Public access to clinical trial data

HMA - Human stakeholders meeting

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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.

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

POLICY PAPER

Key points:

- Data secrecy perpetuates reporting bias, where the benefits of medicines are overrated 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

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

EU Regulation on clinical trials:
further enhance clinical data transparency

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)

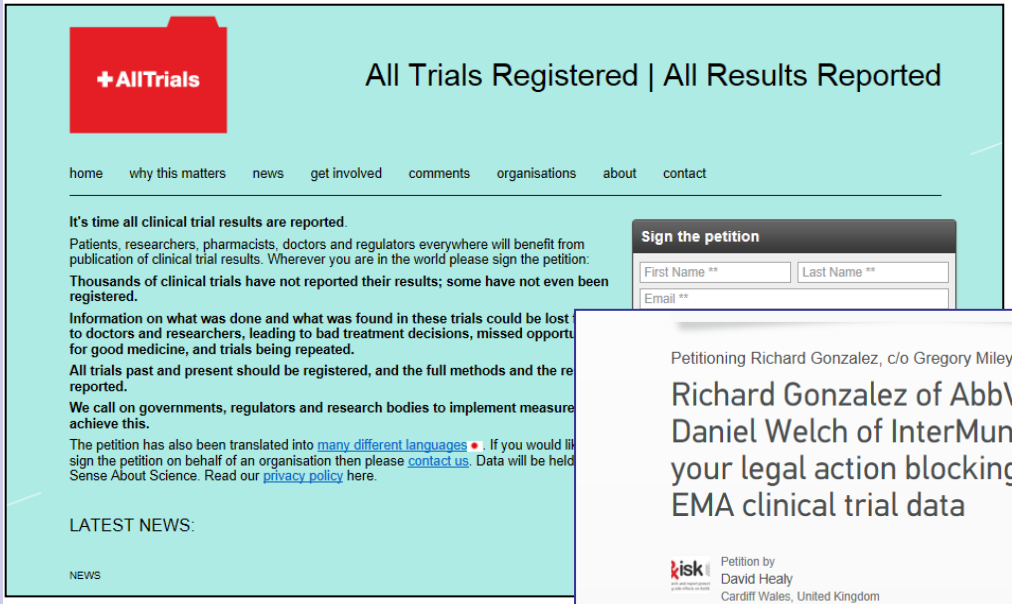
Access to clinical trial data: key points (II)

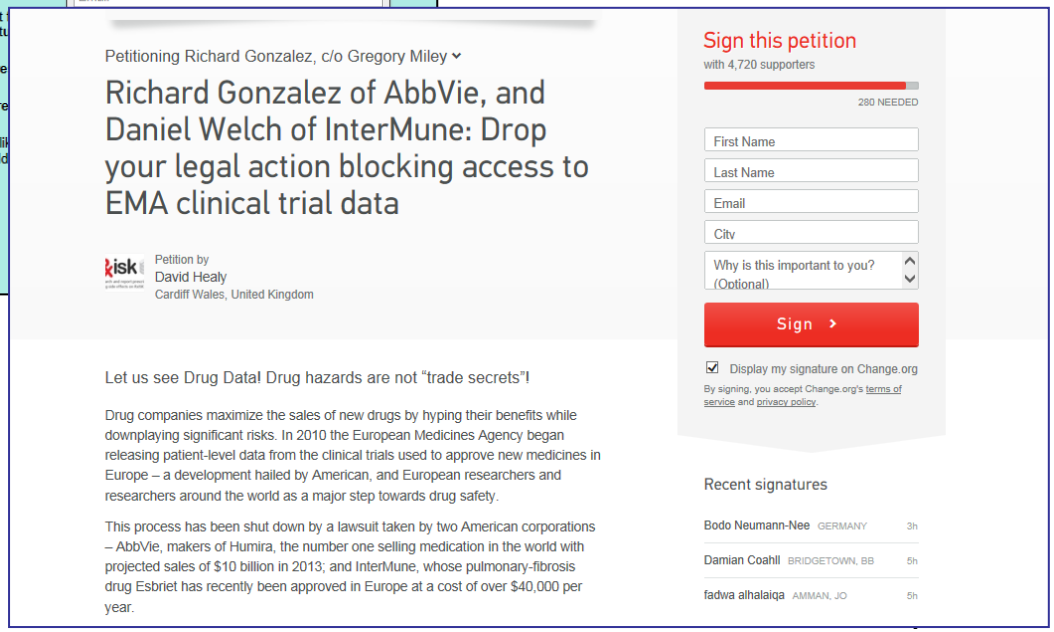
- Making clinical trial data publicly available is important for **public health**, **scientific** and **ethical** reasons

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





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