We identified randomized clinical trials of drugs and devices published between December 1, 2011, and November 31, 2012, in biomedical journals for which Journal Citation Reports 2012 reported an impact factor greater than 11 and that published details on the “Role of the Funding Source/Sponsor.” We excluded phase 1 or 2 trials and secondary trial analyses.

We categorized trials as having industry funding with collaboration when any for-profit organization funded the trial and had any role in its design, analysis, or reporting; as having industry funding without collaboration when any for-profit organization funded the trial but had no role in its design, analysis, or reporting; and as having neither industry funding nor collaboration.

Two authors (N.R. and N.Z.), blinded to industry funding and collaboration, independently assessed the following trial design features and outcomes: blinding (double, single, or none), intention-to-treat analysis, discussion of limitations (defined as using the word stems “weak” or “limit” when describing trial design in the Discussion section), superiority or non-inferiority design, comparator drug (active vs placebo), primary outcome (positive [ie, statistically significant superiority or noninferiority favoring the product of the sponsor or sponsors], negative, or mixed), primary end point (clinical, surrogate [any radiology, pathology, or laboratory value], or mixed). Differences were resolved by consensus. Interrater agreement was high (κ = 0.9350). One investigator (N.R.) subsequently recorded allocation concealment, funding (industry and/or government/nonprofit), and industry collaboration.

We conducted 2 sets of analyses comparing trial variables between trial groups (neither industry funding nor collaboration vs industry funding with collaboration and neither industry funding nor collaboration vs industry funding without collaboration) using relative risks (RRs) and Fisher exact tests. Statistical analyses were conducted using SAS version 9.3 (SAS Institute Inc). All P values were 2-tailed, with significance defined as P < .05.

Results | There were 219 articles from 10 high-impact journals describing the results of drug and device trials included in our analysis; 86 trials (39%) had industry funding with collaboration, 66 (30%) had industry funding without collaboration, and 67 (31%) had neither industry funding nor industry collaboration (Table). When compared with trials having neither industry funding nor collaboration, trials having industry funding with collaboration were significantly more likely to report a positive primary outcome (69.8% vs 52.2%; RR, 1.34; 95% CI, 1.03-1.75 [P = .03]) and use a surrogate primary endpoint (51.2% vs 16.4%; RR, 3.11; 95% CI, 1.75-5.56 [P < .001]) and less likely to discuss limitations (40.7% vs 58.2%; RR, 0.70; 95% CI, 0.50-0.97 [P = .04]). In contrast, there were no differences between trials having neither industry funding nor collaboration and trials having industry funding without collaboration.

Discussion | Among clinical trials published in high-impact journals, industry funding with collaboration in the design, analysis, or reporting was associated with increased likelihood of reporting a positive primary outcome and decreased likelihood of reporting of trial limitations. Collaborative trials’ more...
mon use of a surrogate primary end point may, in part, explain why these trials were more likely to have a positive primary outcome. While publication bias may contribute to our findings, our study was also limited by our exclusion of high-impact journals that do not publish details on the “Role of the Funding Source/Sponsor,” which was needed to assess trial collaboration.

Our results suggest that, in addition to disclosure of industry funding source, greater transparency of industry funders’ role in trial design, analysis, and reporting might be valuable for assessing potential bias in trial findings.

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