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Safety Monitoring and Signal Detection for the Novel COVID-19 Vaccines on a Global Scale

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Introduction

Up to 15 October 2021, VigiBase, World Health Organization's (WHO) global database of suspected adverse reactions (ADRs) to medicinal products (ICSRs)¹, contained over 28 million reports from more than 140 member countries of the WHO Program for International Drug Monitoring (PIDM). VigiBase is managed by Uppsala Monitoring Center (UMC) on behalf of the WHO.

Since the end of November 2020, 2.2 million ADR reports for COVID-19 vaccines were entered in VigiBase accounting for 60% of all vaccine reports in the database. The large number of reports received in a short time requires semi-automated data handling and signal prioritization exceeding previous signal detection operations.

Aim

To monitor the safety of the COVID-19 vaccines from a global perspective.

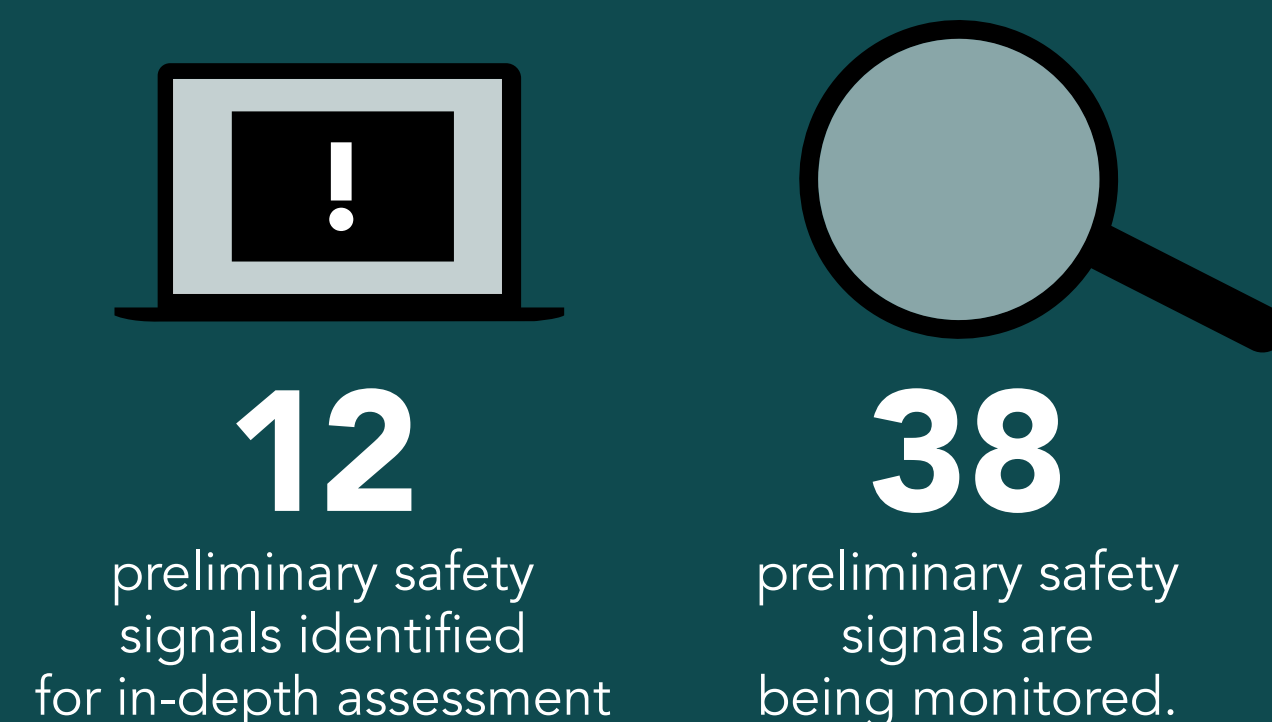
Methods

Screenings of VigiBase are performed regularly. Statistically ranked drug-event combination lists that focus on a theme, e.g. low- and middle-income countries, emerging safety signals, or testing new methods are prepared. Multi-disciplinary teams then assess the combinations together. This is typically done during focused multi-day workshops. To complement this, general regular screenings are performed and hints from other sources (e.g., scientific literature, media reports, etc.) are followed.

Several statistical methods are used in the screening efforts. Disproportionality analysis compares the observed number of reports for a drug-event combination to the expected number based on the overall reporting in the database. **vigiRank**² an algorithm combining five strength-of-evidence parameters into a score, provides a ranking of drug-event combinations. **vigiGroup** clustering³ automatically groups reports with similar adverse event profiles in a data driven way. Its purpose is to uncover clinically coherent pictures that might otherwise evade detection. **vigiPoint**⁴ is a tool to quickly explore differences in one set of reports compared to one or more reference sets. This enables exploration of various covariates. Features that are significantly and robustly different are highlighted for review.

Identified preliminary safety signals are subject to weekly prioritization. Points to consider for prioritizing a combination for in-depth assessment include e.g. multinational reporting, the reaction's seriousness, etc.

Confirmed safety signals are shared with the WHO PIDM member states.



Results

Up to 15 October 2021, 12 safety signals have been identified for in-depth assessment via different signal detection activities. Another 38 preliminary safety signals are being monitored.

Conclusion

VigiBase is the world's largest database of suspected ADRs to medicinal products. Therefore, UMC is in a good position to monitor the vaccines' safety maintaining the global perspective with the potential to find emerging safety signals early.

References

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