



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Policy 0070: where we are

PhUSE workshop London

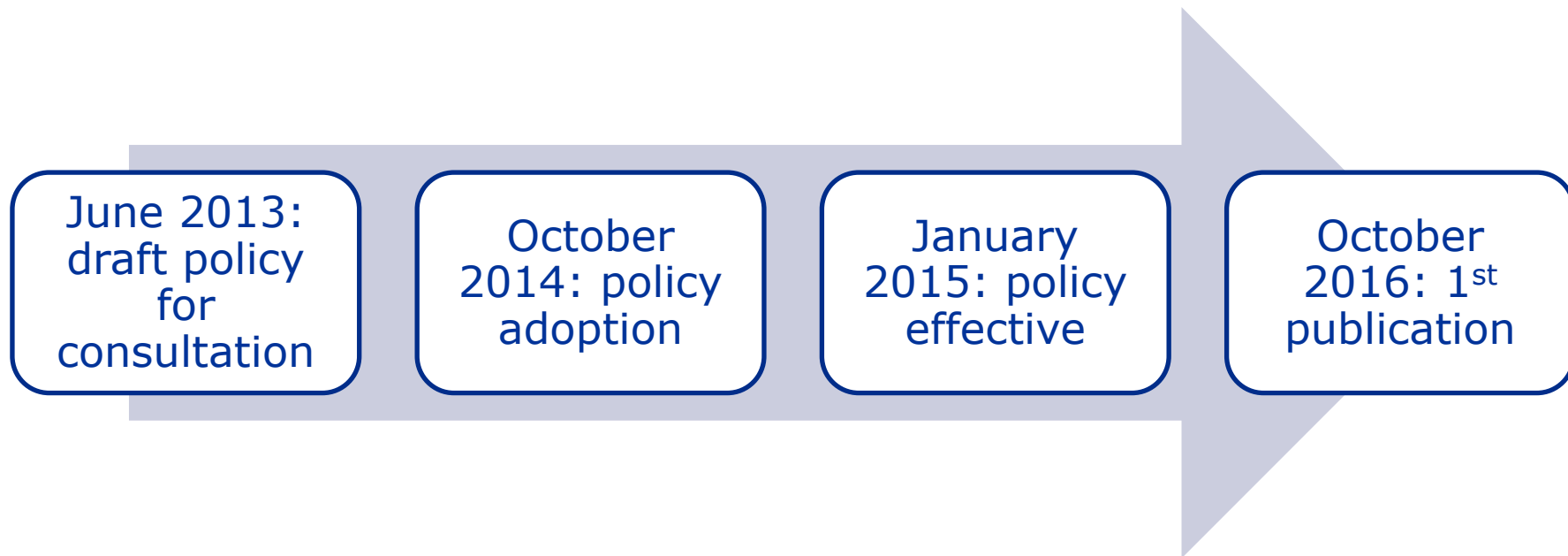
Presented by Karen Quigley on 19 June 2017
Clinical Data Publication Manager

An agency of the European Union





Policy 0070 / Clinical Data Publication (CDP)





Policy Benefits:

- EMA commitment to transparency, regulatory decision basis of medicinal products
- Proactive publication enables public scrutiny: establishes trust, confidence
- Better public information: Public access enables application of new knowledge in future research, increases efficiency of medicine development, learning from experience
- Avoids clinical trials duplication: limits unnecessary patient exposure
- Enhanced scientific knowledge/value of secondary analysis: sharing scientific knowledge, contribution to public health, confirmation of regulatory decisions/need to review regulatory decisions taken.

Aims of Clinical Data Publication

- take regulatory decision-making one step closer to EU citizens;
- promote better-informed use of medicines;
- allow all medicine developers to learn from past successes and failures;
- application of new knowledge in future research;
- enable public scrutiny.
- Survey currently on website collecting views of users-open until August
<https://clinicaldata.ema.europa.eu/home>



Clinical Data Publication (CDP) process in numbers

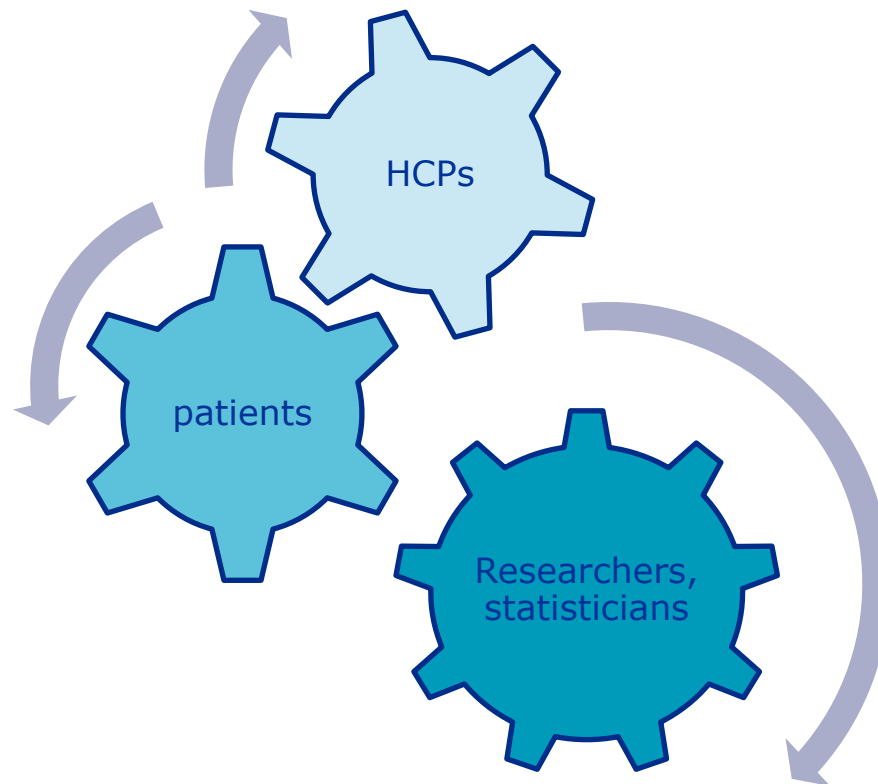
Product	Date of publication	No of documents published
Zurampic	20 October 2016	246
Kyprolis	20 October 2016	115
Armisarte	23 November 2016	19
Caspofungin Accord	23 November 2016	2
Tarceva	21 December 2016	7
Praxbind	21 December 2016	25
Palonosetron Hospira	30 January 2017	2
Aripiprazole Mylan	31 January 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
Feriprox	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
Total	24	1,034

Clinical Data Publication - an overview

- Back-log in term of number of products in waiting list: 207 procedures in the backlog (231 procedures falling under Policy 0070 minus the published 24)
- Number of procedures ongoing **with** pilot phase: 15
- Number of procedures ongoing **without** pilot phase: 6
- Number of procedures shortly starting **with** pilot phase: 8
- Number of procedures shortly starting **without** pilot phase: 20

Target audience

- Patients
- HCPs
- Researchers.....
- Drug developers
- Others?





What we have seen so far

- Quality of anonymisation report (AnR) increased over the past few months - consistency between what is described in AnR and applied in CSRs;
- Consistency of classification of direct/quasi identifiers;
- Redaction is method of choice as a anonymisation technique;
- Redaction of patient narratives in full;
- Aggregated data mostly retained;
- Automated tool vs manual review



MAHs engagement

- Good engagement from MAHs
- No non-compliance to date
- Pilot meeting for first procedure - assistance to MAHs-SMEs
- Flexibility in adapting guidance
- Preparing packages ahead of invitation letters
- Webinars – raise questions directly e.g documents in-out scope



Data utility

- Should be integrated in the risk assessment;
- Do the anonymised reports lead to:
 - Same conclusions compared to the original reports?
 - Distorted conclusions?
 - Any conclusions possible?
- Expectations of end users different
- Have we struck the right balance?



Case narratives

- Treated differently – some redacted in full others not
- Better techniques and alternative approaches to show whether it is too conservative
- Provide case studies that disprove the need for the level of anonymisation applied

EMA Technical Anonymisation Group (TAG) (1/2)

The overall objective of the TAG is to further develop best practices for the anonymisation of clinical reports, by monitoring and addressing any issues arising in the context of the implementation of phase I of policy 0070.

- To learn from the experience gained with the publication of the first clinical reports and to assess best practices in the field of anonymisation, assess patient re-identification and any privacy risk, taking into account EU law on data protection;
- To understand the challenges encountered by pharmaceutical industry while anonymising the reports for publication.



EMA Technical Anonymisation Group (TAG) (2/2)

- To investigate if data transformation resulting from the anonymisation techniques used can lead to a different interpretation of the study results;
- To investigate the scientific utility of the clinical data published as a function of the methodology used by the Applicant/MAH in the anonymisation of the reports, and establish whether secondary analysis of clinical data can be successfully undertaken using the data published by the Agency;
- To follow new technological developments that might impact on the anonymisation of clinical reports and establish measures to keep the risk of re-identification to an adequate level.



Annual report and Phase II

- Annual report will be produced end of 2017 published early 2018 (cover 15 months)
- Precise content of annual report under discussion
- Phase II in future – later stage - individual patient data (IPD)

Support to applicants/MAHs

- Guidance and Q&A regularly updated
- Quarterly webinars
- EMA webform* for any other queries



*http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/landing/ask_ema_landing_page.jsp with "CDP-" to start the line with subject of your enquiry



Any questions?

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**