Useful links to regulatory/government publications

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Abbreviations

ABPI – Association of the British Pharmaceutical Industry

CONSORT – Consolidated Standards of Reporting Trials

CRUK – Cancer Research UK

EC – European Commission

EMA – European Medicines Agency

ENCePP – European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

EU – European Union

EudraCT – European Union Drug Regulating Authorities Clinical Trials

HRA – Health Research Authority

ICMJE – International Committee of Medical Journal Editors

IFPMA – International Federation of Pharmaceutical Manufacturers and Association

MHRA – Medicines and Healthcare Regulatory Authority

PhRMA – Pharmaceutical Research and Manufacturers of America

PMCPA – Prescription Medicines Code of Practice Authority

UK – United Kingdom

WHO – World Health Organization

WMA – World Medical Association

Useful links to regulatory/government publications

Registries and portals

Global

WHO International Clinical Trials Registry Platform (ICTRP), www.who.int/ictrp/en/

IFPMA Clinical Trials Portal, http://clinicaltrials.ifpma.org/clinicaltrials

The ISRCTN register, www.controlled-trials.com/isrctn

Current controlled trials, www.controlled-trials.com/mrct/

EU

EU Clinical Trials Register, www.clinicaltrialsregister.eu

European Clinical Trials Database of all clinical trials commencing in the European Union from 1 May 2004 onwards. The EudraCT database has been established in accordance with Directive 2001/20/EC, https://eudract.ema.europa.eu/

ENCePP Electronic Register of Studies, www.encepp.eu/encepp/studiesDatabase.jsp

UK

UK Clinical Trials Gateway, www.ukctg.nihr.ac.uk

CR UK clinical trials database, ww.cancerresearchuk.org/cancer-help/trials/

USA

US National Institute of Health, www.clinicaltrials.gov

Useful links to regulatory/government publications

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Pharmaceutical industry commitments and statements regarding trial disclosure:

Industry position statements

IFPMA Joint position on the disclosure of clinical trial information via clinical trial registries and databases, 6 January 2005, http://clinicaltrials.ifpma.org/clinicaltrials/fileadmin/files/pdfs/FINAL%20Position%20Clinical%20Trials%20Information%20January%2005.pdf

IFPMA Joint position on the disclosure of clinical trial information via clinical trial registries and databases, updated 18 November 2008, http://clinicaltrials.ifpma.org/clinicaltrials/fileadmin/files/pdfs/EN/Revised_Joint_Industry_Position_Nov_2008.pdf

IFPMA Joint position on the disclosure of clinical trial information via clinical trial registries and databases, updated 10 November 2009, http://clinicaltrials.ifpma.org/clinicaltrials/fileadmin/files/pdfs/EN/November_10_2009_Updated_Joint_Position_on_the_Disclosure_of_Clinical_Trial_Information_via_Clinical_Trial_Registries_and_Databases.pdf

IFPMA Joint position on the publication of clinical trial results in the scientific literature, 10 June 2010, http://clinicaltrials.ifpma.org/clinicaltrials/fileadmin/files/pdfs/20100610_Joint_Position_Publication_10Jun2010.pdf

Codes of Practice

ABPI Code of practice for the pharmaceutical industry second 2012 edition, www.abpi.org.uk/our-work/library/guidelines/Pages/code-2012.aspx

IFPMA Code of Practice 2012, www.ifpma.org/fileadmin/content/Publication/2012/IFPMA_Code_of_Practice_2012_new_logo.pdf

Industry guidelines

ABPI Best practice model for the disclosure of results and transparent information on clinical trials, produced 2007, revised 2008, www.abpi.org.uk/our-work/library/guidelines/Pages/best-practice-model.aspx

PhRMA's Principles on conduct of clinical trials and communication of clinical trial results, 2011, http://phrma.org/sites/default/files/pdf/042009_clinical_trial_principles_final_0.pdf

EFPIA and PhRMA Principles for responsible clinical trial data sharing. Our commitment to patients and researchers, 2013, http://transparency.efpia.eu/uploads/Modules/Documents/data-sharing-prin-final.pdf

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Government and regulatory authority – trials transparency

UK

HRA

The HRA interest in good research conduct, Transparent research, May 2013, http://www.hra.nhs.uk/documents/2013/08/transparent-research-report.pdf

HRA confirms its action plan on transparent research, July 2013, www.hra.nhs.uk/hra-news-and-announcements/hra-confirms-its-action-plan-on-transparent-research/

Trial registration to be condition of the favourable REC opinion from 30 September 2013, http://www.hra.nhs.uk/about-the-hra/who-we-are/transparency/

Commons Select Committee

Committee to inquire into clinical trials and disclosure of data, 13 December 2012, www.parliament.uk/business/committees/committees-a-z/commons-select/science-and-technology-committee/news/121213-clinical-trials-inquiry-announced/

Science and Technology Committee - Third Report, Clinical Trials, Published 17 September 2013, http://www.publications.parliament.uk/pa/cm201314/cmselect/cmsctech/104/104.pdf

NICE

Health Committee – Eighth Report: National Institute for Health and Clinical Excellence, 2013, www.publications.parliament.uk/pa/cm201213/cmselect/cmhealth/782/78202.htm

EU

EMA

European Medicines Agency policy on access to documents (related to medicinal products for human and veterinary use), 1 December 2010, www.ema.europa.eu/docs/en_GB/document_library/Other/2010/11/WC500099473.pdf

Draft policy 70: Publication and access to clinical-trial data, June 2013, www.ema.europa.eu/ema/pages/includes/document/open_document.jsp?webContentId=WC500144730

Decision of the European Ombudsman closing his inquiry into complaint 2560/2007/BEH against the European Medicines Agency, www.ombudsman.europa.eu/en/cases/decision.faces/en/5459/html.bookmark

Publication and access to clinical-trial data: an inclusive development process, www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000556.jsp&mid

Release of data from clinical trials, www.emea.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000555.jsp&mid=WC0b01ac0580607bfa

Workshop on access to clinical-trial data and transparency kicks off process towards proactive publication of data, November 2012, www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2012/11/news_detail_001662.jsp&mid=WC0b01ac058004d5c1

Access to clinical-trial data and transparency. Workshop report. 2012, www.ema.europa.eu/docs/en_GB/document_library/Report/2012/12/WC500135841.pdf

Publication of clinical reports: EMA adopts landmark policy to take effect on 1 January 2015, http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2014/10/news_detail_002181.jsp&mid=WC0b01ac058004d5c1

ENCePP, *Electronic Register of Studies* aims to provide a publicly accessible resource for the registration of pharmacoepidemiological and pharmacovigilance studies, www.encepp.eu/encepp/studiesDatabase.jsp

European Parliament, Commission and Council of the EU

Commission Guideline — Guidance on posting and publication of result-related information on clinical trials in relation to the implementation of Article 57(2) of Regulation (EC) No 726/2004 and Article 41(2) of Regulation (EC) No 1901/2006, http://ec.europa.eu/health/files/eudralex/vol-10/2012_302-03/2012_302-03_en.pdf

EU Public consultation on the protection of business and research know-how, http://ec.europa.eu/internal_market/consultations/2012/trade-secrets_en.htm

Proposal for a regulation of the European Parliament and of the Council on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC. European Commission. 2012, http://ec.europa.eu/health/files/clinicaltrials/2012_07/proposal/2012_07_proposal_en.pdf

Article 78(1) of the European Commission's EU Clinical Trials Regulation proposal, http://ec.europa.eu/health/files/clinicaltrials/2012_07/proposal/2012_07_proposal_en.pdf

Directive 2001/20/EC on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use, of 4 April 2001, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:121:0034:0044:en:PDF

Germany

Medicinal Products Act in the version published on 12 December 2005 (Federal Law Gazette [BGBl.]) Part I p. 3394, last amended by Article 1 of the Law of 25 May 2011 (Federal Law Gazette I p. 946), www.gesetze-im-internet.de/englisch_amg/englisch_amg.html#p0930

USA

FDA

Food and Drug Administration Amendments Act (FDAAA) of 2007, www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FoodandDrugAdministrationAmendmentsActof2007/default.htm

Useful links to regulatory/government publications

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Other – trial transparency

About the WHO International Clinical Trials Registry Platform (ICTRP), www.who.int/ictrp/about/en/

The CONSORT Statement, www.consort-statement.org/consort-statement

Good publication practice for communicating company sponsored medical research: the GPP2 guidelines, BMJ2009; 339:b4330, www.bmj.com/content/339/bmj.b4330

International Committee of Medical Journal Editors (ICMJE), 2013. *Uniform requirements for manuscripts submitted to biomedical journals: publishing and editorial issues related to publication in biomedical journals: obligation to register clinical trials*, www.icmje.org/publishing_10register.html

WMA Declaration of Helsinki – Ethical principles for medical research involving human subjects, www.wma.net/en/30publications/10policies/b3/

Note: All web links accessed in October 2013

ABPI clinical trial disclosure toolkit disclaimer

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