

## 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**36** marketing authorisation applications including 2 withdrawn applications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

## What is published and when?

- ▶ Clinical reports are published on a dedicated website ([clinicaldata.ema.europa.eu](http://clinicaldata.ema.europa.eu)) for:
  - all marketing-authorisation applications submitted to the Agency as of 1 January 2015
  - all applications submitted to extend the existing clinical indication of a medicine as of 1 July 2015
- ▶ the reports are published once authorisation is granted by the European Commission
- ▶ reports supporting applications that are withdrawn

## Users

**3,641** registered



## Usage

**22,164** views



**80,537** downloads



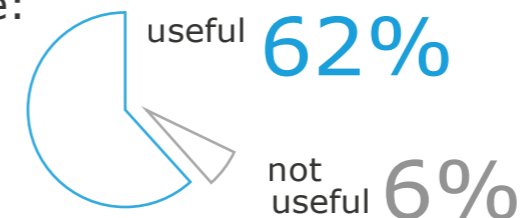
## Who benefits?

- ▶ 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

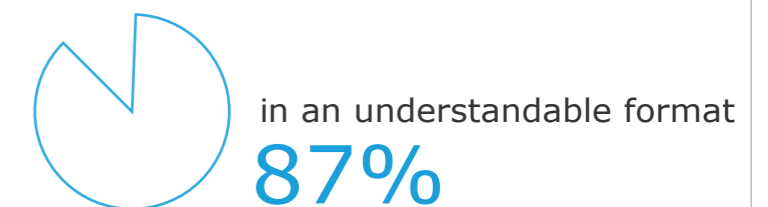


## Responders of a recent survey say that ...

▶ Data are:



\*32% remaining responders are unsure



▶ Publishing clinical data helps:

