

# PROFESSIONAL INTERNATIONAL STUDY MANAGEMENT

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# The Founders

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- ❖ **Gernot Cremer, PhD (General Manager):** 20 years pharmaceutical industry experience in international clinical research including all aspects of clinical project management, monitoring, drug safety and regulatory affairs for drug and device development.
- ❖ **Dirk Strickmann, MSc (Clinical Operations Manager):** 15 years pharmaceutical industry experience in international clinical research including all relevant aspects of clinical project management, monitoring and regulatory affairs for drug development.
- ❖ **Bernhard Breier, MSc (Regulatory Affairs Manager):** 15 years pharmaceutical industry experience in international clinical research, including all relevant aspects of regulatory affairs, clinical project management and monitoring for drug development.



# P.R.I.S.M.A.

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**Project  
Management**

**Regulatory  
Affairs**

**Monitoring**

**Drug Safety**

**Medical  
Writing**

**Quality  
Assurance**

**IT**

**P.R.I.S.M.A.**

# Coverage

- ▴ **Austria**
- ▴ **Belgium**
- ▴ **Czech Republic**
- ▴ **France**
- ▴ **Germany**
- ▴ **Italy**
- ▴ **Poland**
- ▴ **Scandinavia**
- ▴ **Spain**
- ▴ **Switzerland \***
- ▴ **The Netherlands**
- ▴ **United Kingdom**



\* No legal representative service in Switzerland, as not an EU member state

# Services

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- ▲ Protocol Design and Development
- ▲ Study Feasibilities
- ▲ Site Identification, Selection and Initiation
- ▲ Clinical Study Monitoring
- ▲ Project Management
- ▲ Regulatory Affairs
- ▲ Medical Monitoring
- ▲ Drug Safety
- ▲ Quality Assurance
- ▲ Legal Representative Services
- ▲ Medical Writing
- ▲ Clinical Research Consulting
- ▲ Contract Management and Investigator Payments
- ▲ Insurance Handling

Via our Partners:

- ▲ Data Management, Biostatistics

# Therapeutic Expertise: Drug Studies

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- ▲ Acute Coronary Syndrome
- ▲ Acute Myeloid Leukaemia
- ▲ Acute Myocardial Infarction
- ▲ Amyotrophic Lateral Sclerosis
- ▲ Analgesia
- ▲ Atherosclerosis
- ▲ Bioequivalence Bone Metastasis
- ▲ Breast Cancer
- ▲ Cachexia
- ▲ Cardiomyopathy
- ▲ Colitis Ulcerosa
- ▲ Congestive Heart Failure
- ▲ Coronary Artery Disease
- ▲ Crohns Disease
- ▲ Diabetes Mellitus
- ▲ Diabetic Nephropathy
- ▲ Diabetic Neuropathy
- ▲ Depression
- ▲ Erectile Dysfunction
- ▲ Generalized Anxiety Disorder
- ▲ Gout
- ▲ Hepatitis B and C
- ▲ Hypercholesterolemia
- ▲ Hypertension
- ▲ H. Pylori eradication
- ▲ Influenza
- ▲ Morbus Bechterew
- ▲ Multiple Myeloma
- ▲ Osteoarthritis
- ▲ Osteoporosis
- ▲ Ovarian Cancer
- ▲ Prostate Cancer
- ▲ Pulmonary Hypertension
- ▲ Renal Cell Cancer
- ▲ Rheumatoid Arthritis
- ▲ Schizophrenia
- ▲ Stroke
- ▲ Systemic Sclerosis
- ▲ Transplantation
- ▲ Vaccination

# Therapeutic Expertise: Device Studies

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- ▶ **Aortic Valve Repair**
- ▶ **Atrial Fibrillation**
- ▶ **Carotid Stents**
- ▶ **Catheters**
- ▶ **Congestive Heart Failure**
- ▶ **Coronary Stents**
- ▶ **Dialysis**
- ▶ **Glucometer**
- ▶ **Coronary Stents**
- ▶ **Mitral Regurgitation**
- ▶ **Stroke**
- ▶ **Thrombolysis**
- ▶ **Ultrasound**
- ▶ **Post-surgical adhesions after laparoscopic gynecological surgery**
- ▶ **Wound Closure**

# Why P.R.I.S.M.A.!

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- Small company – full attention and dedication to each awarded project
  - → Quick decisions, fast action
  - → No staff turnover since inception
- Creative and driven to provide highly individualized client-oriented services
- Strong and experienced team
- Proactive communication
- Committed to quality
- Proven client satisfaction (references available upon request)