Quorum

Social Media Tools: Considerations for Use in Clinical Research

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DESCRIPTION

Social media is increasingly being used to support clinical trials as a recruitment, networking, and promotional tool. Utilizing these tools offers many benefits, but is not without risks. This whitepaper will discuss the intersection between social media and clinical trials, and the new challenges researchers face when using social media tools.

TOPICS

Social Media Tools in Clinical Research

The accelerating pace of technological advancements over the last 50 years has affected society and culture in ways that often cannot be predicted or controlled. Advances in medical technology have improved the efficiency and safety of clinical trials, and, concurrently, advances in communication technology have drastically changed the way we interact with each other. During the past 10 years, the meteoric increase in the usage of social media platforms across the globe has rendered them one of the most prominent methods of communication.

Social media is increasingly being used to support clinical trials—for example, as a subject recruitment and retention tool, to improve professional networking and education, in organizational promotion, to improve patient care and education, and to promote public health programs.[1] Utilizing these tools offers many benefits, however, there are also some risks. The focus of this whitepaper will be to discuss the intersection between social media and clinical trials and the new challenges researchers face when using social media tools. Mediating these risks is paramount in maintaining the integrity of clinical research.

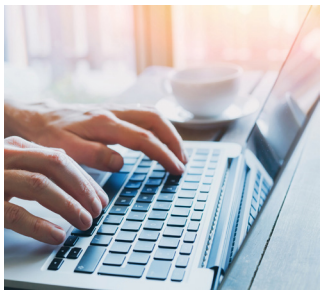
Background

Clinical research has improved the quality of life for millions of people around the world, providing information on investigational drugs and devices that may one day become better therapeutic options. The success of the clinical research enterprise is predicated on enrolling qualified subjects into studies, and retaining them for the duration of the protocol. One of the main sources of this success has been the integration of social media tools in clinical research.

What Are Social Media Tools?

Social media is an all-encompassing term used to describe online websites or app platforms including, but not limited to, Facebook, Twitter, and Instagram. The hallmark of these platforms is that they provide an avenue for both broad scope and ease of communication with the dynamic ability to interact with anyone in the world at any time, as individuals or in curated groups, quickly and almost effortlessly. The reach and ease of social media-based communications make them appealing and useful as a means of identifying and recruiting study participants. Enrolling adequate numbers of qualified participants has historically presented one of the biggest barriers to timely initiation of clinical research trials.

In recent years, social media has provided a means for clinical research sponsors to reach populations who were previously inaccessible. Using social media tools, sponsors have been able to connect with orphan disease populations, provide online support networks, and improve study-wide enrollment and education. The utility of social media in recruitment is captured by statistics pertaining to how health-related information is accessed.



Information and Access

A 2017 analysis by Statista showed that 81% of Internet users enjoy social media. Of these, 80% are looking for health information. A survey by PwC Health Research Institute found that 90% of 18-to-24 year-olds relied upon this source, using it twice as often as the more senior population.[2,3,4] Social media usage by doctors has risen dramatically from 41% in 2010 to 90% in 2011.[5] Furthermore, a growing majority of clinical participants—particularly those with chronic conditions—are seeking out social media and other online sources to acquire health information, connect with others affected by similar conditions, and play a more active role in their healthcare decisions.[6-9] This is especially appealing for people with orphan diseases, those who belong to a vulnerable population, or those who live in rural areas. Online sources can also provide patient populations with information on different trial options for their conditions.

However, awareness of a trial is not the same as understanding the potential risks and benefits of participation in the study. There is evidence to suggest that another barrier to enrollment is a lack of awareness (by referring physicians as well as potential participants) of what might be gained by participating, or that participating in clinical research is even an option. The National Cancer Institute (NCI) HINTS (Health Information Trends Survey) found that 34% of Americans have not heard of a clinical trial.[10]

Communication through social media tools are one solution to this dilemma. By offering a user-friendly platform, social media can be used to educate potential participants and provide an online venue for enrolled subjects to discuss the study. It can also serve as a space within which study physicians interact with, educate, inform, and monitor subjects. However, sometimes information that is shared can have problematic consequences.

One recent example was the case of Ms. Burtchell, a 53-year-old resident of East Palatka, Fla., who was diagnosed with Multiple Sclerosis (MS) that involves relapses interspersed with remission. Journalist Amy Dockser Marcus wrote about Ms. Burtchell in an article that appeared in *The Wall Street Journal:*

> "... By 2007 she estimates she had suffered nearly 30 relapses and was so exhausted she had difficulty caring for her young son. She enrolled in a trial for an experimental therapy from ... that aimed to be the first pill for the disease, which was treatable only with injectable drugs. The trial matched one of injectable therapy, Avonex, against the experimental oral drug, called fingolimod. Ms. Burtchell started a blog to chronicle her experience from start to finish. In the post after her first treatment, she told why she believed she was getting fingolimod. In the past, she had taken injections for her condition. In the trial, she didn't feel the stinging or pain she remembered from shots—a sign, she believed, that her injection in the trial was a placebo. Also, after she was given a pill, she noticed a nurse recorded a fall in her blood pressure, which she knew was a potential side effect of the experimental drug. Nearly three months into the trial, Ms. Burtchell posted that, for the first time since her MS diagnosis, she was able to hop on one foot. "Maybe it's the Fingolimod...," she speculated. "Whatever it is, I feel better every day." When information on the study was revealed, it turned out she was indeed getting the experimental drug.[11]"

In that same article, Craig H. Lipset, head of clinical innovation at a leading pharmaceutical company, comments that clinical trial participants who share too much "could effectively chill a new drug before it ever gets to patients by misinterpreting early signals."[11]

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Given the divergent cultures of medical research—which values privacy, confidentiality, one-on-one interactions, and formal conduct—and social media—which values sharing, transparency, connection, and informality—it is not surprising that the increased use of social media platforms has generated dismay in the clinical research field.[12] Access to information and community support can create a positive experience for the research participant, but seeking this information isn't risk free. One of the biggest challenges with social media use is managing user-generated online content. This is especially important in situations such as the example discussed above. The clinical research industry should take steps to protect research participants from user-generated content that might compromise study integrity.

Managing User-Generated Content

At Quorum, we work with sponsors and sites to protect the rights, welfare, and safety of research participants. In the context of social media, we apply these principles by assisting the sponsor and sites with identifying and circumventing the following potential problems:

1. Language or interactions that promote therapeutic misconception, make unfounded promise of benefit, or are unduly influencing or misleading, or otherwise inappropriate statements or comments that may bias or skew the reporting or results of a study.
2. Breaking study blinds, and putting participants' personal health information at risk of disclosure.
3. The risks associated with public perception and personal testimony on clinical trials vs. an actual clinical finding.

Preserving Scientific and Ethical Integrity in the Context of User-Generated Content

There are many stages of the research process, from conception to implementation to analysis and dissemination of results. At each stage, scientific and ethical vulnerabilities exist that, if exploited, can undermine the validity and utility of research results.

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According to Communicating Science Effectively: A Research Agenda from The National Academies Press: Sciences, Engineering and Medicine, the sources of scientific dispute fall into the following loose categories:

- Conflicts over the beliefs, values, and interests of individuals and organizations, rather than simply a need for scientific knowledge, are central to dispute.
- The public perceives uncertainty either in the science or its implications or as a result of communicators making different and sometimes contradictory statements in the public sphere.
- The voices of organized interests and influential individuals are amplified in public discourse, making it difficult for the state of the scientific evidence to become clearly known.

We have added another point, which is based on real-life experience.

- User-generated content on social media is a potential source for statements that can influence the outcome of a clinical trial. Comments that provide past, current, or future participants with misinformation can threaten the integrity of research. The broad and instantaneous distribution patterns of social media can amplify the potential negative impact of user-generated statements.

Study Blinds and Maintaining Data Integrity

User-generated posts can influence how other participants recognize and report their own symptoms. The posts can trigger the following psychological phenomena:

- Social Proof, where people assume the actions of others in an attempt to reflect correct behavior for a given situation.

- Confirmation Bias, the tendency to interpret new evidence as confirmation of one's existing beliefs or theories.

- The Placebo Effect, the belief in a beneficial effect, produced by a placebo drug or treatment, that cannot be attributed to the properties of the placebo itself, and must therefore be due to the patient's belief in that treatment.

All these phenomena can alter the clinical data collected in a study and potentially lead to harm.

If the study is blinded, some participants may be taking a placebo while others receive active drug. Information shared on social media posts may lead to inaccurate symptoms reporting and experiences. We should also be concerned about how public journalists, blog writers, or other communicative avenues project and interpret study participant claims.

In addition, sharing or seeing information could put pressure on research participants to withhold seemingly unimportant information in an attempt to remain on the study drug. Participants may be embarrassed about or uncomfortable with sharing this information even though a serious risk could be associated with the information. This is an important consideration in cases where the study drug may be working for participants with varying levels of side effects.

Breaking study blinds is not limited to conversations between participants. There is potential that conversations between study staff and participants can lead to study blinds being broken. While such breaking of blinds is generally unlikely, this is important to consider if/when information pertaining to a non-double-blind study is discussed in public or on social media. Inadvertent slips in conversation can increase the risk of study-related information being shared to a participant from a staff member.

While reading the minds of research participants is not possible, sponsors and CROs can work with IRBs to stay on top of these issues by developing a sound and efficient social media management plan. Such a plan provides a preemptive means by which all study staff or a designated staff member can be trained to deal with user-generated content that compromises study integrity. Mediating risk associated with inappropriate/misleading or therapeutically misleading comments, study result testimonials, or otherwise inappropriate language can add another layer of protections to your study. With Food and Drug Administration (FDA) guidance, Quorum has provided details on what elements make a quality social media management plan.

Public Perception in Clinical Research

According to a survey conducted by Sprout Social, a social media management and optimization platform, 70% of the survey population claimed that use of social media improves transparency, thus providing easy access to information.[14] That same survey also mentioned that a social media manager has approximately 24-48 hours to respond to content posted before it has the potential to be seen by the social media community at large or "go viral"[14] (commonly understood to mean the exponential sharing and passing of information on social media in a very short period of time). While going viral can make information more accessible, there are concerns around misinformation being spread and the public's perception of that information.

Discussions among scientists and the general public provide, in essence, a self-correcting environment that ameliorates this issue. Having questions or concerns answered by the principal investigator and study staff reduces risk associated with misinformation being provided to participants or potential participants. In a publication from the National Academies of Sciences, Engineering, and Medicine titled, Communicating Science Effectively some points were raised regarding how the scientific community interacts with public perception:

> *"Public debate about the issues—among the scientific community, policy makers, and citizens—can help uncover common ground among people holding diverse sets of values. Although this is not always the case, clear information from science can enable people to make more informed choices. Healthy debate also can strengthen the science, challenging its claims and leading to a push for better forms of evidence. Communicating science is almost always a complex task in part because scientific information and its implications are understood, perceived, and interpreted differently by different individuals, social groups, communities, and decision-making bodies. This phenomenon is not unique to science, but is important because it makes the process of communicating science difficult."*[13]

While public perception of a research study may remain neutral in most cases, controversy can arise when public opinion influences the outcomes of clinical research with little or no scientific data to support those opinions. In addition, curious research participants may also attempt to discover which treatment arm they belong to, and this investigation can influence reporting. These issues can be amplified when use of social media tools are added to the equation.

As previously discussed, user-generated social media content is an unpredictable variable in clinical research. Two potential and particularly problematic effects on public perception are:

1. Positively reinforcing opinions of the public before statistically significant and conclusive claims can be made about the safety and efficacy of an investigational drug. Such opinions can lead to therapeutic misconception, undue influence, and an unfounded degree of comfort with joining a research study.

2. Negative claims and comments can also influence the outcome of a clinical trial. Participant claims about lack of efficacy or opinions on study staff that can stifle progression of clinical research or become a detriment to a clinical research group's credibility. These types of claims are especially concerning because there is potential for them to be misleading or completely fabricated by research participants who are not happy with the outcomes of an investigational drug trial.

Controversies stem from the human tendency to focus on positive and negative outcomes associated with something that an individual does not fully or accurately understand. As a scientific community, it is our duty to educate the public in a way that prevents laypeople from irresponsibly engaging in social media and contributing to controversies.

SEEKING INFORMATION ON THE USE OF SOCIAL MEDIA IN CLINICAL TRIALS

Social media has helped many clinical trials succeed and will continue to play a role in the success of research. Ultimately, the responsibility for management and maintenance of social media tools used for research falls on the sponsor. IRBs and the FDA will continue to provide guidance for best practices on how we should communicate while involved in clinical research.

Quorum has provided much content on how to effectively use social media in clinical trials. You can find more of that information at quorumreview.com/knowledge-center. We recommend reading "Human Subject Protection in the Age of Social Media" and viewing our webinar "Embracing Social media in Clinical Trials."

Resources

1. Ventola, C. Lee. "Social Media and Health Care Professionals: Benefits, Risks, and Best Practices." Pharmacy and Therapeutics 39.7 (2014): 491–520. Print.

2. Fox, Susannah. "Health Topics: Food safety, drug safety, and pregnancy information are among eight new topics included in our survey." Pew Research Center (2011)

3. Statista. Social Media Statistics and Facts. https://www.statista.com/topics/1164/social-networks/

4. PwC Health Research Institute Survey. https://www.pwc.com/us/en/health-industries/health-research-institute/publications/pdf/health-care-social-media-report.pdf

5. George DR, Green M, Navarro A, Stazyk K, Clark M. Social media in medicine reexamined: Results from a national survey on medical students' use of Facebook and other networking technologies. Am J Bioethics. In press.

6. Bosslet G, Torke A, Hickman S, Terry C, Helft P. The Patient–Doctor Relationship and Online Social Networks: Results of a National Survey. J Gen Intern Med. 2011:1–7. [PMC free article] [PubMed]

7. Modahl M, Tompsett L, Moorhead T. [Accessed January 15, 2013.]; Doctors, Patients & Social Media. 2011 Available at: http://www.quantiamd.com/q-qcp/DoctorsPatientSocialMedia.pdf

8. Fox S, Jones S. The Social Life of Health Information. Pew Internet & American Life Project. 2009

9. Fox S, Purcell K. Chronic Disease and the Internet. Pew Internet and American Life Project. 2009

10. Thompson, Mike. (2014). Social Media in Clinical Trials. American Society of Clinical Oncology educational book / ASCO. American Society of Clinical Oncology. Meeting. 34. e101-5. 10.14694/EdBook_AM.2014.34.e101.

11. Marcus, Amy D. "Researchers Fret as Social Media Lift Veil on Drug Trials: Online Chatter Could Unravel Carefully Built Construct of 'Blind' Clinical Trials" Wall street Journal; July 29, 2014.

12. George, Daniel R., Liza S. Rovniak, and Jennifer L. Kraschnewski. "Dangers and Opportunities for Social Media in Medicine." Clinical obstetrics and gynecology 56.3 (2013): 10.1097/GRF.0b013e318297dc38. PMC. Web. 12 Sept. 2018.

13. National Academies of Sciences, Engineering, and Medicine. 2017. Communicating Science Effectively: A Research Agenda. Washington, DC: The National Academies Press. https://doi.org/10.17226/23674

14. Sprout Social. "Call Out Culture: People, brands & the Social Media Power Struggle" https://media.sproutsocial.com/uploads/2017/08/2017-q3-sprout-social-index.pdf

About Quorum

Quorum Review IRB is the most preferred central IRB. We help clients accelerate research through faster study start-up, reduced fulfillment time, and the largest offering of complimentary study support services. We are the only IRB to offer harmonized IRB and IBC review, API integrations, award-winning site support, and consulting services that move your research forward. Quorum provides a better experience with custom guidance and a personalized client-friendly approach. Our commitment to your success means:

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- 99.8% of initial documents delivered early or on time

The Quorum philosophy of One-Touch Collaboration™ builds flexibility and timeliness into your research reviews for increased efficiency:

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- One board
- One study contact
- One start-up timeline

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- Increase accuracy
- Customize your data delivery
- Operate from a single system
- Automatically update your eTMF system

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