

Evaluating **vigiGroup** for adverse event cluster analysis

What is **vigiGroup**?

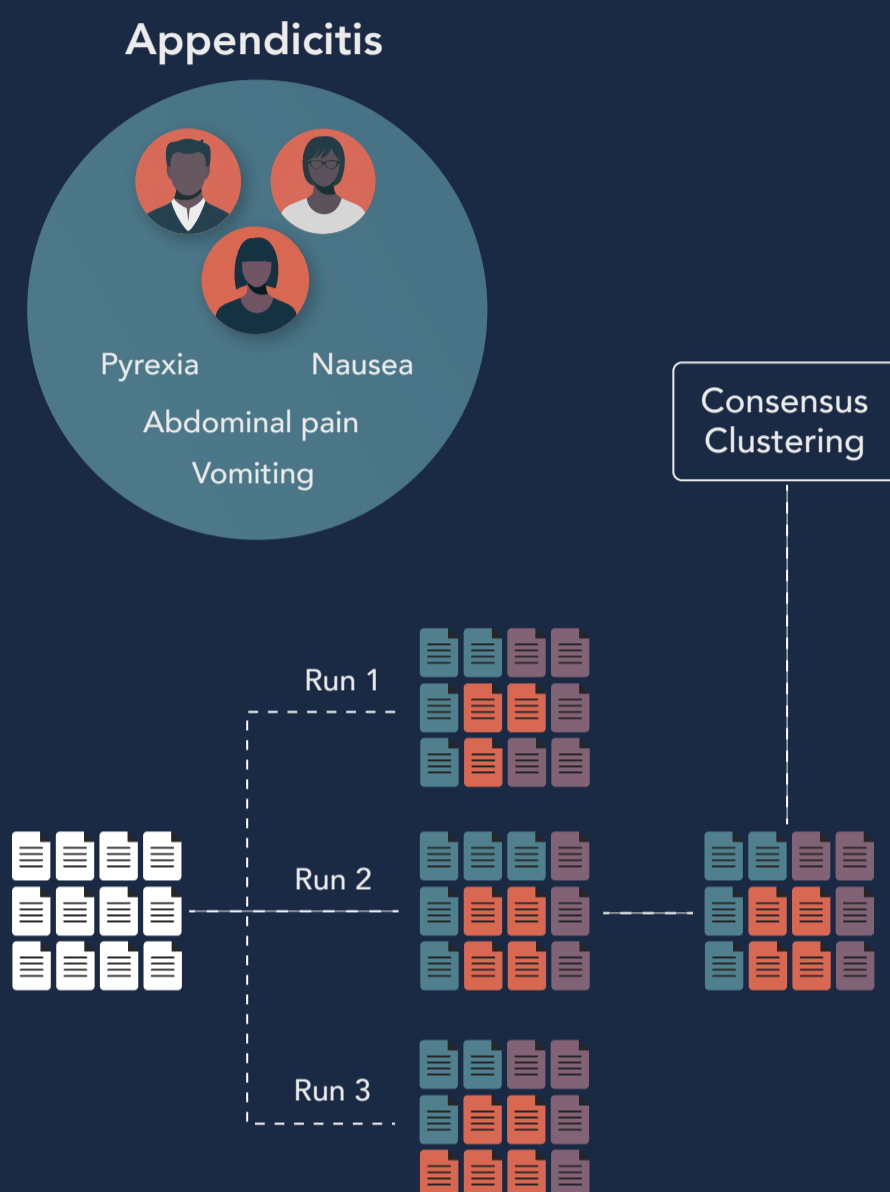
vigiGroup is a clustering method developed at UMC which can identify groups of reports with similar adverse event profiles.

In contrast to standard signal detection methods which focus on one adverse event term at a time, **vigiGroup** considers the complete set of reported terms. This provides new, complementary ways of looking at safety data.

How does it work?

vigiGroup is based on a standard clustering algorithm (called a mixture model) modified to improve its use in signal detection.

For example, multiple runs of the standard algorithm produces slightly different results, affecting how often the terms appear in each cluster. To solve this problem, **vigiGroup** combines the clusterings created during repeated runs of the algorithm into one consensus clustering. This better captures the clinical patterns which were repeatedly identified in the initial clustering runs.

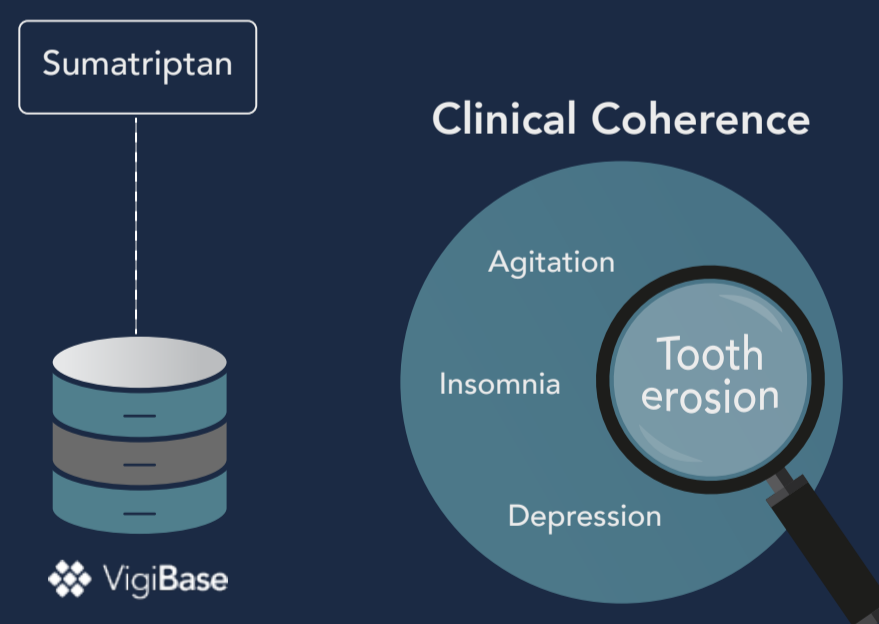


How was **vigiGroup** evaluated?

In this study, we applied **vigiGroup** to adverse event reports from Vigibase, for three drugs, one of which was Sumatriptan.

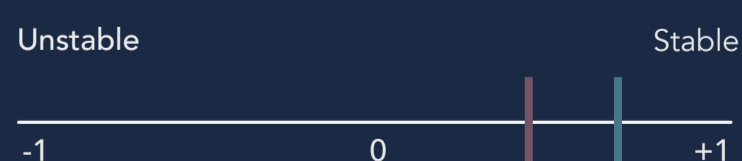
Stability was measured by applying the methods multiple times and using a score for stability, the adjusted Rand index, to quantify the similarity of the resulting clusters.

To systematically test if the resulting clusters were clinically coherent, an intruding term was added to the most common adverse event terms in a cluster. If a clinical expert could spot the term, it was a sign that the cluster was clinically coherent.



What did we find?

vigiGroup's consensus clustering improved both stability and clinical coherence as compared to the standard mixture-model algorithm.



Drug	Method	Intruder detection rate
Sumatriptan	Mixture model	85%
	vigiGroup	88%

Drug	Method	Adjusted Rand index
Sumatriptan	Mixture model	0.62
	vigiGroup	0.86