

**ERGOMED**

**25**  
YEARS

## Your Partners in Drug Development and Safety

Specialist services to the pharmaceutical industry spanning all phases of clinical trials, post-approval pharmacovigilance, and medical information.





# Bringing expertise to deliver medicines our world can trust

Founded in 1997, Ergomed is dedicated to the provision of global specialized services in the pharmaceutical and biotech industry.

Today, Ergomed supports pharmaceutical companies with services spanning all phases of clinical trials, post-approval pharmacovigilance, and medical information.

Recognized internationally in both rare disease and oncology drug development for its expertise, Ergomed offers a full range of quality clinical research and clinical trial management services along with an industry-leading suite of specialized pharmacovigilance solutions.

By providing this full-service offering, Ergomed enables emerging and established life sciences companies to meet their regulatory obligations, maximize their drug development success and their product value.

**24**

offices  
worldwide

**50+**

countries with  
active clinical  
trials

**1800+**

professionals

**1900+**

studies  
completed

**450+**

oncology  
studies

**330+**

rare disease  
studies

# Specialized Drug Development Solutions

**Our Clinical Research Organization (CRO) provides global, full-service Phase I-IV clinical development and trial management services. With a strong heritage in Europe and the United States of America, we assist clients by providing complete solutions tailored to their unique requirements.**

With experience in over 1800 trials, we planned, managed, monitored, and reported clinical trials with a range of technologies that include: small molecule drugs, monoclonal antibodies, and other targeted agents, as well as cancer vaccines, immunotherapy, radioactive agents, and photodynamic therapies.

Ergomed has proudly assisted clients with project directorship, project management, regulatory affairs monitoring, safety and medical monitoring, data management, biostatistics, medical writing, site management support, and study physician support.

**25+**  
years'  
experience

**40%**  
of workforce  
with PhD, MD  
or advanced  
degree

- Site management program specifically designed to increase study performance
- Specialist expertise in orphan drug development
- Therapeutic specializations: oncology, respiratory, neurology and orphan drugs/rare disease.



# Our Strong Oncology Heritage

**Ergomed Clinical Research is an oncology leader with a sole focus on forming lasting relationships with our biopharmaceutical clients and passion in delivering novel, innovative cancer treatments to patients.**

Our seasoned team have diverse oncology experience and are well-versed in successfully completing oncology study needs. We specialize in all areas of the clinical trial life cycle from feasibility to market approval..

Ergomed pairs our robust clinical teams with study physician models, unique site management, and advanced study designs to better support our sites, which results in quicker patient identification/enrolment. This creates quality sample data across the globe, whilst ensuring compliance and meeting local regulatory requirements.

**450+** oncology studies  
**43%+** of our study portfolio

- Oncolytic Virus
- Breast, Endometrial, Head & Neck, Gastric, Lung, Pancreatic, Prostate, and Ovarian Cancer
- Immuno-Oncology Trials
- Carcinoma, Leukemia, Lymphoma, Melanoma, Neuroblastoma
- Stem Cell Therapy
- Cellular & Gene Therapy.



# Discover Our Rare Disease Advantage

**Ergomed is the leading expert in assisting biotech and pharmaceutical companies in orphan drug development.**

Our orphan disease toolkit reflects a genuine family and patient-centric approach to recruitment and retention. Our close links to patient advocacy groups maximize our partners' chances of success.

Ergomed is specialized in designing and executing complex clinical development programs requiring innovative regulatory and clinical approaches in Europe and the US.

Through our site management model and study physician team support, we find hard-to-locate patients around the globe and work with the investigative sites, creating the best designs to maximize clinical programs and registries.

**125+**  
unique  
indications

**330+**  
rare disease  
studies

- Thought-leaders in the orphan drug community
- True family and patient centricity and Patient Organization Advisory Board
- Global reach and access to patients with rare and ultra-rare diseases.



# Transforming Drug Safety

**PrimeVigilance offers holistic, top quality, cost-effective, and innovative clinical safety and pharmacovigilance/vigilance services for pharmaceutical, biotechnology and medical device companies.**

We have been instrumental in setting-up centralized safety databases and in the management of multiple protocols to allow for consistent processing and safety reporting obligations to be streamlined across sponsors' portfolios in the context of multiregional clinical campaigns and complex clinical trials/studies.

Since 2008, we have contributed in the development of study specific documents (e.g. SMPs, SAE/pregnancy forms) and core documents (e.g., reconciliation plans, safety part of protocols, RSIs) to ensure process alignment and operational efficiencies.

Our 'one-stop shop' Innovative, Generics & Biosimilars, Vaccines and Medical Devices and Combination products business units are serving your post-marketing PV commitments, as well as overseeing clinical trial safety and share valuable intelligence across the board in collaboration with our clinical safety business unit.

**350k+** cases processed per year  
**30+** EU/UK QPPVs

[www.primevigilance.com](http://www.primevigilance.com)

- Partnership model of engagement
- Project execution excellence
- Automation expertise
- Regulatory experts and PV thought leaders.



# Real World Evidence

## Strengthen the value of your products through Real World Evidence.

Real World Evidence brings credibility to your product's study results, as it satisfies the industry's ever growing need for more information about the real-life safety and effectiveness of medicines.

Ergomed provides a unique set of services specifically tailored to the specialized needs of pharmacoepidemiology and Real World Evidence generation studies.

Therapeutic Specialties include: oncology/hematology, neurology/CNS, and allergy/respiratory and orphan.

- Complete services for observational research, including PASS, registries and other peri-approval programs
- Expertise in various study types addressing clinical, medical affairs and market access objectives
- Unique fit-for-purpose operational strategy using dedicated processes and tailored real-world data collection solutions.

**110+**  
studies

**2.5k+**  
sites

**43k+**  
patients



Your guide and support along the  
drug development continuum.

## Contact Us

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