Social media for pharmacovigilance

Is there any value?

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Weybridge, October 2016

Disclaimer

This document represents proposals for discussion. Strategies/Concepts/Projects described herein may need significant modifications before implementation, and no project should be considered final until it has been fully approved by the appropriate Novartis review process. Novartis will only implement programs that are fully consistent with all applicable laws and regulations as well as Novartis companies’ policies.

Dr Lewis is Project Coordinator for IMI WEB-RADR and acknowledges the support of the WEB-RADR consortium in many aspects of the presentation that follows. The opinions presented are those of Dr Lewis, and are not intended to represent IMI, WEB-RADR or any participant within the consortium.

Definition of social media (digital media)
Multiple threads of social media

Social media user numbers continue to grow

- **Facebook**: 1.71B 1.49b (0.85m)
- **Twitter**: 310M 304m (140m)
- **YouTube**: >1b >1b (800m)
- **Pinterest**: 100m 72.5m (21m)

### Electronic Health (eHealth)
- Using information and communication technologies for the provision of health-related services (diagnosis, monitoring, treatment)

### Telemedicine
- Delivery of health care at a distance using information and communication technologies for consumer healthcare.

### Digital Health
- The intersection of the digital revolution with consumer healthcare, includes genomics (use of gene chips to store a patient's genetic identifiers and responses).

### Pharmaceutical industry use of social media

*Main use of social media by MAHs is for marketing and sales*

- Sponsors are primarily using social media for commercial purposes to distribute information about:
  - Medicines (to healthcare professionals and non-HCPs);
  - Diseases, and the treatment of disease;
  - Company matters including announcements;
  - AND listening to patient + HCP conversations about medicines
- A minority of companies use social media for:
  - Patient engagement,
  - Patient recruitment and retention within clinical trials


### MAH governance of the use of social media

*MAHs have developed controls governing use of digital media*

- Nearly all MAHs have developed guidelines to address 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.
Good Pharmacovigilance Practice (GVP) VI

PV guidance on digital media from September 2014 focuses on ICSRs.

VI.B.1.4. Information on suspected adverse reactions from the internet or digital media

MAHs should **regularly screen internet or digital media under their management or responsibility, for potential reports of suspected ADRs**. In this aspect, digital media is considered to be company sponsored if it is owned, paid for and/or controlled by the MAH.

- The frequency of the screening should allow for potential valid ICSRs to be reported to the competent authorities within the appropriate reporting timeframe
- Marketing authorisation holders may also consider utilising their websites to facilitate the collection of suspected ADRs

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AE reporting via social media

Do not be misled by urban myths concerning the volume of ADRs!


All brand mentions
- 257,177 posts; 224 brands
- 100%

Filtered for relevance
- 24%

With AE terms
- 9%

3.3% mentions are case reports
- 1 in 7 = name & contact info

Adverse Event reports
- 0.4% of all brand mentions
- 3.3% contain AE-specific data

Proto AE reports via social media

Reports received via WEB-RADR social media dashboard

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<th>Verbatim text</th>
<th>Active substance(s)</th>
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Digital media and safety issues (GVP Module VI)

Screening social media not under the control of the MAH

- VI.B.1.1.4. Information on ADRs from digital media (ctd.)
  - If a MAH becomes aware of a report of suspected adverse reaction described in any non-company sponsored digital medium, the report should be assessed to determine whether it qualifies for reporting.

- VI.C.2.2.6 Emerging safety issues
  - Good practice for the MAH to monitor special internet sites or digital media (e.g. patients’ support or special diseases groups)
    - Check if they describe significant safety issues which may necessitate reporting in accordance with VI.C.2.2.6.
    - Frequency of the monitoring depends on the risks associated to the medicinal product
Issues with pharmacovigilance & digital media

Many questions have been raised about the value of monitoring media

• What systems & processes should be built into health apps to enable the capture & reporting of suspected ADRs?
• Who is under the obligation to report these ADRs given the chain of use, access rights, ethics and data privacy?
• Which systems & methods should be applied to signal detection involving digital media?
• Who will run the screening for signals, and against which data sources? [N.B. 'social media' is not a single source]

Social media: Substantial caveats for MAHs

• We must obey the law
• We should operate ethically
• We must not cross the boundaries of the doctor-patient relationship

But...

• We should be encouraged by the opportunities digital & social media offer

Overview of Novartis PV of digital media

Highlighting challenges of monitoring the different channels
Novartis Corporate Social Media Channels

- Safety Operations must be involved in AE reporting activities for the Corporate social media channels
- Named contact person from each social media channel and SOPs set up for digital media & app development
- Business representatives (Commercial, Patient Safety, Development Informatics & QA) discuss how to handle Corporate social media programmes and the roles and responsibilities of Novartis associates & vendors
- All seven Corporate channels are managed by one service provider; staff are trained in ADR reporting

Case Study Screening MAH-sponsored blog

Example of challenges when a social media site is successful

- MAH received a major finding for not screening a blog of patient diaries & exchanges of information
- EFPIA position paper on digital media
  - MAH should not be expected to monitor informal communications between patients, sharing information by use of diaries, blogs, chat rooms, etc., on websites provided by the MAH
- EMA response
  - Guidelines amended to clarify MAHs are expected to screen all areas of digital media under MAH management or responsibility
- MAHs should announce screening on websites

Screening a blog: MAH experience

First the good news, then the bad news

- MAH created a US ‘message board’ and a ‘blog’ facility supporting a non-prescription (consumer) medicinal product
  - Direct to consumer advertising ‘shared experiences’
  - Consumers can share their experiences with non-prescription weight-loss drug using the programme e.g. sharing of recipe and exercise ideas, ‘buddying’ for moral support and encouragement
  - Use of the internet for such purposes is commonplace amongst weight loss and other health-related on-line communities
MAH blog screening: no new signals

Despite review of over 12,000 case reports no new signals detected

• MAH screened the message board for AE reports since the US launch of the product
  – c. 6,500 posts screened each month
  – ~8% of all posts included an AE
  – c. 80 hours spent each month to screen website and enter ICSRs onto the MAH safety database
  – >12,000 AE reports identified (23-month period)

• No new safety signals identified

Social media: From telling to engaging

New apps and mobile technologies will continue to evolve

• Best practices include:
  – Establish relationships through two-way dialogue and human connections that encourage participation
  – Demonstrate patient and customer responsiveness through timely, transparent responses and request feedback
  – Share content that makes the public want to interact with the company and specific brands
  – Use of innovative strategies to leverage information and drive online influence

Conclusions: PV of social media

Commentary on social media and changes in pharmacovigilance

• Patients increasingly aware of medical information
• Rapid growth as MAHs exploit opportunities
• Potential for two-way interactions hard to ignore, so mobile reporting capabilities will increase
• There are risks to manage but in return MAHs must offer real benefits or advantages to patients
• MAHs will develop social media sites rapidly
• Important that PV is carefully managed; inspection findings & warnings have been issued