Specialist Cohort Event Monitoring (SCEM) methodology

DSRU establishes a cohort of specialists prescribing the study drug.

Specialist makes the clinical decision to prescribe the study drug.

Specialist registers on the DSRU SCEM recruitment website and downloads information sheets, consent form and study questionnaires.

When required, valid informed consent is sought from the patient to include them in the study.

The baseline questionnaire is completed by the specialist or a member of the care team, returned to the study team at the DSRU and processed.

After the index date (the exact period depends on the study), a follow-up questionnaire is sent to be completed, returned and processed.

Selected events of medical interest, deaths (where cause not known) and pregnancies are followed up.

[Patient confidentiality is maintained throughout]

Further detail 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