Medical Library Association Comments to
The International Committee of Medical Journal Editors (ICMJE)
Regarding Proposals for Sharing Clinical Trial Data
Submitted: April 5, 2016
https://forms.acponline.org/webform/comments-icmje%E2%80%99s-proposals-sharing-clinical-trial-data

The following comments were prepared by members of MLA's Scholarly Communication Committee.

Requirement to Share Data Agreement
"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)

MLA agrees with this general approach.

Comment
The Medical Library Association supports requiring the submission of all underlying deidentified individual patient data, as it permits reuse by validated researchers for approved new studies, thereby expanding the original purpose and value of the data, which could in turn encourage innovation and lead to new discoveries. Approved repositories for such datasets must document and support versioning in order to offer appropriate granularity of data characteristics to interested researchers, as well as to enforce funder requirements, such as the NIH Public Access Policy (https://publicaccess.nih.gov/) and the NIH Genomic Data Sharing policy (GDS) (https://gds.nih.gov/). Health sciences librarians are currently involved in identifying such repositories, and are familiar with Institutional Review Board (IRB) and informed consent processes. However, consistent with other data and publication sharing policies as well as to address the concerns of researchers regarding secondary analyses of the data, the timeline should be extended to 12 months to allow time to properly prepare the metadata and all other data files for sharing. Consideration should be made as to how sharing of the data within the stated timeline will be enforced since publication of the manuscript will have already occurred.

Providing Credit Agreement. "…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)

MLA agrees that an alternative means of providing credit to those who generate and share clinical trial data sets needs to be developed.

Comment
The Medical Library Association supports the adoption of a standard data citation format by ICMJE. This should be separate and distinct from the article citation, so that either may be cited, alone or together. The data citation must include a unique and persistent identifier, such as a DOI number, which can be assigned by a repository prior to submission to the journal, and will always point to the dataset in question. Unique identifiers are helpful for authors, as well. As a "means of providing appropriate

credit," we highly recommend that ICMJE require, not merely suggest, that authors register for an ORCID number to ensure that credit is given where credit is due.

Six Month Timeframe Agreement. Proposed 6 month Timeframe following publication for sharing deidentified individual patient data (see *editorial* for further details)

MLA agrees with this general approach

Comment
As stated above, consistent with other data and publication sharing policies as well as to address the concerns of researchers regarding secondary analyses of the data, the timeline should be extended to 12 months. The policy should consider how data sharing within the stated timeline will be enforced since publication of the manuscript will have already occurred.