AUGMENTING POST-MARKET SURVEILLANCE OF SERIOUS DRUG-INDUCED ADVERSE EVENTS WITH ARTIFICIAL INTELLIGENCE (AI)-AGGREGATED CASE REPORTS: PROOF-OF-CONCEPT FOR PD-1/PD-L1 INHIBITORS FOR NSCLC

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Background The United States Food and Drug Administration Adverse Event Reporting System (FAERS), EudraVigilance and the World Health Organization’s VigiBase are global gold standards for reporting of adverse events (AEs). However, these platforms rely on spontaneous reporting and are limited by under-reporting, time-lag between event occurrence and discovery as well as lack of drug-event causality. Peer reviewed published case reports are a high quality source of AE reports. However, the breadth and use of this source of AE data is poorly understood, and has not been previously systematically explored.

Methods Using an illustrative example of PD-L1/PD-1 inhibitors for the treatment of non-small cell lung cancer, we extracted serious immune-related AEs from OpenCaseTM, a digital platform that systematically aggregates and structures real world evidence from case reports in published peer-reviewed literature. We similarly extracted serious immune-related AEs reported to the FAERS database and compared the characteristics, frequency and types of serious immune-related AEs reported by each source, from 2015 to 2021.

Results Over the study period, we captured a total of 1,717 serious immune-related AEs across both OpenCaseTM and FAERS. Of these, over 75% of reported AEs were from non-US sources. The geographic and socio-demographic distribution by country, age and sex were similar across OpenCaseTM and FAERS. OpenCaseTM captured a total of 556 unique serious immune-related AEs, compared to 1,161 in FAERS. We collected a total of 73 unique types of serious immune-related AEs across both data sources. After removing duplicates, we found that OpenCaseTM captured a total of 15 unique types of serious immune-related AEs, not captured in FAERS.

Conclusions Our study demonstrates the overwhelming value of aggregated published peer-reviewed case reports for augmenting gold standard serious immune-related AE reporting by FAERS, both in terms of the amount (frequency) and quality (unique types). These findings suggest that FAERS and other global AE reporting databases should consider the systematic incorporation of case report AE data into their post-market surveillance of PD-1/PD-L1 inhibitors for non-small cell lung cancer.

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