ERGOMED

Real World Evidence

Strengthen the value of your products through Real World Evidence (RWE)

Our RWE advantage:

- Experience in all types of RWE studies
- Access to numerous therapeutic databases
- A cross-functional team of experts to develop strategies and dedicated processes.

60+ studies

2k+ sites

37k+ patients

A suite of services for evidence-based safety and effectiveness from Ergomed plc.

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 utilization of medicines, effectiveness 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.

Ergomed brings you a unique set of services specifically tailored to the specialized needs of pharmacoepidemiology and RWE Risk Management.

Therapeutic specialties include:

- Rare diseases/oncology
- Neurology/CNS
- Allergy/respiratory.

Outcomes Research:

- Complete services for peri-approval programs e.g. post-authorization safety study (PASS), post-authorization efficacy study (PAES), registries, natural history studies
- Protocol design strategies: addressing regulatory, scientific and commercial objectives
- Tailored operational strategies: focusing on challenges of feasibility, enrollment and retention in RWE studies
- Risk-based quality management and monitoring solutions, ensuring quality, compliance and data accuracy.

Epidemiology and Risk-based Management:

- Risk-management plan development and maintenance
- Risk and benefit risk analysis
- Development of new approaches to risk minimization
- Societal, economic and humanistic burden of illness
- Systematic reviews, meta-analyses and disease modeling including survival assessments.

Medical Information:

- 24/7 multilingual call center
- Validated drug safety database
- Receipt of adverse events and product quality complaints
- Development and maintenance of standard response documents (SRDs)
- Global regulatory intelligence and submissions
- Qualified EEA QPPVs and NPRPs staff
- Global and non-indexed literature screening
- Aggregate report writing: periodic benefit-risk evaluation reports, periodic adverse drug experience reports, development safety update reports.

Health Economics and Market Access:

- Health economic analysis to inform product reimbursement and access
- Global value dossiers and reimbursement submissions
- Market access and lifecycle strategies that reveal the full value of healthcare therapies
- Advisory boards and Delphi panels.

Case Study:
Global PASS Registry

6,500+
enrolled

Setting

Global PASS Registry Study involving nearly 300 sites across 15 countries in Europe, North and South America, and the Asia-Pacific region.

Objective

Assessing the long-term safety and disease activity in patients with relapsing remitting multiple sclerosis (RRMS) in a clinical practice setting.

Challenges	Ergomed's Solution
Planned study duration — 20 years	Ergomed ensures continuity with a dedicated internal team and sites with strong procedures for handover and training.
Site retention throughout the study	Consistent and regular communication establishes structured site management and positive motivation. Result: 93 % of the sites are still active after 13 years.
Patient retention	Long term strategies put in place at the beginning - these strategies are being implemented and updated as required. As an example, timely "check in" and support from the Ergomed Site Management team - ensuring constant patient follow-up by the sites. Result: Continual improvement of patient retention, with an annual withdrawal rate of 1%.
Change in regulatory requirements during the study	Maintaining continuous communication with regulatory authorities/ institutional review boards/ ethics committees to ensure alignment of regulatory requirements across all countries. The study has been successfully adapted over the years to changing regulatory requirements, proven by annual audits.
Maintaining data quality	The study delivered a 10-year data analysis in 2018 which resulted in numerous publications, contributing significantly to multiple sclerosis treatment and research.

To learn more about Ergomed plc's expertise in Real World Evidence and how it brings credibility to your product's results, contact us at:

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Ergomed plc

The Ergomed group of companies is dedicated to the provision of specialist services to the global pharmaceutical industry and supports companies with services spanning all phases of clinical trials, post-approval pharmacovigilance and medical information. We offer a full range of high-quality clinical research and clinical trial management services and internationally recognized expertise in orphan drug development together with an industry-leading suite of specialist pharmacovigilance solutions.