The New Imperative

The role of social media in our day-to-day lives has created an opportunity for orphan disease researchers to capitalise on, granting access to a wider participant pool for recruitment

Barbara Zupancic at Worldwide Clinical Trials

The social media revolution has created opportunities for communication in all aspects of life, including clinical research. It provides new ways for patients to gain information related to medical care and connect with other patients and support networks. Clinical trial advertising and associated regulations are changing rapidly; print advertising has been on a steady decline, while online advertising continues to grow as more and more companies see the value and potential to reach large numbers of patients via the internet. For ultra-rare and rare disease researchers, the geographic reach and capabilities for targeted messaging present new means of accessing patients worldwide. As social media becomes a primary resource for global communication, the opportunities available to research organisations are too compelling to be ignored. Sponsors and research organisations must address the reality of social media from an information management perspective in order to preserve the systems and protocols that maintain the integrity of drug development processes.

From a regulatory standpoint, the FDA has responded to aspects of social media use with respect to clinical trials. These draft guidance documents, released in 2011 and 2014, address the presentation of benefit and risk information within the character limitations on various digital platforms, the correction of third-party misinformation related to prescription drugs and medical devices, the fulfilment of regulatory requirements for post-marketing submissions of interactive promotional media for prescription human and animal drugs and biologics, and the methods of responding to unsolicited requests via social media for off-label information on prescription drugs and medical devices. These seminal documents do not fully address the ways in which current social media engagement by patients and other stakeholders can affect the execution of clinical trials and the regulatory viability of resulting study data.

Opportunities

The opportunities for medical research stakeholders to advance clinical trial performance through social media engagement are self-evident, but the scale can easily be overlooked. Statista set the global rate of social media penetration at 45% in January 2019 (1). With almost all

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young people in developed countries engaging in digital media at nearly full saturation, social media has become a hub for educational and promotional communications. For researchers working in the orphan disease space, where patients are rare and widespread, adoption of digital media is becoming an operational imperative in order to reach sufficient numbers of target patients (2).

In addition to the dissemination of information, digital and electronic media pose a number of opportunities to those working in pharmaceutical R&D, particularly with respect to rare and orphan diseases.

Patient Recruitment

Given that patients with rare diseases and their caregivers are actively seeking treatments, social media platforms provide an ideal venue for researchers seeking to build cohorts of hard-to-find patient populations. Facebook alone, with more than 1 billion users, is an arena for promoting novel treatment ideas, engaging with patients and their caregivers to learn more about their experiences, and actively recruiting both patients and medical care professionals to participate in clinical trials.

International Clinical Trials, *November 2019 issue, pages 12-14.*

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Retention
Patient retention is of particularly critical concern in orphan disease studies, where cohorts are small and recruitment of new patients is difficult. The social engagement and dialogue opportunities presented through digital media platforms have been proven to support clinical trial compliance and reduce attrition rates. Communication via commonly used social media sites can provide encouragement and support to study participants (3).

Patient Advocate Engagement
As regulatory and legislative interests are moving increasingly towards patient centricity, patient advocacy becomes a valuable resource to drug development programmes (4). Social media provides a platform for researchers to communicate and collaborate with disease-specific support and advocacy groups. Such groups often disseminate clinical trial information to their many members. Their ultimate goal is the treatment and care of patients, so these groups can add crucial momentum to industry efforts to promote awareness of medical breakthroughs and win approval for much-needed novel treatments.

Targeted Advertising
Advertising services provided by social media platforms such as Facebook have proven particularly beneficial when trying to connect with patient populations that are hard to reach, and, therefore, they are well suited to rare and orphan disease populations (5). Electronic media ads have also proven useful in targeting medical care professionals who are seeking advisory and research information for their patients (2).

Geographic Reach
Electronic media provides a low-cost, high-speed means of connecting with patients and caregivers, even for those in remote locations and those who do not have access to conventional standards of healthcare. For researchers working with orphan and rare diseases, this fast and economical access to remote patients is essential to building suitable cohorts.

As a business proposition and research opportunity, social media engagement is becoming a necessary next step for sponsors and CROs seeking to maintain their position in the orphan and rare disease research space. The spontaneous and instantaneous engagement and communication taking place via digital media provides researchers and drug developers with geographic reach, access to patient experience and disease symptom data, and opportunities to engage with medical care professionals and patient advocates.

Vulnerabilities

Stakeholders must remain engaged and vigilant because of the potential for misinformation, blind breaking, and biased recruiting when engaging with social media. Without a clear view of the ways in which social media communications create vulnerabilities for drug development programmes and clinical trial operations, sponsors and CROs are under increasing threat to their general brand messaging, the performance of specific studies, and the integrity of study data.

Haphazard Brand Messaging
Without clear, authoritative messaging from the sponsors and research organisations involved in the development of novel treatments, there is a potential for a plethora of misinformation. While digital media is a useful resource for recruiting study subjects, the positive messaging can be undermined by participants expressing their frustrations in a public post (6). It is critical that stakeholders driving clinical trials and overseeing regulatory compliance take a collaborative approach to information management with respect to social media.

Biased Recruiting
While social media provides the opportunity to recruit higher numbers of patients without a large investment of time or money, it also introduces the risk of cohorts that are not suitably cohesive or demographically representative, particularly in terms of race and gender (2). Without a better framework in place to offset the impact of social media user demographics, such biases are inevitable and can place clinical trials at high risk of failure.

Privacy Issues
While the openness of social media communication is essentially a positive force, it introduces a new threat to clinical trial operations where regulatory and legislative requirements outline explicit privacy protections. Studies have suffered from incidences of blind breaking when trial participants share information online in attempts to identify which of them are receiving placebo treatments (6). At best, such protocol violations cause expensive delays as researchers must discontinue these patients and recruit new ones. At worst, they create disincentives to new patient recruits and can even place the study at risk of failure due to protocol violations.

Undue Influence on Symptom Reporting
When patients are sharing their experiences in public forums, there is a risk that clinical trial participants may be influenced in their reporting of symptom data (6). In cases of patient-

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reported outcomes and observer-reported outcomes, there is a risk that the individuals responsible for reporting symptoms and outcomes may be inadvertently influenced by information they receive from public posts. Particularly in orphan and rare disease studies, where there is a dearth of patient homogeneity, such influence on symptom reporting by patients or caregivers can be detrimental to data integrity (7).

The only way to safeguard against misinformation and protocol violations is to step into the fray with effective strategies for monitoring and managing potential threats to the success of ongoing development and research initiatives.

Strategies

For pharma research to thrive in the face of the opportunities and vulnerabilities posed by the inevitable growth of social media, it is imperative that strategies be enacted to protect the effective execution of drug development projects. The open flow of information among patients, caregivers, medical professionals, and the scientific community is a resource that is most valuable when the appropriate constraints enable the protection of privacy and safeguard against misinformation.

Collaborative Messaging

As sponsors work with CROs to design and execute drug studies, they should agree on a plan for the curation and dissemination of information intended for public consumption. A clearly organised communication strategy creates a consistent, authoritative message that serves to counterbalance and correct misinformation.

Proactive Approach to Information Sharing

As part of the clinical study design process, CROs may develop a digital forum in which participants can engage in a frank exchange of experiences and ideas with one another and with other trial stakeholders. This monitored setting would provide a space for communication while also safeguarding trial protocols.

Updated Recruitment Methods

Best practices for recruitment should be established specific to the arena of social media, where user demographics do not proportionately reflect real-world populations.

The Bottom Line

In the face of increasing digital media interaction worldwide, the bottom line for pharma sponsors and CROs, particularly those working in the orphan disease space, is that engagement is necessary for growth, whereas a lack of engagement can jeopardise success in any future programmes. Social media platforms offer the geographic reach and opportunity for an exchange of information among patients, caregivers, and researchers – both key factors contributing to success in orphan disease research. As for the related risks, a coordination of efforts will be required on the parts of industry stakeholders and regulatory agencies to develop a consistent and reliable framework for social media engagement related to drug development initiatives. The goal should be to optimise the positive opportunities of social media for orphan disease patients and researchers alike, articulate and enforce appropriate constraints that protect vulnerable aspects of research projects, and mitigate any risks posed to the success of beneficial medical treatments.

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About the author

Barbara Zupancic is the Senior Director, Patient Recruitment and Retention, at Worldwide Clinical Trials. Barbara has over 15 years of experience in clinical research, specifically focused on patient recruitment and feasibility. Passionate about engaging patient volunteers to better the lives of many, Barbara has spent countless hours in the field working with various types of research sites and patient groups. Barbara's passion is in the rare disease arena as well as CNS, specifically Alzheimer's disease. She is a frequent speaker at conferences, has conducted numerous webinars, and is a published author. Barbara has a Bachelor of Science in Psychology, Masters of Science in Counseling Psychology and Research, and an MBA in Management.