

17 January 2022

ICMJE statement on clinical trial data contained in assessment reports

Dear Editors,

A research article published in *BMJ Open* in 2021 showed that [over 80% of NICE appraisals contain redacted data](#), including data on clinical trial outcomes that are of importance to patients, clinicians and researchers. Health Technology Assessment (HTAs) agencies in other countries also [routinely redact data](#).

A significant portion of these data are redacted as being “**academic in confidence**” (as opposed to “commercially confidential information”) based on widespread concern among researchers that disclosure of data in a public HTA report could prevent them from later publishing the outcomes of the trial in a peer-reviewed journal.

Several medical journals, including the BMJ, have informed us that researchers’ fears in this regard are unfounded, and that trial data contained within reports published by HTAs and regulatory agencies (including EMA and FDA assessment reports) does not constitute ‘prior publication’ and would not compromise researchers’ ability to later publish trial outcomes in peer-reviewed journals. However, not all journals share this position.

We are currently advocating with HTAs to discontinue their “academic in confidence” redactions so that patients, clinicians, and researchers can access all relevant elements of HTA reports.

In this context, it would be extremely helpful for ICMJE to highlight, clarify and support journals’ existing position by formally issuing the following statement:

“The ICMJE will not consider results data contained in assessment reports published by HTAs, medicines regulators, medical device regulators, or other regulatory agencies to be prior publication.”

By eliminating the putative rationale for “academic in confidence” redactions, such a statement by ICMJE would put an end to the current misguided redaction practices of HTAs.



Please do not hesitate to contact us if you require additional information, or if you would like to discuss this issue further with us.

Could you please let us know by when you expect to reach a decision on this issue?

Thank you for your time, we look forward to hearing from you,

A handwritten signature in black ink that reads "Leeza Osipenko".

Leeza Osipenko, PhD
London, UK

Signing on behalf of six medical and health groups:

- Cochrane
- Consilium Scientific
- Health Action International
- International Society of Drug Bulletins
- TranspáriMED
- Transparency International Global Health

