The EMA increases transparency of clinical trial data

EPF statement

EPF welcomed the European Medicines Agency's new policy on publication of clinical data, adopted on 2 October 2014, as a significant step forward towards greater transparency of the regulatory process on clinical trials.

Patients are increasingly becoming active participants in their own care. Patient involvement is a vital element to ensure the future high quality and sustainability of European healthcare systems. In order to empower patients to make informed decisions in partnership with health professionals, it is vital that both clinicians and patients have access to all the relevant information needed to make those decisions. We trust the EMA policy will significantly contribute towards that goal.

Sharing data is also good for science and a moral imperative, demonstrating respect for the patients who volunteer in trials. Sharing data benefits patients, industry and by extension the wider society: it enables science to progress more quickly towards new and better therapies; limited resources can be used more efficiently; duplication of research, which is unethical, is reduced. Transparency is also vital for generating and maintaining trust of patients and the wider public in medical research.

Whilst applauding the EMA's commitment to transparency, EPF has some remaining concerns about certain details of the new policy.

Terms of use

The EMA policy foresees two different levels of access to data – view-on-screen only for the general public, and less restrictive for "academic and other non-commercial research purposes". All users will need to sign up to the EMA's terms of use. In order to download, save, edit or print the information, patient groups will need to register under the non-commercial research terms of use, providing an email address and identity. However, we have some concerns about the references to third-party rights and intellectual property contained within these terms of use, which leave it open for companies to take direct legal action under UK law against any researchers who could be deemed to be in non-compliance with those terms.

EPF will be monitoring the application of the terms of use in collaboration with other stakeholders, in particular patient organisation representatives. We suggest these terms are carefully reviewed at the latest by June 2016 and earlier if necessary, to ensure they do not hinder patients' and researchers' access to vital information.

Redaction of commercially confidential information

EPF supports the view that data contained in clinical study reports (CSR) are not *generally* considered commercially confidential once a marketing authorisation process has concluded – a view which is in line with the new Clinical Trials Regulation (Regulation 536/2014). However, a company may ask for some specific information to be removed from a CSR prior to publication, if it can provide a justification for its request.

These are important decisions, which must balance the legitimate economic interests of a company against the public interest in favour of disclosure. EPF is concerned at the lack of transparency around the decision-making process, which foresees only a bilateral discussion between the EMA and the company concerned without any provisions for seeking the views of other stakeholders, such as patients.

EPF believes that there should be transparency concerning what redactions were made to a CSR and on what basis. We suggest that an independent audit of redactions should be undertaken prior to the review of the policy in June 2016, to ensure that the policy is functioning in a way that is reasonable and proportionate.

Individual patient data

EPF supports the EMA's decision to postpone finalising its policy on patient-level data until it has consulted further with stakeholders. This is sensible, given the complexities relating to sharing individual patient data.

We agree that the data sharing policy should "enable legitimate learning from sharing patient-level data while preventing rare but potentially damaging instances of patient identification." In our response to the first EMA consultation, we highlighted a number of concerns which would need to be addressed; these include defining what kind of data sharing would be considered to fall within the scope of previous informed consent; the criteria for sharing data and potential controlled access arrangements; protection of patient confidentiality; who should make decisions in each case; and what structures and processes would need to be set up for evaluating requests.

We have suggested setting up a working group at the EMA to define transparent and clear criteria for the release of patient-level data. This group should include a large enough number of patient organisation representatives to ensure that the views of the diverse patient community are integrated in the discussions.

EPF is committed to continuing its constructive collaboration with the European Medicines Agency to ensure that the transparency measures are developed and implemented in a way which is fit for purpose, ethical, and acceptable to patients.

More information:

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