

Clinical Trial Disclosure Requirements: Implications for Publishing Data

Colin Mitchell, Joseph Johnson

Complete Healthcare Communications, Inc., Chadds Ford, PA

Abstract

Background: Recent legislation by the United States federal government and the State of Maine mandates that data from clinical trials on prescription medications must be made publicly available within one year of study completion.

Purpose: To discuss the implications of this legislation for medical publications

Methods: Several journals within the field of urology were contacted regarding their policy on publishing data that had been posted on a publicly available web site. Strategy for disclosing public posting of data was discussed with our client.

Results: Most journals responded that public posting of clinical trial data in compliance with governmental regulations was acceptable and would not jeopardize publication. Two publishers, Elsevier and Wiley-Blackwell, have explicit policies allowing posting of data prior to publication, although each individual journal's policy is decided by its editor. One journal instructed us not to submit manuscripts containing data that had been made publicly available; after further dialogue, that journal decided to allow submissions containing posted data. Our client adopted the policy of disclosing the web site and the reason for posting within the submittal letter and manuscript for all submissions containing data that had been made publicly available.

Conclusions: The impact of Clinical Trial Disclosure Requirements on the publication of data is much less than we expected. We recommend confirming the policy of each journal prior to submission and adopting a uniform policy for disclosing the posting of clinical trial data.

Introduction

- In June, 2005, Maine became the first state to pass legislation requiring the public disclosure of clinical trial results.
- The Maine law, LD 1618, required drug manufacturers conducting business in Maine to make public information on clinical trials, including:
 - The name of the trial sponsor
 - A summary of the purpose of the trial
 - Trial dates
 - Trial results
- The Food and Drug Administration Amendments Act (FDAAA) was signed into law September 27, 2007.
- FDAAA established the requirement that clinical trial databases must include links to information on results from applicable drug clinical trials no later than December 25, 2007.
 - FDAAA covers controlled clinical drug trials other than Phase 1 clinical investigations.
- Required information includes:
 - Baseline demographic and clinical characteristics of the subjects
 - Results for all primary and secondary outcomes for each arm of the trial
 - Serious adverse events
 - Frequent adverse events (>5% in any arm)
 - Contact information to direct scientific inquiries
 - Information on agreements between the trial sponsor and investigators that could restrict the ability of investigators to disclose trial results
- PhRMA has established a clinical study results database: www.clinicalstudyresults.org.
- Results must be posted by 1 year after trial completion.

- It was initially unclear how our ability to publish data would be impacted by publicly posting data.
 - In some cases, it might not be possible to publish the primary manuscript within 1 year of study completion.
 - Secondary outcomes not included in the primary manuscript may be posted prior to publication.

Objective

- To describe our experience of the implications of this legislation for medical publications

Methods

- Our team at Complete Healthcare Communications, Inc. contacted all journals our client routinely utilizes to inquire about their policy on publishing data posted on a publicly available web site.
 - In conjunction with our client, we have adopted a policy of complete transparency regarding our involvement in the publications process.
 - Our involvement is acknowledged in all manuscripts and posters and slides presented at professional meetings.
 - We routinely engage in direct communication with journal editors and societies.

Results

Journal Responses

- Elsevier and Wiley-Blackwell have explicit policies allowing online posting of data prior to publication.
 - For Elsevier journals, this is covered under Authors' rights for posting pre-print versions of articles.
 - Elsevier provides authors "the right to post a pre-print version of the journal article on

Internet web sites including electronic pre-print servers, and to retain indefinitely such version on such servers or sites"

- All Elsevier and Wiley-Blackwell journals expressed no concern with posting of data to a public web site in accordance with governmental regulations prior to publication.
- However, publication policies for individual journals are ultimately up to journal editors; they are not beholden to the policies of the parent publishing company.
- Several journals had not adopted a position on publishing data posted to a public web site and had to consult internally before providing us with an answer.
- Only 1 journal, *The Journal of Urology*, told us that they would not publish data that had been posted on a public web site.
 - "If the study results are posted on a web site then please do not submit the manuscript to *The Journal of Urology* since this would violate number 5 of our submission requirements noted in Information for Authors which states: 'that the manuscript or portions thereof are not under consideration by another journal or electronic publication and have not been published previously'."

Follow-up Correspondence With *The Journal of Urology*

- Given that all other journals agreed to publish data posted on a publicly available web site, we followed-up with *The Journal of Urology* regarding their decision.
- Points of emphasis included:
 - Spelling out the State of Maine and US government requirements
 - Our client's need to be compliant with this legislation

- Difficulties in publishing prior to 1 year after last patient, last visit
- Posted results have not been peer reviewed
- Posted results are not citable
- Posted results have not been circulated/distributed
- Copyright is still assigned to journals
- Other journals did not consider posting to constitute prior publication
- Similar mandates for publicly-funded studies will be forthcoming
- *The Journal of Urology* responded that they would publish data posted on a publicly available web site provided that the web site on which the data were posted and the reason for which they were posted were indicated in the submittal letter.
- A listing of all journals that agreed to publish data posted on a publicly available web site is provided in **Table 1**.

Table 1. Journals That Agreed to Publish Data Posted on a Publicly Available Web Site

Urology Journals

BJU International
European Urology
International Journal of Urology
International Urogynecology Journal
Journal of Pediatric Urology
Journal of Sexual Medicine
Journal of Urology
Journal of Wound, Ostomy and Continence Nursing
Neurourology and Urodynamics

General Practice Journals

Current Medical Research and Opinion
International Journal of Clinical Practice

Health Outcomes Journals

Health and Quality of Life Outcomes

Disclosure Policy

- In conjunction with our client, we developed a publication policy for disclosing when data had been posted on a publicly available web site.
- This policy is that we would indicate the web site and the reason for posting in the submittal letter and in the manuscript itself for all submissions.
- Issues in determining the disclosure language included:
 - Bodies other than the US government and State of Maine would likely adopt similar policies
 - Many of our publications appear in non-US journals
- Disclosure language: "The data from this study have been posted online at www.clinicalstudyresults.org (unique identifier NCTXXXXXXX) in compliance with governmental regulations."

Conclusions

- We recommend discussing a journal's publication policy with the editor when submitting a manuscript containing data posted on a publicly available web site.
- We also recommend developing a disclosure policy and language to use when submitting a manuscript containing data posted on a publicly available web site.

5th Annual Meeting of the International Society
for Medical Publication Professionals
April 20-22, 2009
Philadelphia, PA