Unlocking the Potential of Social Media in Drug Safety

Drug safety and pharmacovigilance (PV) have evolved and grown significantly more complex over the past decade due to higher data volumes, evolving regulations, increased influence of emerging markets and the emergence of social media and innovative technological advances. The phenomenal reach of the internet has led to a revolutionary shift in how people are communicating with one another, with digital platforms and applications quickly becoming the go-to form of communication in the era of Web 2.0.

However, unlike other areas such as clinical medicine, the use of the internet and social media has progressed slower in product safety and PV. This presents the biopharmaceutical industry with exciting opportunities, and challenges, for the appropriate and effective use of social media for the detection, assessment, understanding and prevention of adverse effects and other drug-related issues. Within the last decade, social platforms have become powerful sources for news updates, viral marketing, online networking and entertainment, and hold the promise to drive consequential and valuable changes in PV.

Social media presents new channels and methods for companies to move away from traditional PV systems and safety reporting methods towards more patient-centric models for reporting, analysing and monitoring of safety data. These channels have the capability to allow swift and open communication between drug companies and their consumers, patients and healthcare providers, thereby helping foster transparency and build public trust. With this said, careful evaluation and assessment of employing social media as a PV tool needs to be conducted; in terms of its meaningfulness and impact on outcomes, validity of the use of data obtained via social media channels, adherence to regulations and laws and overall cost-benefit analysis.

This article examines how the influence and reach of the internet and social media can be harnessed to drive valuable outcomes for the PV industry. It details the industry's current state and future considerations for use of social media in PV, possible areas of influence, expected challenges, potential solutions and next steps.

Social Media in Pharmacovigilance - Current Regulations and Impact

Today, biopharmaceutical companies operating in the social media space have a responsibility to document and follow-up on any potential adverse outcomes communicated through these forums. Companies must comply with all applicable legislations including the European legislations (Regulation 726/2004 (as amended by Regulation 1235/2010) and Directive 2001/83/EC (as amended by Directive 2010/84/EU)[1,2] and the US Food and Drug Administration (FDA) guidance for product promotion on social media and the internet by biopharmaceutical and medical device companies[3,4,5,6]. The FDA draft guidance documents address different aspects including how pharmaceutical and device companies should respond to off-label inquiries, including inquiries from digital platforms[3], how to provide benefit and risk information on internet and social media platforms with character space limitations (e.g. Twitter)[4], how to address misinformation about company products on the internet and social media websites[5] and how to fulfill company post-marketing regulatory requirements for submission of "interactive promotional media" for their FDA-approved products[6].

These regulatory guidelines have helped clarify, to a certain extent, the thinking and approach of regulatory authorities towards evaluating content shared on internet and social media platforms, and serve as an important first step towards providing guidance for companies to develop and implement their social media strategies for PV.

Today, biopharmaceutical companies are actively engaged in identifying and understanding the value drivers for adopting a comprehensive PV social media strategy including proactively creating social media platforms that solicit, capture, monitor and report AE activities, and also examining the successes and challenges of the of the social media platforms being used. For example, there are now multiple sites and applications for safety reporting, such as MedWatcher, a free tool that allows patients and physicians to submit "adverse event" reports to the FDA via smartphone or tablet. The primary purpose of such tools is to provide patients or healthcare professionals (HCPs) information on drugs, devices, interactions and other pharmaceutical information, while some also allow reporting of adverse events (AEs).

Companies provide their employees with social media guidance and best practices to facilitate effective safety reporting via social media[7]. By employing appropriate and sufficient controls over social media sites, organisations can avoid potential gaps/risks in the areas of reporting, identification and monitoring of AE data, thereby developing a cohesive and effective social media ecosystem.

Social Media for Safety Data Reporting and Follow-up

Social data offers some advantages over traditionally reported safety data or data mined from health and reimbursement records. Social reports are rapid, closer to real-time data and potentially richer sources than reports filtered through HCPs. Social media channels have the potential to act as a significant source of AEs, data on off-label use and impact of treatments on quality of life. One of the key areas of influence is, therefore, to establish social media as a safety reporting channel by expanding its existing use and unlocking its potential as a value-add for companies' PV strategies.

Social media platforms, by design, can work to increase connections between companies and healthcare consumers. This gives companies an opportunity to directly connect, engage and encourage patients and consumers to report more, helping address the concern of adverse events going unreported.

Per the applicable FDA draft guidance for AE reporting and good pharmacovigilance practices (GVP) Module VI[2], only valid

individual case safety reports (ICSRs); consisting of four criteria; identifiable patient, identifiable reporter, suspect product and adverse event/reaction, qualify for reporting. Further, GVP module VI (Section VI.B.2, page 12) states: "When collecting reports of suspected adverse reactions via the internet or digital media, the term "identifiable" refers to the possibility of verification of the existence of a reporter and a patient (see VI.B.1.1.4)."

In a social media setting, patients are likely to be reporters themselves, without any confirmation of data from healthcare professionals (HCPs). Credibility and origin of these self-generated reports are key issues. Also, there is concern that social media with no appropriate checks on provenance can open the avenue to unscrupulous attacks from "pseudo-reporters". Further, the absence of oversight of the social media means that data may be inadequate and inconsistent, and require additional follow-up. Another concern is around the fact that PV data obtained via social media would contain personal data related to the patient (subject of the case) and the reporter (patient's healthcare provider, family member or the patient themselves). Overcoming these hurdles for confirmation of "identifiability" of both patient and reporter, and thereby validation of incoming safety data obtained via social media, becomes critical.

Companies need to prioritise and focus on company-managed social media websites to help decrease the chances of receiving incomplete and/or duplicate adverse event reports from different online reporting channels and help maintain the reliability of incoming data.

Validation of the reported information in a credible and identifiable way is possible by allowing posts/shares on company-monitored websites only after the user has registered and recorded basic user information. This can help PV teams verify the reported data with respect to the four minimal criteria to confirm case validity, confirm that a patient exists within each potential reporting scenario, and follow up with any additional questions on the report.

This processing of personal data for PV by companies needs to be in compliance with the applicable data protection laws, along with transparent and robust processes to ensure personal data protection. A data protection notice should be given on company-sponsored sites, that user-generated information deemed to be an adverse event (AE) or product complaint (PC) will be collected by the company in order to meet legal obligations, with explanation on why such information is beneficial for the protection of public health. It should also be noted that the company may follow up directly with the individual who generated the AE/PC information in order to gain more information. Regular training in data protection requirements is recommended for all company staff involved in PV activities[8].

Social Media and Big Data Challenges

Social media is a promising source for new safety data and potential emergent safety signals. However, this data is unstructured, without governing data quality standards and specific business area orientation. In addition, the sheer size of the information and its rapidly changing nature, makes it a big data problem. Consequently, companies may struggle to integrate adverse event reports received through social media with reports received from more standard sources like email correspondence or physician hotlines. In addition, the retrieval and analysis of safety data, obtained via social media channels entails extra workload and additional resources, given the size and success of social media.

Another concern is the potential bias introduced by the "reporter population" and thereby accurate representation of the reported safety data. Of the large number of social media users, only a small percentage (1%) are actually commenting and reporting AEs, while most others are only occasional contributors or simply observers/readers. Also, many elderly individuals do not use social media and this is important because it creates a strong user bias for PV as this demographic is a large user of prescription medications.

There are a number of additional technical challenges to be addressed here, including:

1. Duplicate safety information i.e. same adverse drug reaction (ADR) reported by the same, or a different, user, on multiple digital media platforms
2. Multiple languages and how data collected in different languages maps to standard ADR
3. Data privacy and personal data protection
4. Data curation and cleaning to mitigate the risk of spreading rumours/false safety concerns

On top of all this, are the global diversity challenges, not just confined to linguistic issues and translation, but relating to social structures, practices and intangibles[9]. Overcoming these social media hurdles for validation and consolidation of incoming data is problematic and requires intensive efforts of the PV teams.

Social Media and Global Initiatives

Both biopharmaceutical and life sciences companies, along with regulators, now recognise the benefit of adapting automated tools for big data analytics to help manage and differentiate between signals received from social media platforms and any accompanying noise.

Google Insights for Search is a tool that allows one to look at any public concerns, as measured by web traffic, which can include drugs and disease terms and browsing possible associations. Although an interesting tool, it currently lacks precision, has limited use in deriving possible associations between adverse events and a companies' products, and does not help companies prioritise amongst an influx of incoming social media signals[9]. The FDA is currently actively exploring a number of such social media-based tools and strategies, including Google-based search tools towards optimising safety data gathering from social media sites.

The WEBAE project (Web Adverse Events) aims to form a specialist public-private consortium between the EFPIA (European Federation of Pharmaceutical Industries and Associations) and the Applicant Consortium to undertake research for the development of policy and technology solutions in pharmacovigilance to strengthen the protection of public

health[10]. This will enable mining of publicly available web and social media content and help adopt methodologies and data-mining algorithms applicable to social media content in order to find emerging, self-reported medical insights such as adverse events associated with medicines and medical devices. This programme also intends to enable direct reporting of suspected ADRs to national competent authorities via EudraVigilance, with required applications available to all users of tablets, smartphones, and mobiles for all major platforms as well as social networking sites.

Employing Social Media as a Transformational Asset for Risk Communication

There are multiple ways for industry to positively engage consumers and healthcare providers while adhering to the regulatory guidance[1, 2, 3, 4, 5]. The first step is switching to a proactive company mindset that focuses on listening, educating, building trust, increasing safety awareness, and improving health outcomes. Some ways that PV teams can use social media to engage and improve awareness about the safety of a product, and provide more value to patients and healthcare professionals, can be seen in Figure 1.

Figure 1: Using social media to engage and improve awareness about product safety

Summary

The use of social media forums and channels focusing on various health-related topics, including diseases and associated treatments, has increased rapidly in recent years. However, unlike many other areas in the healthcare industry, social media do not yet play a major role in drug safety and PV. Appropriate engagement of consumers and healthcare providers through social media by PV teams, certainly holds the promise of better outcomes (Figure 2).

Figure 2: Social media promises better outcomes

There are many questions that need to be addressed before the industry can be comfortable with the use of social data for drug safety surveillance.

Though traditional PV methods will certainly prevail, social media has the potential to become an added new-age tool to cull data in real time, making it an early indicator of potential safety issues for further investigation. Further, companies can generate more robust product safety profiles by leveraging the additional social media information. Overall, the benefits of social media engagement for PV seem to significantly outweigh perceived risks. The time is now right to elevate the PV role to a more strategic level through appropriate and effective use of social media to drive better PV outcomes.

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Supriya Desai MD, PGDBM is a Clinical Research and Pharmacovigilance (PV) Executive with over 16 years of experience in clinical practice and in various leadership roles in the healthcare industry including clinical research, drug safety and PV. In her current role as Medical Director and Practice Head at Sciformix, she provides scientific and operational leadership to a global medical team (across India, Philippines and US); involved in medical review activities across pharmacovigilance, safety writing, signal management and allied safety surveillance activities, spanning diverse therapeutic areas.