Patient Voice in Drug Safety

Natalie Gavrielov, Data2Life

The importance of patients' involvement in drug development has been recently emphasized by the Regulators and Health Authorities. Under FDA PDUFA VI legislation, the process of drug development should include information collection on disease burden, drug benefits and risks directly from the patients (1). One of the approaches that allows the representation of patient perspective on a true large scale is collecting patient-generated content in social media (SM). The implementation of this approach has so far been delayed due to numerous obstacles involved in SM processing. Specifically in the field of drug safety, the challenges of working with on-online patient-reported adverse events (AEs) include processing vast volumes of patient-generated and clinically unsubstantiated reports, dealing with layman colloquial language, misreporting of drug names and clinical events as well as misinterpretation of patient experience.

Data2Life AE identification in SM is performed using the Statistical Learning method, which includes Feature-Based methods and uses lexical, syntactic and semantic features. These methods perform language pattern recognition to identify associations made by the author of the post between a drug and a clinical event. In addition, these methods are able to classify potential associations into such categories as indication, interaction and AE. Using these methods we have been able to set up a data pipeline, which processes millions of posts and identifies among them drug-event pairs, which are classified as patient-experienced AEs. Using disproportionality algorithms on these AEs we were able to identify drug safety signals that show a sensitivity of 55%, specificity of 84% and accuracy of 73%, when compared to World Health Organization (WHO) safety signal identification. These results demonstrate that patient-generated data processed with Data2Life analytical pipeline are consistent with the WHO safety datasets, and provide a valid source of additional AEs, which can be incorporated in drug safety examination throughout the product life cycle.

1. https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM511438.pdf.
2. Liu Jing, Zhao Songzheng, Zhang Xiaodi. An ensemble method for extracting adverse drug events from social media.Artificial Intelligence in Medicine http://dx.doi.org/10.1016/j.artmed.2016.05.004