Background

• The pharmaceutical industry has faced criticism for poor disclosure of clinical study results, although the reporting of industry-funded studies appears to be improving. Furthermore, evidence is growing that the support of professional medical writers improves the quality of reporting of clinical trials. The Centre for Evidence-Based Medicine Outcome Monitoring (COMPare) project is evaluating the outcome reporting of clinical trials. The researchers assessed the outcomes reported in the top 5 medical journals by comparing the articles with the corresponding study protocol or clinical trial registry entry. We conducted a sub-analysis of the publically available COMPare data to examine the relationship between outcome reporting, funding source and medical writer support.

Research design and methods

• We examined each publication evaluated by COMPare to obtain the funding source (industry/part-industry or non-industry) and whether there was medical writer support. Outcome reporting was compared between the groups using Chi² or Fisher Exact tests for binary variables, and student t test with Satterthwaithe correction for quantitative variables.

Results

Characteristics of the study groups

• Study funding was industry/part-industry (n=34, 50.7%), non-industry (n=32, 47.8%) and not stated (n=1, 1.5%) (Table 1). Industry/part-industry funded studies mainly evaluated pharmaceutical interventions (n=31, 91.2%); more than one third (n=9, 40.6%) of non-industry sponsored studies were of non-pharmaceutical interventions. Acknowledged medical writer support was provided in 17 studies, all of which were industry funded.

Table 1. Characteristics of the groups of articles.

<table>
<thead>
<tr>
<th></th>
<th>Industry funded (n=34)</th>
<th>Non-industry funded (n=32)</th>
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<tbody>
<tr>
<td>Journal</td>
<td></td>
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<tr>
<td>Archives of Internal Medicine</td>
<td>3 (9.2%)</td>
<td>2 (6.3%)</td>
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<tr>
<td>The BM</td>
<td>1 (2.9%)</td>
<td>2 (6.3%)</td>
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<tr>
<td>The Lancet</td>
<td>12 (35.3%)</td>
<td>12 (37.5%)</td>
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<tr>
<td>The New England Medical Journal</td>
<td>13 (38.2%)</td>
<td>9 (28.1%)</td>
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<tr>
<td>The Journal of the American Medical Association</td>
<td>5 (14.7%)</td>
<td>7 (21.9%)</td>
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<tr>
<td>Intervention assessed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmaceutical</td>
<td>31 (91.2%)</td>
<td>19 (59.4%)</td>
</tr>
<tr>
<td>Non-pharmaceuticalc</td>
<td>3 (8.8%)</td>
<td>13 (40.6%)</td>
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<tr>
<td>Declared medical writer support</td>
<td>17 (50%)</td>
<td>0</td>
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</table>

aIncludes surgical techniques, screening methods and non-pharmacological interventions.

Outcome reporting

• The mean proportion of pre-specified outcomes reported was 66.5% vs. 64.0% for industry/part-industry funded and non-industry funded publications, p=NS; Figure 1.
• Industry/part-industry and non-industry publications reported similar numbers of non-pre-specified outcomes (mean 4.3 vs. 6.6, p=NS; Figure 2).
• The proportion of completely reported studies, as assessed by the researchers, was similar for industry/part-industry and non-industry and funded publications (14.7% vs. 9.4%; p=NS).
• The mean proportions of pre-specified outcomes reported were similar for industry/part-industry funded publications with and without medical writing support (61.7% vs. 63.4%; p=NS).
• Industry-funded articles with medical writer support were less likely to include non-pre-specified outcomes (mean 6.5; p=0.03) than those written without this support and sponsored by industry (mean 6.3; p=0.01) (Figure 3).

Figure 1. Outcome reporting according to funding source. Mean number of pre-specified outcomes reported, n=66. Industry/part-industry funded (n=34) and Non-industry funded (n=32).

Figure 2. Reporting of non-pre-specified outcomes by funding source. Mean number of non-pre-specified outcomes reported, n=50. Industry/part-industry funded (n=34) and Non-industry funded (n=32).

Figure 3. Reporting of non-pre-specified outcomes by funding source and medical writer support. Mean number of non-pre-specified outcomes reported, n=66. Industry funded, with medical writer support (n=17) vs. Industry funded, no medical writer support (n=19) vs. Non-industry funded, no medical writer support (n=32).

Pre-specification of clinical trial outcomes

The findings of clinical trials inform decision making by doctors, patients and payers. All outcome measures in clinical studies should be identified and described completely. If outcomes are not described adequately, clinicians may be unable to carry out the treatment on the basis of the information provided. Pre-specification of outcomes reduces the risk of selective reporting and undetermined post hoc changes in the measures evaluated (so-called outcome switching).

There are legitimate reasons for trials departing from the study protocol. However, authors should explain such changes in the published article. Ipsen is committed to the correct reporting of clinical trial findings. We ensure that the details in clinical trial registries match the protocol and are updated following any major amendments. We are putting procedures in place to ensure that outcomes are aligned between the clinical trial registry and the corresponding publication.

Strengths and limitations

• We used publically available data generated by independent researchers to assess the effect of funding source and medical writer support on the quality of outcome reporting.
• Authors sometimes choose to disclose trial outcomes in more than one publication. If this was not stated in the primary manuscript, such outcomes were classified in COMPare as not reported.
• Some journal editors check pre-specified outcomes against the corresponding study protocol rather than the clinical trial registry.

Conclusions

• There remains a need to improve the reporting of clinical trial outcomes. In this small sample, publications sponsored by industry and non-industry organizations showed similar levels of reporting.
• Publications developed with medical writer support reported the fewest non-pre-specified outcomes.

Disclosures

The authors are employees of Ipsen Pharma.

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References