Clinical data publication - background

- In October 2016, EMA started to publish clinical reports underpinning the market authorisation of new medicines for human use.
- Hundreds of clinical reports submitted by pharmaceutical companies have already been published.
- Clinical data publication is a groundbreaking transparency initiative and, worldwide, EMA is the first regulatory authority to provide such broad access to clinical data.

Data published so far

- 50 medicines relating to 54 regulatory procedures
- 36 marketing authorisation applications including 2 withdrawn applications
- 18 variations to extend the clinical use of a marketed medicine
- 3,279 documents
- 1.3 million pages

Users

- 3,641 registered
- 22,164 views
- 80,537 downloads

Usage

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Responders of a recent survey say that...

- Data are:
  - useful 62%
  - not useful 6%
  - in an understandable format 87%
  - *32% remaining responders are unsure

- Publishing clinical data helps:
  - EMA to build trust and confidence in its scientific and decision-making processes - 3/4 responders
  - researchers to re-assess the clinical data - 2/3 responders

Who benefits?

- Patients
  - Better medicines, protection from unnecessary trials
- Academia and researchers
  - Enhanced scientific knowledge
- Pharma industry, including small and medium-sized enterprises
  - Quality research & development and innovation
- Healthcare professionals
  - Better practice of medicines

For more information on clinical data publication visit our website.