

Elsevier Editorial System(tm) for The Lancet
Manuscript Draft

Manuscript Number:

Title: Data Sharing: Experience from tropical medicine research unit (In response to Taichman DB, Shahni P, Pinborg A, et al. Data sharing statements for clinical trials: a requirement of the International Committee of Medical Journal Editors. Lancet 2017; 389: e13-14 published 10 June 2017)

Article Type: Correspondence

Keywords: data sharing, consent, low and middle income countries

Corresponding Author: Dr. Phaik Yeong Cheah, Ph.D.

Corresponding Author's Institution: University of Oxford

First Author: Phaik Yeong Cheah, Ph.D.

Order of Authors: Phaik Yeong Cheah, Ph.D.; Nicholas P Day

Manuscript Region of Origin: THAILAND

Title Page

Correspondence

Data Sharing: Experience from tropical medicine research unit

***^{1,2}Phaik Yeong Cheah, ^{1,2}Nicholas Phillip John Day**

1. Mahidol Oxford Tropical Medicine Research Unit, Faculty of Tropical Medicine, Mahidol University, Bangkok, Thailand
2. Centre for Tropical Medicine and Global Health, Nuffield Department of Clinical Medicine, University of Oxford, Oxford, UK

*Correspondence to: Associate Professor Phaik Yeong Cheah (phaikyeong@tropmedres.ac)

Mahidol University-Oxford Tropical Medicine Research Unit, Faculty of Tropical Medicine, Mahidol University, 420/6 Rajvithi Rd, Rajthevee, Bangkok, 10400, Thailand

We applaud the ICMJE for arriving at a workable compromise on the data sharing requirements it expects of clinical trial authors.¹

Since January 2016, we have trialled in our Southeast Asia-based tropical research unit a data sharing policy where requests are processed through a Data Access Committee (DAC).² We have thirteen applications to date. Requests raising concerns included one for data in real time from an ongoing clinical study, requests for data from historical trials performed without patient consent for data sharing, and requests from pharmaceutical companies for data from trials conducted in low- and middle-income countries (LMICs) for the purpose of registering products in developed countries. Some requests were for data from clinical studies that were not trials - a situation not covered by the ICJME policy. Although almost all our data were generated in LMICs, requests from LMIC institutions were conspicuously absent, highlighting the need to protect LMIC researchers and prevent exacerbation of current inequities. Servicing the requests required well-resourced and well developed data management services, DAC time and access to legal expertise to negotiate data access agreements - all difficult to provide in many LMICs.

Implicit in the new ICMJE proposals is the expectation that the data sharing process will evolve over time, as will safeguards for primary researchers and research participants. This process would be well served by a research agenda based on the controversies highlighted in the wide range of responses to ICMJE's original 2016 data sharing proposal - many of which came from LMICs.³

250 words

Declaration of interests

PYC is the coordinator of the Mahidol Oxford Tropical Medicine Research Unit (MORU) Data Access Committee. NPJD is the Chair of the DAC and the Director of MORU. We declare no competing interest.

Author Contributions

PYC and NPJD contributed equally to the letter.

Acknowledgements

We thank all DAC members.

Funding

The Mahidol Oxford Tropical Medicine Research Unit is funded by a core grant from the Wellcome Trust.

References

1. Taichman DB, Shahni P, Pinborg A, et al. Data sharing statements for clinical trials: a requirement of the International Committee of Medical Journal Editors. *Lancet* 2017; 389: e13-14
2. Mahidol Oxford Tropical Medicine Research Unit Data Sharing Policy, January 2016. Available at <http://www.tropmedres.ac/data-sharing>

3. Taichman DB, Backus J, Baethge C, et al. Sharing clinical trial data: a proposal from the International Committee of Medical Journal Editors. *Ann Intern Med* 2016; 164: 505–06.