



20<sup>TH</sup> ANNUAL MEETING

ISOP 2021

8-10 NOVEMBER 2021

INTEGRATED PHARMACOVIGILANCE  
FOR SAFER PATIENTS



P103

## Exploring the Safety Profiles of the COVID-19 Vaccines in VigiBase Using vigiGroup, a Novel Method for Clustering ICSRs

# Exploring the Safety Profiles of the COVID-19 Vaccines in VigiBase Using vigiGroup, a Novel Method for Clustering ICSRs

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### vigiGroup

Disproportionality has been a stalwart of post marketing safety surveillance; however, it has some drawbacks, such as neglecting the context that the report provides or focusing on single terms<sup>1</sup>. vigiGroup is a novel ICSR clustering method which can complement disproportionality analysis. The clustering method functions by grouping reports based on their co-reported terms, with the objective of creating clusters of reports with the same clinical picture<sup>2</sup>.

### Applying vigiGroup on the covid-19 vaccines

From January onwards VigiBase started to receive tens of thousands vaccine reports each week, for each of those weeks the vigiGroup cluster analysis was applied on the accumulated data and the resulting clusters were manually reviewed by pharmacovigilance experts. The need for a structured and reliable manner of reviewing the data became apparent quickly and a web app was developed to display all the results. The web app was continuously supplemented with requested features from the reviewers.

### Results

A number of potential safety signals have been identified from reviewing the clusters. These include appendicitis, hearing loss/tinnitus for all COVID-19 vaccines and delayed local reactions to the Moderna vaccine, which were identified in the web app with the aid of embedded data visualisation tools. Several more signals have been strengthened by further incorporating vigiGroup as a complementary tool to traditional disproportionality analysis. We have moreover demonstrated the efficacy of the algorithm by recovering labelled adverse reactions, such as hypersensitivity and anaphylaxis, and emerging safety signals, e.g. myocarditis, for all the vaccines.

### Conclusion

We have explored the use of prospective signal detection using the novel clustering method vigiGroup and found it to be a promising tool in both finding signals as well as complementing the usual signal work based on disproportionality analysis.

### References

1. J. H. A. B. G Niklas Norén, Shrinkage observed-to-expected ratios for robust and transparent large-scale pattern discovery, *Statistical Methods In Medical Research*, 2013.
2. E.-L. M. R. C. G. Niklas Norén, "Consensus clustering for case series identification and adverse event profiles in pharmacovigilance," Accepted in *Artificial Intelligence in Medicine*.

