

# 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.



# Specialist Drug Development and Safety Solutions

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

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

Our business includes a full range of high-quality clinical research and clinical trial management services and internationally recognised expertise in orphan drug development together with an industry-leading suite of specialist pharmacovigilance solutions.

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

**17**  
offices  
worldwide

**53**  
countries with  
active clinical  
trials

**900+**  
professionals

**600+**  
studies  
completed

**100+**  
supporting  
products in over  
100 countries

**300k+**  
ICSRs  
processed  
per year.

# Transforming Drug Development

**Ergomed, our Clinical Research Organisation (CRO) provides complete Phase I-IV clinical development and trial management services, assisting clients by providing complete solutions tailored to their unique requirements.**

With experience in over 600 trials, Ergomed has 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.

Assisting 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.

**20+**  
years'  
experience

**25%**  
staff with  
PhD or MD

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



# Discover the Orphan Advantage

**PSR is the leading expert in assisting biotech and pharmaceutical companies in orphan drug development and supports the Ergomed global CRO offering.**

Our orphan disease toolkit reflects a genuine family and patient approach to recruitment and re-intention. Our close links to patient advocacy groups maximise our partner's chances of success.

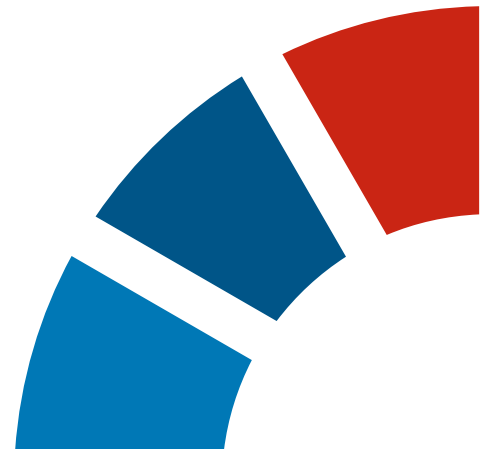
PSR is specialised in designing and executing complex clinical development programs requiring innovative regulatory and clinical approaches in Europe and the US.

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 maximise clinical programs and registries.

**10+**  
years'  
experience

**160+**  
orphan  
projects

- Thought-leaders in the orphan drug community
- True family and patient centricity and Patient Organisation Advisory Board
- Access to global and hard to find patients in key geographical areas.



# Transforming Drug Safety

**PrimeVigilance provides global, top quality, cost-effective, innovative Life Cycle Management Services to enable emerging and established life sciences companies to meet their regulatory obligations and to maximise product value.**

PrimeVigilance covers the entire product life cycle, assisting clients with the effective management of their drug safety information, and offering expert consulting services from former regulators and opinion leaders.

Our drug safety services include: case management, signal management, risk management, pharmacoepidemiology, audits, services of qualified persons for pharmacovigilance, training, strategic advisory, literature searches and medical information services.

**10+**  
years'  
experience

**25+**  
QPPVs

- Global leader in QPPV services
- Automisation in pharmacovigilance expertise
- Choice of leading drug safety databases
- Regulatory experts and key opinion leaders.



# Real World Evidence (RWE) Risk Management

**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 in the real-life utilisation of medicines and safety.

Ergomed provides a unique set of services specifically tailored to the specialised needs of pharmacoepidemiology and RWE risk management.

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

**50+**  
studies

**2k+**  
sites

**37k+**  
patients

- Experience in all types of late phase projects
- Access to many therapeutic databases
- Over 30% of studies are observational
- Studies include a 20-year long registry with approx. 5,000 patients enrolled across 4 continents
- Preferred partnership with big and mid-size pharma companies.



Your guide and support along the  
drug development continuum.

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