Published in final edited form as:

Contemp Clin Trials. 2007 July ; 28(4): 358–369. doi:10.1016/j.cct.2006.10.005.

Presentation in relation to publication of results from clinical trials

Aynur Ünalp, MD, PhD^{*}, Susan Tonascia, ScM^{*}, and Curtis L Meinert, PhD^{*}

^{*} Center for Clinical Trials, The Johns Hopkins University, Bloomberg School of Public Health, 615 North Wolfe Street, Room W5010, Baltimore Maryland 21205

Abstract

Background—Results from clinical trials are typically disseminated first by presentation at scientific meetings. An important question has to do with the role of presentation in improving the quality of manuscripts submitted to the journals as well as the effect of presentation in speeding, or delaying subsequent publication. The aim of this research is focused on presentation practices of trialists to examine their effect on the timing of publications of clinical trial results.

Methods—Six hundred and one (601) trials published in 1996 and 1997 were identified via MEDLINE using medical subject heading “clinical trials” or the occurrence of the term in the text and by limiting to publication type “clinical trial”. Authors of those trials were surveyed to determine prior presentation history for the identified trials.

Results—Among the 601 trials identified, complete responses to questionnaires were obtained for 379 (63 percent) trials. The median time from completion to first submission of the primary results manuscript was 11 months and the median time from completion to publication was 25 months for the 220 trials involving presentation prior to submission for publication. The corresponding median times from completion to first submission and publication for the subset of trials not involving presentation prior to the submission were 8 and 19 months (159 trials), respectively. The adjusted relative hazard for publication for trials involving presentation prior to first submission was 0.55 versus trials not involving presentation prior to first submission (95% confidence interval, 0.44 to 0.69).

Conclusion—Despite the importance of dissemination of results prior to publication, investigators should carefully weigh a potential gain in quality against a potential for delay in submission of the primary results manuscript by presentation at scientific meetings. The findings of our study suggest that presentation prior to submission may increase time to publication. Inclusion of presentation dates in clinical trial registers should be considered to allow future studies investigating presentation and publication practices.

Keywords

Dissemination of results; presentation; publication; presentation and publication policy; clinical trials

1. Introduction

A number of people have addressed questions concerning the role presentation plays in the publication process. Most of that work has been conducted by identifying presentations and

Corresponding author: Aynur Ünalp (410 614 4851; Fax: 410 995-0932; aunalp@jhsph.edu).

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then following them forward to determine if the work presented comes to publication [1–22]. The percent of those presentations that resulted in publications ranged from 26 percent to 66 percent in studies representing different medical specialties. In a review by Scherer and Langenberg, a subsequent publication rate of 56 percent was reported in randomized controlled trials [22].

Investigators engaged in clinical trials, may face particularly complicated decisions as well as opposing opinions as to how and when to disseminate trial results. Presentation at scientific meetings to allow timely dissemination of results in relation to publication has been the preferred policy within several cooperative investigative groups. An earlier policy that prohibits release of research findings before publication to the news media and health care professionals has been criticized on several occasions, with the main criticism converging on the possible delay in exchange of clinically important new information among care givers.

We postulated that presentation of results would extend or shorten the time it takes to publish results from completed studies and thus contribute to or alleviate publication bias evidenced by a significant proportion of presentations not getting published. The starting point for this study was published results from clinical trials, with a survey instrument to authors to determine whether the results were presented prior to submission to a journal for peer-review. The primary objective was to determine whether prior presentation affected the time from completion of the trial to publication of the results. Other objectives included estimation of median time from trial completion to landmark events in publication cycle of clinical trials such as first submission to a journal, final submission, acceptance for publication, and publication.

This paper is an outgrowth of a PhD dissertation of one of the authors [23] and describes the findings from a survey study. The study was approved by the Institutional Review Board of the Johns Hopkins Bloomberg School of Public Health (July 1998; CHR # H.34.98.06.02.B).

2. Methods

Clinical trials were identified in November 1998 via Ovid MEDLINE, supported by the Welch Medical Library at the Johns Hopkins University. The search involved identification of articles with the medical subject heading “clinical trials”, as indexed by the National Library of Medicine or the occurrence of “clinical trial” or “clinical trials” in the text (37,511 articles). Selected articles were limited to those with human subjects (35,612 articles), in English (32,152 articles), published in years 1996 and 1997 (9,382 articles), and “clinical trial” as publication type (2,027 articles). The abstracts of those articles were reviewed to select only primary results papers from randomized clinical trials that were available at either the libraries of the Johns Hopkins University or the University of Maryland (601 articles).

Individual articles were collected and read to extract information characterizing the trial, such as sample size, duration, direction of results, and the end date of the trial. Some of that information, such as dates for completion of trial, presentations (first, second, third), submissions (first, final), and acceptance for publication, was transcribed onto a questionnaire when available which was then sent to the corresponding author for the article with a request to review and, where necessary, correct or provide missing information (questionnaire in reference 23).

The completion date for the trial was the cutoff date for the dataset used for analysis in the paper or the date data collection was reported to have ended in the absence of the former date. Hence, if the trial was stopped early, the date of the recommendation to stop was reflected in the completion date.

The questionnaire was mailed December 1998 – January 1999 with reminders to non-respondents 6 to 8 weeks later, with a second mailing of the questionnaire for non-respondents approximately 3 months after the original mailing. In the absence of a response to the second mailing, a different investigator was identified and the mailing protocol was repeated.

The characteristics of trials represented in tables are as determined or classified by one of the authors (AÜ) based on information in the papers and as described elsewhere [23]. When there was a reported presentation prior to publication, the presentation variable was further categorized according to timing of presentation in relation to first submission of the results paper to a journal. Authorship formats are as defined by Meinert [24]. Conventional authorship is the form of authorship involving only individuals as named authors. Corporate authorship is a form of attribution in which authorship is attributed to a corporate entity such as an agency, institution or collaborative group. The modified conventional format is one where the masthead listing includes the name of the research group in addition to the listed authors, eg, Nancy Jones and Harry Brown for the XYZ Research Group.

The variable “Core journals” is as defined by MEDLINE, presently representing 120 widely read medical journals; previously known as AIM (Abridged Index Medicus) journals prior to discontinuation of the index.

The direction of results was categorized as either a positive result that indicates a beneficial effect measured by a difference between treatment groups, or a negative result that is opposite in nature or direction to that postulated or desired, or a nil result that relates to an inconsequential treatment effect that is not statistically different than zero [24].

Statistical analysis was performed using Stata Release 6 [25]. The characteristics of 601 trials including both survey respondents and non-respondents were included in Table 1. The 379 trials for which dates of presentation were available, were divided for purposes of this study into two groups: *no presentation before first submission* (n=159) and *presentation before first submission* (n=220). The characteristics of 379 trials by presentation status were included in Table 2. The median time to first submission, final submission, and acceptance were estimated from completion of the trial as reported by the investigators of 379 trials in Table 3. The median time to publication was estimated from completion of the trial as reported in 601 articles for Table 4.

Main outcome measure was time to publication from completion of the trial as reported by the investigators. The plots represented in Figure are Kaplan-Meier [26] product limit estimates for time to publication. The log-rank test was used to compare the equality of the publication curves. The Cox proportional hazards regression model was used to estimate publication hazard rates [27]. Analyses using Cox proportional hazards regression for relative time to publication were performed with data obtained from 379 trials in which dates of presentation of primary results were available.

The relation between presentation and time to publication was also analyzed in multiple proportional hazards regression models to account for other covariates. The model building process in Cox proportional hazards using the purposeful selection method included variables that either were judged to be of importance or were significant in a univariate analysis at the 25% level [28]. Variables were then eliminated backwards at a cutoff value of $p > 0.20$ using the partial likelihood ratio and Wald tests [28]. We could not identify any significant two-way interactions. The unadjusted and adjusted hazard ratios represented in Table 5 are Cox proportional hazard ratios. The variables used for adjustment are all the variables listed in Table 5. The assumption of proportional hazards over time was checked with Schoenfeld residual analysis and was found to be satisfactory [25].

3. Results

Responses to survey questionnaire

The study sample consisted of 601 primary results papers. Of the 601 articles, investigators from 417 (69 percent) trials replied between January and December 1999. The response to questionnaire was incomplete in an additional 38 (6 percent) trials. The description of study population, percent distribution of variables and design features of the trials, comparing the survey respondents with the non-respondents are reported.

The authors reported presentation of results at a scientific meeting prior to publication in 290 (77 percent) of the 379 trials for which information on presentation was available. The majority of the investigators presented first either for the purpose of an “exchange of information” (46 percent) or because of “presumed immediate clinical importance” (42 percent). This was followed by “pressure from investigators” or from “sponsors” (7 percent), and other reasons such as academic advancement, requests outside of study, facilitation of publication, and hindrance of presentation by publication (5 percent). Only 15 investigators who presented prior to publication reported a delay in submission of the results paper to allow for presentation [23].

Characteristics of selected clinical trials by response status

The characteristics of the 601 trials represented are summarized in the last two columns of Table 1. In about three-fourths (76 percent), the authors reported a positive result. Just over 4 percent were negative and the remainder (20 percent) reported nil (inconsequential) results. Nearly half (46 percent) had sample sizes of < 100, 56 percent were single center, and nearly three-fourths (72 percent) involved treatment and followup periods of < 1 year. The only differences by response status large enough to yield conventional p-values of < 0.05 were for trial site, monitoring committee, funding source, and duration of treatment and followup.

Characteristics of selected clinical trials by presentation status

In 70 trials, presentation occurred after or within same month of first submission of results paper to a journal for publication. Table 2 provides a summary of characteristics similar to that provided in Table 1, but by whether or not the first submission was preceded by presentation for the 379 trials for which there was a response to the questionnaire. Largely, the characteristics of trials preceded by presentation were the same as for those not preceded by presentation. The only difference reaching a nominal p-value of < 0.05 was for the variable “Site” with a higher fraction of trials conducted in academia presented prior to the first submission.

Landmark events in publication of selected clinical trials

Table 3 provides median time to landmark events in publication cycle from trial completion relative to presentation status. Panel A provides times for the 220 trials in which results were presented prior to the first submission to a journal, Panel B provides times for the complement of that subset (159 trials), Panel C is for the 70 trials reporting presentation after the first submission, and Panel D is for all 379 trials for which we have date information. The median time to publication for trials involving presentation prior to first submission in Panel A was 25 months (interquartile range: 19 to 35 months). The corresponding time for the complement subset of trials was 19 months in Panel B (interquartile range: 13 to 29 months). The median time to publication for the subset of 70 trials presenting after the first submission was similar to that for trials not presenting prior to the first submission (18 months versus 19 months). The median time to publication for all 379 trials on which we have data was 23 months (Panel D).

The unadjusted Kaplan-Meier publication curves by the presentation status (ie, no presentation prior to first submission and presentation prior to first submission) are shown in Figure. Overall,

in the first 5 years of followup after trial completion, the “*no presentation before submission*” group had a shorter time to publication than the “*presentation before submission*” group and the median times from trial completion to publication were 19 versus 25 months in respective groups [log-rank test, $\chi^2(1) = 21.61$, $p < 0.00001$]. The covariate adjusted graphs of fitted data using Cox proportional hazards regression models (not shown) were similar to unadjusted Kaplan-Meier curves.

Estimation of time to publication by clinical trial characteristics

The median times to publication from completion of the trial and corresponding interquartile ranges by trial characteristics as reported in 601 articles are given in Table 4. The biggest time differential was for “Authorship” with median time for papers having a corporate form of authorship standing at 15 months versus 24 months for papers having a conventional authorship format. Another interesting finding was for “Direction of results” with median time of 19 months for papers having reported a negative result versus 24 months for papers having reported a positive result.

Proportional hazard ratios for time to publication

The unadjusted and adjusted relative times to publication, expressed as hazard ratios and corresponding 95% confidence intervals, using a Cox proportional hazards regression analysis, are presented in Table 5 for various trial characteristics. The hazard ratios presented in Table 5 were obtained from 379 trials in which dates of presentation of primary results were available.

Hazard ratios > 1.00 are indicative of shorter times to publication than the reference category; hazard ratios of < 1.00 are indicative of the reverse. By and large, the differences between the unadjusted and adjusted hazard ratios were modest. The biggest differences were for “Authorship” and for “Direction of results: Negative”. Trials involving presentation before submission of the results paper had a longer time to publication than trials involving no presentation before submission [adjusted HR=0.55, 95% CI: 0.44 to 0.69]. In general, trials with corporate authorship format [adjusted HR=2.25, 95% CI: 1.18 to 4.27], mortality as the outcome [adjusted HR=2.03, 95% CI: 1.22 to 3.38], and that were published in core journals [adjusted HR=1.53, 95% CI: 1.21 to 1.92] had a shorter time to publication. Trials with nil (inconsequential) results [adjusted HR=0.74, 95% CI: 0.56 to 0.97] had a longer time to publication than those reporting positive results.

4. Discussion

The results summarized above and in Table 5 provide some support for the study hypothesis that prior presentation may affect the time from completion of the trial to publication of the results. The estimated unadjusted hazard ratio was 0.62 [95% CI: 0.50 to 0.76] comparing trials with presentation before first submission to trials with no presentation before first submission. The interpretation is that trials with presentation before first submission published primary results at a rate that is 38 percent lower than for trials with no presentation before first submission. The 95 percent confidence interval suggests that the rate could be as much as 50 percent lower to only 24 percent lower. Likewise, the estimated adjusted hazard ratio points to a significant benefit for the no presentation before first submission group, controlling for other potential confounders.

To the best of our knowledge, this study is the first one that focuses on whether prior presentation of primary results would extend or shorten the time it takes to publish results from clinical trials. The median time of 23 months for publication of primary results from completion of a trial reported here may be an underestimate since our sample consisted of clinical trials with published results. If a sample of clinical trials were included from inception and followed

up until publication, the estimated median time to publication would be longer to allow more presentations at annual scientific meetings in the time interval studied. In our study, we accounted for this natural occurrence by using the first presentation date in the categorization of trials according to the presentation status. Similarly, estimated publication times were related to the number of submissions a manuscript had gone through until acceptance by the journal published the primary results paper included in this study. We accounted for several submissions of a manuscript by using the first submission date provided in survey responses in the categorization of trials according to the presentation status. Albeit imperfect, we think that an evaluation of presentation practices of investigators might contribute to the understanding of publication practices, even if investigators cannot completely control the time when they present results from clinical trials and they may consider presentation of results at more scientific meetings the longer it takes to prepare and submit the results paper to a journal.

We were limited by the information provided either in the article or in answer to the survey as there is no universal trial registry or comprehensive database for presentation of results at scientific meetings. Further, we could not validate the accuracy of the dates for trial completion, presentation, and submission from another source. We repeated the analyses with date of completion of trial defined as end of patient followup to see if this would affect the findings but found no differences in the outcomes of the current study using these two different completion of trial definitions since in two thirds of the trials, the end of patient followup and dataset finalization dates were reported to be within the same month. We then decided to present our results with date of completion of trial defined as dataset finalization date for primary results paper analysis. In the majority of trials (84 percent), the dates for prior presentation of the results were not included in the trial reports. The date the results paper was submitted to the journal was reported in 56 percent of the journals and the date the results paper was accepted by the journal was reported in 70 percent of the journals. Also the reporting of landmark dates for a trial such as Institutional Review Board or Ethics Committee approval, start and end of patient recruitment, end of treatment and followup was incomplete in the selected articles.

Despite inherent limitations described above such as inclusion of clinical trials with published results only and missing data due to low response rate (69 percent) and incomplete survey results (6 percent), we think the findings presented in Table 3 shed some light to how long it takes from trial completion to landmark events in publication cycle of clinical trials such as first submission to a journal, final submission, acceptance for publication, and publication.

The results here are consistent with the notion that presentation may lead to time lag bias [29]. It is also conceivable that investigators, once having presented, may feel that their responsibility to disseminate results has been met, to say nothing about “loss of interest” once the presentation has been made. We are not able to address this issue given our starting point, namely a published results paper, but there is certainly plenty of evidence to indicate that only a fraction of that which is presented ultimately comes to publication. For example, Denis Halmagyi, in an unpublished review of the records of the Surgical Research Society of Australasia, showed that only 42 percent of presentations came to publication [1]. This investigation was followed by others in surgery [2,3], cardiology [4], anesthesiology [5,6], pediatrics [7,8], ophthalmology [9–11], oncology [12], family medicine [13], orthopedics [14–16], emergency medicine [17,18], radiology [19], social medicine [20], and psychiatry [21]. The percent of presentations that resulted in publications ranged from 26 percent to 66 percent, and a subsequent publication rate of 56 percent was reported in randomized controlled trials in a review by Scherer and Langenberg [22].

The argument that prior presentation leads to better papers cannot be addressed here since we have no way of knowing what papers preceded by presentation would have been like had they not been so preceded. However, for what it is worth, the fraction of papers preceded by

presentation was lower for core journals than for the remainder and was lower for multicenter trials and trials having the corporate form of authorship. In reality, because the process of producing and publishing papers is complicated, one cannot ever, with assurance, identify all the factors serving to speed or slow production of published results papers. Hence, there may be other factors in addition to presentation and other variables included in this study that account for the time differentials observed but, if so, we have failed to include them. The results are surprisingly robust in that the effect of adjustment by multiple regression for variables such as sample size, authorship, and type of journal had little bearing on the differences seen in time to publication (Table 5).

Our results also lend some credence to the “publish first, present later” philosophies of some trial groups [30–32] that were developed in parallel to the Ingelfinger Rule [33–35] of the *New England Journal of Medicine* and other major medical journals aimed at preserving the originality of the results published [36]. The restriction implied by the Rule did not apply to the abstracts published in connection with scientific meetings, or press reports resulting from formal and public oral presentations. However, distribution of essential substance such as a complete manuscript including figures and data at scientific meetings might hinder consideration for publication. Ingelfinger’s successor, Arnold Relman, turned the Rule into a gatekeeper function and used peer review as the rationale [37,38]. In his defense of the Rule, Relman stated that medical research should be subjected to peer review and published in the scientific literature before it is touted to the public or profession. Furthermore, physicians should have an opportunity to read the full reports of new developments in order to make an informed judgment. With the evidence as well as the conclusions at hand, physicians are in a better position to evaluate medical news on behalf of their patients. Premature publicity about medical research that has not yet been documented may cause confusion among the lay public and the professionals alike, as in the case of the University Group Diabetes Program (UGDP) [30]. In the case of the UGDP, the negative study findings were presented at a national meeting which was held 6 months prior to publication. During the interim period, patients taking oral antidiabetic medications and their physicians were left with little information.

In a recent survey conducted by Wilkes and Kravitz [39] to describe the attitudes of North American medical journal editors; the majority of the respondents agreed that discussion of scientific findings with the press (84 percent) in the interest of quick dissemination to the patients and physicians, was acceptable, but only in accord with the Ingelfinger Rule, i.e., after publication of the article. This policy has been criticized on several occasions [40–42], with the main criticism converging on the possible delay in exchange of clinically important new information among care givers. Because of this, recently, some cooperative groups have adopted a “present first, publish later” policy in the belief that the results would be disseminated in a more timely fashion.

The median time to presentation is just 7 months for the entire set of trials involving presentation. However, the results here do not support arguments for presentation prior to publication as a vehicle for timely dissemination of results, but whatever the advantage in dissemination via meeting halls, that advantage has to be balanced against the increased time such activities translate into in regard to publication. The audience reached in presentations, even if at major meetings, pales in comparison to that reached via indexed journal articles and a delay, even if only a few months, likely translates into thousands of person years when measured against audiences reached with indexed journals.

Results in over half (220/379; 58%) of the trials for which we had information on presentation were presented prior to the first submission for publication and 76% (290/379) were presented sometime prior to publication. These statistics, per se, are not surprising since trialists, like other scientists, are schooled to present. In trials, presentation of results prior to preparation of

a finished results manuscript is touted as a vehicle for sharpening interpretation and analysis of the results as well as for speeding production of a finished manuscript. However, we failed to find evidence indicating presentation speeds production of a published manuscript. Indeed, if anything, the evidence is that publication is slowed. The median time from first submission to publication was 19 months for trials not reporting presentation prior to the first submission versus a median time of 25 months for trials presenting prior to the first submission.

The question of whether the estimated difference in time to publication by presentation status is important or can reliably be measured in study designs other than the current one, needs to be further evaluated. We suggest that clinical trial registers record presentation dates at scientific meetings to allow inclusion of presentation status in future studies investigating publication practices of trialists.

Acknowledgments

Grant support: This project was supported in part by the Doctoral Dissertation Research Support of the Department of Epidemiology and by training grant T32EY07127 from the National Eye Institute for the Clinical Trials Training Program.

We are grateful to investigators who replied to our survey questionnaire. The corresponding author thanks her thesis readers – Nancy Min PhD, Barbara Hawkins PhD, Marie Diener-West PhD, Mark Steinhoff MD – and former reviewers of this paper for their constructive comments.

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Figure. Time to publication by presentation category

Kaplan-Meier publication curves by presentation category are compared by using log-rank test, $\chi^2(1) = 21.61$, $p < 0.00001$

Table 1

Characteristics of trials: overall, and by respondents vs nonrespondents

	Respondents		Nonrespondents		Total	
	No.	%	No.	%	No.	%
Country of conduct ($p = 0.39$)*						
North America	196	51.7	121	54.5	317	52.7
Europe	145	38.3	86	38.7	231	38.4
Other	38	10.0	15	6.8	53	8.8
Site ($p = 0.04$)						
Academic institution	328	86.5	178	80.2	506	84.2
Other	51	13.5	44	19.8	95	15.8
Authorship format ($p = 0.28$)						
Conventional	312	82.3	171	77.0	483	80.4
Modified conventional	55	14.5	41	18.5	96	16.0
Corporate	12	3.2	10	4.5	22	3.7
Journal of publication ($p = 0.84$)						
Core journals	167	44.1	87	39.2	254	42.3
Other	212	55.9	135	60.8	347	57.7
Sample size ($p = 0.91$)						
< 100	174	45.9	103	46.4	277	46.1
≥ 100	205	54.1	119	53.6	324	53.9
Centers ($p = 0.15$)						
Single center	221	58.3	116	52.3	337	56.1
Multicenter	158	41.7	106	47.7	264	43.9
Purpose ($p = 0.12$)						
Treatment	313	82.6	194	87.4	507	84.4
Prevention	66	17.4	28	12.6	94	15.6
Primary outcome ($p = 0.13$)						
Mortality	20	5.3	10	4.5	30	5.0
Morbidity	64	16.9	24	10.8	88	14.6
Symptom	251	66.2	153	68.9	404	67.2
Surrogate marker	44	11.6	35	15.8	79	13.1

	Respondents			Nonrespondents			Total		
	No.	%		No.	%		No.	%	
Monitoring committee (p = 0.000001)									
No	275	72.6		193	86.9		468	77.9	
Yes	104	27.4		29	13.1		133	22.1	
Direction of results (p = 0.10)									
Positive	280	73.9		178	80.2		458	76.2	
Negative	20	5.3		5	2.3		25	4.2	
Nil	79	20.8		39	17.6		118	19.6	
Funding source (p = 0.01)									
Government any	145	38.3		61	27.5		206	34.3	
Industry only	120	31.7		97	43.7		217	36.1	
Other	15	4.0		10	4.5		25	4.2	
Unknown	99	26.1		54	24.3		153	25.5	
Duration trt/followup, per person (p = 0.01)									
< 1 yr	261	68.9		175	78.8		436	72.5	
≥ 1 yr	118	31.1		47	21.2		165	27.5	
Total	379	63.1		222	36.9		601	100.0	

* p-values for difference between respondents and non-respondents are calculated using one-way ANOVA and are two tailed

Table 2

Characteristics of trials: Presentation vs no presentation prior to submission

	Presentation before 1st submission		No presentation before 1st submission		Total	
	No.	%	No.	%	No.	%
Country of conduct (p = 0.78)*						
North America	115	52.3	81	50.9	196	51.7
Europe	85	38.6	60	37.7	145	38.3
Other	20	9.1	18	11.3	38	10.0
Site (p = 0.02)						
Academic institution	198	90.0	130	81.8	328	86.5
Other	22	10.0	29	18.2	51	13.5
Authorship format (p = 0.81)						
Conventional	183	83.2	129	81.1	312	82.3
Modified conventional	31	14.1	24	15.1	55	14.5
Corporate	6	2.7	6	3.8	12	3.2
Journal of publication (p = 0.69)						
Core journals	95	43.2	72	45.3	167	44.1
Other	125	56.8	87	54.7	212	55.9
Sample size (p = 0.68)						
< 100	99	45.0	75	47.2	174	45.9
≥ 100	121	55.0	84	52.8	205	54.1
Centers (p = 0.95)						
Single center	128	58.2	93	58.5	221	58.3
Multicenter	92	41.8	66	41.5	158	41.7
Purpose (p = 0.36)						
Treatment	185	84.1	128	80.5	313	82.6
Prevention	35	15.9	31	19.5	66	17.4
Primary outcome (p = 0.75)						
Mortality	13	5.9	7	4.4	20	5.3
Morbidity	39	17.7	25	15.7	64	16.9
Symptom	145	65.9	106	66.7	251	66.2
Surrogate marker	23	10.5	21	13.2	44	11.6

	Presentation before 1st submission		No presentation before 1st submission		Total	
	No.	%	No.	%	No.	%
Monitoring committee (p = 0.70)						
No	158	71.8	117	73.6	275	72.6
Yes	62	28.2	42	26.4	104	27.4
Direction of results (p = 0.32)						
Positive	168	76.4	112	70.4	280	73.9
Negative	9	4.1	11	6.9	20	5.3
Nil	43	19.5	36	22.6	79	20.8
Funding source (p = 0.52)						
Government any	91	41.4	54	34.0	145	38.3
Industry only	66	30.0	54	34.0	120	31.7
Other	9	4.1	6	3.8	15	4.0
Unknown	54	24.5	45	28.3	99	26.1
Duration trt/followup, per person (p = 0.22)						
< 1 yr	146	66.4	115	72.3	261	68.9
≥ 1 yr	74	33.6	44	27.7	118	31.1
Total	220	58.0	159	42.0	379	100.0

* p-values for difference between respondents and non-respondents are calculated using one-way ANOVA and are two tailed

Table 3

Time from trial completion to first submission, final submission, acceptance, and publication by presentation category

	Median time	Interquartile range
A. Presentation prior to 1st submission *		
Time to 1st submission (173 [†])	11 mos	7 – 20 mos
Time to final submission (203)	15 mos	9 – 24 mos
Time to acceptance (204)	20 mos	13 – 30 mos
Time to publication (220)	25 mos	19 – 35 mos
B. No presentation prior to 1st submission		
Time to 1st submission (117)	8 mos	4 – 14 mos
Time to final submission (130)	10 mos	4 – 18 mos
Time to acceptance (146)	14 mos	8 – 22 mos
Time to publication (159)	19 mos	13 – 29 mos
C. Presentation after 1st submission		
Time to 1st submission (43)	5 mos	3 – 10 mos
Time to final submission (51)	8 mos	5 – 13 mos
Time to acceptance (61)	12 mos	7 – 19 mos
Time to publication (70)	18 mos	13 – 24 mos
D. Regardless of presentation history		
Time to 1st submission (290)	10 mos	5 – 18 mos
Time to final submission (233)	13 mos	7 – 22 mos
Time to acceptance (350)	18 mos	11 – 27 mos
Time to publication (379)	23 mos	16 – 33 mos

* Where only month is reported and where presentation and submission is reported as occurring in the same month, presentations in those instances are counted as occurring after submission.

[†] Number of trials for which we have indicated date information are included in the parenthesis.

Table 4

Time to publication by trial characteristic as reported in 601 articles

	No. of trials	Median time	Interquartile range
Country of conduct			
North America	317	23 mos	17 – 31 mos
Europe	231	25 mos	19 – 33 mos
Other	53	22 mos	18 – 26 mos
Site			
Academic	506	24 mos	18 – 32 mos
Other	95	24 mos	14 – 31 mos
Authorship format			
Conventional	483	24 mos	18 – 32 mos
Modified conventional	96	23 mos	15 – 30 mos
Corporate	22	15 mos	10 – 21 mos
Journal of publication			
Core journals	254	22 mos	17–29 mos
Other	347	25 mos	19–34 mos
Sample size			
< 100	277	23 mos	18 – 31 mos
≥100	324	24 mos	17 – 32 mos
Centers			
Single center	337	24 mos	18 – 32 mos
Multicenter	264	23 mos	17 – 32 mos
Purpose			
Treatment	507	23 mos	18 – 32 mos
Other	94	26 mos	18 – 34 mos
Primary outcome			
Mortality/morbidity	118	22 mos	14 – 30 mos
Other	483	24 mos	18 – 32 mos
Monitoring committee			
No	468	25 mos	18 – 32 mos
Yes	133	22 mos	15 – 30 mos
Direction of results			
Positive	458	24 mos	18 – 32 mos
Negative	25	19 mos	14 – 31 mos
Nil	118	23 mos	18 – 33 mos
Funding source			
Government any	206	22 mos	15 – 30 mos
Industry only	217	25 mos	19 – 33 mos
Other	25	21 mos	18 – 30 mos
Unknown	153	25 mos	18 – 33 mos
Duration trt/followup, per person			
< 1 yr	436	25 mos	19 – 32 mos

	No. of trials	Median time	Interquartile range
≥ 1 yr	165	22 mos	14 – 31 mos
Total	601		

Table 5
Relative time from trial completion to publication via Cox proportional hazards* by selected characteristics

	No. of trials	Hazard ratio		95% CI	
		Unadjusted	Adjusted*	Unadjusted	Adjusted*
Presentation prior to 1 st submission					
No	159	1.00	1.00		
Yes	220	0.62	0.55	0.50–0.76	0.44–0.69
Country of conduct					
North America	196	1.00	1.00		
Europe	145	0.96	0.96	0.77–1.19	0.74–1.23
Other	38	1.09	1.12	0.77–1.55	0.78–1.62
Site					
Academic institution	328	1.00	1.00		
Other	51	0.95	0.88	0.71–1.28	0.63–1.22
Authorship format					
Conventional	312	1.00	1.00		
Modified conventional	55	1.31	1.09	0.98–1.75	0.76–1.58
Corporate	12	2.51	2.25	1.40–4.49	1.18–4.27
Journal of publication					
Other	212	1.00	1.00		
Core journals	167	1.67	1.53	1.36–2.07	1.21–1.92
Sample size					
< 100	174	1.00	1.00		
≥ 100	205	0.95	0.81	0.77–1.16	0.64–1.03
Centers					
Single center	221	1.00	1.00		
Multicenter	158	1.00	0.92	0.82–1.24	0.70–1.22
Purpose					
Treatment	313	1.00	1.00		
Prevention	66	0.86	0.89	0.66–1.12	0.67–1.19
Primary outcome					
Symptom	251	1.00	1.00		

	No. of trials	Hazard ratio		95% CI	
		Unadjusted	Adjusted*	Unadjusted	Adjusted*
Mortality	20	1.86	2.03	1.17–2.95	1.22–3.38
Morbidity	64	1.02	1.18	0.78–1.35	0.86–1.62
Surrogate marker	44	0.86	0.86	0.62–1.19	0.61–1.22
Direction of results					
Positive	280	1.00	1.00		
Nil	79	0.84	0.74	0.66–1.09	0.56–0.97
Negative	20	1.19	0.94	0.76–1.88	0.58–1.53
Monitoring committee					
No	275	1.00	1.00		
Yes	104	1.29	1.14	1.03–1.63	0.88–1.48
Funding source					
Government any	145	1.00	1.00		
Industry only	120	0.86	0.86	0.67–1.10	0.67–1.11
Other/unknown	114	0.84	0.89	0.65–1.07	0.67–1.17
Duration trt/followup, per person					
< 1 yr	261	1.00	1.00		
≥ 1 yr	118	1.19	1.23	0.95–1.48	0.96–1.57
Total	379				

* Adjustment was performed with all variables included in this table.