



Fact Sheet

Project Leadership

Why Project Leadership?

Applying state-of-the-art project management principles in clinical development is crucial for the successful conduct of a clinical trial. Each day saved on the way to marketing authorization translates into a higher sales potential of the medicinal product or the medical device. Each day of delay can cause heavy financial constraints.

Growing restrictions and stringent regulatory requirements affect the design of clinical trials, magnifying project limitations. Risk-based and quality by design management approaches, as proposed by the European Medicines Agency, will further increase the complexity of clinical trials.

Therefore, it is essential that a clinical trial is managed in a professional way by a project leader who owns the required skills to prevent foreseeable mistakes. Through accurate planning, efficiently directing, managing and controlling project work, the project leader will guide the project team to successful project completion.

What We Can Do for Our Customers

PPH plus project leaders are responsible for:

- ensuring that all contracted deliverables are submitted on time and on budget, meeting the required quality standards
- leading multidisciplinary, multicultural clinical trial teams in each phase of clinical development
- continual monitoring of team functionality and performance to establish good working relationships as a basis for effective cooperation
- ensuring all project activities are aligned with customer specifications, adhering to PPH plus and/or customer SOPs

In particular, our project leaders are prepared to assume – globally or regionally – responsibility for the following tasks and duties:

- Project initiation and planning activities, set-up of work breakdown structures, and assignment of roles and responsibilities to project team members
- Continuous risk-based quality management of the project throughout the entire study with particular emphasis on the start-up phase to identify and mitigate risks



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- Integration and implementation of all service area plans including sponsor interaction/approval of plan development (e.g., for investigator recruitment, patient recruitment, clinical monitoring, data management, drug safety)
- Conduct and evaluation of feasibility studies
- Preparation of essential documents (e.g., clinical trial protocol, patient information and consent) in cooperation with the customer, PPH plus team members or service partners
- Organization and conduct of study-specific training for all team members and meetings (e.g., kick-off and investigator meetings)
- Direction and coordination of multidisciplinary teams, maintenance of effective communications and team orientation towards project objectives
- Set-up, update and ongoing quality control reviews of electronic and paper documents, comprising regular Trial Master File (TMF) checks, throughout the project life cycle
- Organization, direction, evaluation of all of activities and reporting of achieved progress during the entire study conduct
- Ensure customer satisfaction by obtaining formal approval of interim and final key deliverables
- Documentation and review of lessons learned with input from project team members and appropriate customer information

Customer Benefit

The dual qualification in team leadership and expert knowledge in clinical trial conduct of our project leaders ensures a smooth and efficient conduct of clinical trials at regional and/or international level. By this, clinical trials will stay within scheduled timelines, human and financial resources.