EMA/240810/2013

Submission of comments on 'Policy 0070 on publication and access to clinical-trial data'

Comments from:

Name and affiliation
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The AllTrials campaign is an initiative of Bad Science, *BMJ*, Centre for Evidence-based Medicine, Cochrane Collaboration, James Lind Initiative, *PLOS* and Sense About Science and is being led in the US by Dartmouth's Geisel School of Medicine and the Dartmouth Institute for Health Policy & Clinical Practice. It was launched in January 2013 to call for all clinical trials to be registered and results reported.

Clinical trials are investigations designed to assess the effects – wanted and unwanted - of healthcare interventions in people. The Declaration of Helsinki, which is the World Medical Association's statement of principles for medical research involving people, states that every investigator running a clinical trial should register it and report its results. Millions of volunteers have participated in clinical trials to help find out more about the effects of treatments on disease, yet that important ethical principle about reporting has been widely ignored. Information on what was done and what was found in these trials could be lost forever to doctors and researchers, leading to bad treatment decisions, missed opportunities for good medicine, and trials being repeated.

This is what led to the AllTrials campaign in January 2013, a campaign which is now supported by 57,700 people and over 400 organisations worldwide, including research funders, regulatory bodies, consumer organisations, medical Royal Colleges, professional and learned societies, journals, pharmaceutical company GSK and more than 200 patient groups.

We support the European Medicines Agency's aim to ensure full access to clinical trial information the Agency holds. We believe that if data is submitted to support a marketing authorisation for a medical product in Europe then this data should be available for scrutiny by researchers. We agree that the EMA has a role to play in the dissemination of this data.

We welcome the EMA's proposal to proactively publish clinical study reports from clinical trials submitted in support of a marketing authorisation application. Clinical study reports contain a large amount of detailed information about the methods, analysis, results and conclusions of a clinical trial, information which is needed to make and to scrutinise decisions about medicines and to assess published summary findings. This information should be publicly available. Individual patient data in a report can be redacted and should be available on request to researchers with a commitment that no reasonable request will be refused.

We support the EMA's policy that in general the data included in clinical trial study reports should not be considered commercially confidential once a marketing authorisation has been granted or the decision making process on an application for marketing authorisation is complete.

There is no good reason to delay full reporting of clinical trial results. It will have huge benefits for patients, health workers, doctors, pharmacists, regulators and researchers. It will benefit treatment decisions now and research into future options. We urge the EMA to implement its new policy as soon as possible.

Comments on text

Line number(s) *(e.g. 20-23)*	Comment	Proposed changes, if any *(If changes to the wording are suggested, they should be highlighted using 'track changes')*
27-35	We support this position. With full information about effects and side effects, a better risk/benefit calculation can be made by doctors, and individual patients. Healthcare commissioners and regulators can make a more accurate cost/benefit assessment which ensures that the treatments available are those that are truly the most effective.	
36-43	We support this position. We agree with the need for a different approach to sharing patient data. We believe this draft policy protects personal data.	
52-56	We support this position. The effect of publishing the full reports of clinical trials will be to provide a richer research base for both industry and academia. This means greater potential for collaboration and interdisciplinary work, more productive research, and potential value from unused Intellectual Property.	
67-72	We support this position. Those requesting access to clinical trial data should be held to the same standards of transparency as the researchers who produced the data.	
78-82	We support the Agency's policy to continue to reactively release clinical trial data already held as outlined in the Agency's current policy on access to documents.	
128 – 136	We support this categorisation. We agree that clinical trial data should not be assumed to be commercially confidential information and should be deemed CCI only in duly justified cases.	

Line number(s) *(e.g. 20-23)*	Comment	Proposed changes, if any *(If changes to the wording are suggested, they should be highlighted using 'track changes')*
138 - 154	We support this categorisation. We support the policy to designate all clinical trial documents without personal data "open access" and to make them available to download from the Agency's website from the time of publication of the EPAR for marketing authorisation decisions or withdrawals.	
155 – 162	We support this categorisation. We agree that raw personal data should not be handled in the same way as category 2 documents and should not be pro-actively publicly released. We recommend that this data is available to researchers on request with no reasonable request refused.	
219 – 221	We agree that "C" data should be made available from the time of publication of the EPAR for marketing authorisation decisions or withdrawals.	
235-236	We support the policy that all documents listed in Annexes 1 and 2 should be fully searchable.	
237 – 238	We support the policy to publish a cumulative list of clinical trials for each product including a unique study identifier and basic information about each trial.	
239 – 241	We support the policy that the applicant should provide relevant unique study identifiers in the list.	
242-244	We support the policy that clinical trial data should be provided in the format in which they were analysed by the applicant.	
250 – 253	We support this policy coming into effect on 1st January 2014 and the proposal to advise trial sponsors that clinical trial data submitted to the	

Line number(s) *(e.g. 20-23)*	Comment	Proposed changes, if any *(If changes to the wording are suggested, they should be highlighted using 'track changes')*
	agency on or after 1st March 2014 and designated open access shall be subject to the policy.	
256 – 261	We support the proposal to work with trial sponsors and other concerned parties to put in place appropriate standards, rules and procedures for de-identification of patient data. We urge you not to delay implementation of the policy any longer than necessary to do that.	

Please add more rows if needed.