



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

The PPH plus Mission

We provide state-of-the-art management consultancy and project leadership in clinical trial programs to pharma, medical device 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 PPH plus services, or to explore new partnering opportunities, please contact:

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Your Drug Development Architect – Service Offer

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

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

Medical Leadership Our physicians have a thorough understanding of the principles of clinical development. They provide medical liaison and advisory services, as well as medical trial monitoring with insight and dedication.

Feasibility Surveys PPH plus offers the most innovative technologies and a wide range of experience in the planning and execution of feasibility surveys.

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

Pharmacovigilance Services PPH plus medical advisors offer expertise in workflow improvement of safety reporting in clinical trials and well-designed SAE report forms.

Project Leadership and Risk-based Study Management

PPH plus takes study management to the next level by targeting principal outcomes and focuses study oversight on key risks to increase monitoring efficiency.

Productivity Optimization PPH plus assists with the development of new structural and operational paradigms best suiting the customer's organization.

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

Vendor Selection Services PPH plus 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 and Risk-based Monitoring Systems





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Therapeutic Area Know-how:

- Aesthetic Dermatology and Dermatology
- Autoimmune Diseases
- Cardiovascular Disorders
- Endocrinology and Metabolism
- Gastrointestinal Disorders
- Gynecology
- Infectious Diseases including HIV and other viral Infections
- Oncology
- Orthopedics – Tissue Engineering
- Osteoporosis
- Otolaryngology
- Pediatrics – Vaccines and Therapeutics
- Psychiatry and Neurology
- Respiratory Disorders
- Rheumatology
- Urology

Operational Expertise:

- Project and people leadership
- Medical trial monitoring and medical expert data review
- Clinical operations
- Medical coding
- Trial site services
- Clinical trial regulatory and Ethics Committee submission
- Strategic sourcing in clinical drug development
- Process improvement
- Productivity benchmarking
- Organizational design of clinical development units
- Pharmacovigilance services

Medical Leadership in Clinical Development





Customer benefits

For Small and Medium-sized Enterprises

- Effective project management by PPH plus project leaders backed up by medical expertise and senior executive attention
- Utilization of our therapeutic area experience and of our relationship with key opinion leaders
- Optimized trial site productivity due to effective site support and PPH plus 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' European legal entities are short of infrastructure and size

For Big Pharma

- Additional competent staff when overloaded and understaffed for project execution and vendor selection
- High-quality recovery solutions when not fully satisfied with current or previous CRO and project management sourcing models and services
- When expected by sponsor and/or if required by the complexity of a project, 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

