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Press release

Unparalleled access to clinical data - one year on

Over 3,000 clinical documents published, 3,600 registered users and positive stakeholder feedback

One year ago today, the European Medicines Agency (EMA) became the first regulatory authority to give open access to clinical data submitted by companies in support of their marketing authorisation applications.

EMA's flagship policy on the publication of clinical data[1] enables citizens, including researchers and academics, to directly access the clinical reports[2] underpinning the regulatory evaluation of a medicine's clinical efficacy and safety via its clinical data publication (CDP) website[3]. This facilitates the independent re-analysis of data after a medicine has been approved and enhances scientific knowledge. Increased transparency facilitates knowledge sharing, leading to more efficient medicine development programmes and ultimately benefitting innovation.

Patients and healthcare professionals can find out more about the data supporting the approval of medicines they are taking or prescribing.

In a recent survey[4] of web users to evaluate implementation of the policy, three quarters of responders agree that the proactive publication of clinical data helps EMA to build public trust and confidence in its scientific and decision-making processes. Two thirds of responders agree that the data made available helps researchers to re-assess the clinical data.

As of 20 October 2017, clinical reports on 50 medicines, including orphan, biosimilar and generic medicines, as well as medicines for use in children, are publicly available on the CDP website. This amounts to 3,279 clinical documents, totalling more than 1.3 million pages. The majority of the data relates to the approval of new medicines, but there is also data for medicines that are already authorised and for which an extension of their clinical use has been sought.

Published data have attracted a total of 3,641 users[5], resulting in 22,164 document views and 80,537 document downloads for non-commercial research purposes.

EMA provides detailed guidance and hosts regular webinars with industry stakeholders to facilitate the publication process for these data.

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62% of responders in EMA's survey say that the data are useful and 87% say the data are presented in an understandable format, despite the redaction or anonymisation of certain information in line with European legislation on personal data protection. Participants in the survey included researchers, healthcare professionals, patients and industry.

EMA's initiative has shaped the global debate towards more transparency and benefits academic research and the practice of medicine as a whole.

Notes

1. More information on EMA's policy on publication of clinical data is available on our website here.
2. On the basis of the data submitted to EMA, now available on the clinical data website, the Agency provides recommendations on whether a medicine should be authorised for use in the EU. The assessment reports for all these scientific opinions are available here on our website.
3. The clinical data website is accessible here.
4. The survey was web-based, voluntary and available for three months. Full results will be published in due course.
5. 697 of the 3,641 users are registered for 'non-commercial research purposes'.
6. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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