

# AgroStat 2016

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## ***VERACITY SCORING OF SOCIAL MEDIA CONTENT***



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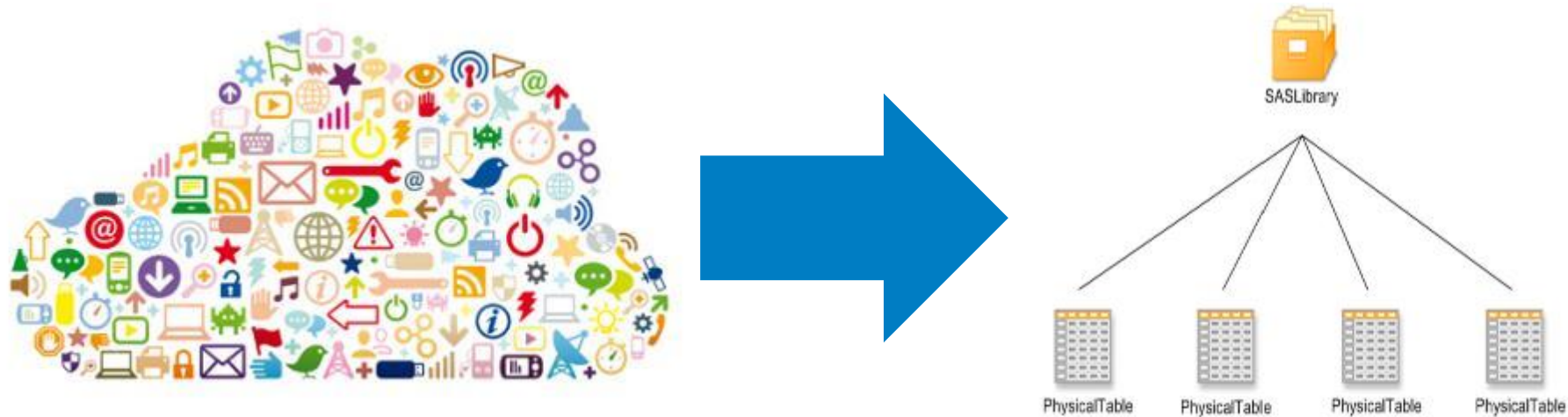
*“While the individual man is an insoluble puzzle, in the aggregate he becomes a mathematical certainty”*

*Sherlock Holmes*



## SOCIAL MEDIA INSIGHTS ON HEALTH AND SAFETY

Great interest in collecting and understanding health related information from a variety of Web data sources



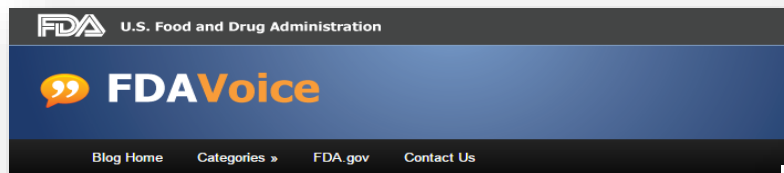
Unsolicited Self-Reported Symptom-Treatment-Outcome Measurement



The objective of this requirement is to provide FDA with the resources needed to use social media to inform and evaluate FDA risk communications. Specifically, the objective is to provide FDA with:

- Analyses of social media that provide baselines on consumer sentiment prior to FDA communication and that depict changes in social media buzz following FDA communications
- In-house capability for social media monitoring; and Surveillance through **social media listening for early detection of adverse events** and food-borne illness.
- The scope of work includes social media buzz reports, a social media dashboard, and quarterly surveillance reports related to specific product classes.

# FDA PATIENT PREFERENCE INITIATIVE



TAG ARCHIVES: PATIENT PREFERENCES INITIATIVE

## Listening to Patients' Views on New Treatments for Obesity

Posted on January 29, 2015 by FDA Voice

By: Kathryn O'Callaghan and Jeffrey Shuren, M.D., J.D.

Surgical Endoscopy  
January 2015

Date: 01 Jan 2015

## Incorporating patient-preference evidence into regulatory decision making

Martin P. Ho, Juan Marcos Gonzalez, Herbert P. Lerner, Carolyn Y. Neuland, Joyce M. Whang, Michelle McMurry-Heath, A. Brett Hauber, Telba Irony

## Public Workshop - The Patient Preference Initiative: Incorporating Patient Preference Information into the Medical Device Regulatory Processes, September 18-19, 2013

The Food and Drug Administration (FDA) is announcing the following public workshop entitled "The Patient Preference Initiative: Incorporating Patient Preference Information into the Medical Device Regulatory Processes".

The purpose of this workshop is to discuss ways to incorporate patient preferences on the benefit-risk trade-offs of medical devices into the full spectrum of the Center for Devices and Radiological Health (CDRH) regulatory decision making. It also aims to advance the science of measuring treatment preferences of patients, caregivers, and health care providers.

## DEFINITION PROMS

A Patient Reported Outcome is any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else.

Guidance for Industry

Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims

U.S. Department of Health and Human Services

Food and Drug Administration 2009



Any outcome evaluated directly by the patient himself and based on patient's perception of a disease and its treatment(s) is called patient-reported outcome (PRO).

Reflection Paper on the Regulatory Guidance for the use of Health Related Quality of Life (HRQL) Measures in the Evaluation of Medicinal Products  
European Medicines Agency 2005





PharmaSUG 2013 - Paper AD22-SAS

## **Methods and Application for Determining the Integrity and Veracity of Medical Device Safety Related Data in Social Media**

Mark Wolff, SAS Institute Inc., Cary, NC, USA

Michael Wallis, SAS Institute Inc., Cary, NC, USA

### **ABSTRACT**

As more individuals, organizations and institutions rely on the internet for information to support decision making, the integrity and veracity of those data have become a critical issue. A key area of interest is the applicability and utility of social media data for device safety monitoring. Such data offer a potentially valuable resource for post-marketing device safety surveillance for the industry and regulators. Adoption of these data as a resource has been hampered by concerns related to the accuracy and reliability of these data and a lack of guidance from regulators. Applying the capabilities of SAS Text Analytics we propose a method for qualifying the veracity of unstructured data collected from internet sources. Further, we describe its application in post marketing medical device safety monitoring and signal detection.



## EXAMPLE “TWITTER DOTH PROTEST TOO MUCH, METHINKS”

MARCH 4, 2013

# Twitter Reaction to Events Often at Odds with Overall Public Opinion

*By Amy Mitchell and Paul Hitlin*



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## **TWITTER** RECENTLY PUBLISHED RESEARCH

### ***Drug Safety***

### ***Digital Drug Safety Surveillance: Monitoring Pharmaceutical Products in Twitter***

***Published online: 29 April 2014***



*"The resulting dataset contained a high volume of irrelevant information, but provided a useful starting point."*

*"We did not seek to verify each individual report as truthful, but rather to identify overall associations between Twitter and official spontaneous report data as a preliminary proof of concept."*

# **SAS** ANALYTIC APPROACH TO VERACITY & DATA INTEGRITY

## **RULES**

Known Patterns events

Rules and thresholds based on known behaviors

- Biological/Clinical Plausibility

- Product label

- IP Address/URL

- Author ID

## **ANOMALY DETECTION**

Unknown Patterns and Behaviors

Algorithms used to understand unusual patterns

- Multivariate outlier/inlier detection

- Constant findings

- Clustering/association analysis

- Distribution analysis

## **PREDICTIVE MODELS**

Complex Patterns

Identify patterns which describe inaccurate information

- Apply unsupervised/supervised learning techniques

- Like patterns of comments and content

- Author verification

- Higher level concept disambiguation

## **NETWORK ANALYTICS**

Associative Linking

Discovery through automated link analysis

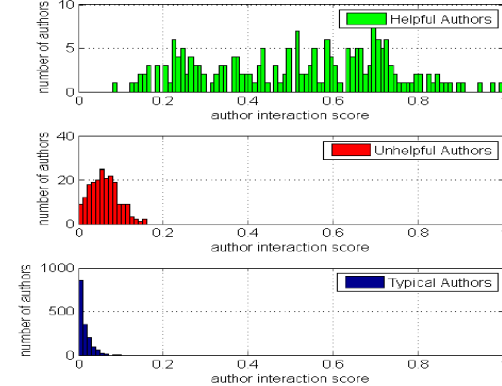
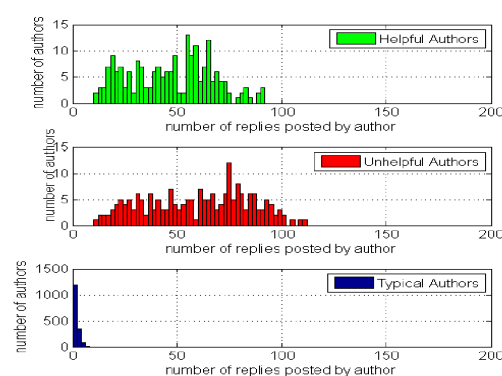
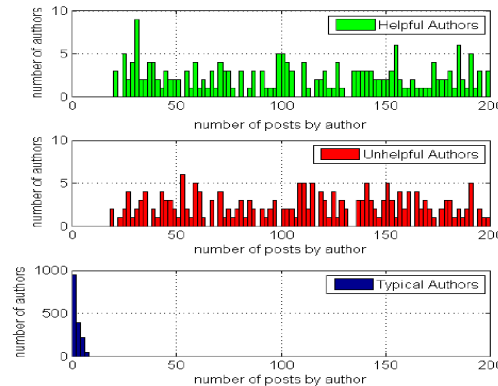
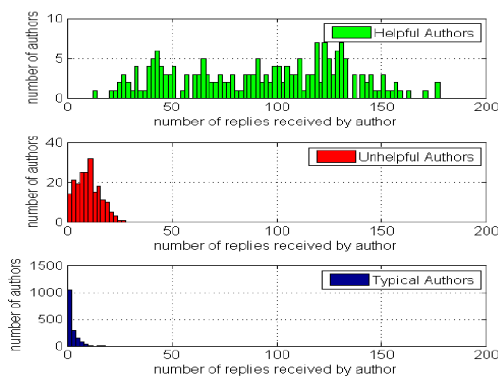
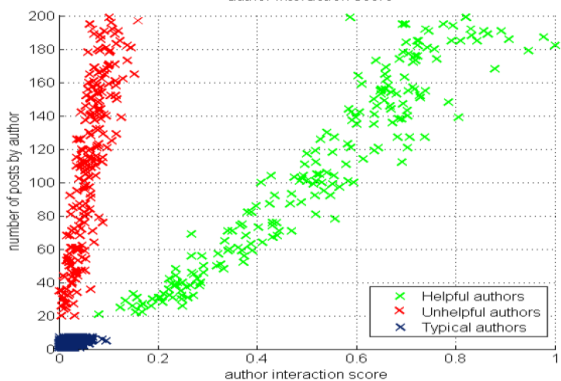
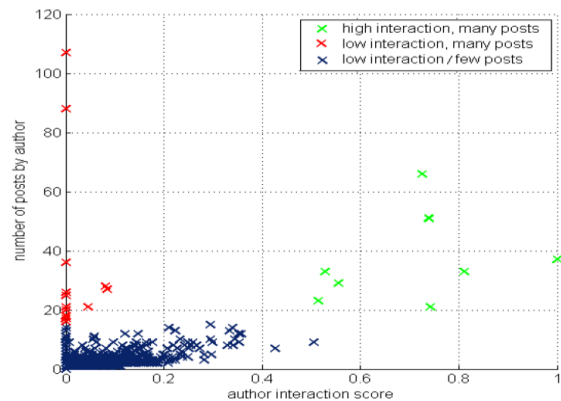
- Collusive networks

- Understand complex multivariate relationships over time

- Use vectors and momentum of events/behavior as predictor

- Link authors to malicious content

*Proactively apply combinations of all approaches at entity and network levels*



## APPROACH AUTHOR VALIDATION

- Aggregate all posts for an identified Author
- Establish base line distributions and frequencies
  - Number of posts as a function of time
  - Frequency of key terms
  - Identify word count of each post
  - Identify cross-posting
- Apply Text Analytic technique to model each authors corpus of posts (Text Fingerprint)
- Score all posters with library of Author Models
  - This identifies bots or whether the poster is using multiple aliases or is acting in collusion

*I am a person who has refractory epilepsy due to a malformation of the brain . I have had this for 36 years aftermuch trying of new meds to get more control my Epileptologist highly recommended the VNS. After much debate and doubt about it I did go through with it last Fall 2004. I wish I could report all positive on it. However from getting sick from the surgery, having lost my voice for 8 weks due to a paralysis of a vocol cord near the vagus nerve. To even being verysensitive to the VN's once It was turned onl have incredible doubts about the test that have been done. Know there are some major issues in my mind. I encourage all to research it as much as possible. Make sure you feel that it would be in best interest for your brother and ask him if he feels it is what he feels is what he wanted. If you want to talk further let me know. Best to your family!*

AUTHOR: cedar  
DATE: 04/12/2005  
TIME: 1:46pm

### Important Predictors of Social Media noise in PROM Analysis

- Frequency of Posting
- Word Count
- Cross-posting



### How to build a “Lie Detector” for the internet;

- Semantic Field Normalization/Contextualization for Self-Reported Symptom-Treatment-Outcome Measurement in Web-based Media Sources
- Adaptation of “Semantic Nets” to Establish Veracity of Symptom-Treatment Outcome Reports in Health Related Web Interactions
- *Behavioral context as a pathway to crafting semantic field normalization mappings in Clinician/Patient Reported Outcomes Data (C/PROM)*

# US FDA PATIENT PREFERENCE

## Obesity

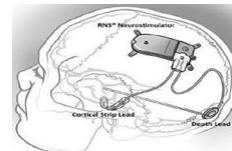
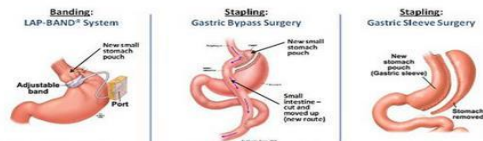
### *Gastric Balloon, Band, Sleeve, Surgery*

- Efficacy
  - Duration
  - Quality of Life
  - Weight Loss
- Safety
  - Adverse Events
  - Device Malfunction
  - Hospitalization
- Usage
  - Daily Life Impact

## Epilepsy

### *RNS (Neuropace), VNS, DBS, AED*

- Efficacy
  - Duration
  - Quality of Life
  - Seizure Reduction
- Safety
  - Adverse Events
  - Hospitalization
- Usage
  - Daily Life Impact

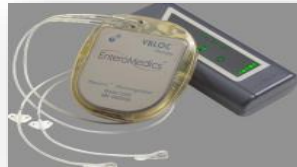




# Patient preferences considered for the first time in FDA decision to approve first-of-kind obesity device

RTI Health Solutions partnered with the FDA to conduct a study on patients' preferences which contributed to the Agency's regulatory decision to approve a first-of-kind device to treat obesity

This was the first time a patient preference study impacted a new device approval



## Incorporating patient-preference evidence into regulatory decision making

Surgical Endoscopy

January 2015

Martin P. Ho, Juan Marcos Gonzalez, Herbert P. Lerner, Carolyn Y. Neuland, Joyce M. Whang, Michelle McMurry-Heath, A. Brett Hauber, Telba Irony



*turning knowledge into practice*



# Harness Patient Preference from Social Media



"Identify and Incorporate the Patient Voice into Our Decision-making on Medical Devices" – FDA Voice

Emily McRae<sup>1</sup>, Cheyanne Baird<sup>1</sup>, Joe Boland<sup>1</sup>, Pat Dougherty<sup>1</sup>, Martin Ho<sup>2</sup>, Telba Irony<sup>2</sup>, Mimi Nguyen<sup>2</sup>, Kathryn O'Callaghan<sup>2</sup>, Michael Wallis<sup>1</sup>, Mark Wolff<sup>1</sup>, Anindita Saha<sup>2</sup>

<sup>1</sup>SAS Institute Inc., Cary, NC; <sup>2</sup>Center for Devices and Radiological Health, Food and Drug Administration; Silver Spring, MD

## Objectives

- Explore the feasibility of collecting patient preference information from a variety of social media sources on selected topics.
- Apply sentiment scoring method to reveal context-specific sentiment levels related to medical device treatments.

## Background

- Social media has become a popular medium for individuals to express their opinions.
- After conducting a patient preferences survey on weight loss devices, CDH explored using sentiment analysis to harness patient preference from unstructured posts of social media for comparison with the survey results.
- Sentiment analysis is an evolving technology that applies text analytics to analyze a document and infer the author's sentiment about a topic of interest, such as a medical treatment.
- CDRH and SAS collaborated to capture web-based patient sentiments on the benefits, risks, and other attributes of medical treatment to treat obesity and epilepsy.

## Materials and Methods

- Identified most popular websites on treatments of obesity (surgery, sleeve, band, balloon) and epilepsy (RNS, VNS, DBS, AEDs)
- Veracity Scoring (Signal to noise reduction)
- Segmentation and Data Cleansing
- Sentiment Analysis
- Visualization and Exploration
- Incremental data crawling for real time sentiment analysis compared to baseline

## Patient Forums

### Epilepsy

- <http://www.coping-with-epilepsy.com/>
- <http://epilepsyfoundation.ning.com/>
- <http://forum.epilepsysociety.org.uk/>

### Obesity

- <http://www.bariatricpal.com/>
- <http://www.obesityhelp.com/>
- <http://weightlossurgery.proboards.com/>
- <http://www.wlsurgery.com/>

## Patient Preference Attributes

- |                     |                     |
|---------------------|---------------------|
| <b>Obesity</b>      | <b>Epilepsy</b>     |
| • Efficacy          | • Efficacy          |
| • Duration          | • Duration          |
| • Quality of Life   | • Quality of Life   |
| • Weight Loss       | • Seizure Reduction |
| • Safety            | • Safety            |
| • Adverse Events    | • Adverse Events    |
| • Device            | • Hospitalization   |
| • Malfunction       | • Usage             |
| • Hospitalization   | • Daily Life Impact |
| • Usage             |                     |
| • Daily Life Impact |                     |

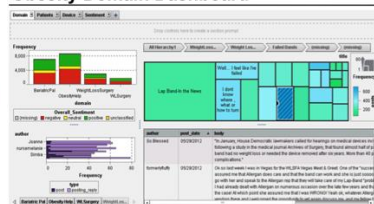
## An Example of Sentiment Analysis

**Gastric Sleeve** Thanks for starting this thread. I had my **surgery** on 10/27. My **surgery went well**. I did take **longer in recovery** than most but I don't really remember that to much. I was on my **pain drip** and I used it every time the light turned green. I **didn't feel pain** but they had said to try to **stay ahead of the pain** so that is what I did. I was up and walking around 9pm on the day I had surgery. My surgery was at 2pm. My hubby stayed the whole time I was **in the hospital** and that was a huge help. I just felt **more comfortable** with him there. I went home Tuesday around supertime and didn't need any **pain medicine** at all once I got home. And by that first weekend I was getting in my **protein** and my liquids. I was surprised by that. My incisions were all **good** and are pretty much healed up now. I walked **everyday** and **most days** I did get my hour in. It did **make me feel better** I am sure of that. I have been back to the gym and working on getting my stamina back. I had a good **2 week post op** appointment and was **happy** about that. Everything I introduced my sleeve in the soft food stage has **gone well**. So for that I am **grateful**. So I am **following my doctors orders** and doing **two shakes a day** and one **small meal**. I usually have my meal at dinner time with my family. It hasn't bothered me to cook for my family and then eat my little bit of whatever. There is **no way** I want to **mess** this up. I didn't get thru all this to not **follow the rules** and so far **following the rules has been working**.

Blue = Topic or attribute definitions • Green = Positive • Red = Negative • Black (bold) = Neutral

## Results

### Obesity Domain Dashboard



### Epilepsy Domain Dashboard



### Obesity Device Sentiment Overtime



### Epilepsy Device Sentiment Overtime



## Conclusions

Developed upon advanced text analytics, sentiment analysis is a powerful method to harness timely patient preference information from unstructured yet increasingly big data in the social media to complement data collected from other sources.

## Acknowledgments

The authors would like to acknowledge Division of Reproductive, Gastro-Renal, and Urological Devices and Division of Neurological and Physical Medicine Devices for their input on patient preference attributes and dashboard design.



- ...Sir Arthur Conan Doyle

“...You can, for example, never foretell what any one man will do, but you can say with precision what an average number will be up to. Individuals vary, but the percentages remain constant. So says the statistician.”

*Sherlock Holmes*

