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	EAHP supports the reasoning provided by EMA for its change in policy in relation to clinical trial data transparency – fundamentally, a great public benefit will be served.	
36-43	EAHP has confidence in the EMA's ability to abide by European legislation and protect patient's data, whilst at the same time making appropriately redacted information about clinical trial results more openly available.	
50	EAHP supports the premise that *"CT data cannot be considered CCI; the interests of public health outweigh considerations of CCI."* This is also supported by the European Ombudsman.	
57-61	In many regards, this is a cited objection to transparency across many areas: "*If we release this information 'unqualified' people will not fully understand its meaning and misuse the information".* Yet, EAHP consider that this has rarely come to pass in other areas of public policy where transparency has been extended, and is moreover a societal risk that goes beyond the remit of the EMA per se e.g. the accuracy and diligence of media reporting. Yet even without change in EMA policy on trial transparency this risk will persist, whether a small, or a large amount of information is released. More importantly, with greater information available, qualified and credible sources will always be in a position to give a well-informed opinion about any emerging issues, whereas this may not be the case currently, due to a reduced availablility of information.	
67-72	EAHP 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.	
128-136	EAHP 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.	
138-154	EAHP support this categorisation. We support the policy to designate all clinical	

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')*
	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	EAHP 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	EAHP agree that "C" data should be made available from the time of publication of the EPAR for marketing authorisation decisions or withdrawals.	
235-236	EAHP support the policy that all documents listed in Annexes 1 and 2 should be fully searchable.	
237 – 238	EAHP 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	EAHP support the policy that the applicant should provide relevant unique study identifiers in the list.	
242-244	EAHP support the policy that clinical trial data should be provided in the format in which they were analysed by the applicant.	
251-252	EAHP support this policy coming into effect on 1st January 2014 and the proposal to advise trial sponsors that clinical trial data submitted to the agency on or after 1st March 2014 and designated open access shall be subject to the policy.	

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')*
256-261	EAHP 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.	

Please add more rows if needed.