10th Stakeholders Forum

Harnessing mobile apps and social media for product safety

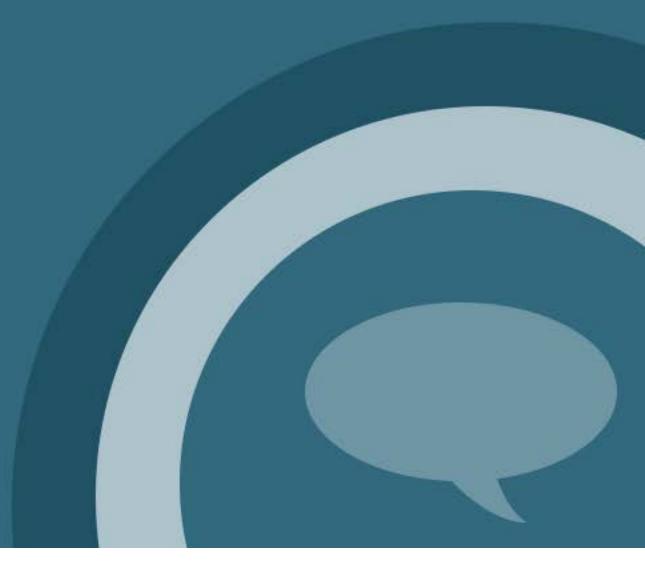
Phil Tregunno, MHRA



WEB-RADR Consortium

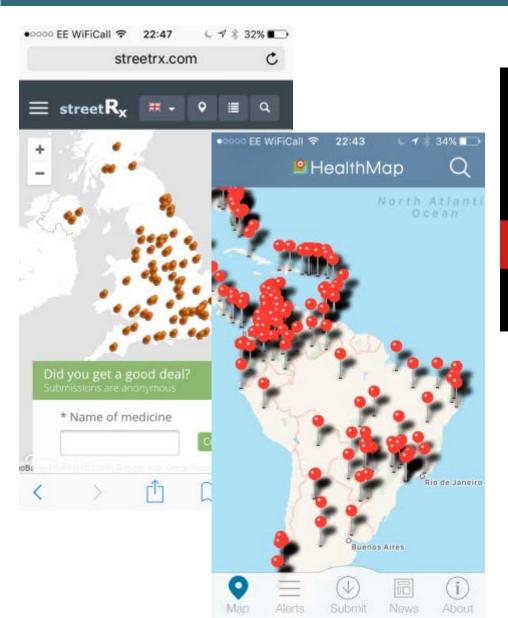


Mobile Apps





Mobile technology



Science MAAAS

| Home | News | Journals | Topics | Careers | |
|---------|------------------|----------------|--------------|------------------|----------------------|
| Science | Science Advances | Science Immuno | logy Science | Robotics Science | Signaling Science Tr |

SHARE

POLICY FORUM | BIG DATA



The Parable of Google Flu: Traps in Big Data Analysis

David Lazer^{1,2,*}, Ryan Kennedy^{1,3,4}, Gary King³, Alessandro Vespignani^{5,6,3}



Apps Launched

| •••• 3 4G 13:41 7 66% ■ | Packa | • | nder developmen the project | t for other MS by |
|---|---------------------------|---------|--------------------------------|-------------------------------------|
| | e 4G 11:13 bijwerkinge | | the tools mi | g how utility of ght be expanded |
| | centrum lare | эD | through AP | S |
| Password | | •••• EE | 4G 11:13 78% 💷 🗅 | |
| | | | 40 1113 70% | Evidence |
| Login | Email | | IALMED | based |
| | Wachtwoord | | Agencija za lijekove | evolution of |
| | | | i medicinske proizvode | tools |
| | Inloggen | | | |
| Create your account | | | | WEB-RADR |
| Forgot Password | | | Email | WED-RADR |

Value

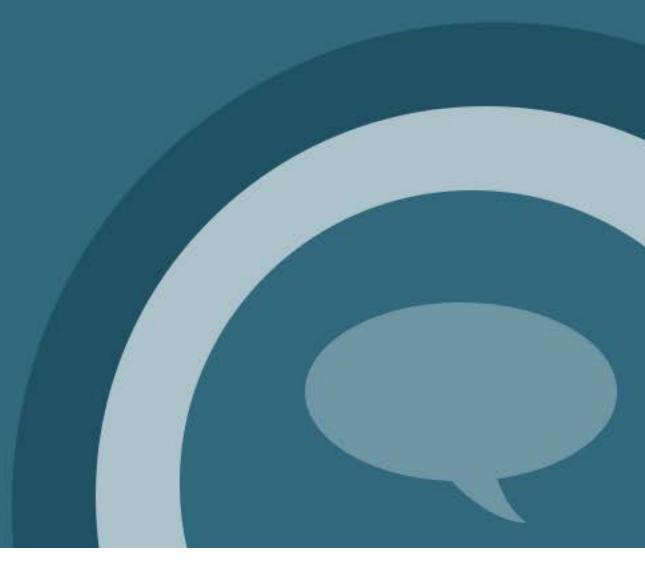
Patient evaluation

- Patient focused studies to understand barriers and facilitators to the use of the app
- Most value in the news feeds and data streams that we can make available

Scientific Value

- Initial view indicates that the data are equivalent value to traditional data
- Quality & Value under formal evaluation but already contributing to signal detection

Social Media





Adverse Events In Social Media

Challenges in detecting events

- Idiomatic expressions, slang, mistakes
- Symptoms vs indications
- Large volume of potentially irrelevant data
- Challenging to code into MedDRA

Challenges in signal detection

- Either stand-alone or combine with spontaneous reporting
- If combining how do we do it?

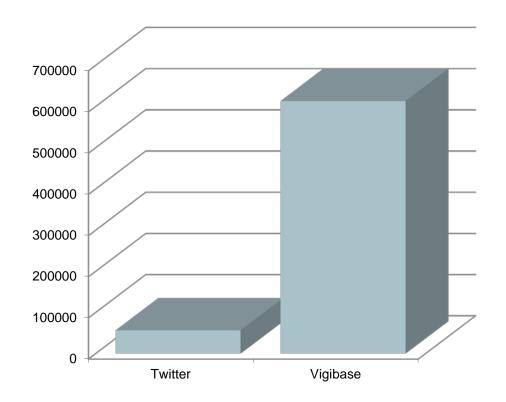




Comparisons with Vigibase

Step One: How many adverse events in Twitter vs Vigibase

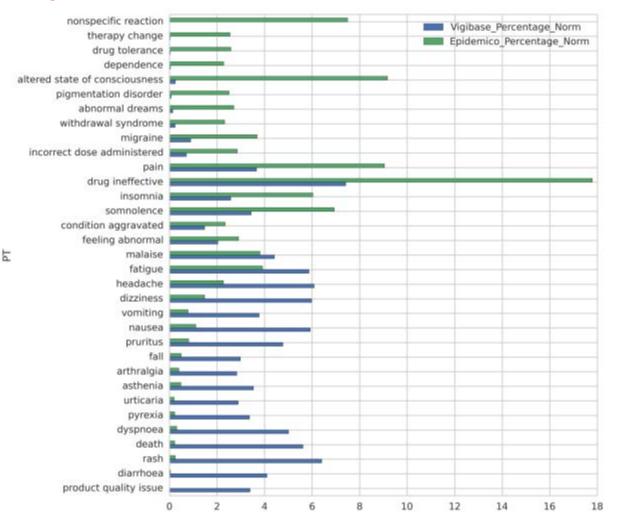
- Data collected: March 2012 -> March 2015
- 38 WEB-RADR generics
- Threshold at "Epidemico score" of 0.7 (Twitter)
- Remember: detected events





Comparisons with Vigibase

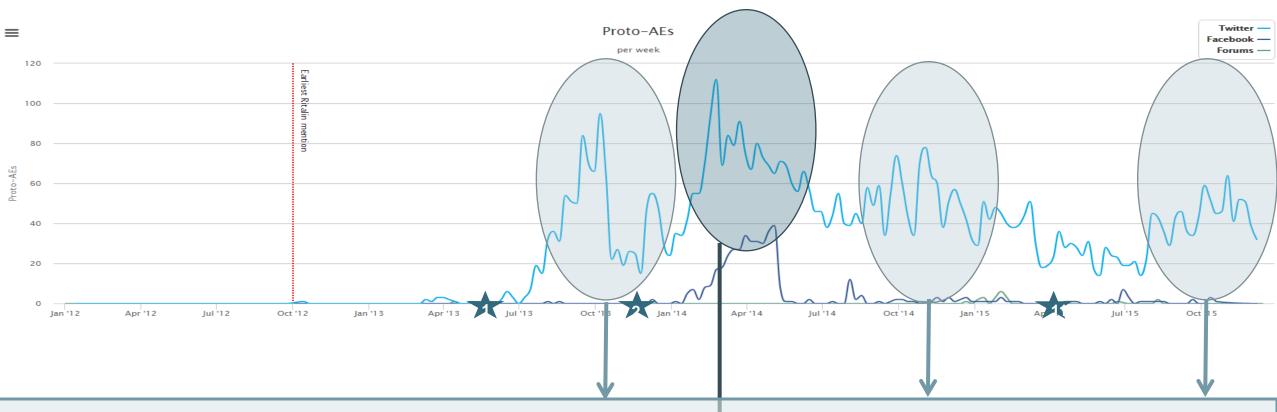
Comparisons at the Preferred Term level



- Social Media may be data-rich for specific event types i.e. drug tolerance, dependence, withdrawal syndrome,
- For these specific events it could be the informal nature of social media i.e. not reporting to a physician or official body
- Several potential explanations for the observed differences in the mediums...



Social media conversations on Ritalin over time

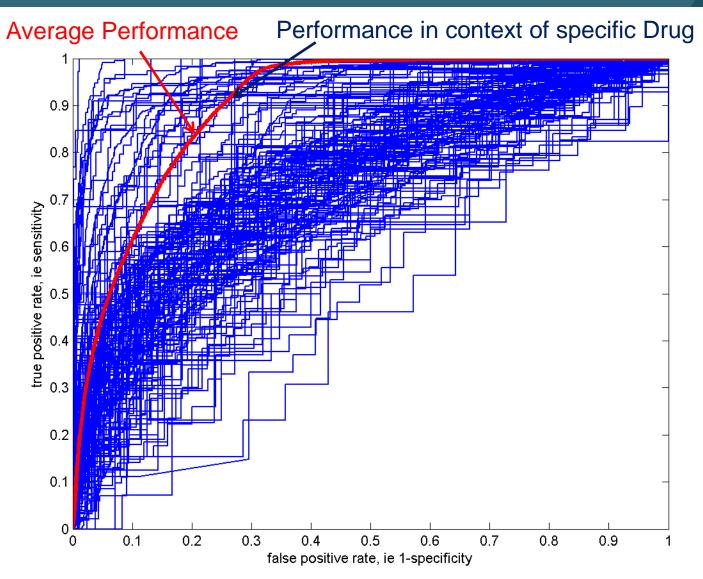


October \rightarrow November – academic work, cold season, contributing to increase mentions

March \rightarrow April– academic work contributing to increase



Performance Varies Across Drugs



| Drug | #Training Data | AUC |
|-----------------------|-------------------|----------|
| humira | 1481 | 0.689893 |
| prednisone | 1700 | 0.740568 |
| co-codamol | 2294 | 0.770509 |
| oxycodone | 1767 | 0.770942 |
| meningococcal vaccine | 1866 | 0.811062 |
| essure | 2877 | 0.931683 |
| flu shot | 4569 | 0.943119 |
| hpv vaccine | 1668 | 0.956768 |
| gardasil | 2140 | 0.970276 |
| vaccine | 5959 | 0.973777 |
| tetanus vaccine | 3069 | 0.975138 |



Where is it useful?

Added value in analysis of:

- Abuse & misuse
- Real world use of medicines



- 'Unexpected benefits'
- Evidence of 'clinical trials' being conducted by users to attain different 'benefits'
- Patterns of abuse both geographically and seasonally
- Patient tolerance and reasons for stopping medication



(drugfree.org)

Where is it useful?

Added value in analysis of:

- Neurological & psychiatric effects
- Pregnancy
- Lifestyle treatments or events



- Large volume of data related to both medicines and events with neuro-psychiatric effects
- Potential for longitudinal analysis of a record; elimination of recall bias over pregnancy?
- Medically less serious events which have a serious impact on the patient and affect compliance



Pregnancy

RETWEET

4







Rebekah Vardy @RebekahVardy · Jun 20 🌃 Come on England..... 🦁 🦁 🦁



| 4 | £7 | 52 | | 444 | |
|---|----|----|--|-----|--|
|---|----|----|--|-----|--|

Policy



- Recommended terms of engagement for technologies within legal and ethical boundaries
- How does the new data fit alongside traditional data
- Where can social media be harnessed to support regulatory decision-making in PV
- Watch this space!



Thank you. Questions?

Contact:

Phil.Tregunno@mhra.gsi.gov.uk WEB-RADR@mhra.gsi.gov.uk

