Industry Usage of Social and Digital Media Communities in Clinical Research

A Tufts Center for the Study of Drug Development White Paper

JUNE 2014

Introduction

Between March and December 2013, The Tufts Center for the Study of Drug Development (Tufts CSDD) convened a working group of 20 pharmaceutical and biotechnology companies, and contract research organizations (CROs) to assess current and anticipated use of social and digital media communities in clinical research; to identify challenges, receptivity and concerns about usage; and to develop a comprehensive set of management principles and policies designed to optimize the value and minimize risk posed by social and digital media use in clinical research.

As part of this effort, Tufts CSDD conducted landscape assessments to gather case examples and to identify vendors offering social and digital media solutions. Tufts CSDD also conducted an online survey among English-speaking adult patients to assess their reactions to providing input into protocol design.

Five primary areas were explored:

(1) General Policies and Principles of Social and Digital Media Use in Clinical Research

(2) Social and Digital Media Community Use in Patient Recruitment and Retention

(3) Use of Social and Digital Media Communities for Development Planning and Study Design

(4) Social and Digital Media Community Use in Pharmacovigilance and Adverse Event Reporting

(5) Use of Digital and Social Media for Social Listening

Social and digital media—here defined as websites, technologies and software applications used interactively to communicate and share information—are gaining ground as important means to improve the clinical research process through more effective engagement of patient communities. At this time, however, regulatory agencies – specifically the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) – have not provided clarity or guidelines specifically addressing the use of social and digital media communities in clinical research.

To date, research sponsors and CROs have neither established specific company policies nor formalized coordinated processes. Instead, most organizations are using social and digital media communities on select programs in an experimental fashion.

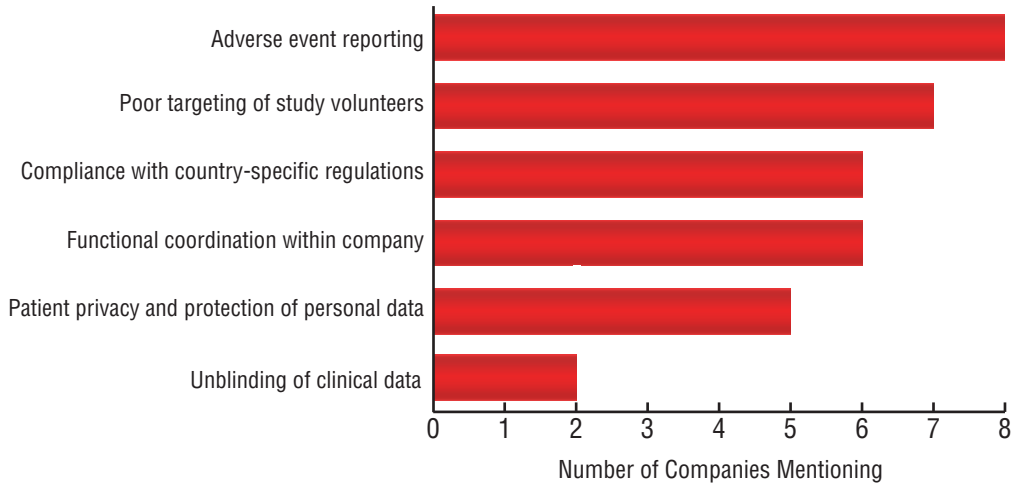
This whitepaper summarizes high-level findings from this nine-month study beginning with an assessment of current practices and usage for each of the primary areas outlined above and ending with considerations, recommended best practices and top reference citations to inform further thinking and discussion.

General Policies and Principles

Summary Assessment

- Drug sponsors are primarily using social media for commercial purposes to distribute information (e.g., about drugs, diseases, and the company) and to listen to patient and professional conversations about marketed products, and NOT to support clinical research.
- A minority of companies, however, report using social and digital media for patient engagement, recruitment and retention.
- Nearly all sponsors have developed guidelines to address employee use of social media. General guidelines include:
  - Rules for discussing company business on personal sites, how to set up a page or site, and privacy issues;
  - Guidelines concerning authorized and unauthorized uses by personnel of social media;
  - Social Media Advisory Board-specified practices;
  - Guidelines for posting video online;
  - Directives that stipulate one-way communication between personnel and patients involved in clinical studies;
  - Restrictions, e.g., for company business only.
- Most companies report that they began to use social media in clinical research in 2010 or later.
- Only one in five companies that use social media directly interacts with patients; most contract out engagement to a third party or use more passive approaches, including placing banner ads on social media sites.
- As a result of widespread concerns, nearly all companies report fragmented and uncoordinated use of social media with little policy or guiding practice in place.
- Top cited concerns include introducing research bias (e.g., falsifying eligibility; un-blinding treatment assignment) and distorting adverse event experience associated with study drug.
- Other concerns include encouraging non-adherence and early drop-out, providing medical advice regarding safety and efficacy, violating privacy and confidentiality, and influencing patient willingness to participate. Social media use raises many concerns; top most is handling adverse event reporting.

Top Concerns About Social Media Use (n=13 Companies)



Considerations Based on Best Practices and Lessons Learned

- There is a critical need to centrally track the wide range of social media initiatives being carried out. At the outset, organizations need to develop a formal mechanism to capture and monitor social and digital media community initiatives being used to support their clinical research activity.
- Eventually this mechanism may play a more active role in reviewing and approving uses to ensure coordinated activity, to assess resource requirements, to leverage organizational knowledge and lessons learned and to support staff training.
- This mechanism may also drive the development of standard operating policies, procedures and rules of conduct related specifically to clinical research with input from cross-functional stakeholders including regulatory affairs and legal.
    - Regulatory/legal considerations include direct-to-consumer communication restrictions outside the US and FDA/OPDP regulations. Also, of importance are product liability concerns, preserving integrity of clinical trials, adverse event reporting, and ownership of postings and account disclosures.
- When preparing to implement a social and digital media initiative, organizations should prepare not only development and launch plans, but also an ongoing maintenance plan and an exit strategy.
- Organizations should also establish key performance indicators to evaluate the success of various initiatives.

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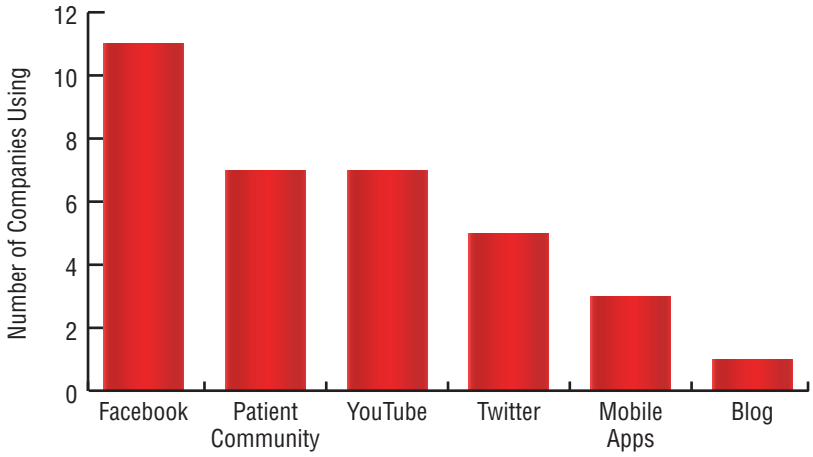
Patient Recruitment and Retention

Summary Assessment

- Based on company reports, social media are being used for patient recruitment on an estimated 11% of all trials with usage largely limited to North American patient communities.
- Although usage in Asia Pacific is low at the present time, sponsors and CROs report that usage is growing rapidly in this region.
- Whereas the majority of respondents have posted patient recruitment ads on social media websites, less than one-third of companies have used social media to 'interactively' engage patients. The most frequently used platforms include Facebook, dedicated social media patient communities, YouTube and Twitter.
- Patient recruitment for clinical trials through social media is expected to grow, with 9 of 14 companies planning to increase adoption of social media to recruit in the U.S. and 5 of 12 planning to do so in Western Europe.
- Sponsors value the metrics that can be gathered using social and digital media for recruitment and retention:
  - 12 of 13 companies report tracking the number of leads generated;
  - 10 of 13 report tracking the number of patients screened;
  - 8 of 13 report tracking screen failure rates and subject randomization rates.

Platforms Used for Patient Recruitment (n=14)



- In a survey of 168 predominantly North American investigative sites, 69 reported that they have used social media for patient recruitment. Sites that had used social media for patient recruitment and retention reported mixed results
- Organizations express a number of concerns about social and digital media community use for recruitment and retention, with the top concerns related to violating patient privacy and failure to target the appropriate patient populations.

Considerations Based on Best Practices and Lessons Learned

- Assess using social and digital media within the context of, and in coordination with, other patient recruitment and retention tactics.
- Identify metrics at the outset that will be used to measure success and compare the cost of randomized patients to other interventions.
- Evaluate, disseminate and share learnings/insights from each campaign.

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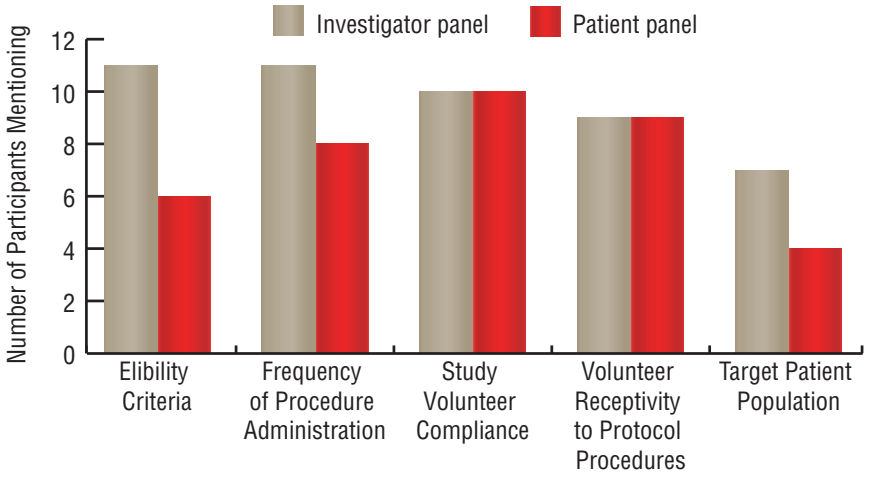
Development Planning and Study Design

Summary Assessment

- None of the companies participating in the working group are using social media to solicit patient feedback on development plans and protocol designs.
- Three other companies were identified that currently use social media for development planning and study design through the use of 'crowdsourcing' techniques to engage patients: Transparency Life Sciences and Genomera (two virtual pharmaceutical companies) and PatientsLikeMe (a group of disease-specific social media patient communities). All three companies license or contract their crowdsourcing solutions.
- Nearly all participating companies (13 of 14) believe input from social media communities would greatly improve the feedback they receive on program planning and protocol design feasibility.
- In a companion Tufts CSDD survey of patients, 24 of 27 said sponsor companies should use social media to solicit patient feedback when designing case report forms; 22 of 27 said sponsors should solicit feedback on protocol procedures and scheduling.

Top Protocol Design Areas that Could Be Informed by Social Media



Considerations Based on Best Practices and Lessons Learned

- Participating companies agree that social and digital media communities will increasingly become an important means to engage and interact with investigative site personnel, health care providers, and patients to gather feedback on draft protocol designs.
- Initial pilot studies on the impact of crowd-sourced protocol designs indicate that patient participation has increased, and investigative site administrative burden has been partially alleviated. Sponsor and CRO companies should develop and routinely gather measures documenting the impact of crowdsourcing on improvements in protocol feasibility and execution.
- A growing number of vendors are expected to enter the clinical research enterprise with expertise in developing crowdsourcing and social media programs to inform protocol and case report form design. This will not only introduce a variety of service offerings but also result in competitive pricing.

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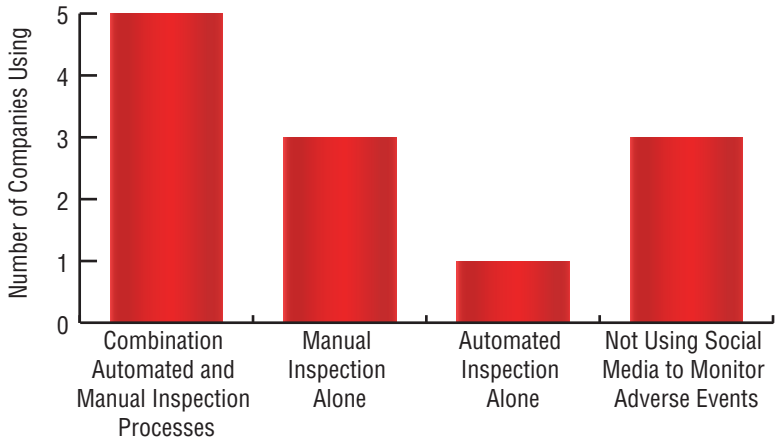
Use of Social and Digital Media Communities in Pharmacovigilance and AE Reporting

Participating companies expressed their greatest concerns with regard to the impact of social and digital media communities on pharmacovigilance and adverse event reporting. As a result, participating companies devoted substantial time and attention to this area culminating in a comprehensive set of conclusions and recommendations designed to inform industry and regulatory agencies.

Summary Assessment

- At the present time, the majority of companies (9 out 12) is not 'actively' soliciting or gathering adverse event (AE) reports on any social media sites (e.g. providing a hyperlink for reporting). Of the 9 companies that report using social media to "passively" monitor AEs, 5 use a combination of automated and manual processes to identify individual case safety reports (ICRs).
- Most companies (7) report that when data are missing from clinical trial-related adverse events reported via social media communities, they attempt to contact the principal investigator to gather additional information. Almost half of the companies (4) report that they attempt to match the adverse event to an existing clinical trial adverse event report.
- Health authority regulatory guidance documents and industry guidelines outline a very general framework within which biopharmaceutical companies – or Marketing Authorization Holders (MAHs) – should operate. But, there are a number of common drug safety-related occurrences

Approaches Employed for Passive Adverse Event Monitoring on Social Media Sites



that do not appear to be addressed by any health authority regulatory guidance; specifically, the concept of "control" of a social media site, frequency of monitoring, standards for reporter authentication, standards for source material, and responsibilities of companies that engage in aggregate data collection and signal detection from social media.

Sample Gaps and Inconsistencies in Health Authority Regulatory Guidance

Ownership and Control

- When is a social media site deemed to be "company-controlled"? This is an important distinction, as there are various potential criteria for ownership, such as editorial authority, purpose of the web site, and financial considerations. Several available guidances (both industry and regulatory) provide different criteria for site ownership. The issue of control is further confounded by the use of various naming conventions, sometimes used interchangeably, such as "sponsored", "controlled", and "owned". This has the potential to cause confusion and inconsistency in application.

- What is the continued responsibility of an MAH if it finds a reportable AE on a non-company-controlled social media site; i.e., should the MAH continue monitoring for additional information; and should the MAH continue monitoring for additional AEs outside of any pre-defined monitoring period?

Frequency of Monitoring

- Regulations and guidance documents suggest monitoring frequencies that vary from not-specified to "regularly," "daily," to the explicit: "The frequency of the screening should allow for potential valid ICSRs to be reported to the competent authorities within the appropriate reporting time-frame based on the date the information was posted on the internet site/digital medium." These inconsistencies do not offer a solution for multi-national biopharmaceutical companies.

Information Gathered Over Time

- None of the guidance documents reviewed addresses the circumstance in which a social media user posts AE information in multiple related posts over time, each one of which taken individually does not contain reportable information, but which, when combined, contain reportable AE information.

Meeting the Requirements for Valid AE

- A valid AE that is reportable to a regulatory agency must meet the following four criteria: identifiable reporter, identifiable patient, suspect drug and adverse event. Interpreting each of these criteria has long posed a challenge for biopharmaceutical companies. The situation has been magnified by the emergence of social media. The relative ease of posting information in an unstructured format and the ability to do so in a semi-anonymous fashion tests the traditional standards for defining a reportable event. Current guidance sets a fairly low standard for "identifiable reporter". This carries practical risks in a high-traffic on-line environment where it is probable that the vast majority of individuals can only be identified by a user name that provides no information on their personal identity. A low standard increases the chance of duplicate or fraudulent AE reports, which can be of particular concern if the reports involve a sensitive safety issue or one that could present a risk to the public health. In social media, these fraudulent postings may made be made in bulk, e.g. by supplying email addresses in a valid format.

Recording Primary Source Data

- Traditionally, primary source data constitute the physical documentation of an AE. Examples include letters, study case report forms, e-mail, or memos documenting telephone conversations. A MAH can archive these either as paper or electronic files to meet requirements for good PV practices. There are no regulations and little guidance for what should be considered primary source data in the context of social media, particularly for information on non-company-controlled sites that cannot be downloaded by the MAH for retention. In general, Internet-based URLs alone cannot be treated as source data, as they are merely pointers to websites subject to editing or permanent removal. What should be considered as primary source data? Will this differ for company-controlled social media sites vs. non-company-controlled social media sites?

Considerations Based on Best Practices and Lessons Learned

Ownership and Control

- Adopt the European Medicines Agency (EMA) standard for "company-controlled" sites; i.e. those for which a MAH governs the content or has influence over the content of an external party's site. For company-controlled social media sites, that site should notify visitors that posts and comments are monitored by the MAH and its agent(s) and that AEs will be collected in order to meet regulatory obligations. We recommend that each site defines what constitutes an AE and explains how collecting safety information helps to protect the public health. The MAH should also disclose its privacy policy and inform AE reporters that company representatives may follow up with them.

- MAHs should only contact the individual who has posted AE information on any social media site if that person can be reached directly through a private channel, such as personal e-mail. In other words, the MAH should not interact with the reporter through a publicly-viewable medium, such as the comments section of a blog, unless it is making a general request for that individual to contact the MAH's call center.

- For non-company-controlled social media sites, AE reporters do not anticipate interacting with MAHs and are entitled to the expectation of privacy. When AEs are identified, MAHs should consider the most appropriate circumstances and methods to contact these individuals, but only if it is deemed legally and ethically feasible to do so. As a rule, we would not consider it a regulatory requirement for a company to further monitor an external site to establish the existence or absence of additional AE reports.

Frequency of Monitoring

- The date an AE is posted on a MAH's controlled site is recognized as "Day 0" of the regulatory calendar for the evaluation and reporting process. Given the short timeframes for certain AE submissions to many health authorities, typically 15 calendar days, MAHs may find it effective to screen company-controlled sites at least once each business day. We do not consider monitoring to be mandatory for non-company-controlled social media sites, although MAHs may wish to screen certain pre-defined sites voluntarily. Day 0 for AEs received through these media should be considered the date on which the MAH or its agent becomes aware of the AE.

Information Gathered Over Time

- MAHs are not required to routinely identify and cross-reference related posts or comments that do not contain the four criteria for a reportable AE. However, individual posts that contain at least an identifiable drug and an event should, at minimum, be stored in the PV or other tracking database.

- There is no obligation to combine information. However, if a MAH becomes aware that separate pieces of information pertain to the same AE, then they should be combined. In addition, MAHs should develop risk-based policies that detail the circumstances under which monitoring an incomplete AE for additional site contacts by the reporter may be warranted. Examples may include serious events commonly associated with medicinal products, such as aplastic anemia, or AEs of special interest for a specific drug.

Meeting the Requirements for Valid AE

- Incomplete, non-reportable AEs are a potential source of safety signals. Therefore, we recommend that MAHs develop processes to review these data on an ongoing basis. It may not be scientifically appropriate or otherwise practical to include such AEs in computer-generated statistical analyses of the PV database, but they should at minimum be assessed periodically to identify unusual trends or unexpected AEs. Positive results should be considered as "hypothesis generating" and should be used as the basis to determine if further investigation of the PV data- base, the medical literature, study data, or other resources is justified.

Recording Primary Source Data

- We recommend that primary source data for any AE identified through social media be preserved as an image, such as a screenshot taken on a computer or mobile device, or an otherwise un-editable copy, such as a PDF file, of the original AE information. The electronic file should record the date on which the AE was detected and the original Internet URL where it appeared. If the event was posted through means other than text, for example a video or audio segment, an electronic copy should be preserved as primary source data, if technologically feasible. If this is not possible, a transcript of the segment should be made and should reference the original URL.

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Social Listening

Summary Assessment

- 7 of 13 sponsors report they regularly engage in "social listening" to learn about marketed drugs. Three companies outsource the practice entirely; four have internal teams working with external providers.
- Half of the companies conducting social listening do so on a daily basis; the other half report that they listen sporadically.
- The primary goals of social listening are to: understand community attitudes and behavior; identify trends; monitor perceptions of product and company positioning; augment/shape ad/marketing campaigns; gauge community receptivity; learn about competitors; gain insight into product/service improvements; and gather input that may shape future research.
- At the present time, two companies report using social listening in clinical research. Sponsors report that the lack of experienced vendors, CROs and internal teams to conduct social listening to inform clinical research is the main barrier to adoption.

Considerations Based on Best Practices and Lessons Learned

- Social listening is actively used in other industries for a variety of purposes that may be adapted to clinical research:
  - Cisco, for example, reports achieving a 281% return on investment from social listening through reducing marketing costs and obtaining valuable new insight into customer needs.
  - TD Bank North listens to internal dialog to gather innovative ideas. This practice prompted the company to move to electronic solutions instead of paper solutions.
  - Johns Hopkins Hospital reports using social listening to identify areas where patient privacy may be compromised. Conversations containing sensitive information inform the hospital to modify its community-facing web offerings.
  - The British Army reports listening to feedback from Facebook and Twitter to determine future content on its website to improve personnel recruitment.
- Social listening initiatives should be started as close as possible to volunteer randomization, if not earlier, to monitor patient experiences in a given trial, participation concerns and challenges that they face.
- The following should be considered when selecting a vendor to provide social listening services, as also stated by Goldbach Interactive:
  - Central, comprehensive management of topic tags;
  - Restriction by language and countries; the ability to listen to countries that speak languages other than English; keywords should include slang terms;

- Comprehensive sources: a human to aggregate and curate social media data; a centralized team to provide ownership with the sponsor or CRO organization;
- Dashboards with filter and comparison options;
- Sentiment analysis; demographic information; identification of influencers and important topics;
- Historical data for retrospective analysis;
- Strong user interfaces that make gathering data easy (unless working directly with a vendor that will curate social media data);
- E-mail alerts and ability to filter to appropriate teams within the sponsor or CRO organization.

- Keyword selection is critical to support effective and targeted social listening. Experienced vendors can assist with the development of keywords.

- Regulatory affairs functions can play an important role in developing social listening guidelines that are aligned with privacy regulations in specific geographic regions. Alternatively, social media vendors based in other countries may know the rules and regulations within the countries in which they operate.

- In the absence of standard guidelines, in the near term sponsor and CRO companies should establish internal guidelines outlining acceptable practices and ethical standards required for social listening activity. These guidelines should detail repercussions in the event that these requirements are not met.

- Sponsors and CROs should always approach social listening with complete transparency. When listening to a private social media community, sponsor and CRO company participation should be announced.

- Social listening should be used in tandem with traditional market research techniques as each approach has unique dynamics and bias.

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Next Steps

This white paper will be distributed to a variety of stakeholders including clinical research professionals and policymakers. Tufts CSDD and participating companies are now presenting the results of this 9-month study at industry conferences in the United States and in Europe. Findings from this study are also being prepared for publication. We also plan to convene a roundtable in Washington, D.C. to share and discuss high-level findings with the Department of Health and Human Services, including the FDA, congressional committees, other government agencies, and non-profit organizations.

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