**Frontiers in signal detection: from spontaneous reporting to big data and social media**

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In post-marketing drug surveillance, signal detection activities constitute a key element. A signal is an “information that arises from one or multiple sources which suggests a new potentially causal association or a new aspect of a known association, between an intervention and an event or set of related events, either adverse or beneficial, that is judged to be of sufficient likelihood to justify verificatory action”. For these activities, it could be used several data sources having different qualities and shortcomings to achieve a timelier and more accurate signal detection. Historically, among data sources, the cornerstone was represented by individual case safety reports sent through the spontaneous reporting system. Recently, evidence from systematic comparative studies suggests that the use of multiple data sources and the parallel use of multiple signal detection methods could achieve a precocious and more precise identification of safety signals. In this scenario, Big Data and social media have emerged as promising data sources thanks to the velocity and amount of generated data. However, technical, ethical, and regulatory aspects remain unsolved. In particular, using social media as data source have technical challenges such as the development of algorithms able to identify and interpret suspected adverse drug reaction based on information posted. In fact, recent studies have evidenced that only a minority of suspected adverse drug reactions identified by algorithms through social media necessitated being reported. From a regulatory and ethical perspective instead, grey area still exists for the applicable “acquis communautaire” and it remains an undefined boundary of what constitutes public and private data making challenging the data acquisition. The use of Big Data as data source instead, if from one side have as advantage the presence of more clinical-oriented data such as those deriving from observational, experimental, and knowledge-based data which are more easily translated to pharmacovigilance applications, it has on the other hand various degree of reliability and bias. As for social media also for Big Data, a wide range of technical and analytical issues exists but also problems related to data volume, privacy, security, and ethics that need to be addressed.