FDA Perspectives on Social Media for Postmarket Safety Monitoring

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Sources of Medical Product Information

- Social media?
- Spontaneous Adverse Event Reports
- Clinical Trials
- Observational Studies
- Registries
- Medical Product Safety Information
- Clinical Pharmacology Studies
- Pharmacogenomic Studies
- Animal Toxicology Studies
- Product Quality Reports
Why is FDA interested in Social Listening?

• Different approach to monitoring postmarket adverse events
  – Potential for faster signal detection?
  – More efficient?
  – Information not available from other sources?

• Comparison to established methods
  – Concerns
    • Data quantity ≠ Data quality
    • Regulatory requirements for reporting
Can Social Media Yield Earlier Detection of Safety Signals?

- Determine if Facebook, Twitter, etc. could lead to earlier detection of rare and serious adverse events (AEs).
- Retrospective analysis of public posts for 10 FDA safety signals, with 6 negative controls.
- Machine learning and NLP tools used to identify posts of interest.
- Total of 935,246 posts harvested.
  - 98,252 AEs identified.
  - 13 posts selected for further review.
- In one case, the first report occurred in social media prior to signal detection in FAERS.

Limitations to Use of Social Media for Detection of Safety Signals?

- If event serious enough to warrant a post, serious enough that patient’s provider may have already reported to FDA.
- Many posts do not describe symptoms using the medical terminology needed to explicitly confirm certain condition or diagnosis.
- Operational social media surveillance burdened by curation of large volume of data.
Reporting to MedWatch

1. Patient Identifier
2. Product
3. Event or Problem
4. Reporter
How does FDA handle Adverse Event (AE) reports from social media?

• For purposes of reporting by companies to FDA, AE reports from social media should be treated as spontaneous reports
  – Spontaneous reports are unsolicited communications from individuals (e.g., health care professional, consumer/owner) to applicants that concern adverse experiences.

• They are reviewed like any other spontaneous report
  – FDA applies the same review process for all reports, regardless of source or product type.

• In our safety surveillance work, FDA considers AE information from all sources, acknowledging that there can be variability in the quality of the reports submitted.
How else does FDA handle social media?

Center for Veterinary Medicine:
- No active “social listening”
- Sponsors have reported about 30 reports that originated from Facebook or Twitter
- Proactive scanning of online resources could be particularly helpful in detecting animal food issues

Center for Food Safety and Applied Nutrition:
- No formal use in traditional signal detection
- Use BrandWatch to scan social media on topics of interest, specifically targeted at monitoring consumer confusion or mis-information

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What is the best way to think about AE reports from social media?

Would it be better to treat AE reports in social media in the aggregate with summary of data in periodic reports?

– Pros
  • Account for the nature of the data source
  • Facilitate better data analysis
  • Focus on pattern identification

– Cons
  • Some social media data are more like detailed case reports than others
Summary: Adverse Events from Social Media

• FDA recognizes there is a wealth of consumer information from social media that may help our safety surveillance.

• FDA continues to explore the value of social media mining for safety signal detection.

• At present, for reporting purposes, adverse event information from social media with the required elements should be treated as spontaneous reports.

• In the future, for reporting purposes, some types of social media data might be better aggregated by source and report in summary fashion.