

## Relationships Between Authorship Contributions and Authors' Industry Financial Ties Among Oncology Clinical Trials

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### A B S T R A C T

#### Purpose

To test the hypothesis that authors who play key scientific roles in oncology clinical trials, and who therefore have increased influence over the design, analysis, interpretation or reporting of trials, are more likely than those who do not play such roles to have financial ties to industry.

#### Methods

Data were abstracted from all trials ( $n = 235$ ) of drugs or biologic agents published in the *Journal of Clinical Oncology* between January 1, 2006 and June 30, 2007. Article-level data included sponsorship, age group (adult v pediatric), phase, single versus multicenter, country (United States v other), and number of authors. Author-level data ( $n = 2,927$ ) included financial ties (eg, employment, consulting) and performance of key scientific roles (ie, conception/design, analysis/interpretation, or manuscript writing). Associations between performance of key roles and financial ties, adjusting for article-level covariates, were examined using generalized linear mixed models.

#### Results

One thousand eight hundred eighty-one authors (64%) reported performing at least one key role, and 842 authors (29%) reported at least one financial tie. Authors who reported performing a key role were more likely than other authors to report financial ties to industry (adjusted odds ratio [OR], 4.3; 99% CI, 3.0 to 6.0;  $P < .0001$ ). The association was stronger among trials with, compared with those without, industry funding (OR, 5.0 [99% CI, 3.4 to 7.5] v OR, 2.5 [99% CI, 1.3 to 4.8]), but was present regardless of sponsorship.

#### Conclusion

Authors who perform key roles in the conception and design, analysis, and interpretation, or reporting of oncology clinical trials are more likely than authors who do not perform such roles to have financial ties to industry.

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### INTRODUCTION

Financial relationships between investigators and industry have prompted widespread concern about the potential for conflicts of interest.<sup>1-6</sup> A conflict of interest denotes a circumstance "...in which financial considerations may compromise, or have the appearance of compromising, an investigator's professional judgment in conducting or reporting research."<sup>7</sup> Financial relationships may take several forms, including industry funding of research or personal financial ties (eg, employment, consulting, or honoraria) between investigators and companies. Financial ties are common, with 14% to 70% of authors of articles or of meeting abstracts disclosing financial relationships to industry.<sup>8-15</sup>

A major criticism of industry-investigator relationships is that such relationships might foster bias in study conclusions. Numerous systematic reviews and meta-analyses indicate that industry-funded studies are more likely than other studies to favor novel interventions.<sup>16-27</sup> The mechanisms underlying these differences and their significance remain to be clarified. For example, compared with other funders, industry sponsors may insist on a higher prior probability favoring the novel intervention before committing resources to a trial, fostering efficiency in therapeutic development without necessarily causing ethical problems. However, industry-funded study reports also appear to draw more favorable qualitative conclusions, controlling for quantitative results, than do

reports of studies funded by other sources.<sup>28-30</sup> Other potential mechanisms include differential publication bias and use of weak control groups in some industry-supported trials.<sup>6,19,31</sup>

Although extensive evidence demonstrates an association between industry sponsorship and conclusions favoring the novel intervention, little is known about the relationship between investigators' personal financial ties and study outcomes. A study of placebo-controlled trials in psychiatry demonstrated an association between the existence of personal financial ties and conclusions favorable to industry, an effect that was confined to the subset of industry-sponsored trials.<sup>32</sup> Other studies show qualitatively similar results.<sup>33,34</sup> Analogous data in oncology are unavailable.

An investigator's ability to affect the outcome or reporting of a study depends, in part, on the roles that she played in the trial. Participation in intellectually central study activities, such as conception and design, analysis and interpretation, or manuscript drafting, affords substantial influence over the outcome of the study or the presentation of results. Involvement in other study activities, such as recruitment or data collection, although essential to success, entails less influence over outcomes. To our knowledge, no studies address whether authors' financial ties vary systematically according to their study roles. In this analysis, we tested the hypothesis that authors with key scientific roles are more likely to have financial relationships with industry than authors without key roles. We also asked whether such an association, if it exists, varies by funding source.

METHODS

Study Population

Trained research assistants hand-searched all issues of the *Journal of Clinical Oncology* (JCO) published between January 1, 2006 and June 30, 2007 to identify eligible articles. JCO was selected because it publishes granular detail on authorship contributions and financial ties,<sup>35</sup> the main variables of interest for this analysis. Articles were eligible if they reported the results of a clinical trial evaluating the safety or efficacy of a drug or biologic agent in human subjects. The drug or biologic agent could be administered alone, with other chemotherapy or biologic agents, or with other therapeutic modalities (eg, chemoradiotherapy). Furthermore, the intervention could be directed at prevention, anticancer treatment, or supportive care. We limited articles to those evaluating drugs or biologic agents because studies of other types of interventions (ie, procedural, psychosocial) are unlikely to have industry sponsorship, potentially confounding comparisons between industry-sponsored and other trials.

Studies were excluded if they were not clinical trials; were retrospective or secondary analyses; contained two or more trials; were group authored; or compared different schedules of a single intervention (Figure 1). The final sample included 235 studies, involving 2,927 authors (because some individuals contributed to more than one study, these authors represent 2,554 unique individuals). Because data were publicly available, the study was not considered human subjects research under 45CFR46.102(f)(2). This study had no external funding.

Data Collection

Research assistants abstracted article- and author-level data from eligible articles. Article-level data included sponsorship (industry, government, foundation, unspecified), number of centers (single, multi-), age group (adults, children), location of corresponding author (United States, other), phase, and number of authors. Author-level data included financial ties, if any, to industry and authorship contributions.

During the study period, JCO required authors to "... disclose any relationships with commercial entities that may have a direct bearing on the relevant subject matter."<sup>36</sup> Categories provided in the disclosure form in-

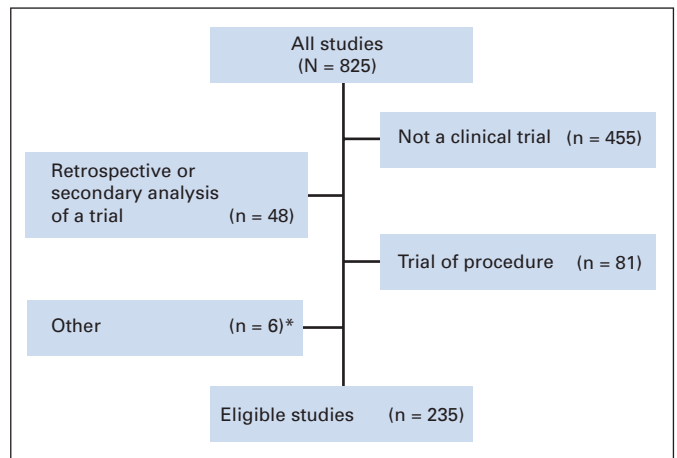


Fig 1. Outcome of manuscript review process. (\*) Report contained two or more trials, trial was authored by a group, and/or trial was comparing different schedules of interventions.

cluded employment, leadership, consultant/advisor, equity, honoraria, research funding, expert testimony, and other remuneration.

JCO also required authors to specify the roles they played in study execution and reporting. Categories included: conception and design; financial support; administrative support; provision of study material or patients; collection and assembly of data; data analysis and interpretation; manuscript writing; and final manuscript approval. Information related to financial relationships and authorship roles, printed after each article, was recorded for each author.

Data Analysis: Variables

The dependent variable was whether or not an author disclosed one or more financial ties to industry. The primary independent variable was whether or not an author reported playing a key study role. Authors were defined as playing a key role if they reported involvement in conception and design, analysis and interpretation, or manuscript writing.

As an alternative to the key role variable, we also determined which authors met the International Committee of Medical Journal Editors (ICMJE) criteria for authorship. The JCO Information for Contributors<sup>37</sup> references the ICMJE authorship criteria, which state that "...[e]ach author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content."<sup>38</sup> In addition, "[a]uthorship credit should be based on 1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published. Authors should meet conditions 1, 2, and 3."<sup>38</sup> We calculated the proportion of authors who satisfied these criteria. Because JCO does not separately report critical revision for important intellectual content, all authors received credit for criterion 2.

Statistical Methods

$\chi^2$  tests were used to examine univariate associations between performance of a key role and having financial ties to industry. Logistic regression models were then used to confirm the association, after adjusting for covariates. To account for clustering of authors within articles, odds ratios (OR) were estimated using generalized linear mixed models. Analyses assumed independence between authors who were listed on different articles. Article-level covariates included in the initial model were: industry sponsorship (yes, no), corresponding author location (United States, other), number of centers (single, multi), trial phase (I or I/II, II, II/III or III, unspecified), age group (adult, pediatric), and number of authors. Covariates that were not significantly associated with the outcome were sequentially deleted from the model using a manual backwards stepwise regression procedure based on likelihood ratio tests. As univariate analyses suggested that the association depended on industry sponsorship, an additional interaction term between key role and industry

sponsorship was included. Because this interaction term was statistically significant, we also report separate subgroup analyses for those trials that did and did not receive industry sponsorship. All covariates included in the final model were retained in these subgroup-specific models.

In addition to the main analysis described above, we conducted three sensitivity analyses. First, because it may seem self-evident that authors who performed key roles are more likely than other authors to receive research funds, the model was refit using a revised financial ties variable that excluded research funding. Second, we refit the model after excluding sponsor employees from the analysis. Third, we used satisfaction of ICMJE authorship criteria, rather than the study-defined key role variable, as the main independent variable.

To reduce the possibility of type 1 error due to making multiple comparisons, we used two-sided  $\alpha$  lower than .01 as the criterion of statistical significance and report 99% CIs. Although the sample size was based on the number of articles published during the 18-month period of data collection, power calculations for univariate comparisons indicated that 1,050 authors would provide 80% power to detect an OR of 1.5 for the outcome, assuming 70% of authors would report playing key roles. We also verified post hoc that the observed sample gave adequate power in the multivariate analysis to detect an increased odds of financial ties among authors with, compared to those without, key roles. In this calculation, we assumed that 60% of authors played key roles; that 40% of authors with key roles had financial ties; a mean cluster size of 12; and an intraclass correlation coefficient of 0.2 among authors of the same article. On the basis of these assumptions, 2,026 authors allowed the detection of an OR of 2 with 90% power.<sup>39</sup> Because the outcome (financial ties) was common, ORs should be interpreted as relative odds, not relative risks.

## RESULTS

### Characteristics of Study Articles

Of 235 articles, 52% reported industry funding, 42% reported government funding, and 24% reported foundation funding (Table 1). Most (80%) were multicenter trials, included adult participants

**Table 1.** Article Characteristics (n = 235)

Characteristic	No.	%
Sponsorship*		
Industry	123	52
Government	98	42
Foundation	57	24
Sponsorship not specified	27	12
No. of centers		
Single	46	20
Multi	189	80
Age group of participants		
Adult	213	91
Pediatric	22	9
Country†		
United States	154	66
Other	81	35
Phase		
I or I/II	41	18
II	97	42
II/III or III	64	27
Not specified	32	14
Total mean No. of authors	12.5	
Standard deviation	4.0	
Range	4-21	

\*Articles may have more than one type of sponsor.  
†Country of corresponding author.

**Table 2.** Authorship Contributions (n = 2,927)

Contribution	No.	%
Conception and design	1,101	38
Financial support	92	3
Administrative support	389	13
Provision of study materials or patients	1,870	64
Collection and assembly of data	1,387	47
Data analysis and interpretation	1,340	46
Manuscript writing	1,176	40
Final approval of the manuscript	2,324	79
Any key role*	1,881	64
Fulfills ICMJE authorship criteria†	1,760	60

Abbreviation: ICMJE, International Committee of Medical Journal Editors.

\*Coded as yes if the author reported involvement in conception and design, data analysis and interpretation, or manuscript writing.

†Coded as yes if the author participated in conception and design, or collection and assembly of data, or analysis and interpretation of data; and the author gave final approval of the manuscript. ICMJE requirements for authorship also include a third criterion, drafting of the manuscript or critical revision of the manuscript for important intellectual content. Because *Journal of Clinical Oncology* does not report critical revision of the manuscript as a separate role, all authors were given credit for this criterion in determining fulfillment of ICMJE authorship criteria.

(91%), and had a United States corresponding author (66%). Phase II trials constituted the largest group (42%). The mean number of authors was 12.5.

### Authorship Contributions

Of 2,927 authors, 64% reported performing at least one key role (Table 2). Specifically, 38% reported involvement in conception and design, 46% reported involvement in data analysis and interpretation, and 40% reported involvement in manuscript drafting. Sixty percent of authors satisfied ICMJE authorship criteria.

### Authors' Financial Ties

Twenty-nine percent of authors reported at least one financial tie to industry (Table 3). The most common categories were research

**Table 3.** Authors' Self-Reported Financial Ties to Industry

Type of Relationship	Financial Ties					
	All Studies (n = 2,927)		Non-Industry-Sponsored Studies (n = 1,409)		Industry-Sponsored Studies* (n = 1,518)	
	No.	%	No.	%	No.	%
Employment	207	7	17	1	190	13
Honorarium	324	11	85	6	239	16
Consultant	300	10	79	6	221	15
Stock ownership	182	6	11	1	171	11
Research funding	336	12	58	4	278	18
Expert testimony	17	1	3	0	14	1
Any financial tie†	842	29	173	12	669‡	44

\*Includes studies with mixed industry and nonindustry funding.

†Coded as yes if the author reported one or more of the above financial relationships.

‡Of these, 629 authors (41% of all authors of industry-sponsored studies) had at least one financial tie to the study sponsor.

**Table 4.** Relationship Between Performance of a Key Role and Presence of Financial Ties

Performance of a Key Role	No. of Authors	Financial Tie				P*
		Yes		No		
		No.	%	No.	%	
All trials	2,927					
Yes		666	35	1,215	65	< .0001
No		176	17	870	83	
Industry-sponsored trials	1,518					
Yes		532	55	432	45	< .0001
No		137	25	417	75	
Non–industry-sponsored trials	1,409					
Yes		134	15	783	85	< .0001
No		39	8	453	92	

\*Unadjusted P values based on  $\chi^2$  analyses. Analyses do not account for clustering of authors within articles.

funding (12%), honoraria (11%), and consulting (10%). Virtually all authors who disclosed stock ownership were also employees (data not shown). Among industry-sponsored trials, 669 (44%) of 1,518 authors reported at least one tie to a commercial entity. Of these, 94% reported at least one tie to the study sponsor. Among authors of non–industry-sponsored trials, 173 (12%) of 1,409 reported ties to a commercial entity.

**Relationships Between Authorship Contributions and Financial Ties**

In univariate analyses, authors who reported playing key roles in study design, analysis, or manuscript drafting were more likely than other authors to have financial relationships to industry (Table 4). This association was present when trials with or without industry sponsorship were considered separately.

Next, we performed multivariate analyses to adjust for article-level covariates (Table 5). These analyses confirmed that authors who reported performing key roles were more likely than other authors to report financial ties (adjusted OR, 4.3; 99% CI, 3.0 to 6.0; P < .0001). The association was stronger among trials with than among those

without industry sponsorship (P = .0038 for the interaction between funding source and performance of key roles), but was present regardless of sponsorship.

In sensitivity analyses, the association between performance of a key role and presence of financial ties to industry persisted when research funding was excluded from the outcome variable (OR, 4.4; 99% CI, 3.1 to 6.3; P < .0001), as well as when sponsor employees were removed from the analysis (OR, 3.6; 99% CI, 2.5 to 5.1; P < .0001). Finally, authors who satisfied ICMJE criteria were more likely than other authors to report financial ties (OR, 3.6; 99% CI, 2.6 to 5.0; P < .0001).

**DISCUSSION**

We examined the relationship between authorship contributions and financial ties to industry among authors of clinical trials published in JCO between January 1, 2006, and June 30, 2007. Consistent with our hypothesis, authors who reported participating in the intellectually central roles of conception and design, analysis and interpretation, or manuscript drafting were more likely than other authors to report financial ties. This relationship was present among both industry-sponsored and non–industry-sponsored trials, although it was stronger among industry-sponsored trials. To our knowledge, this association has not previously been demonstrated either within or outside the oncology setting.

Consistent with previous studies, a substantial proportion of authors reported financial ties to industry. Furthermore, authors of industry-sponsored studies were more likely than authors of non–industry-sponsored studies to report financial ties.<sup>40</sup> Although our data do not address the reason for this difference, we suspect that it is related to the likelihood that authors of an article reporting an industry-sponsored trial view particular financial ties as “having a direct bearing on the relevant subject matter,” rather than to differences between groups in the underlying prevalence of financial ties.<sup>36</sup> JCO requires disclosure of “financial and other relationships with entities that have investment, licensing, or other commercial interests in the subject matter under consideration.”<sup>37</sup> In light of this requirement, authors of non–industry-sponsored trials may appropriately

**Table 5.** Multivariate Analyses of Relationships Between Performance of Key Authorship Roles and Self-Reported Financial Ties to Industry

Model	No. of Authors	Adjusted Odds of Reporting Financial Ties	99% CI	P
All studies	2,927	4.3	3.0 to 6.0	< .0001
Subgroup analyses				
Industry-sponsored studies	1,518	5.0	3.4 to 7.5	< .0001
Non–industry-sponsored studies	1,409	2.5	1.3 to 4.8	.0002
Sensitivity analyses				
Exclusion of research funding from the financial ties composite dependent variable*	2,927	4.4	3.1 to 6.3	< .0001
Exclusion of sponsor employees from the analysis	2,742	3.6	2.5 to 5.1	< .0001
Satisfaction of ICMJE authorship criteria rather than key role as the independent variable†	2,927	3.6	2.6 to 5.0	< .0001

NOTE. Each cell reports the results of a separate generalized linear mixed model (PROC NL MIXED in PC-SAS) that tests the association between existence of a financial tie and performance of at least one key authorship role. All models adjust for age of study participants (adult v pediatric), and corresponding author address (United States v other). Models that include all studies also adjust for source of funding (industry v nonindustry).

Abbreviation: ICMJE, International Committee of Medical Journal Editors.

\*We repeated the main model after removing research funds from the financial ties composite variable.

†We used satisfaction of ICMJE authorship criteria, rather than the study-defined key-role variable, as the main independent variable of interest.

view many of their financial relationships as irrelevant to the subject matter at hand. Given this difference between industry- and non-industry-sponsored trials, studies of authors' financial relationships should be interpreted in light of the mix of sponsorship within the study sample, and future analyses of authors' personal financial relationships should be stratified by type of sponsorship.

Is the strong relationship between playing key intellectual roles and having financial ties to industry—even after excluding research funding—cause for concern? Although authors with the ability to influence study design, analysis, or reporting are more likely than other authors to have financial ties, the implications of this observation depend largely on the underlying mechanisms. One possibility is that industry sponsors select authors with whom they have cultivated financial relationships to play key roles, perhaps because they view such authors as more willing to favor their interests in designing, interpreting or reporting the study. Alternately, senior investigators with stronger reputations or greater experience may be more likely than other investigators both to have financial ties to industry and to play key roles. In other words, seniority, reputation, and experience may represent unmeasured confounders that account for the apparent relationship between having financial ties and performing key intellectual roles. Although the former explanation would be cause for concern, the latter may be less problematic. Although our cross-sectional data do not resolve the question of causal mechanism, two observations support the latter explanation. First, we observed an association between performing key roles and having financial ties in nonindustry-sponsored as well as in industry-sponsored trials. Second, a recent report commissioned by the U.S Food and Drug Administration found that “standing [US Food and Drug Administration] advisory committee members with higher overall measures of expertise were more likely than other standing advisory committee members to have been granted waivers for financial conflicts of interest.”<sup>41</sup> We suspect that this relationship between expertise and the existence of financial ties noted among US Food and Drug Administration committee members also holds true among clinical trial investigators. Whatever the underlying mechanism, the increased prevalence of financial ties among authors who participate in study design, conduct or reporting has particular implications for *JCO*, given the Journal's recent prohibition of most financial relationships between principal investigators and study sponsors.<sup>42</sup>

Our data also illuminate authorship practices in oncology trials. Over the past decade, there has been considerable attention to ensuring that authorship credit accurately reflects those individuals who made “substantive intellectual contributions to a published study.”<sup>38</sup> There is wide agreement that “ghost authors” (ie, individuals who made substantive contributions but did not receive authorship credit) and “honorary authors” (ie, individuals who received authorship credit but did not make substantive contributions) both raise concerns about scientific integrity.<sup>43</sup> Few studies, however, have characterized the contributions reported by authors of published articles.<sup>44-46</sup> We found that only 60% of authors satisfied the ICMJE's authorship criteria, even using a liberal definition that credited all authors with participation in drafting the manuscript or critically revising it for important intellectual content. These results suggest the need for education and discussion about authorship practices within the cancer research community. Finally, because “provision of study materials or patients” was the most common contribution reported after “final approval of the manuscript,” the editors of *JCO* and the

ICMJE should clarify whether or not this contribution is sufficient to satisfy the ICMJE's first authorship criterion.

Our study has several limitations. First, the data were derived from articles published in a single oncology journal during a limited time frame. It is conceivable that patterns of association between financial ties and authorship contributions may differ across disciplines or oncology journals. It is also possible, though we suspect unlikely, that the associations we observed may not generalize to periods either before or after the window of data collection. Second, data on financial ties and on authorship contributions were ultimately derived from author self-report during the submission process, either directly or through the corresponding author. Thus we cannot exclude the possibility of under- or over-reporting of financial ties, or of inaccurate reporting of authorship contributions. Independent confirmation of authors' financial ties would lend confidence to these results. However, such data collection would be challenging and is beyond the scope of the current investigation. Furthermore, misclassification by authors of their financial ties (for example, misreporting of research funding as consulting income) could bias the associations we observed. Third, it is possible that multiple instances of authorship by an individual author could have influenced our results. However, any effect was likely small given that few authors appeared more than once in the data set. Finally, as noted previously, the data do not directly address the causal mechanisms underlying the observed association between authorship contributions and financial relationships.

In conclusion, authors who play central intellectual roles in the conception and design, analysis and interpretation, or reporting of oncology trials are more likely than other authors to report financial relationships with industry. This association is present regardless of sponsorship, although it is stronger in industry-sponsored trials. These data do not prove that authors' financial ties are problematic, nor do they necessarily reflect efforts by sponsors to influence investigators' work. They do, however, suggest an urgent need to clarify the mechanisms underlying these relationships and to determine what, if any, influence they have on the outcomes and reporting of cancer clinical trials.

#### AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

*Although all authors completed the disclosure declaration, the following author(s) indicated a financial or other interest that is relevant to the subject matter under consideration in this article. Certain relationships marked with a “U” are those for which no compensation was received; those relationships marked with a “C” were compensated. For a detailed description of the disclosure categories, or for more information about ASCO's conflict of interest policy, please refer to the Author Disclosure Declaration and the Disclosures of Potential Conflicts of Interest section in Information for Contributors.*

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**Financial support:** Steven Joffe  
**Administrative support:** Steven Joffe

**Collection and assembly of data:** Steven Joffe

**Data analysis and interpretation:** Susannah L. Rose, Monika K. Krzyzanowska, Steven Joffe

**Manuscript writing:** Susannah L. Rose, Steven Joffe

**Final approval of manuscript:** Susannah L. Rose, Monika K. Krzyzanowska, Steven Joffe

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