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## Text Mining From Drug Surveillance Report Narratives

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## **Text Mining From Drug Surveillance Report Narratives**

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Analysis of postmarket drug surveillance reports is imperative to ensure drug safety and effectiveness. FAERS (FDA Adverse Event Reporting System) is a surveillance system that monitors Adverse Events (AEs) from drugs and biologic products. The AEs are reported through MedWatch voluntary reports (initiated from patients and healthcare providers) and mandatory reports (initiated from manufacturers). Much of the information in the voluntary AE reports is narratives or unstructured text. The increasing volume of individual reports, estimated at more than one million per year, poses a challenge for the staff to review large volume of narratives for drug clinical review. We are developing a computational approach using Natural Language Processing and UMLS MetaMap biomedical software to parse the narratives, recognize named-entities in the text and extract consumer/patient and related drug indications and adverse drug reaction information. The goal is to develop a text mining tool that automatically extracts relevant information from the report narratives which can be stored in pre-defined data fields in the FAERS database for efficient searching and querying during clinical review process.

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