

Fast, robust and flexible – statistical screening of national subsets in VigiBase through VigiLyze

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National quantitative signal detection

The new VigiLyze offers disproportionality analysis using IC, PRR or ROR, based on national or regional subsets of VigiBase that the users can define themselves. Side-by-side presentation of the global numbers provides a quick and clear overview and powerful filters help the user focus on combinations of particular interest.



Investigations to document and share information

The new Investigations feature is connected to combinations of drug(s) and reaction(s), which makes it possible to immediately see if someone has already looked at something connected to a drug and/or reaction of interest. It is also easy to see UMC's signals and potentially also other organisations' signals in connection to drug and reaction. This increased transparency will minimise duplication of work.

The screenshot displays the VigiLyze interface. The main table shows search results for 'Colecaciferol' with columns for 'Active ingredient(s)', 'Reaction (PT)', 'Investigation', and 'Sweden' (with sub-columns for N_{observed}, N_{expected}, IC₀₂₅, and IC). A secondary 'Global' column is also present. The right-hand panel shows an 'Investigation' detail view, including 'Information', 'Attachments', 'Name', 'Assigned to', 'Signal status', and 'Scope of original search'. The interface is clean and professional, with a dark blue header and white content area.

In 3.3s

we calculate the background IC for 3,338,522 combinations (which includes figures for both global statistics and statistics for an arbitrary regional subset) originating from 21,050,358 reports.

When background statistics are calculated, sorting, filtering and pagination is done within

0.2s

Background

All national pharmacovigilance centres (NCs) of the WHO Programme for International Drug Monitoring (PIDM) member countries have free access to the WHO global database of individual case safety reports, VigiBase, through the online system VigiLyze. A major update was released on 14 May 2019. A fast and flexible statistical screening of the national subsets of VigiBase data is now possible, using the country's own data as background for disproportionality analysis (DA), or changing the DA background to include multiple countries, thus enabling regional collaborations. One major challenge with enabling dynamic backgrounds is that with this large amount of data (over 21 million case reports from over 130 countries and 3.2 million unique drug-ADR combinations) the number of possible country combinations is astronomical, making pre-calculation impossible when offering users the ability to define backgrounds based on their own country or multiple countries working together.

Objectives

To enable national and regional signal detection for NCs using DA based on VigiBase data while ensuring speed and flexibility in the analytical functions. With the improved regional analysis support we also needed to ensure that the system supports the entire signal management process. Another goal was to minimise the risk for duplication of work through increased transparency within and between organisations of the WHO PIDM.

Methods

The VigiLyze development team implemented DA on-the-fly using highly optimised in-memory representations of the entire dataset and highly optimised algorithms. We identified common denominators in signal management processes and key concepts for the new VigiLyze through interviews and discussions with NCs in different parts of the world. During development, close contact with reference users ensured that relevant and prompt feedback was fed into the agile development process.

Results & Conclusions

The novel in-memory techniques made DA possible not only on the entire VigiBase, but also on any arbitrary subset of VigiBase in real time, solving speed and flexibility issues. The new VigiLyze performs all necessary DA calculations in seconds based on background data specified by the user. It also includes workflow support for signal management, enabling NCs to use VigiLyze to document assessments and decisions connected to drug and reaction information in a structured way. By having access to previous investigations within an organisation and signals shared by other organisations, the risk of duplicating work is minimised. The ambition for the new VigiLyze is for it to become the centerpiece of the WHO PIDM, enabling cross-regional collaborations and information exchange through a common platform. *Please note that VigiLyze is only available to national pharmacovigilance centres who are members of the WHO PIDM.*

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