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Utilizing the 'crowd trial' for pharmacovigilance: a case report

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Objective

The 'wisdom of the crowd' or the 'crowd trial' is a process of taking into account the collective intelligence of a large population sharing experiences regarding health issues and treatments online via social media platforms [Health 2.0], generating novel data sets comprising massive unstructured user-generated content of health reports.

Unlike regulated formal postmarketing reports, the crowd trial takes place spontaneously, continuously and on a very large scale. This crowd trial provides a snapshot of health trends and has become a proxy of postmarket clinical trials of medications and other therapies.

The purpose of this case report is to demonstrate how applying an additional data source originated from e-patient reports helps support drug surveillance and pharmacovigilance processes.

Introduction

Singulair (Montelukast Sodium) is a leukotriene receptor antagonist, indicated to prevent asthma attacks in adults and children. It is also used to relieve allergies in adults and children.

Singulair was approved by the FDA in February 20, 1998. In March 2008, the FDA informed healthcare professionals of investigating the possible association between Singulair usage and behavior/mood changes, suicidality and suicide.

First Life Research (FLR) identifies, analyzes, indexes and aggregates user-generated content by collecting billions of testimonials from social networks. It utilizes cutting edge technologies for massive data aggregation and applies advanced natural language processing (NLP) techniques for continuous analyses, in order to convert this unstructured data into refined information.

Methods

With the proliferation of social networks, the web has become a warehouse of patient discussions and reports, estimated at 10 billion records and growing at a rate of 40 percent per year. These reports are spread across more than 150,000 (and growing) English-language sites, forums and blogs. FLR has searched and mapped thousands of these sites and indexed hundreds of millions of posts (currently 800M) and is engaged in refining statistical methods of signal detection that enables investigation of health trends. FLR can look at large samples and discover small changes, such as drug side effects, which may not be discovered by other means for years.

Results

In this case, FLR detected the mentioned FDA alerts and related clinical manifestations prior to the official alert by 'listening' to the 'crowd trial', in that case, the Singulair users. Fig. 1 displays the first statistical peak (2004–2005) of reports mentioned Singulair usage, generated by the e-patients, discussing sleep disturbances and hallucinations. The second peak (2006) of reports discussed mood alterations and suicidal-related ideations. While the earliest manufacturer label modification took place in September 2007, and soon after (March 2008) FDA publication regarding ongoing safety review of Singulair, FLR demonstrated a drug surveillance and early detection capability few years earlier.

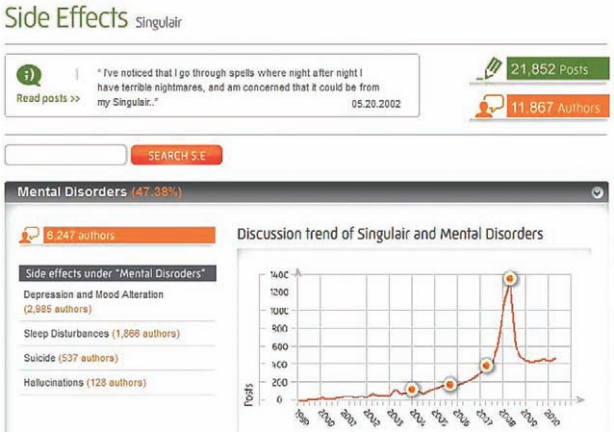

Fig. 1. FLR signal detection in the Singulair discussions trend overtime.

Conclusions

This report shows that by 'listening' into the social web, unforeseen phenomena may be revealed. Specifically, it is evident that advanced technological solutions and signal detection algorithm were able to detect neuropsychiatric events (side effects) in the case of Singulair, more than 2 years prior to any official warning by the regulator or the manufacturer.

'Crowd trial' provides a dashboard of health trends and grants feedback on medications, drug safety, side effects, interactions and drug comparisons.

The insights gained and demonstrated as aforementioned can be used to support and enable better informed decision making processes, both for patients and healthcare providers.

Keywords

Drug surveillance; user generated content; crowd trial; adverse drug reaction

Acknowledgments

The emerging 'wisdom of the crowd' analytics potentially represents a new phase and eventually new tools using data evaluations based on large scale population inputs, and it will benefit greatly all public health environment.

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