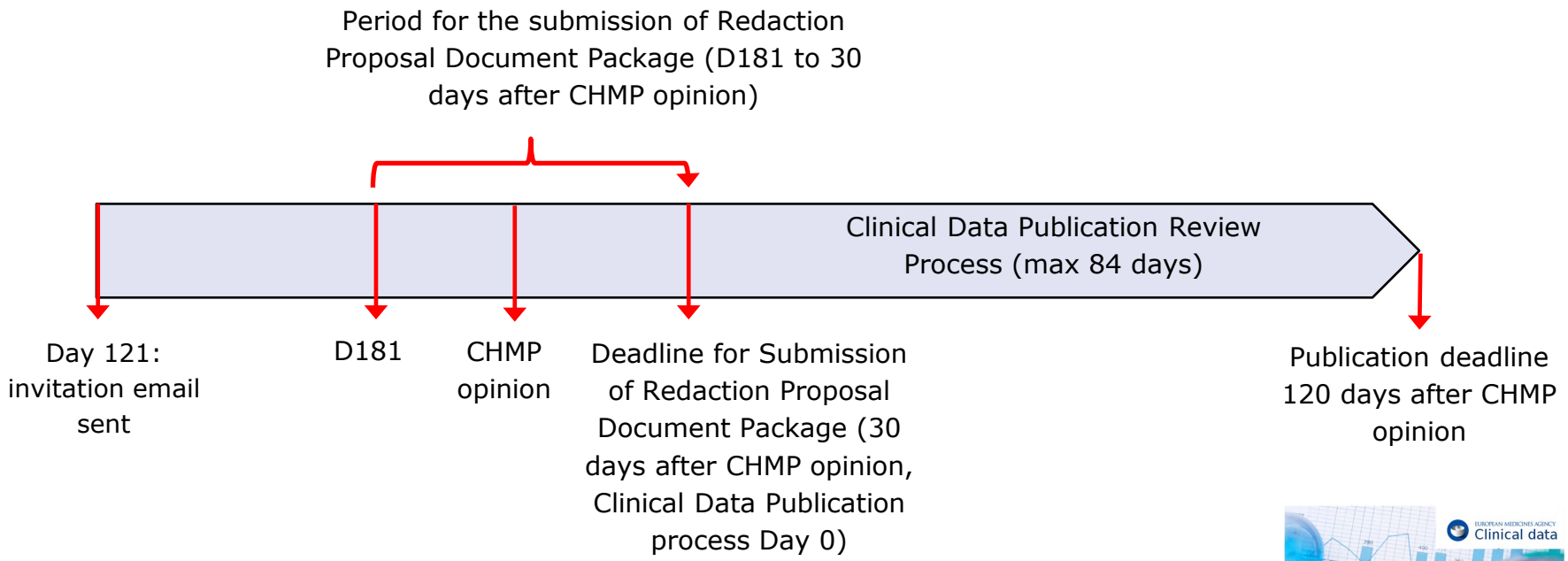
Restart of Policy 0070 in 2023

- 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 to be published
- IT tool to establish list of documents in scope

Restart Policy 0070 Changes

- Narrow **scope** products full new active substances MA
- Look at adapting **publication portal** linked to EMA tracking tool
- Streamlined **process** from documents in scope to review to published
- Improve quality and reduce EMA QC review activities = **increase efficiency**
- Maintain close collaboration with **Health Canada**
- **Harmonisation** and reduce duplication
- Legacy products- ongoing EMA review but no requests for Policy 0070 currently

Clinical data publication timeline (MAA)



New Anonymisation Report template- EMA-HC

- **Mandatory to complete** – instructions prepared
- **Jointly prepared with HC** - applies all procedures
- **Similar 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 will be provided

CDP Guidance documents - Questions and answers document

EMA has developed an updated version of the question-and-answer (Q&A) document to expand on issues addressed in the external guidance and in discussions with 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).

Thank you for your attention

Further information

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