EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Clinical data Publication Webinar

Presented by Documents Access & Publication Service
29 June 2017

EMA update on the guidance and related initiatives

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- **Currents status and upcoming submissions**
- Follow up from previous webinar
- Duplicate submissions
- “Foreign languages” in a Redacted package
- Policy 0070 publication vs Policy 043 requests

Clinical Data Publication (CDP) in numbers

Product	Date of publication	No of published documents
Zurampic	20 October 2016	246
Kyprolis	20 October 2016	115
Armisarte	23 November 2016	19
Caspofungin Accord	23 November 2016	2
Tarceva	21 December 2016	7
Praxbind	21 December 2016	25
Palonosetron Hospira	30 January 2017	2
Aripiprazole Mylan	31 January 2017	12
Cubicin	27 February 2017	28
Coagadex	28 February 2017	7
Empliciti	28 February 2017	19
Palonosetron Accord	16 March 2017	2
Amlodipine-Valsartan Mylan	16 March 2017	11
Descovy	21 April 2017	303
IDELVION	28 April 2017	56
Zonisamide Mylan	02 May 2017	4
Ferriprox	05 May 2017	2
TAGRISSO	05 May 2017	59
Giotrif	18 May 2017	86
Pemetrexed Fresenius Kabi	18 May 2017	2
EndolucinBeta	01 June 2017	2
Rasagiline Mylan	02 June 2017	7
Alprolix	02 June 2017	16
Bortezomib Hospira	12 June 2017	2
Opdivo II/007	21 June 2017	7
Opdivo II/008	21 June 2017	11
Halaven	22 June 2017	33
Total	**27**	**1,085**

Clinical Data Publication (CDP) process in numbers

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Where are we with the procedures by June 2017	
Procedures falling under Policy 0070	231
Procedures published	27 (17 pilot + 10 without pilot)
Procedures ongoing (incl. contacted)	46 (22 pilot + 24 without pilot)
Procedures upcoming (Opinion adopted at July CHMP)	14 (7 pilot + 7 without pilot)

- **63 % of the procedures published had a pilot phase**
- **resource intense**

Accessing Clinical Data Publication (CDP) in numbers

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Usage figures as of 16 June 2017

Number of accounts created	Documents accessed
2,379 general users	15,595 Views
562 non-commercial research users	56,420 Downloads

Average of :

- 7 views per general user
- 100 downloads per non-commercial research user

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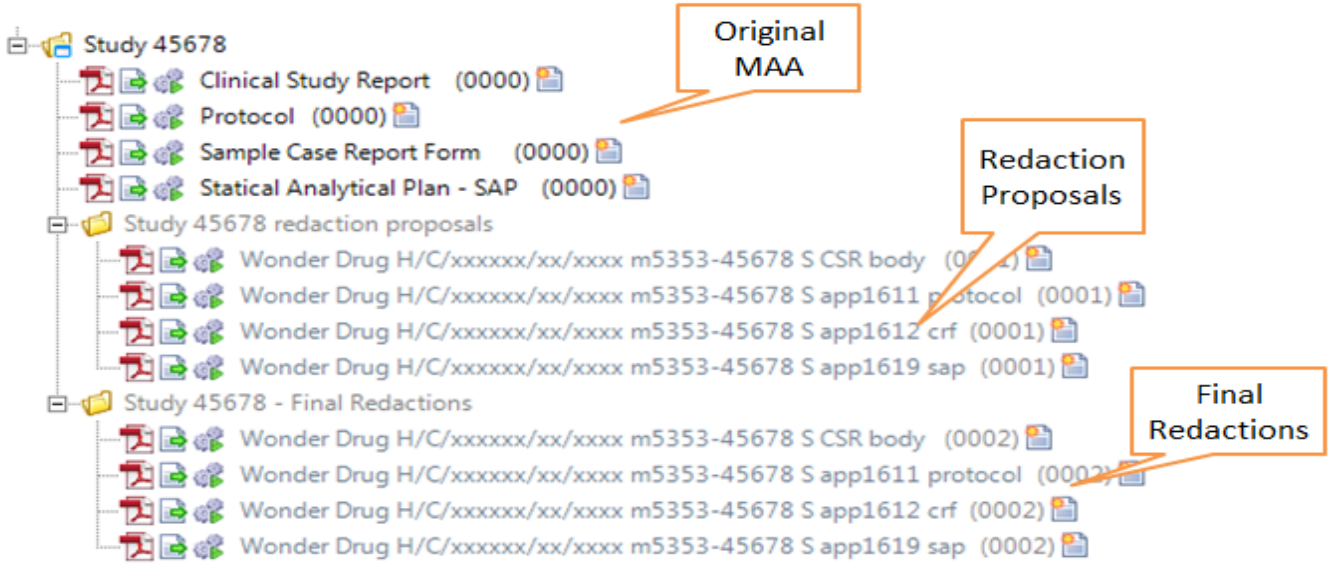
Node extensions are now accepted

EFPIA Proposals for Policy 0070: Operational Strategy

Preferred Option: Node Extensions 'Nested' for Proposed & Final



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Duplicate submissions (1 / 2)

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- *For duplicate product the EMA will request a stand-alone submission of documents packages for a stand-alone publication*
- *Reasons:*
  - Duplicates products may not be exactly identical: different salts, different excipient or different manufacturing sites
  - Duplicate products have their own EPAR on the corporate website so CDP website is matching
  - Duplicate products have different Invented names in different EU countries; patients and health professionals must be able to find the correct name and documents on the CDP website
  - Duplicate products can have different life cycle after the initial MA
- For fully identical packages, there will be 1 review process

Duplicate submissions (2/2) – Proposed text

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"When submitting duplicate marketing authorisation applications, the Agency understands that the clinical reports included in such submissions are ***essentially*** *identical to the ones submitted in the application for the original medicinal product. However, duplicate submissions might contain* ***differences*** *in certain data, such as different salt, different excipient or manufacturing sites.*

As each medicinal product has a ***stand-alone regulatory lifecycle****, it is foreseen that future variations to the marketing authorisation falling under the scope of Policy 0070 (such as line extension or extension of indication applications) may not apply to both the original and duplicate medicinal product but instead can affect the original or the duplicate medicinal product individually.*

Therefore for duplicate marketing authorisation applications, the Agency requires the applicant/MAH to ***submit stand-alone Redaction Proposal and Final Redacted document packages*** *for the purpose of publication. Stand-alone submissions for duplicate marketing authorisation applications are required regardless of whether the same anonymisation process and CCI redactions (if any) are applied in the clinical reports of the original medicinal product. This is also in line with the fact that duplicate products have their* ***own EPARs published****.*

The submission of stand-alone Redaction Proposal and Final Redacted document packages will allow the Agency to ***inform the public*** *of the difference in the content of the submitted documents for duplicate marketing authorisation applications."*

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“Foreign languages” in a Redacted package

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- For sections of documents or separate annexes of a document in a different language translated in English, the Agency agrees to remove them, provided it is identified as follows:
  - Correct label is used
    - removed page numbers (from-to) and the corresponding section title (if applicable)
    - statement to reflect the above (i.e. “foreign language version removed”).
  - Stated by the MAH in the cover letter that the English versions submitted are true and complete copies of the other language versions.
- For separate documents in a different language translated in English, the Agency agrees not to submit them, provided it is stated by the MAH in the cover letter that the English versions are true and complete copies of the foreign language versions.

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Policy 0070 publication vs Policy 043 requests

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- For documents requested under Regulation (EC) No 1049/2001 in order to avoid two procedures running in parallel the Agency will advise the requestor to visit the Clinical data publication website given that:
  - The **same document** is requested
  - The clinical data publication **process in ongoing**

For any questions

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- 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

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