Supplementary Methods

Utilization of VigiFlow, VigiBase, VigiLyze, and VigiAccess in pharmacovigilance research

Pharmacovigilance plays a critical role in monitoring, assessing, and preventing adverse effects associated with pharmaceutical products. The Uppsala Monitoring Centre (UMC, Uppsala, Sweden) has developed several tools—VigiFlow, VigiBase, VigiLyze, and VigiAccess—to enhance global pharmacovigilance efforts and ensure robust data management and validation. This section details the utilization of these tools in our research.

VigiFlow: data collection and management

VigiFlow (https://who-umc.org/pv-products/vigiflow/) serves as a web-based system for managing individual case safety reports (ICSRs) and facilitates adverse event reporting by healthcare professionals, pharmaceutical companies, and national pharmacovigilance centers, either mandatorily or voluntarily. VigiFlow supports ICH E2B-compliant report submissions, facilitating seamless integration and exchange of pharmacovigilance information internationally.

A core feature of VigiFlow is its capability for detailed data entry and management. The system allows comprehensive recording of adverse event information, including patient demographics, medical history, and drug exposure. VigiFlow incorporates built-in validation checks as part of its quality assurance measures, ensuring that reports are complete and accurate before submission. Additionally, VigiFlow provides multi-level access controls to ensure data security and confidentiality, protecting sensitive patient information and ensuring compliance with data protection regulations.

VigiFlow also supports interoperability, allowing data exchange with other pharmacovigilance systems using standardized formats like ICH E2B. Since reporters do not submit adverse events directly to World Health Organization (WHO) but their national pharmacovigilance centers, this capability is crucial for maintaining consistency across different systems and facilitating effective communication and data sharing between national and international entities. Especially in South Korea, the Korea Institute of Drug Safety and Risk Management (KIDS) oversees pharmacovigilance activities and is responsible for reporting to WHO and managing local pharmacovigilance data.

VigiBase: global data repository

VigiBase (https://who-umc.org/vigibase/), maintained by the UMC and endorsed by WHO, is the world's largest repository of adverse drug reaction (ADR) reports, housing over 20 million entries from more than 130 member countries. Funded by contributions from member states, VigiBase supports signal detection through advanced statistical methodologies, facilitates in-depth ADR analyses for researchers, and promotes global collaboration in pharmacovigilance.

VigiLyze: data analysis and visualization

VigiLyze (https://who-umc.org/pv-products/vigilyze/) provides advanced analytical tools for exploring and interpreting VigiBase data. It enables complex queries, graphical representations (e.g., time trends and geographic distributions), and statistical algorithms to detect and evaluate safety signals in real-time. This user-friendly interface enhances the understanding of pharmacovigilance data for researchers and healthcare professionals.

VigiAccess: public access and transparency

VigiAccess (https://vigiaccess.org/) offers public access to VigiBase data, promoting transparency and raising awareness about drug safety. Accessible through an intuitive interface, it allows users to search and retrieve information on adverse reactions, providing valuable insights into pharmacovigilance findings.