EMA and CDISC

CDISC User group Meeting
Eschborn, February 18, 2014

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The Draft Policy

Goal: Enable independent analyses of reported clinical trial data by third parties

Transparency in authority decisions

Frame: The interests of public health outweigh considerations of commercially confidential information

Only data from future studies

Only submitted data… in CTD compatible format

Includes patient data listings, thus, single data elements

Press Releases

Dec 17, 2013

- **All review comments are read**
- **Large support for the agency's plans…**
- **Need for further analysis of certain aspects…**
- **… will continue to work with stakeholders, …**

➔ reiterates the agency's commitment … full transparency …

Jan 22, 2014

… published, once a decision on marketing authorization is complete or the application has been withdrawn.

Links

Video Paul Houston:

https://vimeo.com/user14227930/review/78341826/43a683b19f

Other links:

- http://www.europarl.europa.eu/news/en/news-room/content/20140121IPR33307/html/Clinical-trials-clearer-rules-better-protection-for-patients
- http://ec.europa.eu/health/human-use/clinical-trials/index_en.htm