

## 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

**23**

offices  
worldwide

**60+**

countries with  
active clinical  
trials

**1200+**

professionals

**1800+**

studies  
completed

**100+**

supporting  
products in over  
100 countries

**300k+**

ICSRs  
processed  
per year.

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 and oncology 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.

# Transforming Drug Development

**Our Clinical Research Organisation (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.

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.



**MEDSOURCE**

Now part of Ergomed, an award winning oncology focused US based CRO.



# 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 retention. Our close links to patient advocacy groups maximise our partner's chances of success.

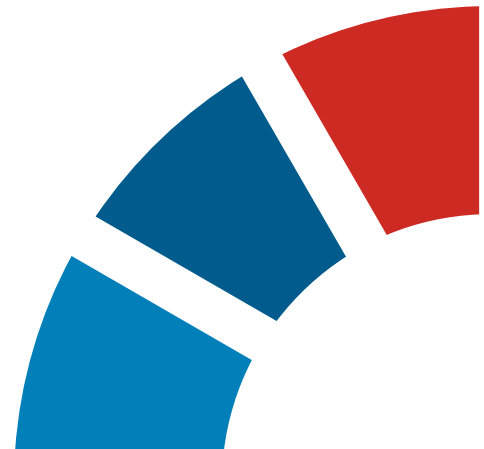
PSR is specialised in designing and executing complex clinical development programs requiring innovative regulatory and clinical approaches in Europe and the US.

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

**170+**  
orphan  
projects

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



# 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

## 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 specialised needs of pharmacoepidemiology and Real World Evidence generation studies.

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

**60+**  
studies

**2k+**  
sites

**37k+**  
patients

- 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.

Your guide and support along the drug development continuum.

## Contact Us

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