

Just look, but don't touch: EMA terms of use for clinical study data are impracticable

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The European Medicines Agency (EMA) receives comprehensive clinical study data from drug manufacturers. These data form the basis for the decision on the approval of new drugs. To make this information available to researchers and decision-makers, EMA issued a draft policy in 2013 for the publication of clinical study data, in which extensive data transparency was planned.

Besides other interested parties, the German Institute for Quality and Efficiency in Health Care (IQWiG) was intensely involved in the subsequent consultations. The result of these consultations is all the more disappointing; in particular the draft on the conditions of use for the EMA interface via which anyone should be able to access the data.

Only reading allowed

Last week it became known what EMA would like to decide on 12 June 2014. According to EMA's plans, interested parties will only be allowed to access the data in a "view on screen only" mode. They will not be permitted to download, save, edit, photograph, print, distribute, or transfer the information. These conditions make any scientific analysis of clinical study data, for instance, within the context of benefit assessments of drugs, absolutely impossible. For benefit assessments, not only an enormous amount of data need to be viewed (often several thousand pages), these data must also be annotated and saved, pooled from different studies, analysed statistically, and shared between

researchers.

The good into the pot, the bad into the crop?

In addition, according to the draft, within the context of market approval applications [drug manufacturers](#) will be able to submit two versions of a clinical study report to EMA: a complete one, by means of which EMA will decide on approval, and an incomplete one for the public.

So far it had been discussed that individual patient data, which may allow patients to be identified, will be deleted from the study reports. Now this step has been extended to cover study results, and the requirements are so vaguely worded that the extent of the redaction of the report is difficult to predict.

Complete data are indispensable

"In view of our experience with industry in the last years, this procedure is alarming", says Jürgen Windeler, IQWiG's Director. "At the same time, our experience with early benefit assessments shows how valuable complete study data are for the discussions on new drugs. We are thus surprised by this sudden step backwards, which from our point of view is simply incomprehensible."

Beate Wieseler, Head of IQWiG's Drug Assessment Department, adds: "Neither journal publications nor other publicly accessible documents reach the information content of complete clinical study data, as available at EMA. We therefore welcomed the EMA draft of 2013 as a major step in the right direction. In contrast, the surprising revision that has now been announced represents no progress whatsoever compared to the status quo: we will neither receive all of the data nor will we be able to estimate how much of the data has been withheld and how

representative the remaining data are."

Redaction of quality-of-life data is possible

For example, EMA deems deletion of information to be legitimate in cases of results on exploratory outcomes, which are not supportive for the approval decision. However, such study results are regularly considered by IQWiG in its assessments, as they often contain analyses of patient-relevant outcomes such as health-related quality of life, which are often not reported in journal publications.

Wieseler states: "We are talking about studies in people who participated in a clinical study because they hoped that with the information gained, better treatments would be developed. This information can only be used to improve patient care if it is publicly available to all. These study data are not only needed by IQWiG, but also by other researchers who prepare systematic reviews or medical societies who prepare guidelines for the treatment of patients."

Comment in the *British Medical Journal*

Wieseler and her colleagues have summarized their criticism of the new EMA policy in a rapid response in the *British Medical Journal*. In this comment they make clear that the current plans deviate strikingly from EMA's paradigm change towards more data transparency announced in 2012. The EMA data made available in the planned manner can basically not be called published, as "data we cannot work with are still hidden – even if we see them on a screen".

Provided by Institute for Quality and Efficiency in Health Care

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