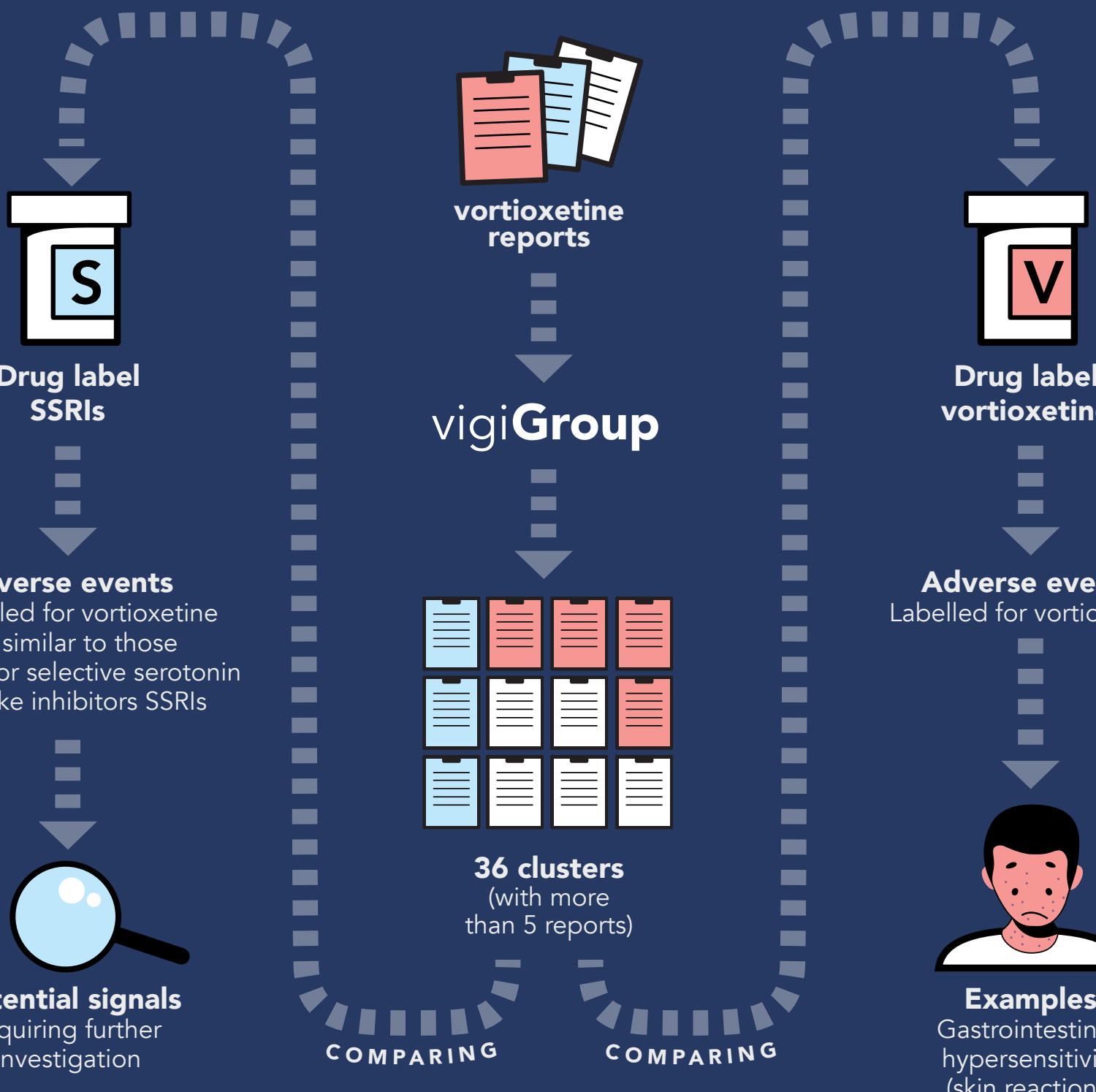
vigiGroup for exploration of a drug's safety profile



What is vigiGroup?

With vigiGroup cluster analysis, we seek to discover patterns in data from adverse event reports based on all recorded signs, symptoms, and diagnoses. Additionally, the algorithm groups adverse event reports based on the clinical conditions described in them, like human experts would. This provides new, complementary ways of evaluating the safety of medicinal products.

How was vigiGroup used?

Reports for vortioxetine from VigiBase were clustered using vigiGroup. Clinical experts reviewed each cluster and identified the clinical condition presented, suggested a mechanism of action, and compared the adverse event to the label of vortioxetine and those of SSRIs.

What was found?

Clusters of adverse events which were consistent with those labelled for vortioxetine and SSRIs in general were identified. Additionally, clusters of adverse events unlabelled for vortioxetine but labelled for SSRIs were also identified, which might represent potential signals for further investigation.

Uppsala Monitoring Centre