Examples of our PASS studies in secondary or specialist care

ROSE Study: Rivaroxaban Observational Safety Evaluation Study

This PASS study monitored the short term (first 3 months) safety and utilisation of rivaroxaban (Xarelto®) prescribed for medical conditions requiring anticoagulation by specialists in secondary care in England and Wales.

Further information is available in these publications:

Evans, A., Davies, M., Osborne, V., Roy, D., & Shakir, S. (2020). Incidence of major and clinically relevant non-major bleeding in patients prescribed rivaroxaban for stroke prevention in non-valvular atrial fibrillation in secondary care: Results from the Rivaroxaban Observational Safety Evaluation (ROSE) study. PloS one, 15(10), e0240489.

Evans, A., Davies, M., Osborne, V., Roy, D., & Shakir, S. (2020). Evaluation of the incidence of bleeding in patients prescribed rivaroxaban for the treatment and prevention of deep vein thrombosis and pulmonary embolism in UK secondary care: an observational cohort study. BMJ Open, 10(11), e038102.

ROSE ACS Study: Rivaroxaban Observational Safety Evaluation Study post-Acute Coronary Syndrome Study

This PASS study monitored the short term (first 3 months) safety and utilisation of rivaroxaban (Xarelto®) when prescribed with antiplatelet therapy or dual antiplatelet therapy for the secondary prevention of atherothrombotic events in adults after acute coronary syndrome (ACS).

Further information is available in this publication:

García-Rodríguez, L. A., Wallander, M. A., Friberg, L., Ruigomez, A., Schink, T., Bezemer, I., Herings, R., Shakir, S., Evans, A., Davies, M., Suzart-Woischnik, K., Vora, P., Balabanova, Y., Soriano-Gabarró, M., & Brobert, G. (2020). Rationale and design of a European epidemiological post-authorization safety study (PASS) program: rivaroxaban use in routine clinical practice. Expert opinion on drug safety, 19(11), 1513–1520.

OBSERVA Study: Observational Safety Evaluation of Asenapine

This PASS study monitored the safety and utilisation of the atypical antipsychotic, asenapine (Sycrest®), in the mental health care setting in England and Wales.

OASIS Study: Observational Assessment of Safety in Seroquel SCEM study

The OASIS study was conducted as part of the risk management plan for the product Seroquel XL prescribed for schizophrenia and mania associated with bipolar disorder. It was designed to examine the short-term (up to 12 weeks) safety and use of quetiapine fumarate in the prolonged-release formulation (Seroquel XL™), along with a comparator group started on the immediate-release formulation, quetiapine IR. The DSRU worked in collaboration with the Mental Health Research Network (MHRN) to recruit patients newly initiated on treatment with quetiapine XL within the mental health care trust setting.

Further details are available in this publication: *Osborne, V., Davies, M., Evans, A., & Shakir, S. A. W. (2020). Observational assessment of safety in seroquel (OASIS): a specialist cohort event monitoring (SCEM) study in England. Therapeutic advances in psychopharmacology, 10, 2045125320954616.*

Further detail on the SCEM methodology used for these studies is available in this publication: *Layton, D., & Shakir, S. A. (2015). Specialist Cohort Event Monitoring studies: a new study method for risk management in pharmacovigilance. Drug safety, 38(2), 153–163*