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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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

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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')*
16-17	The scope of this policy only covers 'data from CTs on which regulatory decisions are based'. While we note this is an important step in the right direction, this policy does only cover trials that go forward for consideration in support of the licensing process. There are therefore large numbers of trials that fall out of scope, and for which accessing data will remain a challenge. As a regulator, and as a central point for trial registry, we would consider that EMA could have a larger role to work toward transparency of trial results. BPS is keen to highlight that it is largely supportive of this initiative.	
39/41-2	The policy notes 'established ways and means to anonymise data and protect patients from retroactive identification' will be put into place, and that EMA have stated there will be further work in this regard (258/9 i.e. plans for a guidance document). In response to this BPS would highlight the importance of a robust approach to protecting patients and ensuring de-identification of data. There need to be clear standards in place to enable data de-identification, particularly in the case of trials on rare diseases.	
69-70	BPS is supportive that researchers undertaking secondary analysis are held to the same standards on openness and transparency as those submitting for licensing approval. However, we note that it is not clear how researchers should make their research public other than via publication in a journal. The secondary analyses, or links to published versions, could be held by the EMA. This would enable monitoring of adherence to the policy.	
81/2	Considering the issues experienced by our members of accessing information via this reactive process, there is a need for EMA to review this position and undertake to determine the feasibility of making legacy data available on the same basis as covered in this policy.	

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112/3	BPS members are not convinced by claims that such clinical trial data does contain commercially sensitive information. We therefore look forward to the outcomes of the court cases regarding the Agency's 2010 access to documents policy and clarification of the concept of commercially confidential information. Given the position of both the EU Ombudsman and European Parliament's Committee on Environment, Public Health and Food Safety that data included in clinical trial reports should not be considered commercially confidential, BPS is cautiously optimistic that there will be strictly limited - if any - need for data to be classified under category 1.	
121-3	It would be useful to have access, under category 2, to SASA dataset files, coding and programming files. This will allow others to check data analysis against the analysis plan and identify any errors in SAS coding.	
126-7	While the different treatment of data is appropriate and proportionate, BPS consider that there also must be transparency around the process for assigning types of data to specific categories, in order that concerns about where the balance between patient confidentially and public health stands can be addressed.	
132	In classing data as category 1 BPS note the EMA has stated that data will 'only be deemed CCI in duly justified cases'. This is a vague statement. While dependent on the outcome of the ongoing legal cases, we would expect that further information be provided on the criteria/justification for commercial confidentiality, and who would be taking this decision.	
176-218	BPS is supportive that the Agency will grant access to category 3 data once specific criteria are met; we consider it appropriate that researchers must demonstrate a valid scientific question and legally bound to ethical use of the data. Line 217 states that EMA will not judge the requester's professional competence to conduct analyses; however, BPS consider that it would be	

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	appropriate to assess those requesting the data to ensure those applicants have the knowledge and ability to manage and use the data in the public interest. In addition, we see the importance of appeals mechanisms to ensure equitable application of the access policy.	
236	It would be useful to provide category 2 information in Excel format, rather than PDF alone.	
	Patients must be informed of this new process, and any updates to consent forms must follow accordingly, as patients willing to participate in trials should be confident that appropriate bodies will protect their interests.	
	BPS members have raised concerns about the potential for charges for accessing this data. We would welcome a clear statement that the process to access category 3 data will not incur additional charges to researchers. The resource implications to EMA of putting this policy into practice will not be insignificant so there will need to be consideration of long-term funding sources.	

Please add more rows if needed.