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The BMJ Press Release

The BMJ's data sharing policy now applies to all clinical trials

First general medical journal to require data sharing for all submitted trials

From today (1 July 2015) **The BMJ** requires sharing of individual patient data for all clinical trials.

This means that trials will be considered for publication only if the authors agree to make the relevant anonymised patient level data available on reasonable request.

The BMJ is the first general medical journal to require data sharing for all trials, extending its initial policy on sharing data for trials of drugs or devices, which took effect in January 2013, says Elizabeth Loder, The BMJ's acting head of research.

In an editorial to mark the launch of the new policy, she explains that the initial policy focused on trials of drug and devices "because many high profile, serious allegations of selective or non-reporting of trial results related to such products." However, she says, growing experience and evidence show that reporting problems are not limited to the corporate sector, but affect academic and government sponsored trials as well.

And she points out that, “to date, all authors have agreed, and we have not rejected a single paper for non-compliance.”

Today’s announcement follows initiatives by the US Institute of Medicine (IOM), the World Health Organization (WHO), and the Nordic Trial Alliance, to encourage data transparency.

For example, a recent IOM report called for a transformation of existing scientific culture to one where “data sharing is the expected norm” while WHO has said the main results of clinical trials should be made publicly available and submitted for journal publication within a year of study completion.

The efforts of industry, too, must be acknowledged, says Loder. In particular, Medtronic’s cooperation with the Yale University Open Data project and GlaxoSmithKline’s leadership on data disclosure efforts stand out.

“Making anonymised patient level data from clinical trials available for independent scrutiny allows other researchers to replicate key analyses, reduces the possibility that studies will be unnecessarily duplicated, and maximises use of the information from trials - an important moral obligation to trial participants,” she writes.

She acknowledges that an initial investment of time and money is needed to prepare trial data for sharing, “but after the first use there are few additional costs; in essence, the value of the data increases with each use,” she concludes.

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Notes to Editors:

Editorial: The BMJ requires data sharing on request for all trials

Link to editorial: <http://www.bmj.com/content/350/bmj.h2373>

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