EMA/240810/2013

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

Comments from:

Name and affiliation
The Federation of European Academies of Medicine (FEAM)

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

7 Westferry Circus • Canary Wharf • London E14 4HB • United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

Introduction

The Federation of European Academies of Medicine (FEAM) welcomes the European Medicines Agency's plans to increase transparency of the data and results from clinical trials on which regulatory decisions are based. We agree that the sharing of clinical trial (CT) data for secondary analyses has great potential to be translated into significant benefits to public health. We are, however, concerned about the proposals relating to the sharing of patient-level Category 3 CT data.

We consider that there should be a well-defined and transparent review process for each request for access to Category 3 data. The EMA's proposed data sharing agreement requires the requester to guarantee that their analysis is 'in the interest of public health'. We argue that requesters themselves cannot objectively make this assessment, and hence that there is a need for a review process that, prior to granting access:

- Ensures the scientific and analytical robustness, and appropriateness of the purpose, of the intended data use.
- Ensures that potentially identifiable patient information will be stored with appropriate safeguards.
- Verifies that the request is appropriate to the nature of patient consent given for the original study.

Ensuring 'good science'
We believe it important to put a mechanism in place that mitigates potential harm that could result from inappropriate secondary interpretation or misuse of clinical trial data. Whilst we agree that greater openness could put clinical trial data under productive scrutiny, the consequences of secondary analyses that wrongfully contradict the published findings could be severe, and are certainly not in the interest of public health. Any use of the outcomes of Category 3 data analysis as a background for change, for instance in regulatory approval, must also follow appropriate expert peer review.

Protecting data
We would be concerned about the security of Category 3 data that leaves the EMA in a potentially identifiable format. To prevent inadvertent and inappropriate disclosures that risks re-identification and patient privacy, the requesters' data-handling competence should be verified and their plan of how to store data securely reviewed. Other bodies that share patient data do so within a 'controlled environment', and further consideration should be given to appropriate mechanisms under which the data is accessed to ensure protection of patient privacy.

Appropriate consent
Requestors cannot necessarily be expected to understand the nature of the consent obtained for the original clinical trial, especially in cases where patients have been recruited from a number of different settings. We therefore suggest that the EMA or an independent panel take on the responsibility of ensuring that a request fall within the boundaries of the original informed consent

Appropriate access to clinical trial data will be an invaluable resource for biomedical research, but public acceptability and trust are essential to its success. To enhance the integrity and ultimate benefit of research, and to minimise the risk of misinterpretation and misuse, controlled

access to patient level data should only follow after appropriate independent review of the proposal. The organisation that takes on this review process will need to comply with quality standards and have a proven record of complying with standard operating procedures in this area, without administrative overload or delay.

Detailed comments on the text of the draft Policy are set out below.

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')*
44-48	Mechanisms whereby patients can provide broad consent for secondary analyses would be very beneficial to ensuring that data can be used to their full potential. We would welcome more explicit guidance from the EMA on how such broad consent should be worded in the future.	
57-61 & 216-218	We would be concerned about patient level data being distributed to individuals who have neither been assessed as competent to handle the data appropriately nor required to demonstrate a robust methodology for how they will proceed with their study. We call for an appropriate review mechanism as outlined in the main body of the response, above.	
109-115 & 129-132	We consider that there should be more clarity on who decides whether information is classified as Commercially Confidential Information (CCI), as well as how the information can be 'duly justified' as being CCI.	
143, 165, 172-175 & 278-281	We would like further details on who will carry out the de-identification of personal data and who will ensure that the de-identification carried out is 'adequate' before it is made available. It is critical that appropriate methodologies are employed to ensure patient privacy is safeguarded.	
149	We are concerned with the statement that personal data of clinical trial personnel is not regarded as confidential.	
180	We would like to seek clarification on whether any company or organisation established in the EU would be able to apply for access.	
183 & 198	We do not consider that the requestor will always be in the position to determine that the purpose for which data is requested is in the interest of public health and in line with the 'sprit' of informed consent. We would also like clarity on who determines what is appropriate in terms of ethics committee submission.	
191-192	There is a possibility that an ethics committee could approve the secondary use of data that is outside the scope of the original consent (as is currently possible under the laws of many member states).	

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')*
199-200 & 207-209	We consider that the data requestor who is going to perform an analysis should follow, rather than merely being made aware of, best practices and methodologies. We do, however, recognise that there may be cases where use of innovative analytics will be proposed that do not confirm to existing good practice.	
222-231	In the interest of transparency and to avoid duplication of work and facilitate collaboration, we believe that information about the requester and other key aspects relating to the secondary analysis should be made available promptly.	
244-245	To encourage openness, data should be shared in a format that is accessible to all requesters. CDISC (Clinical Data Interchange Standards Consortium) standard formats may not be immediately accessible to academic organisations and patient groups.	