



Public access to clinical trial data

HMA - Human stakeholders meeting
27 November 2013

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Health Action International

- A non-for-profit global network
- Established in 1981
- Comprising public health NGOs, healthcare professionals, academics and consumers
- HAI Europe: European office, based in Amsterdam
- Working to increase access to essential medicines and improve their rational use through research and evidence-based advocacy
- Position funded by the Executive Agency for Health and Consumers (EAHC) and Open Society Foundations (OSF)

HAI's recent work on access to clinical trial data

Protecting citizens' health: Transparency of clinical trial data on medicines in the EU

Key points:

- Data secrecy perpetuates reporting bias, where the benefits of medicines are overstated and harms downplayed.
- Full transparency of clinical trial data reinforces evidence-based medicine. Increased public knowledge on the real effects of medicines contributes to rational use and the protection of public health.
- Clinical trial data cannot be considered commercially confidential information. Human health is an overriding public interest.
- Public access to trial data can safeguard patient confidentiality.
- Clinical study reports, including duly de-identified patient-level data, from all clinical trials, must be made publicly available.

Policy paper October 2013

POLICY PAPER

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Health Action International (HAI) is an independent, global network, working to increase access to essential medicines and improve their rational use through research excellence and evidence-based advocacy.

EMA/240810/2013

EMA's 2013 policy on access to clinical-trial data: Transparency in the public health interest

Joint Submission of comments on 'Policy 0070 on publication and access to clinical-trial data (September 2013)

Comments from:
Name and affiliation

Association Internationale de la Mutualité (AIM)
International Society of Drug Bulletins
Medicines in Europe Forum
Health Action International (HAI) Europe

Please note that these comments and the identity of the sender (not contact details) will be published unless a specific justified objection is received. When completed, this form should be sent in Word format (not PDF) to: ctdatapolicy@ema.europa.eu

Brussels, 11 October 2013

Joint letter to Member States' Ministers of Health and Parliamentary Representatives (CoHealth)

EU Regulation on clinical trials: further enhance clinical data transparency

- A clear stance by the Council in favour of freedom of information for European citizens and of public access to clinical trial data is needed.
- Selective publication of only those results which favour the drug in question biases scientific analysis, Member Agency decisions and clinical decision making, therefore putting public health at risk and creating reports of Member States' healthcare systems (4). Moreover, it is an unethical practice contrary to the Helsinki Declaration and to the basic scientific and ethical principles of transparency, and it calls for a political answer (5).
- On 28 May 2013, the Environment, Public Health and Food Safety (EPHF) Committee adopted a perfectly reasonable demand in order to fully allow for independent analysis of clinical trials: that clinical data contained in clinical study reports (CSRs) should not be considered commercially confidential or marketing authorisation has been granted or the decision-making process on an application for marketing has been completed (6), creating a new reach (7).
- This demand is in line with the European Medicines Agency policy on access to documents (1) and with the position of the European Ombudsman who found that clinical study reports (CSRs) do not contain commercially confidential information or personal data (participants' clinical data are previously anonymized) (2). This was confirmed by an in-depth analysis of 78 clinical trials by two researchers from the CoHealth Collaboration in early 2013 (3) (8).
- However, since the beginning of the discussions, the pharmaceutical industry has been fighting heavily against clinical freedom of information rights:
 - In March 2013, two pharmaceutical companies, AbbVie and Intermune, supported by European and US pharmaceutical industries trade associations (EPHA and PHMA), brought cases against the EMA and its 2010 access to document policy at the European Court of Justice (9) (4).
 - In July 2013, EPHA and PHMA proposed additional and non-binding self-regulation principles that would maintain the status quo and are unlikely to be implemented by their members (for access to clinical study reports, demands for applications to be reviewed by a "scientific board" to be appointed by the company in question).
 - In addition, in July 2013, EPHA and PHMA have made concrete proposals for a labelling strategy that entailed "redacting patient groups to express concern about the risk to public health by non-scientific use of data" (5).
- In France, in 2008, several EU governments notified members of CoHealth to combat AEMIS influence, even though the effectiveness of CoHealth's the provision of influenza complications was expressed, on warning letters of access. Health authorities made decisions without access to clinical trial data (10).
- In the African Context: www.hai.europa.eu as well as other campaigns <http://www.hai.europa.eu> (11) (12) (13) (14) (15) (16) (17) (18) (19) (20) (21) (22) (23) (24) (25) (26) (27) (28) (29) (30) (31) (32) (33) (34) (35) (36) (37) (38) (39) (40) (41) (42) (43) (44) (45) (46) (47) (48) (49) (50) (51) (52) (53) (54) (55) (56) (57) (58) (59) (60) (61) (62) (63) (64) (65) (66) (67) (68) (69) (70) (71) (72) (73) (74) (75) (76) (77) (78) (79) (80) (81) (82) (83) (84) (85) (86) (87) (88) (89) (90) (91) (92) (93) (94) (95) (96) (97) (98) (99) (100) (101) (102) (103) (104) (105) (106) (107) (108) (109) (110) (111) (112) (113) (114) (115) (116) (117) (118) (119) (120) (121) (122) (123) (124) (125) (126) (127) (128) (129) (130) (131) (132) (133) (134) (135) (136) (137) (138) (139) (140) (141) (142) (143) (144) (145) (146) (147) (148) (149) (150) (151) (152) (153) (154) (155) (156) (157) (158) (159) (160) (161) (162) (163) (164) (165) (166) (167) (168) (169) (170) (171) (172) (173) (174) (175) 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Opening up EU clinical trial data: Dr. Ben Goldacre

StichtingHAIEurope - 20 video's

370 weergaven

Abonneren 16

Leuk Over Delen Toevoegen aan

Gepubliceerd op 4 dec 2012

Filmed on 13 Nov 2012 at the lunch seminar 'Transparency in Medical Research to Protect Public Health: Opening up EU clinical trial data for safe and effective medicines' in the European

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Access to clinical trial data: key points (I)

- Deficiencies in the current model for reporting scientific research prevent the full effects of medicines from being publicly known:

Only about half of abstracts presented at conferences are later published in full and subsequent publication is associated with positive results. (Scherer et al., 2007)

Studies with positive results are more likely to be published than those with negative results. (Song F. et al., 2010)

Non-publication is more common among trials that receive industry funding than those that do not. (Jones C.W. et al., 2013)

Study publication bias leads to overestimation of treatment effects. (Dwan K. et al., 2008)

Reporting bias is widespread in the medical literature. (McGauran N. et al., 2010)

Access to clinical trial data: key points (II)

- Making clinical trial data publicly available is important for **public health**, **scientific** and **ethical** reasons



Access to clinical trial data: key points (III)

- Self-regulation is not the solution
- Public disclosure of clinical trial data to be requested by law
- Clinical trial data not commercial confidential information. The protection of human health is an overriding public interest
- Clinical study reports, including anonymised patient-level data, must be made publicly available
- Opportunities on the regulatory-side:
 - Revision of the Clinical Trials Directive
 - EMA policy 'Publication and access to clinical-trial data'
 - At national level?

Multi-stakeholder calls for greater data transparency

+ AllTrials

All Trials Registered | All Results Reported

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It's time all clinical trial results are reported.
 Patients, researchers, pharmacists, doctors and regulators everywhere will benefit from publication of clinical trial results. Wherever you are in the world please sign the petition:
Thousands of clinical trials have not reported their results; some have not even been registered.
 Information on what was done and what was found in these trials could be lost to doctors and researchers, leading to bad treatment decisions, missed opportunities for good medicine, and trials being repeated.
All trials past and present should be registered, and the full methods and the results reported.
We call on governments, regulators and research bodies to implement measures to achieve this.
 The petition has also been translated into [many different languages](#). If you would like to sign the petition on behalf of an organisation then please [contact us](#). Data will be held by Sense About Science. Read our [privacy policy](#) here.

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Richard Gonzalez of AbbVie, and Daniel Welch of InterMune: Drop your legal action blocking access to EMA clinical trial data

kisk Petition by David Healy Cardiff Wales, United Kingdom

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Let us see Drug Data! Drug hazards are not "trade secrets"!

Drug companies maximize the sales of new drugs by hyping their benefits while downplaying significant risks. In 2010 the European Medicines Agency began releasing patient-level data from the clinical trials used to approve new medicines in Europe – a development hailed by American, and European researchers and researchers around the world as a major step towards drug safety.

This process has been shut down by a lawsuit taken by two American corporations – AbbVie, makers of Humira, the number one selling medication in the world with projected sales of \$10 billion in 2013; and InterMune, whose pulmonary-fibrosis drug Esbriet has recently been approved in Europe at a cost of over \$40,000 per year.

THANK YOU

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References

- Scherer RW, Langenberg P, von Elm E. Full publication of results initially presented in abstracts. (2007). *Cochrane Database of Systematic Reviews*, 2:MR000005 doi:10.1002/14651858.MR000005.
- Song F, Parekh S, Hooper L et al. Dissemination and Publication of Research Findings: An Updated Review of Related Biases (2010). *Health Technology Assessment*, 14:2 doi:10.3310/hta14080.
- Jones CW, Handler L, Crowel KE. Non-publication of large randomized clinical trials: cross sectional analysis. (2013) *BMJ* 347:f6104
- Dwan K, Altman DG, Arnaiz JA et al. Systematic Review of the Empirical Evidence of Study Publication Bias and Outcome Reporting Bias. (2008) *PLoS ONE*, 3:8
- McGauran N, Wieseler B, Kreis J et al. Reporting bias in medical research - a narrative review. (2010) *Trials* 11:37