



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

Professional International Study Management

# Services

- ❖ Phase I Study Consulting
- ❖ Phase II-IV Study Conduct for Drugs and Devices
- ❖ Protocol Design and Development
- ❖ Study Feasibilities
- ❖ Site Identification, Selection and Initiation
- ❖ Clinical Study Monitoring
- ❖ Project Management
- ❖ Regulatory Affairs
- ❖ Drug Safety
- ❖ Quality Assurance
- ❖ Legal Representative Services

Via our Partners:

- ❖ Clinical Data Management
- ❖ Biostatistics
- ❖ Integrated Report Writing

# Coverage

**We offer clinical study conduct in the following countries:**

- ❖ Austria
- ❖ Australia
- ❖ Belgium
- ❖ Czech Republic
- ❖ Denmark
- ❖ France
- ❖ Germany
- ❖ Greece
- ❖ Ireland
- ❖ Israel
- ❖ Italy
- ❖ Norway
- ❖ Poland
- ❖ Spain
- ❖ Sweden
- ❖ Switzerland\*
- ❖ The Netherlands
- ❖ United Kingdom

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

# Team

Position	No.	Years of Experience	Staff Location
Project Manager	4	2 PhDs/2 MSc. with 10 to 15 years clinical trial experience	Langenfeld, Munich
Regulatory Affairs Manager	1	1 MSc. with 9 years clinical trial experience	Langenfeld
CRAs (SR, NS, SP, SN, AB, ZV, RD, UG, AC, SN)	10	With 2-11 years clinical trial experience	Australia, Belgium, Denmark, Germany, France, Italy, The Netherlands, Israel, Poland, Spain, Sweden
Safety Officers	3	2 physicians with 4-13 years clinical trial experience 1 PhD with 10 years clinical trial experience	Langenfeld



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# Partnerships

- ❖ Research Point, USA
- ❖ PharmaClinical, Israel
- ❖ EMR Associates, Australia
- ❖ Global Drug Development Experts, USA/India. Biostatistics and study conduct in India.
- ❖ Clinical Research Quality Management, Canada
- ❖ SW Consult, Germany – Drug Import, Storage, Labelling and Distribution



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# Therapeutic Experience

## Drug Studies

- ❖ Acute Coronary Syndrome
- ❖ Acute Myeloid Leukaemia
- ❖ Acute Myocardial Infarction
- ❖ Analgesia
- ❖ Atherosclerosis
- ❖ Bioequivalence
- ❖ Bone Metastasis
- ❖ Breast Cancer
- ❖ Cardiomyopathy
- ❖ Colitis Ulcerosa
- ❖ Congestive Heart Failure
- ❖ Coronary Artery Disease
- ❖ Crohn's Disease
- ❖ Depression
- ❖ Diabetes Mellitus
- ❖ Diabetic Nephropathy
- ❖ Drug-Drug Interaction
- ❖ Erectile Dysfunction
- ❖ Generalised Anxiety Disorder
- ❖ 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



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# Therapeutic Experience

## Device Studies

❖ **Aortic Valve Repair**

❖ **Coronary Stents**

❖ **Stroke**

❖ **Atrial Fibrillation**

❖ **Dialysis**

❖ **Thrombolysis**

❖ **Carotid Stents**

❖ **Glucometer**

❖ **Ultrasound**

❖ **Catheters**

❖ **Mitral Regurgitation**

❖ **Congestive Heart Failure**

❖ **Post-surgical adhesions  
after laparoscopic  
gynecological surgery**



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# Project Management

## Our Project Managers:

- ❖ Have weekly meetings with their study team that involves all CRAs including Lead CRA as well as the administrative support (CTAs).
- ❖ Provide weekly status updates via our project tracking tools to the sponsor.
- ❖ Have a weekly meeting with the sponsor that involves key people of the project.
- ❖ Are available for issue-driven communication – if needed on a daily basis.
- ❖ Have responsibility for all project related documents that need to be in place e.g. project plan, safety plan, monitoring plan, escalation plan, communication plan.
- ❖ Are responsible to prepare invoices monthly for services completed. For budget transparency billing will be based on units completed. The line item budget tracker can be adjusted for more or less activity as needed.



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A Unique European CRO with a focus on:

- ❖ Experience
- ❖ Execution
- ❖ Ensuring your goals are met