EU-Risk Management Plans

Post Authorization Safety Studies (PASS) for Risk Characterization and Evaluation of Risk Minimization Purposes

Evidera, PPD's Evidence, Value & Access business, has a broad and comprehensive range of experience in the design and implementation of PASS to meet the EU regulatory requirements in the areas of 1) **Therapeutic Risk Characterization**, and 2) **Evaluation of Risk Minimization Measures**

We also have experience in risk assessment to identify known or potential serious risks associated with a medicinal product and to determine the likelihood of additional Risk Minimization Measures (aRMM) being imposed in the EU as a condition of a Marketing Authorization for the safe and effective use of such a product.

Our scientific and operational team is dedicated to the design and implementation of PASS, based on the analyses of secondary data or primary data collected for this purpose. We have scientific expertise in the development of survey instruments, qualitative and quantitative methodologies, and overall observational research methods.

As an ENCePP member, Evidera conducts all PASS in line with the Guide on Methodological Standards in Pharmacoepidemiology and in full compliance of EU regulation and Good Vigilance Practice (GVP) guidance. Extensive experience and proven processes enable us to deliver PASS solutions efficiently and to the standard of regulatory submissions.

Why Evidera?

- A dedicated team including regulatory, safety, and epidemiology experts with a proven track record of scientific and operational success
- Access to in-house expertise from epidemiologists, clinicians, pharmacologists, data analysts, and statisticians, as well as experts in clinical psychology, psychometric evaluations, and patient-centric approaches to drug safety evaluations. The blend of quantitative and qualitative methodology expertise is a key determinant of success in PASS for risk minimization evaluation.
- Global capabilities for scalable programs and broader safety activities (e.g., REMS programs, patient registries)

The Evidera Model: Key Elements for Successful Evaluations

SCIENCE

- Scientific expertise in drug safety and Risk Minimization (RM)
- High capacity in epidemiology and biostatistics
- Regulatory insights into EMA requirements
- Large RM toolbox with quantitative and qualitative methods to meet RM requirements

OPERATIONS

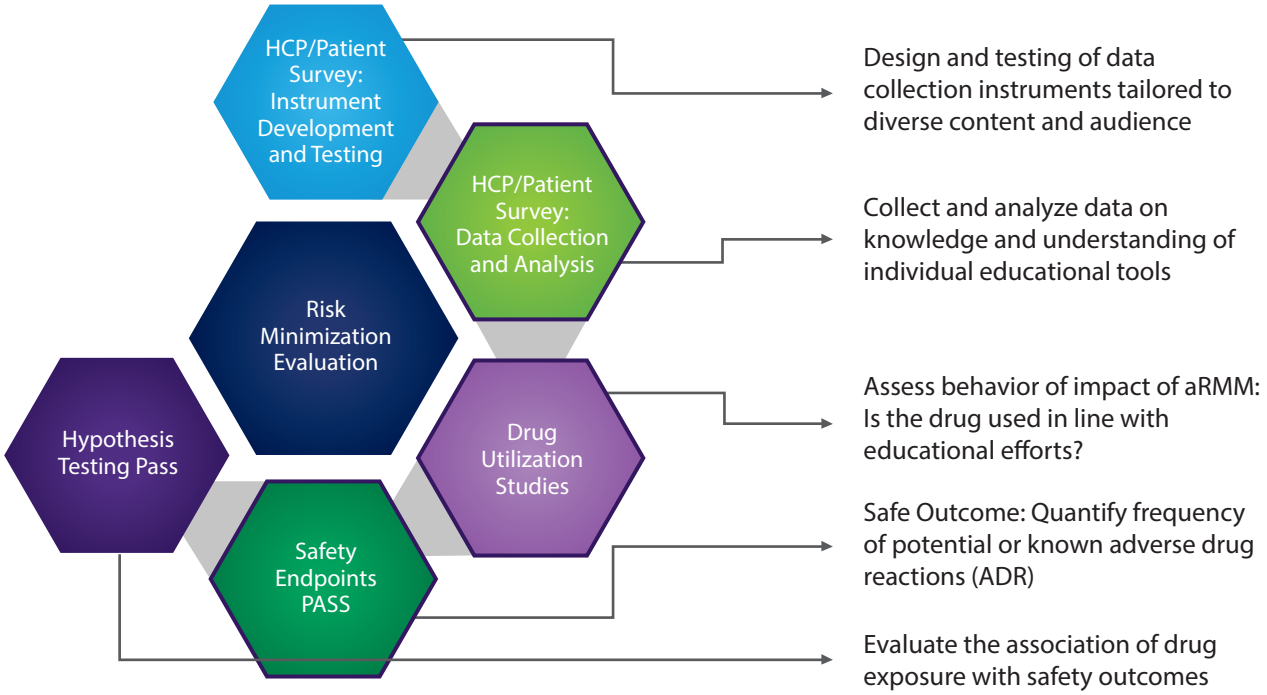
- Access to patients and healthcare providers (HCP) worldwide for primary data collection
- Experience and understanding of ethical requirements across the EU
- Continuous interaction of scientific and operational expertise from study design through execution

TECHNOLOGY

- Electronic data capture system customised to the needs of PASS
- Single analytic engine support for efficient analyses of multiple data sources (e.g., EMR, registries, claims data)
- Innovative use of social media

U.S. +1 301 654 9729 **EUR +44 (0) 208 576 5000** **evidera.com**

Risk Minimization Evaluation Services



PASS Experience

Evidera's experience in providing PASS services dates back more than a decade, covering multiple therapeutic areas and spanning a variety of study designs, data source options, and geographic areas.

PASS Experience with Multiple Data Sources