

## Fact Sheet

### Start-up Services

## Start-up – the Busiest Phase of a Development Project



Well-founded planning is crucial. Schedules continue to fall behind plan, typically because most of the selected investigational sites perform poorly<sup>1</sup>:

- 20-50 % of the sites recruit none to 5 % of the required patients
- 30 % of the initiated sites recruit 70 % of the required patients, but out of the planned timelines

<sup>1</sup>B. Harper et al. Fixing the Protocol Feasibility Process. Journal of Clinical Research Best Practices 2012, 8 (1), 2.

Thereby, huge amounts of money are wasted each year due to these delays. Medical expertise together with previous knowledge of country-specific aspects and investigators' performance is necessary. Thus, in the study start-up phase, expert risk evaluation and mitigation at study design, location and site levels is playing a decisive role for the success of any clinical study.



### What We Can Do for Our Customers

Highly qualified specialists with long-lasting expert knowledge in study start-up lead our Start-up Services. Our experts are used to lead the start-up phase in international clinical studies, comprising the analysis of clinical trial designs, their inherent risks and requirements, at country and site level. The PPH plus Project Leaders have the experience to identify the best teams, locations and sites, as well as to operate with multi-dimensional clinical research analytics and tools for location and site evaluation.

Thus, PPH plus is able to answer trial planning questions reliably, fast and accurately.



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#### PPH plus Unsurpassed Study Start-up Services

- Detailed analysis of regional and global clinical research infrastructure and country-specific conditions for clinical studies
- Observance of national legal and regulatory requirements and standard of care
- Identification and selection of required personnel, contract research organization (CRO), qualifications, trainings, equipment and technologies
- Identification and selection of countries, investigational sites, and cooperation partners most appropriate for the specific study and indication
- Medical-scientific assessment of study protocols regarding their feasibility
- Conduct of site qualification visits
- Generation of various documents to be written prior to study commencement (e.g., study protocol, Patient Information and Informed Consent Form)
- Contract negotiation and management with participating institutions, investigators and third-party service providers
- Collection of essential documents from investigational sites
- Clinical trial applications to competent authorities and Ethics Committees
- Organization and moderation of 'kick-off' and investigator meetings
- Clinical supply packaging, labeling and distribution planning
- Provision of progress reports and interim recommendations for the start-up and conduct of the clinical study to the sponsor team on an ongoing basis
- Preparation of a final feasibility study report with all findings and results together with a estimation of subject recruitment at country and site level, identified study and recruitment risks and proposed mitigation actions or contingencies

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#### Customer Benefit

The scientific qualification and expert knowledge of our Start-up Services team coupled with both our in-depth familiarity with multi-dimensional clinical research analytics and our communication skills assure a reliable assessment of future performance at site, country, and multinational levels. The selection of professional and well-performing sites and cooperation partners speeds up your clinical study, improves data quality, makes the processes more efficient and saves costs. In consequence, your clinical development program is highly likely to be accomplished on time and within scheduled budgets.

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Visit the PPH plus website to learn more about our service offer:  
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