



## **Solutions for cost-effective clinical drug development – project leadership and management consultancy services**

### **The PharmaProjekthaus Mission**

We provide state-of-the-art management consultancy and project leadership in clinical trial programs to pharma and biotech companies from all over the world.

We operate pro-actively, with a pragmatic, hands-on approach to the complex challenges in drug development coupled with an enthusiasm for Good Customer Services.

For additional information about PharmaProjekthaus services, or to explore new partnering opportunities, please contact:

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## Your Drug Development Architect – Service Offer

PharmaProjekthaus provides operational and consultancy services for all clinical trials, from Phase I to IV. PharmaProjekthaus ties all required expertise and skills together and assumes overall responsibility for the execution of clinical development projects and programs.

**Project Leadership** PharmaProjekthaus project leaders excel in project management skills and inspire other project team members to do great work.

**Feasibility Surveys** PharmaProjekthaus offers a wide range of experience in the planning and execution of feasibility surveys.

**Study Start-up** A core PharmaProjekthaus competency is to orchestrate all the required elements for, and contributors to, a successful project launch.

**Medical Project Advice & Services** Our physicians provide medical advisory services with insight and dedication.

**Expert Statistical Consultancy** PharmaProjekthaus promotes a regulatory-framework-compliant integration of state-of-the-art statistical methodology in study design planning.

### **Project Leadership and Risk Management Training**

PharmaProjekthaus provides effective in-house educational services tailor-made to customer needs.

**Productivity Optimization** PharmaProjekthaus assists with the development of new structural and operational paradigms – best suiting the customer’s organization.

**Sponsor-CRO Interface Optimization** PharmaProjekthaus develops customized sourcing strategies and successfully deals with productivity and communication issues at the sponsor-CRO interface.

**Vendor Selection Services** PharmaProjekthaus offers an effective process for the selection of the most appropriate solution providers.

**Extended Services through Alliances** Partnering agreements are in place across a broad spectrum of key services including but not restricted to

- Clinical Monitoring in various geographic regions
- Clinical Quality Assurance
- Strategic Regulatory Consulting
- Pharmacovigilance Solutions
- Technology Validation and Support
- EDC Systems and Software





**Therapeutic Area Know-how:**

- Cardiology
- Dermatology
- Endocrinology
- Gastrointestinal Disorders
- Infectious Diseases including HIV and other Viral Infections
- Oncology
- Pediatrics – Vaccines and Therapeutics
- Psychiatry and Neurology
- Respiratory Disorders
- Urology

**Operational Expertise:**

- Project and people leadership
- Management of interfaces between operational functions
- Clinical operations
- Data management and statistics
- Trial site services
- Medical and regulatory affairs
- Strategic sourcing in clinical drug development
- Process improvement
- Productivity benchmarking
- Organizational design of clinical development structures





## Customer benefits

### For Small and Mid-sized Biopharma

- Effective project management by PharmaProjekthaus project leaders backed up by senior executive attention and input
- Utilization of our therapeutic area experience and of our relationship with key opinion leaders
- Optimized trial site productivity due to effective site support and PharmaProjekthaus project leaders being involved in critical site selection and liaison
- Economic incorporation of available customer resources in project execution and thus reduction of outsourcing costs
- Qualified selection of solution providers – the customer can concentrate on core-business activities.
- Most dependable representation of our customers' interests and responsibilities vis-à-vis authorities, third-party solution providers, and institutions, particularly if our customers don't maintain European legal entities of sufficient infrastructure and size. PharmaProjekthaus assumes the role of the Legal Representative as required by the EU Clinical Trials Directive (2001/20/EC) from non-EU study sponsors.

### For Big Pharma

- Additional competent staff when overloaded and understaffed for project execution and vendor selection
- High-quality recovery services when not fully satisfied with current or previous CRO and project management sourcing models and services
- Comfort, when expecting senior executive attention to and input into each project
- Strategic know-how, when faced with changing objectives requiring creative, risk-assessed, scientifically sound and clinically feasible solutions.

