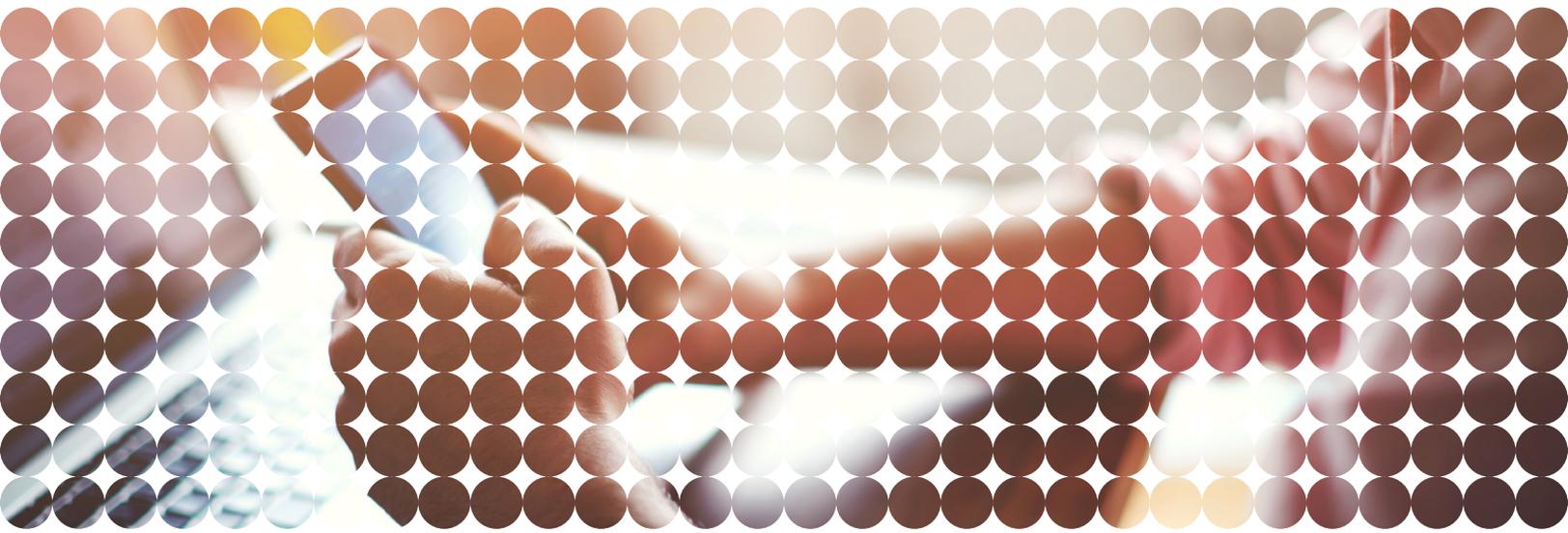




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Social Media in Clinical Trials Patients Will Talk, Blog, Tweet ...

By Brian Bollwage, JD
Vice President, Regulatory Affairs

Marc Hoffman, MD
Chief Medical Officer

Introduction

Social media's impact on marketed prescription drugs and devices is geographically limited to the two countries in the developed world that permit direct-to-consumer advertising: U.S. and New Zealand. However, social media can and does have a much broader potential impact on the clinical trial process.

Social media has been used very successfully as a patient recruitment tool. But recently concerns have been expressed about the potential impact that burgeoning social media may have on the blind of clinical trials and therefore its potential to compromise data integrity of research trials. [1]

The tendency has always existed for patients to attempt to gain insight into their treatment particularly in placebo-controlled or blinded comparator trials. The drive for self-preservation is a powerful force that must be recognized but cannot be controlled when conducting clinical research. Even prior to the rise of social media when patient inquiries were limited to patient interactions in the investigator's waiting room or outside the clinic, this potential to compromise data integrity did exist. But the potential is much stronger now. With the ascendance of patient websites like PatientsLikeMe.com, which now claims more than 250,000 members worldwide, there now exist growing networks that patients may attempt to leverage to improve their individual outcomes in a trial setting.

Trial sponsors and CROs must minimize any potential impact of study subject interactions on the trial outcome. The relatively sympathetic attitude that U.S. and New Zealand authorities have demonstrated in the area of social media use regarding approved products will not carry over to the clinical research arena. The U.S. Food and Drug Administration (FDA) has recently issued guidances concerning social media impact on approved drug products making it clear that the FDA will not hold a sponsor company responsible for unsolicited comments posted on social media by patients or physicians as long as they were not induced by the sponsor company. In fact, the sponsor company has no obligation, in the FDA's view, even to correct the misinformation. So, essentially, social media communications regarding approved drug products will not be held against a sponsor/manufacturer as long as they are not connected to the message.

However, the same will not be true as it applies to the social media impact on the integrity of a clinical trial if, for example, patient interactions result in a significant unblinding. The same tolerance would not be expected; quite the reverse would be expected of ALL relevant authorities globally. That is to say, while the sponsor may not have caused the unblinding to occur, if an unblinding event is significant enough to call into question the integrity of the trial data, the relevant authority can, and would be expected to, consider the disqualification of data from such trials. The potential negative impact on a product's development plans and the costs of "losing" a trial are quite obvious and are likely to occur even if the reasons for questioning a trial's integrity are due to factors outside a sponsor's control.

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Social media has been used very successfully as a patient recruitment tool. But recently concerns have been expressed about the potential impact that burgeoning social media may have on the blind of clinical trials and therefore its potential to compromise data integrity of research trials.

Discouraging Social Media Use

To stay ahead of the curve on this issue, language should be included in the patient informed consent form (ICF) to discourage the use of social media or other patient interaction methods. Obviously sponsors do not want to come across as heavy-handed or appear to be adopting the persona of “Big Brother.” But they can certainly ask patients to limit their discussion of their participation in a clinical trial to their family, friends and health care providers and remind them that most social media sources are unmonitored, unverified and therefore rife with errors and potentially quite misleading. In our opinion, any stronger statement would not likely be more effective in blunting patient-to-patient interaction and even could lead to negative perceptions about the clinical trial, the investigator, the sponsor or the CRO conducting the trial.

Sponsors may want to consider the scope of the statement to be used, on a case by case basis. For example, an open-label, single-arm, active-only study with an end point of survival would see little, if any, benefit from limiting patient interactions at least in regard to the primary efficacy end point. On the other hand, a placebo-controlled trial with a subjective end point like a patient reported outcome in a rare disease state, might result in significant protection of the blind by including such limiting language in the ICF.

Although the FDA issued guidance indicating that the sponsor or developer is not responsible for correcting social media posts about its products, that doesn’t mean that sponsors are absolved of all social media responsibility. Sponsors must remain aware of the potential for social media usage to threaten data integrity, especially for certain kinds of trials.

References

1. Marcus AD. Researchers Fret as Social Media Lift Veil on Drug Trials. Wall Street Journal. 2014 Jul 30.

About Chiltern

Chiltern is the leading, global mid-sized contract research organization that listens to client needs to deliver customized clinical development solutions. Chiltern’s team of more than 4,000 works across 47 countries to provide comprehensive, yet flexible and responsive, services with specialties in Biopharma, Medical Device & Diagnostics, Oncology, Clinical Analytics and Source. Visit Chiltern.com to learn more about solutions that are **Designed Around You®**.



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2528 Independence Blvd., Suite 101
Wilmington, NC 28412
USA
+1 910 338 4760

171 Bath Road
Slough, Berkshire SL1 4AA
UK
+44 (0) 1753 512 000

Lets.Talk@Chiltern.com
www.Chiltern.com