

Know risk factors and what they mean for your product and patient safety.

Improve the Quality of Your Decisions

Our epidemiology group can provide you with quality analyses to improve and expedite decision making throughout your product development process.

Expert advice and results from our studies aid in the understanding and interpretation of data from other sources including:

- Preclinical and early development
- Clinical trials
- Post-approval studies
- Spontaneous reports

No matter what the study or service, we deliver quality data for quality decisions.

Get Meaningful Data Analysis

For any stage of your product's lifecycle, we can perform studies that yield meaningful data by asking the right questions and applying the right methodologies. Our international team of epidemiologists:

- Conduct disease-burden and prevalence studies
- Design and implement post-approval studies (i.e., post-marketing, safety, and surveillance studies)
- Develop risk management strategies and plans
- Conduct product benefit-risk assessments and create meaningful summary displays
- Evaluate the effectiveness of risk minimization strategies
- Help prepare regulatory submissions
- Provide expert advice in scientific advisory boards

Our studies, methods, and applications provide quality data to help you make quality decisions.

Studies of:

- Risk Factors
- Disease Distribution
- Treatment Patterns
- Comorbidities
- Burden of Illness
- Treatment Impact

Methods used:

- Database Studies
- Patient Registries
- Cohort Studies
- Direct Patient and Physician Surveys
- Chart Abstraction
- Naturalistic Trials
- Literature Reviews

What you will know:

- Patterns and correlates of key diseases
- Impact of treatments and other factors on health and safety outcomes
- Impact of alternative treatments on patient outcomes
- Drug usage patterns
- Risks associated with interventions
- Disease conditions and episodes of care

What you will gain:

Analysis for improved product decisions and expert risk management.

Contact Us:
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Key Technical Staff

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See How We've Helped Others

We conducted a retrospective cohort study to assess the incidence of osteonecrosis of the jaw (ONJ) among two cohorts of patients exposed to bisphosphonates. One cohort included patients aged 40 years with breast or prostate cancer or multiple myeloma. The other cohort included men aged 60 years and women aged 50 years with osteoporosis. For each cohort, we calculated sex- and age-standardized incidence of ONJ by exposure to oral bisphosphonates and intravenous bisphosphonates. The study showed that the incidence of ONJ was higher among those with multiple myeloma and users of intravenous bisphosphonates. The study results were published in *Pharmacoepidemiology and Drug Safety*, 2012;21(8):810-17.

We implemented a 3-year post-marketing study to monitor the use of live attenuated influenza vaccine (LAIV) among young children with asthma, recurrent wheezing, and compromised immune function—children precautioned to not receive LAIV. Identified vaccinated children were monitored for frequency of hospitalization or emergency department visits within 42 days after vaccination. Annual analyses showed the frequency of vaccination with LAIV among these cohorts was low. Evaluation of the frequency of hospitalization and ED visits among LAIV-vaccinated versus TIV-vaccinated children identified no new safety signals and confirmed a risk seen in clinical trials. Study results were published in *Vaccine*, 2012;30(42):6099-102.

Rely On Our Technical Team

Our broad range of experience and relationships make us an ideal research partner for your pharmacoepidemiology studies. Academic and government institutions look to our epidemiologists as leading advisors. We have academic appointments at the University of North Carolina (UNC) School of Public Health and School of Pharmacy, Boston University, Harvard School of Public Health, and the University of Dundee. Members of our team have played key roles in the International Society for Pharmacoepidemiology (ISPE), including 2 presidents, 5 members of the Board of Directors, and chairs of various committees. Through our Barcelona-based team, we are a member of the ENCePP research network and a research site in the two major EU-funded research consortia. Many of our studies and protocols are registered in the EU PAS Register.

Receive Quality Deliverables

We offer various publication strategies and deliverables for each study we conduct. Examples include:

- Strategic and scientific consulting
- Peer-reviewed journal articles
- Presentations at professional meetings
- Posters
- Abstracts
- Study reports
- Study protocols
- Quality-controlled databases
- Statistical tabulations of data
- Epidemiology sections of regulatory and internal documents