MULTI-REGIONAL CLINICAL TRIALS
BIOETHICS
COLLABORATIVE

Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard Bioethics Collaborative

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Impact of Social Media on Clinical Trial Integrity | Meeting Summary

The January 22, 2019, meeting of the MRCT Center Bioethics Collaborative convened twenty-one stakeholders from academia, industry, patient advocacy organizations, foundations and independent IRBs to examine the **Impact of Social Media on Clinical Trial Integrity.**

Introduction

Social media use has increased exponentially over the past decade and is now virtually ubiquitous across all age brackets. The clinical research sphere has been no exception, with social media emerging as a medium for conducting research, recruiting participants, and facilitating participant interactions. The use of social media in clinical research carries many potential benefits—for example, it enables the creation of valuable support and communication networks for research participants. It also carries potential risks, however, including the possibility that participants may share information online in ways that permit themselves, other participants, and/or the research team to be unblinded to or inappropriately influence key aspects of the research data. These potential benefits and risks, as well as the practical approaches by which they may be balanced, were the focus of the January 22 meeting of the MRCT Center Bioethics Collaborative.

Meeting Summary

The MRCT Center Bioethics Collaborative meeting began with a high-level overview of the varied ways in which social media interfaces with clinical research. Although research may be conducted via social media platforms, and social media may be a promising tool for participant recruitment and/or engagement, these topics were not the focus of the meeting. Instead, discussion sought to highlight the impact of communication between and among research participants on the conduct and integrity of ongoing clinical trials. For purposes of clarification, *social media* was defined as any mechanism through which research participants interact with each other online. Social media, therefore, was not limited to popular sites like Facebook and Twitter; it extended to small-scale platforms, such as personal blogs, chat rooms, and discussion forums.

Before confronting the ethical and operational challenges presented by social media, attendees discussed the benefits that social media offers clinical trial participants. All individuals have a fundamental need to be heard and understood. This need grows more acute during times of heightened anxiety, confusion, or uncertainty—for example, after a diagnosis, before starting treatment, or during the course of a clinical trial. In search of support, comfort, hope, and communication, clinical trial participants turn to social media. Belonging to a community—whether actual or virtual—allows participants to engage people in meaningful peer-to-peer communication. Moreover, sponsors, investigators, and study personnel can communicate with participants in innovative ways that help to address a need for information. A number of these novel methods were discussed.

Attendees then explored the risks that social media communication poses to study integrity. Publicly sharing information about an ongoing clinical trial has the potential to (1) unblind study participants and/or researchers, (2) encourage participants to withdraw early, (3) enable rogue study participation, such as sharing tips for avoiding exclusion criteria or taking a prohibited concomitant medication, and (4) negatively impact the collection of safety and efficacy data, such as withholding adverse events that should be reported. It was noted that the degree to which these risks are present in a given trial depends on a number of study characteristics. For instance, randomized, double-blind, placebo-controlled trials are particularly vulnerable to these risks, as information sharing among participants may influence perceptions of adverse events and/or efficacy of study drug. Additionally, trials enrolling participants with rare diseases and/or diseases with highly active advocacy communities, as well as studies with subjective endpoints, are particularly susceptible to issues of scientific integrity. In contrast, observational studies or unblinded studies are less susceptible to challenge by social media communications

Attendees agreed that some, but not all, forms of online communication pose risks to the integrity of clinical trials. Attendees also recognized the importance of the benefits of online communication to participants, noting that such benefits should be taken into account when formulating risk-mitigation strategies. As such, attendees suggested that risk-minimization strategies should focus on education, rather than regulation or attempts to forbid it (e.g. by contract in an informed consent document). Ensuring the integrity of clinical trials is a collective responsibility shared by industry, investigators, and participants.

Potential Future Work

To advance and operationalize discussions of the impact of social media on clinical trial integrity, the following ideas were suggested as potential next steps:

- Develop a *Points to Consider* document for sponsors, research sites, and/or IRBs that summarizes the risks and benefits of online communication among research participants. Included in this document could be a description of the study characteristics that make a trial more vulnerable to the negative impacts of social media on scientific integrity, as well as some strategies for assessing risks in these studies.
- Aggregate ongoing initiatives and projects related to educating clinical trial participants about social media use.
- Develop guidance for IRBs and investigators on communicating the expectations and limitations of social media use to clinical trial participants. This guidance could include template Informed Consent Form language.
- Create educational tools for research participants regarding the implications of online communication for clinical trial integrity. Educational tools could consist of pamphlets, other written materials, short videos, comic books, or other.