Outcome reporting, funding source and medical writing support in publications evaluated in the COMPare project

William Gattrell,1,2 Pascal Maisonneuve,3 Monica de Abadal4
1Ipsen Pharma, Milton Park, UK, 2Department of Mechanical Engineering and Mathematical Sciences, Oxford Brookes University, Oxford, UK, 3Ipsen Pharma, Boulogne, France, 4Ipsen Pharma SA, Barcelona, Spain

Objective
The Centre for Evidence-Based Medicine Outcome Monitoring (COMPare) project is evaluating the outcome reporting of randomized controlled trials. COMPare researchers have compared publications in the top 5 medical journals with the corresponding protocol or registry entry.1 In this sub-analysis of the publically available data, we examined the relationship between outcome reporting, funding source and medical writing support.

Research design and methods
For each publication evaluated in COMPare, we obtained the funding source (industry/part-industry or non-industry) and whether there was medical writing support. Outcome reporting was compared between the groups using Chi² or Fisher Exact tests for binary variables, and student t test with Satterthwaite the correction for quantitative variables.

Results
Study funding was industry/part-industry (n=34, 50.7%), non-industry (n=32, 47.8%) and not stated (n=1, 1.5%). Medical writing support was provided in 17 studies (all industry funded). Mean pre-specified outcomes reported were 66.5% vs. 64.0% for industry/part-industry funded and non-industry funded publications; p=NS). Industry/part-industry and non-industry publications reported similar numbers of non-pre-specified outcomes (mean 4.3 vs. 6.6; p=NS). Industry-funded articles with medical writing support were less likely to include non-pre-specified outcomes (mean 2.2) than those written without this support and sponsored by industry (n=17, mean 6.5; p=0.028) or non-industry organizations (n=32, mean 6.6; p<0.01).

Conclusions
There remains a need to improve the reporting of RCT outcomes. In this small sample, the quality of trial reporting was independent of the funding source.

References

This study was sponsored by Ipsen.
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 publicly 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=19, 40.6%) of non-industry sponsored studies were non-pharmacological interventions.

• Acknowledged medical writer support was provided in 27 studies, all of which were industry funded.

Table 1. Characteristics of the groups of articles.

<table>
<thead>
<tr>
<th></th>
<th>Industry/part-industry funded (n=34)</th>
<th>Non-industry funded (n=32)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Journal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Annals of Internal Medicine</td>
<td>3 (8.8%)</td>
<td>2 (6.3%)</td>
</tr>
<tr>
<td>The BM</td>
<td>12 (35.3%)</td>
<td>12 (37.5%)</td>
</tr>
<tr>
<td>The Lancet</td>
<td>13 (38.3%)</td>
<td>9 (28.1%)</td>
</tr>
<tr>
<td>The New England Medical Journal</td>
<td>5 (14.7%)</td>
<td>7 (21.9%)</td>
</tr>
<tr>
<td>The Journal of the American Medical Association</td>
<td>5 (14.7%)</td>
<td>7 (21.9%)</td>
</tr>
<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-pharmacological</td>
<td>3 (8.8%)</td>
<td>13 (40.6%)</td>
</tr>
<tr>
<td>Declared medical writer support</td>
<td>17 (97%)</td>
<td>0 (0%)</td>
</tr>
</tbody>
</table>

The funding source of one article was not stated in the manuscript. Includes 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 2.3) than those written without this support and sponsored by industry (mean 6.5; p=0.023) or non-industry organizations (mean 6.3; p<0.01) (Figure 3).

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 undeclared 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 findigs. 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.

Acknowledgements

We thank the COMPare researchers for making their data publically available. Ashfield HealthCare Communications assisted in poster layout.

References