

Internet and Social Media Promotion of FDA-Regulated Products

Evaluation of uncertainties and challenges from AE Monitoring using the WatchNet™ Frameworks

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Simplify what you do

Presented at FDA Public Hearing: Promotion of FDA-Regulated Medical Products using the internet and social media tools – in Washington DC

Key questions and core themes

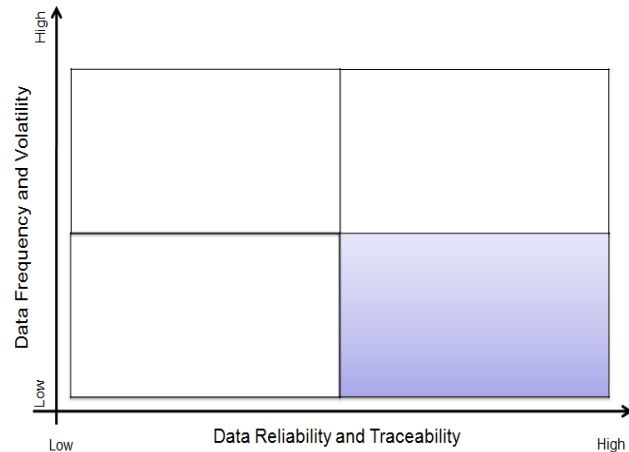
Key Questions

- Challenges of handling AE information from social media?
- Uncertainties regarding information that should be reported from social media on AEs?
- Q&A

Core Themes

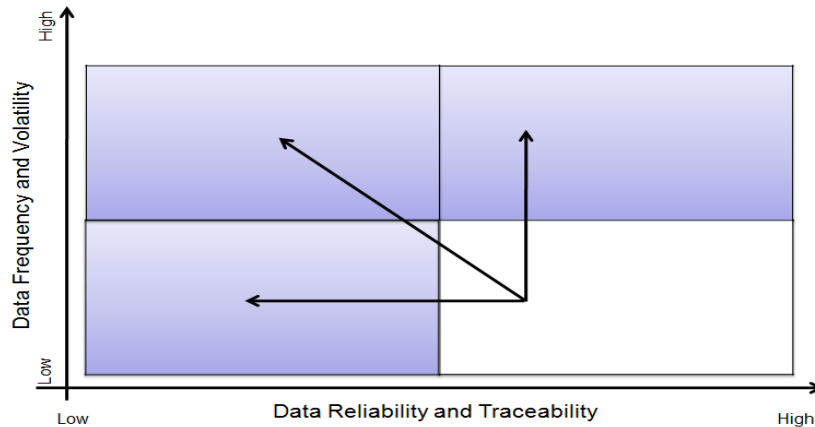
- Volatility
- Traceability
- Frequency
- Reliability

AE Reporting context before social media growth



- Relatively small number of well-controlled, traceable inputs
 - Processes designed for paper based information channels
 - Strong patient reliance on one-on-one communication with HCPs from information
- Companies rely more heavily on printed advertising and phone interaction with consumers
 - AE reports highly traceable and intent to report clear
 - Frequency and volume of AE follow-up controlled by combination of regulation and internal company policy, rather than consumer driven

AE Reporting challenges with growth of social media

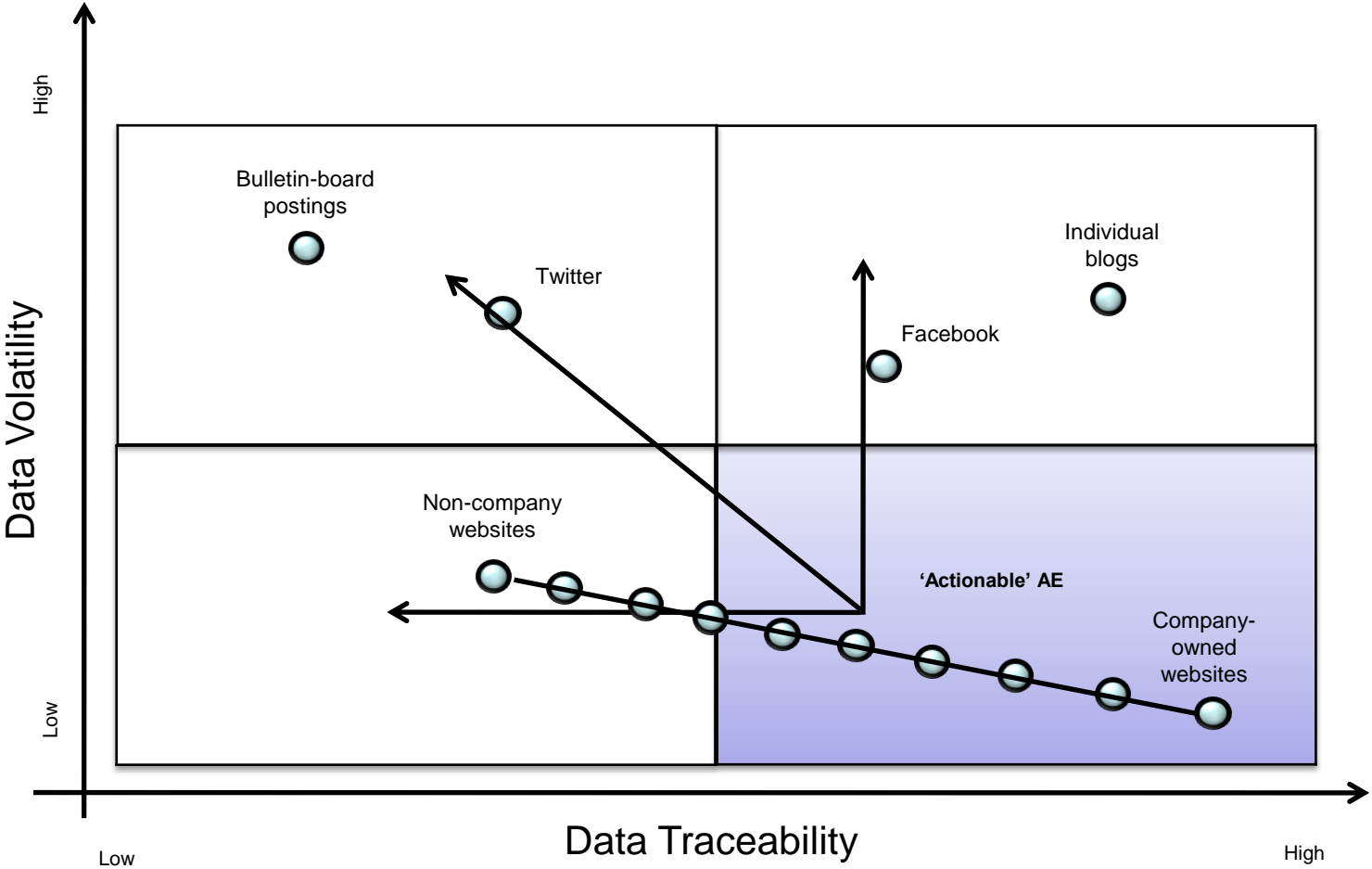


Drivers for Change

- Large number of untrained, poorly traceable, not controlled data sources
- Posts based on 'gut feel' rather than empirical evidence, particularly from consumers

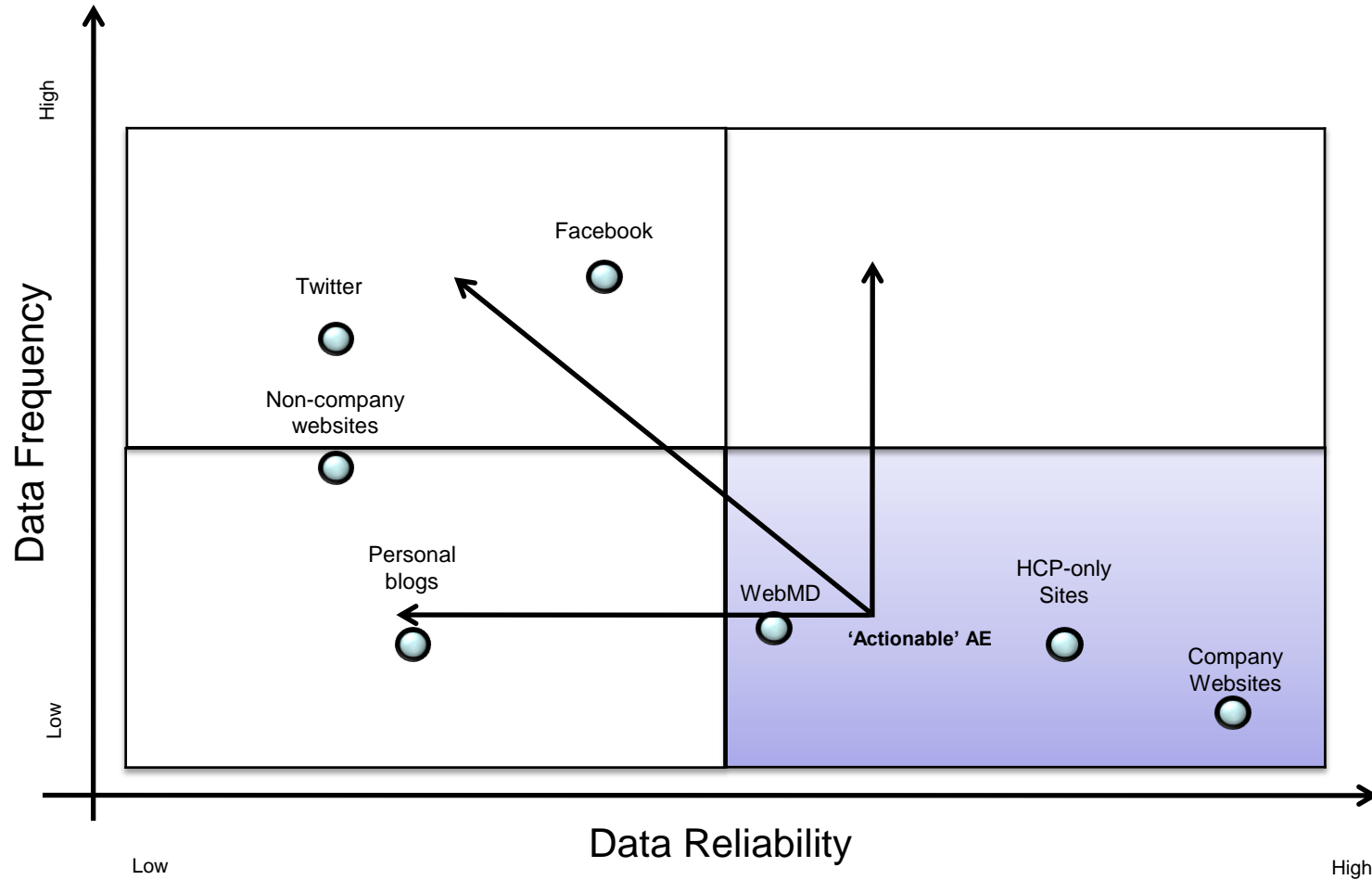
- Significant amount of PV resource time (sample = 80 hours/month) being expended to monitor people's chats with:
 - *No changes* to safety profiles and no significant new findings
 - *No further understanding or enhancements* to known safety profile, and
 - Increased *challenges* of poor case quality follow-up
- Addition of such a large volume of non-serious cases, to database may *negatively* impact the ability to identify important new signals using signal detection tools (i.e. A potential diluting effect)

Data volatility and traceability



Simplify what you do

Data frequency and reliability



Regulatory change will drive future operating procedures and should take into account the following considerations...

Data Quality Considerations

- Initial vs. Follow-up cases
 - Distinguish between initial and follow-up
 - Comments by third parties
 - Parent/child relationships between temporally or contextually related postings
 - Timeliness of posts - multiple posts over multiple days
 - Reporter as moderator/owner of blog
- Materiality
 - Redefinition of reportable criteria (4 minimum down to 2?)
 - Passing or vague remark without mentioning explicit assumed or implied causality
 - Intent to report – Social Media cases as solicited
- Reporting Authentication
 - How determined
 - Veracity determined

Operational Considerations

- Reporting Frequency and Scope
 - Frequency to scan social media sites for AEs
 - Consideration of automated scanning technologies
 - Potential industry standard list of terms to use in scanning, or requirements for keyword proximity to product name
 - Comprehensive list of social media sites, to be considered 'in scope'
- Localization/Internationalization
 - Define language scope for AEs from multiple geographies
 - Postings on social media sites in languages other than English and translation requirements
 - Impact on keyword placement rules for different languages

Proposed Recommendations



■ **Public-Private Sector Collaboration**

- Leverage information mining tools or approved internationally – distributable variance of those developed for other governmental agencies
- FDA would mandate processing of company-sponsored blogs run through tool and accept results
- Offer list of approved information mining tools: develop consistency in evaluating companies as all companies are on same playing field and using system with demonstrated integrity

■ **Proposed Regulatory Changes**

- Post simple AE form on company-sponsored websites with 'blog' or 'chat' feature to enable report from website visitor – MAH could then be required to monitor websites monthly or quarterly as part of Signal Detection efforts
- Cases generated from company-initiated website review should be considered Solicited



Q&A



If you would like further information please contact Tara Churik at
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The WCI logo consists of the letters "wci" in a lowercase, sans-serif font, enclosed within a yellow oval shape.

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