

Answer your epidemiology and drug safety questions with database research.

Experts in Database Research

You have to know and understand data to make it work for you. With deep experience in automated health care database research, we implement scientifically rigorous regulatory safety studies including requests from FDA, EMA, TGA, HC, and other national authorities. We understand both the opportunities and limitations associated with using databases for health research. We'll help you determine if it is feasible and effective to use databases to answer your epidemiology and drug safety questions, including:

- The relative safety profile of medications, vaccines, and other treatments
- Disease prevalence and public health impact
- Background event rates
- Drug utilization, treatment patterns, and patient characteristics

- Comparative effectiveness and value of alternative treatments

Epidemiological Methods

We conduct expert data analyses using appropriate analytical methods, including case control, cohort, and other designs. As part of our process, we:

- Access, process, and store data files
- Extract data for study objectives
- Apply appropriate linkage techniques when multiple data sources are used
- Prepare detailed analysis plans

When appropriate, we also:

- De-identify data to comply with IRB, HIPAA, and other applicable regulations
- Apply sampling statistics to allow for robust inferences
- Use advanced statistical techniques to control for bias and confounding
- Validate study outcomes

We have experience with many data sources and research partners, including:

North America

Canada: Saskatchewan Health

United States:

- HealthCore Integrated Research Database (HIRD)*
- Henry Ford Health System*
- HMO Research Network*
- LifeLink (formerly PharMetrics)
- Medicare claims, including Part D data
- Medicaid claims
- National Death Index (NDI)
- National Center for Health Statistics surveys
- Organ Procurement and Transplantation Network*
- Renal Data System
- Truven MarketScan Commercial Claims and Encounters (CCAЕ) database
- Truven MarketScan Health and Productivity Management (HPM) database

Europe

Denmark: Danish Health databases*

Italy: Friuli-Venezia Giulia databases*

Netherlands: PHARMO Institute Data*

Spain:

- Aragon Institute of Health Sciences (IACS)*
- Information System for the Development of Research in Primary Care (SIDIAP)*

Sweden: Swedish National Registries*

United Kingdom:

- Clinical Practice Research Datalink (CPRD) (previously GPRD)
- The Health Improvement Network (THIN)

Worldwide

- Population-based cancer registries

Contact Us:
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*We work collaboratively with these organizations to design studies and provide specifications for analyses that are conducted at the research partner.

Key Technical Staff

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See How We've Helped Others

Our staff have led database studies and collaborated on publishing results of the studies in peer-reviewed journals. Examples of studies include:

- We estimated the relative risk of upper gastrointestinal complications of individual NSAIDs among 800,000 patients validating close to 2,000 hospital admissions. Study results were published in *Pharmacoepidemiology and Drug Safety*, 2013;22(4):365-75.
- Using the MarketScan Research databases, we implemented a post-marketing study to monitor the use and risk of the live attenuated influenza vaccine among young children with asthma, recurrent wheezing, and compromised immune function. Study results were published in *Vaccine*, 2012;30(42):6099-102.
- We developed an automated computer-based algorithm that partners applied to identify the best match to the National Death Index, and evaluated the risk of long-acting beta agonist use in combination with an inhaled corticosteroid and asthma mortality in a multi-database study in the US. Study results were presented at the 28th ICPE, August 23-26, 2012.

Our Experience and Partnerships to Your Benefit

We can help you identify and access the database(s) most appropriate for your studies. Our status as a not-for-profit, independent research company allows us to conduct research in a wide range of data sources and to collaborate with other organizations.

We have served as a coordinating center for multiple-database studies in the US and Europe. We collaborate with academic and commercial partners during each step of a study, including protocol development, data review, synthesis, and interpretation to ensure data will be analyzed consistently across sites.

In addition to research partnerships for specific studies and projects, we are active in private-public partnerships to develop data assets and research methods to enhance understanding of drug safety.

Dr. Andrews serves as the academic/research community representative and vice-chair of the Steering Committee of the Innovation in Medical Evidence Development and Surveillance (IMEDS) Program.

Dr. Rothman was an advisor on the Mini-Sentinel Data Re-use Committee, a pilot project sponsored by the FDA to create an active surveillance system to monitor the safety of FDA-regulated medical products.

We are a partner center of the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP). Dr. Perez-Gutthann is a member of the ENCePP Steering Committee, and Dr. Arana is the Chair of the ENCePP Research Standards Working Group.

Custom Reports

We deliver the results of your study in the format of your choice, including:

- Reports and regulatory deliverables
- Technical posters
- Presentations at professional meetings
- Peer-reviewed journal articles