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SCIENCE MEDICINES HEALTH

EMA update on Clinical Data Publication (CDP)

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Documents Access & Publication Service
29 January 2018

EMA update on CDP

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- **Current status and upcoming submissions**
- Overview of 2017: CDP annual report

Current status and upcoming submissions

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Where are we with procedures by 31 Dec 2017

Procedures falling under Policy 0070	337
Procedures published	64
Procedures ongoing *with* pilot phase	7
Procedures ongoing without pilot phase	12
Procedures shortly starting *with* pilot phase	11
Procedures shortly starting without pilot phase	23

EMA update on the guidance and related initiatives

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- Currents status and upcoming submissions
- **Overview of 2017: CDP annual report**

Clinical Data Publication –1 year data

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Type of procedure published	
Initial marketing authorisation	36
Extension of indication	18
Line extension	0
Total number of procedures published	54

Documents published	
Anonymisation Report	54
Module 2.5	63
Module 2.7.1-2.7.4	160
Module 5.3 (CSR)	3,002
Total number of documents	3,279
Total number of pages	1,308,244

Proportion of Commercially Confidential Information

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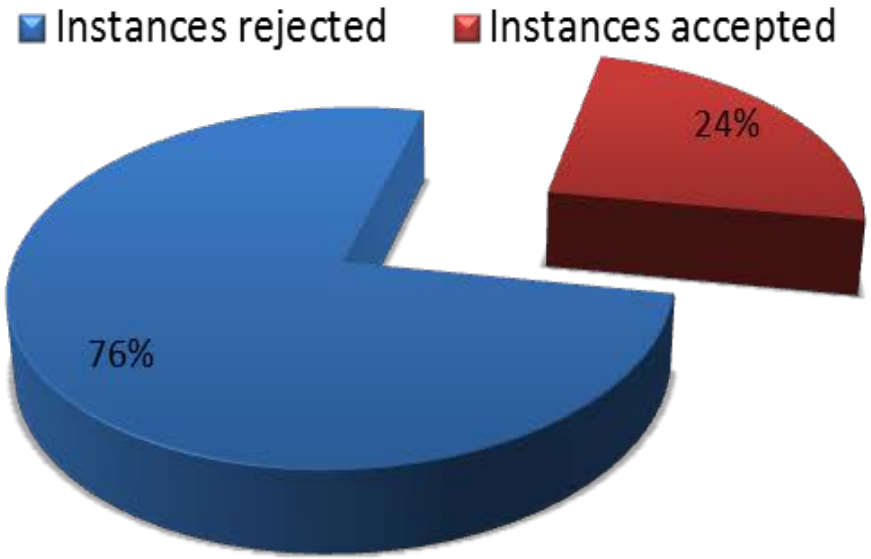
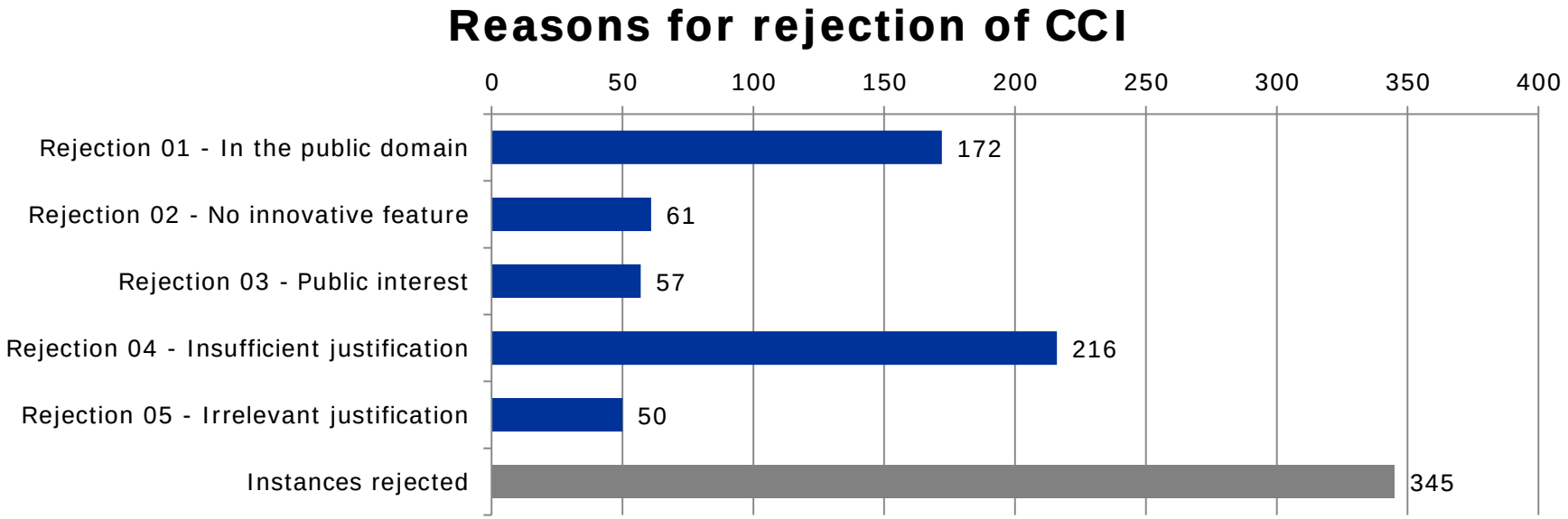
	Procedures		Documents		Pages	
Total published	54		3,279		1,308,244	
CCI proposed by the MAH / Applicant	28	52%	145	4.4%		
CCI was accepted by EMA	19	35%	48	**1.46%**	134	**0.0102%**

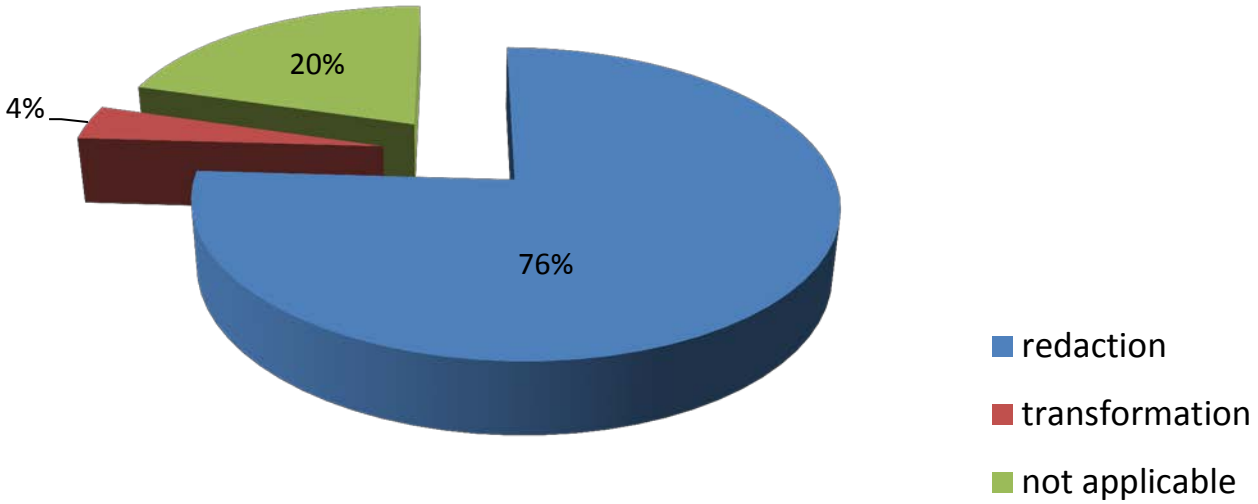
Commercially Confidential Information (CCI)



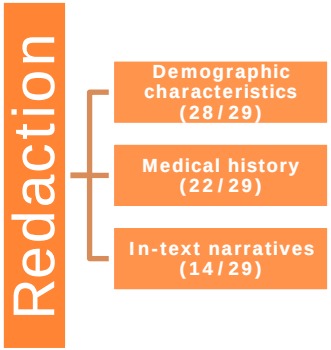
Rejection of CCI per code



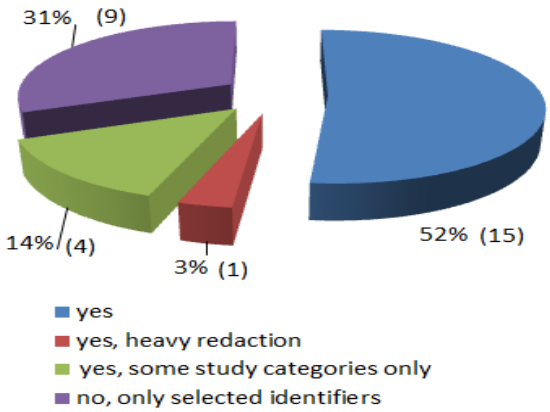
Anonymisation technique (all procedures)



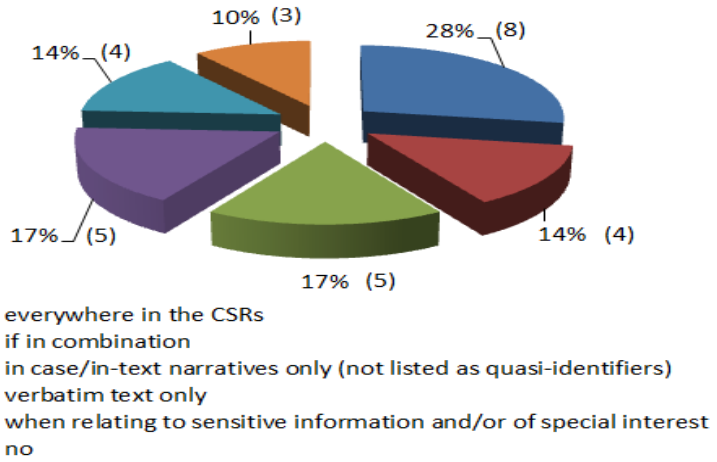
Anonymisation applied



Full redaction of case narratives



Redaction of adverse events



Improvement for 2018

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- **Quality of Redaction Proposal Document package**

  14/54 procedures were invalid (26%)

- **Quality of Final Redacted Document package**

  19/54 procedures were invalid (35%)

- **Quality of Anonymisation report (AnR)**

  ✓ Many AnRs not customised to the product; should be considered:

  - Disease/study size population and study setting;
  - Uniqueness of variable values;
  - Are the variables presented in combination (e.g. listings)?

  ✓ List of quasi-identifiers not specific to the package.

  ✓ Inconsistencies between AnR and redaction/transformation of identifiers.

Improvement for 2018 (cont')

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- ✓ Lack of rationale for **full redaction of narratives**:
  - o Redaction of variables not listed as quasi-identifiers; Case narratives are not a quasi-identifier but are made of identifiers to be listed
  - o Redaction of lab values;
  - o Redaction of adverse events (preferred terms).
- ✓ Redaction of case narratives in addition to another methodology (e.g. transformation + redaction).
- ✓ Impact of anonymisation on **data utility** not adequately addressed:
  - o Same conclusions compared to the non-anonymised clinical reports?
  - o Distorted conclusions?
  - o Any conclusions at all possible?
- ✓ **EMA's comments** to be implemented or feedback to be provided.

Improvement for 2018 (cont')

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- **Quality of CCI proposals**
  - ✓ Proposing CCI is not compulsory!
  - ✓ **76%** of the proposed CCI rejected.
  - ✓ Most commonly used rejection codes
    - o Rejection code 01: Information already available in the **public domain** or publicly available
    - o Rejection code 04: **Insufficient** justification
  - ✓ **Specific**, **pertinent**, **relevant**, **not overstated** and **appropriate** justification for each of the pieces of text proposed to be redacted.
  - ✓ Limit proposed redaction to the **very specific text**
  - ✓ Please share your experience with colleagues within your Company

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

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