Pharmacoepidemiology & Risk Management

Our mission is to provide expertise and research of the highest methodological standards that evaluate the benefits and harms of medicines in the real-world, for a global client base.

Academic Rigor & Corporate Efficiency

Evidence generation spans the whole product lifecycle.

PRE-APPROVAL SETTING
- Epidemiology of disease on a national and global base
- Unmet needs and treatment gaps
- Patient journey through healthcare system
- Intolerance or non-response to existing treatments
- Size of target population

POST-APPROVAL SETTING
- Patterns of drug use in the real-world
- Treatment adherence and persistence
- Comparative effectiveness
- Safety surveillance and signal detection
- Effectiveness of risk minimisation interventions

The world of evidence is changing, with regulators and payers increasingly seeking the demonstration of value beyond clinical outcomes. We will guide you through the generation of scientific and valid evidence on drug benefit-risk in the real-world.

Our expertise is unique as we are recognized as leaders in pharmacoepidemiology with access to an extensive network of collaborators and key opinion leaders around the world.
The YOLARX team includes 10 professionals with training in pharmacoepidemiology, pharmacovigilance, biostatistics, pharmacy, software engineering and business management. Collectively, members and affiliates of YOLARX have published over 125 publications in high ranking peer reviewed journals and over 150 presentations in scientific conferences.

As consultants and contract researchers to the pharmaceutical industry and regulatory authorities, we are experienced with the processes, requirements, and constraints of industry-sponsored research. We have been involved in training as well as the design, execution, statistical analysis, and publication of a variety of studies in the areas of neuro-psychiatry, cardiovascular and metabolic disease, infectious disease, hematology/oncology, immunology/inflammation, pain, ophthalmology, pulmonary disease, vaccinology, rare disease and biosimilars. This exposure to industry-sponsored research has trained us in being efficient and in delivering high quality work within the very short timelines frequently imposed by these clients.

Our services include:

**CONSULTANCY**
- Database mapping (we developed a proprietary method for searching and assessing fit-for-purpose data sources, with feasibility assessment)
- Medical writing (protocol, statistical analysis plan, implementation plan, study report, manuscript, abstract, poster, slide presentations)
- Target population sizing (estimation and modeling)
- Selection of outcomes for value differentiation
- Global and local risk management plans and PASS studies

**STUDY CONDUCT**
- Systematic review and meta-analysis (including EPI-MAP)
- Database acquisition and analysis (US, EU, Canada, Asia, Latin America)
- Knowledge and understanding surveys of prescribers
- Field studies (protocol, implementation plan, feasibility assessment)
- Drug utilization studies
- Advisory boards, Delphi panels, and focus groups
- Assessment of effectiveness of risk minimisation interventions

**TRAINING**
- On-site or online training modules in real-world investigations, tailored to your needs (e.g., Medical affairs, Operations, Management)

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YOLARX Team.

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