

# Key References

---

[Clinical Trial Disclosure](#)

[Data Protection](#)

[Commercially Confidential Information and Personal Protected Data](#)

## **Clinical Trial Disclosure**

Clinical Trial Registration: A Statement from the International Committee of Medical Journal Editors (2004)

[http://www.icmje.org/news-and-editorials/clin\\_trial\\_sep2004.pdf](http://www.icmje.org/news-and-editorials/clin_trial_sep2004.pdf)

EC Reg 1049/2001 Regulation regarding public access to European Parliament, Council and Commission documents) (2001)

<http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32001R1049&from=EN>

EMA External guidance on the implementation of the European Medicines Agency policy on the publication of clinical data for medicinal products for human use (EMA/90915/2016, issued 2 March 2016)

[http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Regulatory\\_and\\_procedural\\_guideline/2016/03/WC500202621.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2016/03/WC500202621.pdf)

EMA Policy/0043 Access to documents (related to medicinal products for human and veterinary use) (EMA/110196/2006, issued 1 December 2010)

[http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Other/2010/11/WC500099473.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Other/2010/11/WC500099473.pdf)

EMA Policy/0070 Publication of clinical data for medicinal products for human use (EMA/240810/2013, issued 2 October 2014)

[http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Other/2014/10/WC500174796.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Other/2014/10/WC500174796.pdf)

EU Reg 536/2014 Regulation on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (2014)

<http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014R0536&from=EN>

FDA Amendment Act (FDAAA) 801 (2007)

<http://www.fda.gov/RegulatoryInformation/Legislation/SignificantAmendmentstotheFDCAct/FoodandDrugAdministrationAmendmentsActof2007/FullTextofFDAAALaw/default.htm>

Date: 22 Mar 2016

FDA Modernization Act (FDAMA) 113 (1997)

<http://www.fda.gov/RegulatoryInformation/Legislation/SignificantAmendmentstotheFDCAAct/FDAMA/FullTextofFDAMAlaw/default.htm>

German Federal Ministry of Health: Announcement concerning the publication of results of clinical trials pursuant to Section 42b Medicinal Products Act (Arzneimittelgesetz, AMG)  
<https://www.pharmnet-bund.de/static/.content/.galleries/downloads/en/information-dataprotection-investigators-resultsclinicaltrials.pdf>

Joint EFPIA-PhRMA Principles for Responsible Clinical Trial Data Sharing. Our Commitment to Patients and Researchers.

<http://transparency.efpia.eu/uploads/Modules/Documents/data-sharing-prin-final.pdf>

Questions and answers on the European Medicines Agency policy on publication of clinical data for medicinal products for human use (2015) (EMA/357536/2014 Rev. 1, issued 8 June 2015)

[http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Report/2014/10/WC500174378.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Report/2014/10/WC500174378.pdf)

Sharing Clinical Trial Data: A Proposal From the International Committee of Medical Journal Editors (2016)

<http://www.icmje.org/news-and-editorials/M15-2928-PAP.pdf>

WHO Statement (14 Apr 2015)

[http://www.who.int/ictrp/results/WHO\\_Statement\\_results\\_reporting\\_clinical\\_trials.pdf?ua=1](http://www.who.int/ictrp/results/WHO_Statement_results_reporting_clinical_trials.pdf?ua=1)

## Data Protection

Data Protection Directive 95/46/EC (24 Oct 1995)

<http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31995L0046&from=en>

EU data protection regulations No. 45/2001 (18 Dec 2000)

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:008:0001:0022:en:PDF>

HIPAA Privacy Rule of 1996

<http://www.hhs.gov/sites/default/files/privacysummary.pdf>

<http://www.legislation.gov.uk/ukpga/1998/29/contents>

UK Data Protection Act (1998)

<https://www.gov.uk/data-protection/the-data-protection-act>

UK Freedom of Information Act 2000

<http://www.legislation.gov.uk/ukpga/2000/36/contents>

## Commercially Confidential Information and Personal Protected Data

Anonymisation: managing data protection risk code of practice

<https://ico.org.uk/media/1061/anonymisation-code.pdf>

CORE Reference Preface: Data Privacy, Commercially Confidential Information, Disclosure and Redaction references

<http://www.core-reference.org>

HMA/EMA Guidance document on the identification of commercially confidential information and personal data within the structure of the marketing authorisation (MA) application - Release of information after the granting of a marketing authorization (2012)  
[http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Other/2012/03/WC500124536.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/03/WC500124536.pdf)

HMA/EMA recommendations on transparency (EMA/484118/2010, issued Nov 2010)

[http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Other/2010/12/WC500099536.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Other/2010/12/WC500099536.pdf)

Principles to be applied for the Deletion of CCI for the Disclosure of EMEA Documents (EMEA/45422/2006, 15 April 2007)

[http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Regulatory\\_and\\_procedural\\_guideline/2009/10/WC500004043.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004043.pdf)

K. El Emam, K Abdallah. De-identifying Clinical Trials Data. *Applied Clinical Trials*, Mar 20, 2015.

<http://www.appliedclinicaltrialsonline.com/de-identifying-clinical-trials-data>

K. El Emam, S Rodgers, B Malin. Anonymising and sharing individual patient data. BMJ 2015; 350: h1139.

<http://www.bmj.com/content/350/bmj.h1139>

J-M Ferran, J Lanoue. PharmaSUG 2015 - Paper DS10. PhUSE De-Identification Working Group: Providing De-Identification Standards to CDISC Data Models.

<http://www.lexjansen.com/pharmasug/2015/DS/PharmaSUG-2015-DS10.pdf>

Article 29 Data Protection opinion 06/2013 on open data and public sector information ('PSI') reuse.

[http://ec.europa.eu/justice/data-protection/article-29/documentation/opinion-recommendation/files/2013/wp207\\_en.pdf](http://ec.europa.eu/justice/data-protection/article-29/documentation/opinion-recommendation/files/2013/wp207_en.pdf)

Article 29 Data Protection working party opinion 05/2014 on Anonymisation Techniques.

[http://ec.europa.eu/justice/data-protection/article-29/documentation/opinion-recommendation/files/2014/wp216\\_en.pdf](http://ec.europa.eu/justice/data-protection/article-29/documentation/opinion-recommendation/files/2014/wp216_en.pdf)