

EFSPI comments to ICMJE data sharing proposal

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“As a condition of consideration for publication of a clinical trial report in our member journals, the ICMJE proposes to require authors to share with others the deidentified individual patient data (IPD) underlying the results presented in the article (including tables, figures, and appendices or supplementary material)...” (see [editorial](#) for further details)

Requirement To Share Data Agreement

✓ I agree with this general approach

The European Federation of Statisticians in the Pharmaceutical Industry (EFSPI) supports responsible data sharing. From a statistical point of view, responsible data sharing includes that patient data are handled in a strictly confidential manner to avoid misuse under all possible circumstances and that shared data will be used for further development of science as much as possible applying good statistical principles.

In our view, patient data cannot be de-identified in such a way that re-identification is virtually impossible, given today’s technical possibilities, let alone future capabilities. Therefore patient data should only be shared using strict access controls to the data.

Good Clinical Practice requires an independent review of the research protocol and qualified researchers to conduct and analyze a clinical trial. Similar standards should be required for secondary analyses of clinical trials.

In our view, transparency is a two-way effort. Secondary researcher should be obliged to register their studies and to publish, or at least web-post, their results. This is the only way to assess the multiplicity problem raised by secondary research.

Proposed 6 month timeframe following publication for sharing deidentified individual patient data (see [editorial](#) for further details)

6 Month Time Frame Agreement

In our view only data that is not under regulatory review should be available for sharing. Hence we believe that a general 6 month timeframe is not appropriate.

“The ICMJE will also require that authors include a plan for data sharing as a component of clinical trial registration.” (see [editorial](#) for further details)

Require a Data Sharing Plan Agreement

- ✓ I agree with this general approach

The European Federation of Statisticians in the Pharmaceutical Industry (EFSPI) believes that a proper planning of the future data sharing is essential, including agreed principles of restricted access and pre-specified plans for secondary analyses as indicated above. However, if the sponsor of the trial has a general data sharing policy in place we do not see a benefit in requesting an additional study specific data sharing plan.

“...those who generate and then share clinical trial data sets deserve substantial credit for their efforts. Those using data collected by others should seek collaboration with those who collected the data. However, because collaboration will not always be possible, practical or desired, an alternative means of providing appropriate credit needs to be developed and recognized in the academic community. We welcome ideas about how to provide such credit.” (see [editorial](#) for further details)

Providing Credit Agreement

- ✓ I agree that an alternative means of providing credit to those who generate and share clinical trial data sets needs to be developed

As a minimum any publication based on shared data should have a statement in the publication reflecting the research being presented is based on shared data and to cite where the data came from.

Other Comments

While pharmaceutical companies already have systems in place that allow responsible data sharing (e.g., ClinicalStudyDataRequest.com) ICMJE could assist academia in setting up similar possibilities. Please see also our forthcoming papers on the statistical aspects of data sharing: Fletcher et al. Statistical guidance for responsible data sharing: An overview. Tucker et al. Ensuring patient confidentiality when sharing patient-level data from clinical trials. Hollis et al. Best Practice for Analysis of Shared Clinical Trial Data. Sudlow et al. EFSPI/PSI Working Group on Data Sharing: Accessing and Working with Clinical Trial Patient Level Datasets – a Primer for Researchers. BMC Medical Research Methods (in press).