ERGOMED

PRIMEVIGILANCE

REAL-WORLD EVIDENCE CASE STUDIES

PHARMACOEPIDEMIOLOGY & RISK MANAGEMENT

Strengthen the Value of Your Products Through Real World Evidence

Traditional data collection can only do so much for the success of your product. Real world evidence (RWE) brings credibility to your product's study results, as it satisfies the industry's ever growing need for more information on the real-life utilization of medicines and safety. The questions of benefits and risks have to be addressed in the real-world even more than in a controlled clinical trial setting.

That's why Ergomed and Primevigilance have come together to bring your study a unique set of services specifically tailored to the specialized needs of pharmacoepidemiology and RWE risk management.

CASE STUDY 1: Global Pass Study

Ergomed's RWE team is currently managing a global PASS Registry Study involving nearly 300 sites across 15 countries in Europe, North and South America, and the Asia-Pacific region.

The study is planned to take 20 years, with the objective of assessing the long-term safety and disease activity in patients with relapsing remitting multiple sclerosis (RRMS) in a clinical practice setting.

Currently at the 11-year point, the study has over 6,200 patients enrolled.

In order to maintain a high level of quality and to uphold a defined history of tracking all stakeholders' collaboration over a period of 11 years, Ergomed's RWE team has had to apply many strategies including:

- Aligning with changing regulatory requirements across all countries
- Consistent and regular communication to maintain site motivation
- Data entry and remote monitoring over infrequent patient visits
- Long-term planning for site and patient retention

These have resulted in the successful collection of high quality real-world data on long-term safety and effectiveness, providing valuable information for clinicians and patients considering the benefit-risk profile of RRMS therapies.

CASE STUDY 2: Rare Disease Registry

Rare disease research has for years been limited to randomized clinical trials. While looking deeper into what is happening in the real world setting, registries, natural history and other epidemiology studies now serve as key pillars for future research, enabling us to find new treatments and even further reduce the time to making them available to patients in need.

Often, these studies have diverse objectives, spanning from the need to address multiple stakeholders' perspectives.

One of our rare disease registry studies has included 5 EU countries with the objectives of:

- Collection of additional safety data on the use of the drug in the pediatric population
- Data collection to characterize the progression of the disease, clinical outcomes, mortality and morbidity in both treated and non-treated patients, and
- Increasing disease awareness in the medical community and the subject/potential subject population

The ERGOMED team has developed strategies to address the above objectives in the most effective way. These have included:

- Developing consent forms taking into consideration patients and their families
- Maximizing data collection through an eCRF design that reflects clinical practice, identification of critical data points and processes
- Increasing site and patient awareness via educational sessions, national coordinators, site reimbursement

As a result, the study has provided important real-world insights into the disease progression and available therapy, and met its objectives in enrolling a large cohort of pediatric patients, demonstrating an important disease burden for this understudied population.

CONTACT US:

info@ergomedplc.com