SIG

Measuring impact of pharmacovigilance activities

Mandate

- 1. Develop and review methods for modelling health outcomes of pharmacovigilance activities based on parameters such as population attributable risk, prevalence of exposure, behavioural changes, switching therapies etc., including data requirements and relevant data sources
- 2. Provide recommendations for revision of the ENCePP Guide on Methodological Standards in Pharmacoepidemiology

Deliverables

Input Guide Methodological Standards in Pharmacoepidemiology adopted in July 2018. In the Guide a chapter on methods for pharmacovigilance impact research (5.9) and Annex 2 have been added

Several participants group published articles on the subject

Presentations and contributions to sessions ISPE, ISOP, DIA Presentation ISOP 2019



4 July 2018 EMA/458754/2018 ENCePP Secretariat



Annex 2 to the Guide on Methodological Standards in Pharmacoepidemiology

Methods for pharmacovigilance impact research

Next activities?

No new activities are planned, since the mandate is fulfilled

Steps taken to involve ISOP in the activities of this SIG

SIG on hold on hold until there is a new mandate?