EMA/240810/2013

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

Comments from:

Name and affiliation
Drug Commission of the German Medical Association

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')*
	The Drug Commission of the German Medical Association (DCGMA) is grateful for the opportunity to comment on the EMA policy “Publication and access to clinical trial data”. The DCGMA is taking the opportunity to make some general comments on the policy, followed by a detailed proposed change of the text. The DCGMA concurs with the Agency that “access to CT data in an analysable format will benefit public health in future” and commends the Agency’s initiative with this policy for transparency. The DCGMA also lauds the commitment of the Agency for the protection of patient personal data and is keen on the exact protocols and specifications for de-identification of said data, as it is of paramount importance. In regards to the purpose of this guidance document as outlined in Chapter 1, the DCGMA assumes that clinical trial study reports in the format of the ICH E3 guideline will probably cover most of the interests from external parties on access to clinical trial documents and data. There will be only a small number of requesters who wish to have ‘controlled’ access to raw data beyond the full study reports. Performing a proper re-analysis on the basis of raw-data will need much expertise, high skills and technical equipment usually not available to interested clinicians. The DCGMA suggests establishing an active tool to monitor whether requesters have in fact published results from re-analyses based on raw-data obtained from EMA within a reasonable timeframe. There is currently no mention of measures by the EMA in case the requester has not or cannot publish study results derived from his re-analysis (e.g. lack of staff, no funding, manuscript not accepted by any journal etc.).	

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	The DCGMA suggests establishing a special expert group at the EMA to regularly evaluate requests for full clinical data sets (including raw data; Category 3-data) and to give an opinion on acceptance or rejection of the request. By this means, scientifically unsubstantiated or sub-standard requests could be rejected. The DCGMA looks forward to the implementation of the policy and the analyses that will result from it.	
285-292	The DCGMA agrees with the categorization in Section 4 'Policy Statement'. However, Category 2-documents will contain data on CT personnel. In context with Annex II and its footnote 4, these documents may contain 'data, such as the list of investigators; individual investigators' names, addresses, appointments, qualifications and clinical duties; similar information of other persons carrying out observations of primary or other major efficacy variables, such as a nurse, physician's assistant, clinical psychologist, clinical pharmacist or house staff physician; the author(s) of the report, including the responsible biostatistician(s).' The DCGMA holds the view that making public 'addresses, appointments, qualifications and clinical duties' of investigators is not acceptable. This would publicly provide sensitive information of investigators which could be problematic, e.g. in psychiatry. Moreover, the DCGMA is of the opinion that 'names, addresses, appointments' of nurses, physician's assistants etc. involved in a clinical trial are not needed nor acceptable in terms of transparency. The knowledge of such data will not have impact on the evaluation of a study's validity. Also, there will be a huge fluctuation of personnel (investigators, nurses and others) during the study period (maybe even within one year), and many of these persons will be 'lost to follow up'. We do not see an 'overriding public interest' for publication. The DCGMA recommends to focus on making public only data about principal investigators, biostatisticians and other key personnel (e.g. laboratory personnel) and abstain from regulating such data from other non-academic study personnel. The same argument is valid for Category 3-data, with reference to Annex II, item '6: Investigators and study administrative structure' (access: 'Open, 4') and to footnote 4 of the Annex document (see above). The DCGMA is of the	This section contains personal data, such as the list of principal investigators; ~~individual investigators' names, addresses, appointments, qualifications and clinical duties; similar information of other persons carrying out observations of primary or other major efficacy variables, such as a nurse, physician's assistant, clinical psychologist, clinical pharmacist or house staff physician;~~ the author(s) of the report, including the responsible biostatistician(s). The Agency takes the view that these persons have a role and responsibility for public health in ensuring the integrity of trial data and protecting patients' welfare. ~~In light of the overriding public interest, these personal data are considered exempt from PPD considerations.~~

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	opinion that such data are not needed and not acceptable to ensure transparency.	

Please add more rows if needed.