13 February 2015

Submission of comments on 'Draft proposal for an addendum, on transparency, to the "Functional specifications for the EU portal and EU database to be audited - EMA/42176/2014"' (EMA/641479/2014)

Comments from:

Name of organisation or individual
AllTrials Campaign

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received.

When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF).

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1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment (if any)	Outcome (if applicable) *(To be completed by the Agency)*
	All clinical trials should be registered and all results reported. Some pharmaceutical companies, such as GSK, do not distinguish between their clinical trials and have committed to registering and reporting all trials they sponsor. This is the standard that can be achieved. We still haven't heard of any examples of information from registration or summary results that should be commercially confidential. Any deferrals to making information public must be justified and those justifications should be independently audited and policed. The phases of trials must be clearly defined and a differentiation made between trials in healthy volunteers and trials in patients. There must be prompt and public reporting of any serious adverse events seen in trials. If a trial is stopped because of safety concerns, information about that trial should be made public immediately.	

2. Specific comments on text

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome *(To be completed by the Agency)*
Question 4 Lines 435-436		Comment: Trials need to have contact details for patients, doctors and researchers seeking further information. Patients and doctors may be seeking information about enrolment or to find out results of a past trial, researchers may want more information about scientific aspects of a trial or to request data.	
Question 6 Lines 606-609		Comment: We support proposal 1.1. Information from all trials on a drug – including trials for non-approved indications – should be made public. Such uses are extremely common in routine clinical practice. It is therefore senseless and dangerous for trials on such uses to be exempted from robust reporting requirements.	
Question 7 Lines 641-642		Comment: The default should be transparency. IMPD-Q sections should be made public and any request to withhold that information should be justified and those requests should be regularly audited.	
Question 8 Lines 652-654		Comment: There should not be an option to defer publication of registration information of a Phase IV trial on a product with marketing authorisation. Details about these trials can provide information about the risks and benefits of treatments currently being prescribed and taken by patients. Patent laws will protect any potential commercially confidential information	

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome *(To be completed by the Agency)*
		about these trials.	
Question 9 Lines 704-708		Comment: We support Proposal One. Study and product specific documents should be made public at the time of the decision on the trial. The default should be to make information public. Deferrals in making that information public should be justified but each of the other proposals would result in information being withheld without justification.	
Question 11 Lines 745-746		Comment: For Phase I clinical trials with healthy volunteers, any deferrals to making information public must be justified, and those justifications should be independently audited and policed. If a Phase I trial in healthy volunteers is stopped because of safety concerns, information about that trial should be made public immediately.	
Question 17 Lines 857-858		Comment: Trial sponsors should not be principally responsible for redacting information about unexpected events. Where redactions are necessary to protect personal or commercially confidential information, they should be justified and those justifications should be independently audited.	

Please add more rows if needed.