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CORRESPONDENCE

Access to Patient-Level Trial Data

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Article

To the Editor:

The Chief Medical Officers Roundtable (CMOR), of which we are members, welcomes the Perspective article by Eichler et al. (Oct. 24 issue),[1] who are representatives of the European Medicines Agency (EMA), on access to patient-level trial data. CMOR formulates positions on medical topics, and its members include chief medical officers of major biopharmaceutical companies. CMOR supports a transparent, harmonized process for access to patient-level clinical trial data.

Any approach to clinical trial data sharing must be in the interest of patients. Data sharing should be based on two tenets. First, principles should apply uniformly to all who generate clinical trial data — industry, academia, regulators, health systems, foundations, and others. There will be little benefit to patients if access does not occur across sectors. Second, the responsible release of data requires input from independent experts and agreements to respect confidentiality, promote scientific excellence, refrain from misleading conclusions (which can harm patients if they discontinue beneficial treatment),[2] and safeguard future innovation by retaining incentives for investigators.

Access should be determined after the submission of a proposal to a panel that includes independent experts. Evaluation should be based on scientific merit, relevance, researcher qualifications, potential conflicts of interest, and plans for dissemination of findings after peer review. To this end, the CMOR supports the consensus study launched by the Institute of Medicine. It is, to our knowledge, the only broadly inclusive initiative and has the international participation of academia, industry, the National Institutes of Health, the Food and Drug Administration, the EMA, journals, patient organizations, foundations, and others.[2]

Contrary to the assertion by Eichler et al. that industry opposes the sharing of patient-level data, many companies are creating processes like those mentioned above.[2] Industry already shares results through ClinicalTrials.gov, public websites, and scientific publications.[3]

Furthermore, the European Federation of Pharmaceutical Industries and Associations and the Pharmaceutical Research and Manufacturers of America have moved beyond the status quo in adopting the Principles for Responsible Clinical Trial Data Sharing, which will be implemented in January 2014 and include the following major points.[4] First, patient- and study-level clinical data, protocols, and clinical-study reports should be made available on request to qualified researchers pursuing legitimate research projects for medicines and indications approved in the United States and the European Union. Second, there should be public disclosure of synopses of clinical-study reports after approval in the United States and the European Union. Third, summaries that are written in lay language should be provided to patients involved in clinical trials. Fourth, procedures should be adopted to implement these principles. And fifth, researchers need to make a commitment to publish study results, whether negative or positive. The CMOR fully supports the sharing of patient-level clinical trial data, by all who generate such data, in the interest of patients.

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Dr. Barron reports being an employee of Hoffmann–La Roche and Genentech and holding stock and stock options in Roche; and Dr. Rosenblatt, being an employee of and holding stock and stock options in Merck. No other potential conflict of interest relevant to this letter was reported.

4 References

1 Eichler H-G, Petavy F, Pignatti F, Rasi G. Access to patient-level trial data -- a boon to drug developers. N Engl J Med 2013;369:1577-1579
Free Full Text | Web of Science | Medline

2 Nisen P, Rockhold F. Access to patient-level data from GlaxoSmithKline clinical trials. N Engl J Med 2013;369:475-478
Free Full Text | Web of Science | Medline

3 Rawal B, Deane BR. Clinical trial transparency: an assessment of the disclosure of results of company-sponsored trials associated with new medicines approved recently in Europe. Curr Med Res Opin 2013 November 11 (Epub ahead of print).

4 EFPIA and PhRMA. Principles for responsible clinical trial data sharing: our commitment to patients and researchers (http://phrma.org/sites/default/files/pdf/PhRMAPrinciplesForResponsibleClinicalTrialDataSharing.pdf).