EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Webinar: Revision of Clinical data Publication Guidance

Presented by Documents Access & Publication Service
9 December 2016

Clinical Data Publication Guidance*

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:
3 March 2016

* http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2016/03/WC500202621.pdf

CDP – first publications

Product	Date of publication	Nº of documents published	Nº of pages	Nº of pages with CCI redacted
Zurampic	20 October 2016	246	185,000	2
Kyprolis	20 October 2016	115	75,000	0
Armisarte	23 November 2016	19	95	6
Caspofungin Accord	23 November 2016	2	48	0
Total		**382**	**260,143**	**8**

CDP website statistics (24/10– 24/11/2016)

- **234 academic/non-commercial research users registered**
- **1017 general users registered**
- **Number of documents viewed: 4,486**
- **Number of documents downloaded: 16,570**

Update of the Guidance – CSRs from previous submissions

Section 2, '**Clinical reports submitted as part of previous / other regulator procedures**'

⇒ CSRs submitted as part of, or cross-referred to, within a regulatory application are in the scope of policy 0070

Eg. CSRs submitted to support a paediatric extension of indications while previously submitted under article 46 of Regulation 1901/2006 will be published

Update of the Guidance – Out of scope

Chapter 2, Section 3.3.1.8**: "Out of Scope of phase I of policy 0070 – Per patient/per visit line listings"**

⇒ Sections where per patient per visit IPD is identified can be removed, not redacted, from the documents and replaced by a blank page as follows:

- removed page numbers (from-to) and the corresponding section title
- Pages after cut to stay with original numbering
- statement reading:

"*Out of Scope of phase I of Policy 0070- Per patient/per visit line listings*".

Update of the Guidance – Incomplete package

Incomplete package submissions: Chapter 2, Sections 3.3.1.3, 3.3.3.3 and 3.3.1.9

⇒ Emphasis on the importance of submitting complete packages (e.g. absence of the cover letter or declaration text renders the submission invalid)

⇒ Invalid package requires resubmission of complete package

Best practice warnings: Chapter 2, Sections 3.3.1.6, 3.3.1.13, 3.3.3.9

⇒ Practical aspect: when package with correct naming convention, applicant to ignore the warning message from the system

Update of the Guidance – CCI and PPD

CCI identification in some clinical reports: Section 3.3.1.10, Annex 1.4

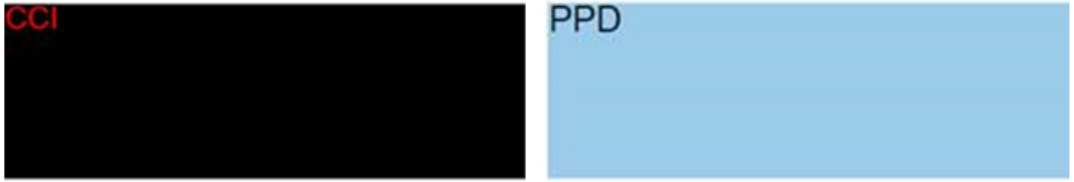
⇒ Clarification when CCI proposed in some of the documents but not all

CCI and PPD colour coding: Section 3.3.3.4, Section 3.3.1.8

⇒ Practical aspect: Colour coding to apply for PPD and CCI

for CCI: black background with red overlay text;

for PPD: blue (pantone 291 C - corresponding to RGB colours 115, 203 and 235) background with black overlay text;



Update of the Guidance - Agreement

Final redacted document package cover letter: Section 3.3.3.5 Annex 1.6

⇒ Clarifications of agreement with EMA redaction conclusions

⇒ full agreement / partial agreement (interim relief proceedings)

⇒ Practical aspect:

- final package cover letter presents both options to choose from
- To address full/partial agreement; applicants to choose *Clinical data publication final version* from drop down list in the formatted table when submitting the package

Update of the Guidance – MA Transfers

Chapter 2, Section 4 **MA transfers**

⇒ If transfer of MA during redacting consultation phase, Transferee will take over from Transferor

⇒ No interruption of the process

⇒ Practical aspect: inform EMA that contact person has changed

Update of the Guidance – Formatted table

Chapter 2, Section 3.3.1.9, Section 3.3.1.11, Section 3.3.3.5 - **Formatted table**

⇒ Revised to align with final redacted document package cover letter

⇒ Practical aspect:

- eCTD sequence of the procedure to be included under point 10
- Sequence number written as stated in the EU Module 1 v3.0.1 specification
- To address full/partial agreement; applicants to choose *Clinical data publication final version* from droop down list when submitting the package

CDP - Lessons learned from first experiences

- **Not a lot of CCI proposed** as compared to ATD
- **Anonymisation**: we are all **on a learning curve**
  - Must to follow the template,
  - Must be very clearly written,
  - Must be adapted to the products and the type of studies,
  - Identifiers must be clearly listed,
  - Data utility must be considered,
  - Report must match the proposed redactions,
  - Labelling of redaction must be followed,
- If questions about process, sections/docs in/out of scope; **to be flagged for discussion** with EMA

CDP – what is next?

- CDP guidance, **a living document**, will be updated with experience
- **Pilot phase** is continuing but is very resource intensive
- **Waiting list** of about 100 procedures
  - Publication for 4 products
  - Companies have been contacted for 15 products
- **Letters are sent** to Pharmaceutical Industries about 2-3 months before submission of proposed redacted package

Thank you for your attention

Further information

[Insert relevant information sources or contact details as applicable.]

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