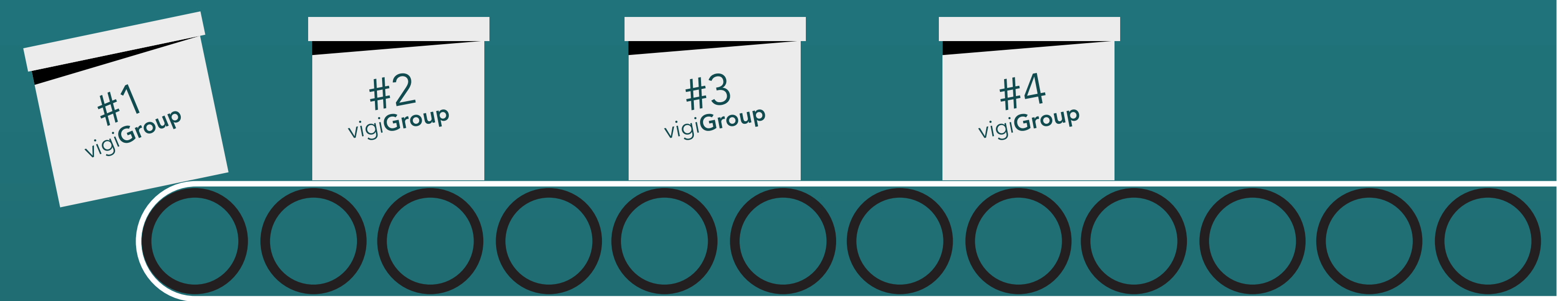


# Evaluating the Efficacy of Clustering Methods Applied to Adverse Event Reports

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VigiGroup is a cluster analysis algorithm developed at the Uppsala Monitoring Centre which aims to produce clinically coherent groups of adverse event (AE) reports to help overcome limitations with screening only single AE terms. However, clustering methods are difficult to evaluate. This poster describes how we evaluated proposed improvements to the algorithm.



A series of proposed improvements were made to vigiGroup, and each passed through a battery of fast, automated evaluation metrics.



## Bad Performance on Known Clusters

We applied the method to datasets which included report groups which were known to share a similar clinical picture. We measured how well these known clusters were recovered.

## Chosen model

Based on these automated metrics, we picked the most promising model for a detailed comparison to vigiGroup's original formulation.

## Clinically Incoherent

Pairs of AE reports were assessed by a clinical expert as either describing similar or different clinical pictures. We then measured how often our method clustered the related pairs together, and separated the unrelated pairs.

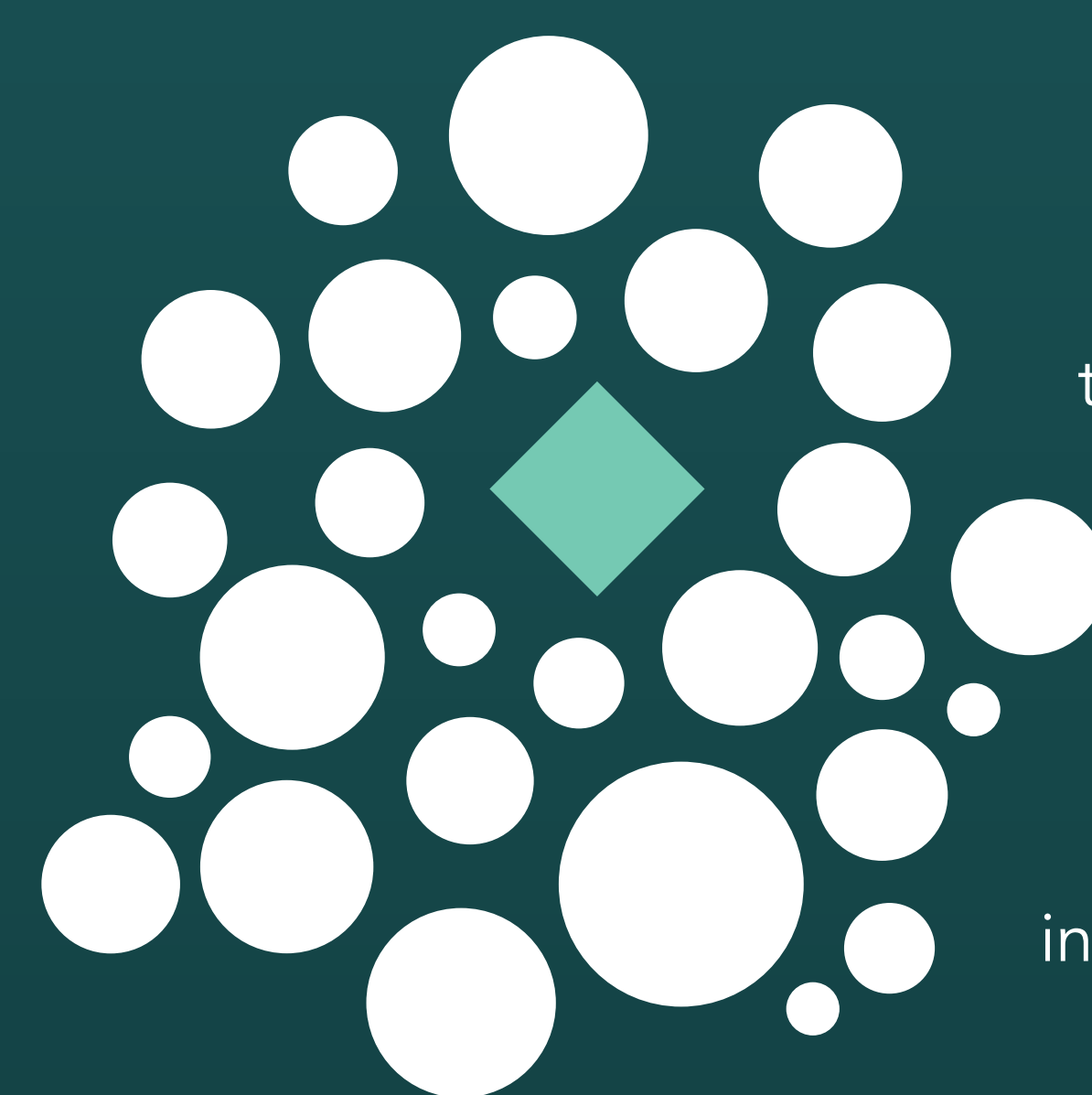
## Unstable

We use the adjusted Rand index, a standard measure of cluster stability, to determine whether our method produced consistent results

## In Depth Evaluation

Domain experts made an inventory of all clinically coherent themes present in the clusters produced by the methods and in the summary of product characteristics.

- **The efficiency** of the method was quantified by how many clusters each method produced compared to the number of distinct clinical themes.
- **The coverage** was quantified as the fraction of the safety profile of the drug captured by each method.
- **The coherence** was quantified as the fraction of clusters produced by each method that had identifiable clinical themes.



## Intruder detection

Intruder detection measures another type of cluster coherence. Term intruder detection involves adding unrelated AEs to the summary of the cluster. Report intruder detection involves adding an additional report to a cluster. Each are quantified as the fraction of intruders recognised by a domain expert.

## Results

Whilst the proposed improvements to vigiGroup showed promise, the in-depth evaluation by domain experts showed that the original formulation was more successful. It was found that defining metrics driven by clinical expertise was invaluable in understanding the difference in the behaviour of the methods and evaluating their practical applicability.

