

## **Post-Approval Safety Monitoring and Benefit-Risk Assessment: Post authorization safety study (PASS)**

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Good Pharmacovigilance system requires effective and detailed clinical information for the assessment of the risk-benefit balance of medicines both during the clinical development and the post-marketing phases.

According to new European legislation, pharmacovigilance practice has radically changed over the last few years.

Now more than ever all stakeholders involved in pharmacovigilance are looking for effective tools to meet the increasing regulatory demands and harmonise pharmacovigilance activities. This symposium aims to give all stakeholders in Pharmacovigilance a better understanding on how to better monitor drug safety during the entire life cycle of drugs.

This symposium will put together regulators and academic experts to share their experience, discuss the practical implications of the above changes and identify the most effective ways to go ahead.