EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Clinical data Publication Webinar

Presented by Documents Access & Publication Service
23 March 2017

An agency of the European Union

Clinical Data Publication (CDP) Guidance

EUROPEAN MEDICINES AGENCY

Introduction, scope, definitions

External guidance on the **procedural aspects** related to the submission of clinical reports for the purpose of publication in accordance with EMA policy 0070

Guidance on the identification and redaction of **commercially confidential information** (CCI) in clinical reports submitted to the EMA

Guidance to pharmaceutical industry on the **anonymisation** of clinical reports for the purpose of publication in accordance with EMA policy 0070

Published on EMA website:

http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2016/12/WC500218567.pdf

*

EMA update on the guidance and related initiatives

EUROPEAN MEDICINES AGENCY

- **Currents status and upcoming submissions**
- Cross-referred studies
- Out of scope sections
- New tool kit
  - External validation checklist
  - Abbreviated Anonymisation report template
  - Q&A

Clinical Data Publication (CDP) in numbers

EUROPEAN MEDICINES AGENCY

	Product	Date of publication	No of documents published	No of pages	No of pages with CCI redacted
1	Zurampic	20 October 2016	246	185,000	2
2	Kyprolis	20 October 2016	115	75,000	0
3	Armisarte	23 November 2016	19	95	6
4	Caspofungin Accord	23 November 2016	2	48	0
5	Tarceva	21 December 2016	7	2,929	0
6	Praxbind	21 December 2016	25	23,789	0
7	Palonosetron Hospira	30 January 2017	2	36	0
8	Aripiprazole Mylan	31 January 2017	12	808	0
9	Cubicin	27 February 2017	28	4,206	0
10	Coagadex	28 February 2017	7	2,573	2
11	Empliciti	28 February 2017	19	26,247	0
12	Palonosetron Accord	16 March 2017	2	24	0
13	Amlodipine-Valsartan Mylan	16 March 2017	11	808	0
	Total		**495**	**321,563**	**10**

Clinical Data Publication (CDP) process in numbers

EUROPEAN MEDICINES AGENCY

Where are we with procedures on 21st of March 2017	
Number of procedures ongoing *with* pilot phase	20
Number of procedure ongoing without pilot phase	15
Number of procedures shortly starting *with* pilot phase	5
Number of procedures shortly starting without pilot phase	7
Total of procedures for which MAHs / Appl. Have been contacted	**47**

EMA update on the guidance and related initiatives

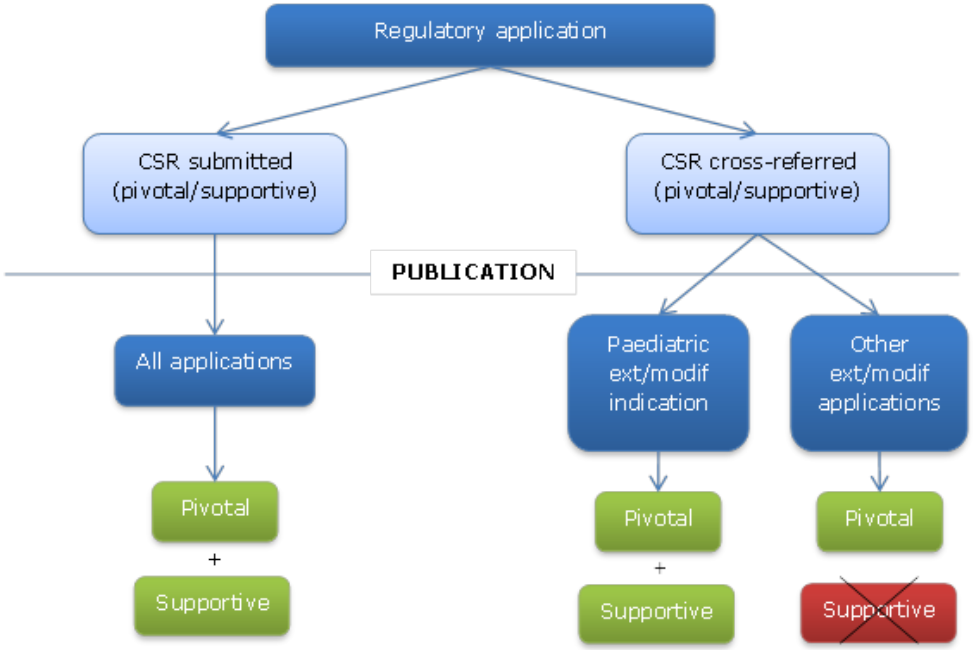
EUROPEAN MEDICINES AGENCY

- Currents status and upcoming submissions
- **Cross-referred studies**
- Out of scope sections
- New tool kit
  - External validation checklist
  - Abbreviated Anonymisation report template
  - Q&A

Clinical study reports cross referred to (1/2)

EUROPEAN MEDICINES AGENCY

- For **Clinical reports submitted as part of previous/other regulator procedures:** *Will be published (except paediatric):* **Pivotal CSRs** assessed to support a modification of indications or a line extension even if submitted in the past



Clinical study reports cross referred to (2/2)

EUROPEAN MEDICINES AGENCY

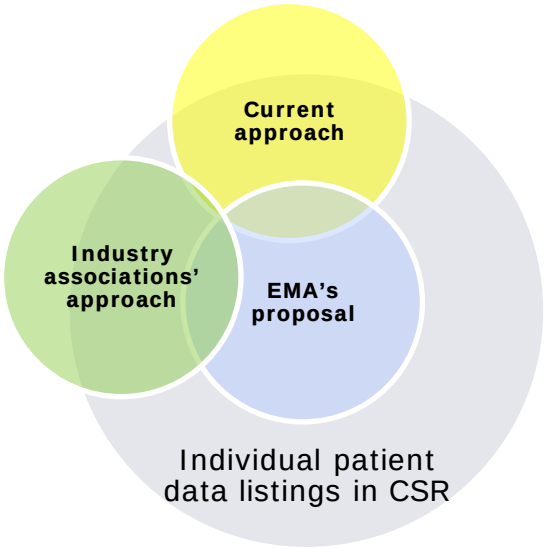
Current wording	Proposed wording
"Clinical reports […] cross-referred to within a regulatory application will be subject to publication […]. This includes CSRs previously submitted in the context of earlier regulatory procedures which form the basis of the regulatory decision for those applications falling in the scope of the policy"	**Extension of indication to include paediatric population or modification of a paediatric indication** "All clinical study reports cross-referred to within a paediatric extension or modification of indication application submitted in the context of regulatory procedures not falling within the scope of Policy 0070 will be subject to publication." **Other extension or modification of indication and line extension applications** "Where clinical study reports are cross-referred to within extension or modification of indication and line extension applications, only the pivotal clinical study reports submitted in the context of regulatory procedures not falling within the scope of Policy 0070 will be subject to publication."

EMA update on the guidance and related initiatives

EUROPEAN MEDICINES AGENCY

- Currents status and upcoming submissions
- Cross-referred studies
- **Out of scope sections**
- New tool kit
  - External validation checklist
  - Abbreviated Anonymisation report template
  - Q&A

Out of scope sections (1/2)



Current approach
'*All* patients *all* visits'

- Data utility better kept
- 'All patients all visits' concept difficult to manage
- Identification difficult, complex, more workload

Ind. associations' approach
'*More than one patient more than one visit*'

- It overcomes the limitation of 'All patients all visits' concept.
- Over-redaction= data utility more compromised
- Identification difficult, complex, more workload

EMA's proposal
'*Abnormal Laboratory Value Listing*'

- Clearer definition of "out of scope"
- Covers a large majority of individual patient data listings
- Identification less difficult, less complex – reduced workload
- Individual patient data listings in other sections anonymised.

Out of scope sections (2/2)

EUROPEAN MEDICINES AGENCY

Current wording	Proposed wording
'The Agency considers per patient per visit data as those listings including values of the measured parameters (e.g. lab values) listed for **all** patients recruited and covering **all** study visits. Therefore, for example, tables listing values of the measured parameters (e.g. HbA1C) or outcomes (protocol deviation, death, SAE, overall survival) at a certain **single** time point will not be considered per patient per visit line listing.'	'All sections of the CSR body (sections 1 to 15 as per ICH E3) are subject to publication. EMA notes that the CSRs may contain **individual** patient data listings within the body of the report. In particular, as per ICH E3, these individual patient data listings are most likely to be found in section 14.3.4 Abnormal Laboratory Value Listing. Therefore, individual patient data listings contained in CSR section **14.3.4 "Abnormal Laboratory Value Listing"** can be considered out of scope of phase 1 of Policy 0070. Consequently, it is acceptable to have them removed from the clinical study reports prepared for publication. If ICH E3 format is not followed for a particular CSR, the individual patient data listings included in the corresponding section presenting "Abnormal Laboratory Values" may be considered out of scope and removed from the clinical study report. Nevertheless, individual patient data listings presented in other sections of the clinical study report (e.g. concerning PK and immunogenicity results, laboratory values, case narratives or protocol deviations) cannot be considered out of scope and should not be removed. They should instead be anonymised. It is important to note that data presented as **aggregated** patient data listings within section 14.3.4 "Abnormal Laboratory Value Listing" should NOT be removed.

EMA update on the guidance and related initiatives

EUROPEAN MEDICINES AGENCY

- Currents status and upcoming submissions
- Cross-referred studies
- Out of scope sections
- **New tool kit**
  - **External validation checklist**
  - **Abbreviated Anonymisation report template**
  - **Q&A**

New “Toolkit”

EUROPEAN MEDICINES AGENCY

To help out with the preparation of clinical data packages submission

- External validation checklist
- Abbreviated anonymisation report template
- Q&A

External validation checklist (1/2)

- Validation issues (identified in **bold in the checklist**) can lead to an unsuccessful validation. MAHs will be asked to resubmit the revised package (procedure re-starts from **Day 0**)
- Aimed to help Industry ahead of submission of **'Redaction Proposal Document' package**
- To improve quality of submitted packages validated at the Agency
- **Do not include** in submitted packages

External validation checklist (2/2)

EUROPEAN MEDICINES AGENCY

Operational start-up phase: Examples of most common validation issues

Cover letter	**Declaration** confirming that the redacted/anonymised clinical reports are true and complete copies of those submitted for scientific review **is missing**
Justification Tables	**One (1) justification table submitted per package** instead of per study report; OR **number** of submitted JTs **differ** from number in the cover letter
Clinical reports	Information that is labelled as CCI in the clinical reports **does not match the CCI proposals described**/listed in the corresponding JTs; **Out of scope** sections (if applicable) **are not correctly identified** in documents (e.g., if ICH E3 format is not followed)
Anonymisation Report	**AnR is not included** in the submitted package
Naming Convention	Correct **naming convention is not followed** for all documents submitted

Abbreviated Anonymisation Report

EUROPEAN MEDICINES AGENCY

New template for submissions of clinical reports not containing patient identifiers

- To be used for all applications where the applicant/MAH has not identified any patient (direct OR quasi) identifiers.
- No assessment of the risk of re-identification and no anonymisation process have been performed.

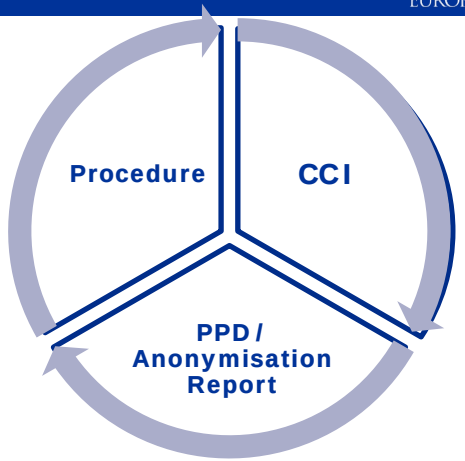
The types of applications for which we may come across such scenario are:

- Article 10(1) – **Generic application**
- Article 10(3) - **Hybrid application**
- Article 10a - **Well-established use application**

Questions & Answers (Q&As)

EUROPEAN MEDICINES AGENCY

- Overview of the Agency's position on issues that are typically addressed in discussions or meetings with applicants/MAHs
- Intended to complement existing external guidance document
- It will be updated regularly to reflect any new guidance updates during the implementation of Policy 0070



When shall I submit my package?

Will my package submission be eligible for a pilot phase?

What does the Agency not consider to be CCI?

Can patient narratives be removed from the CSRs?

For any questions

EUROPEAN MEDICINES AGENCY

- Prior to being contacted by EMA,

  ⇒ use the EMA webform* with "**CDP-**" to start the line with subject of your enquiry

  *http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/landing/ask_ema_landing_page.jsp

- Once you have received an invitation letter,

  ⇒ contact the CDP coordinator mentioned in the letter

Thank you for your attention

Further information

European Medicines Agency
30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Follow us on **@EMA_News**