Fact Sheet

Feasibility Services

Feasibility Surveys & Effective Study Planning

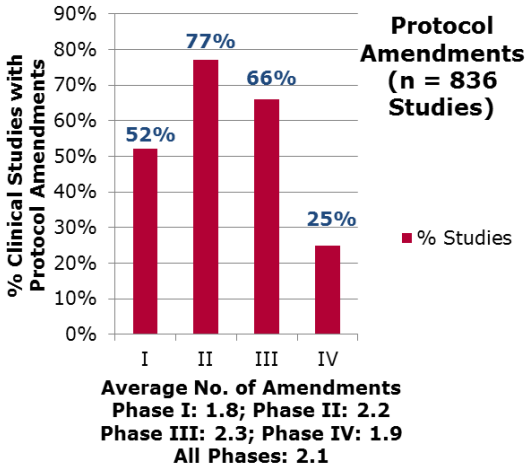
Sites and clinical trial teams struggle to succeed against budgets and timelines[1]:

- 90 % of clinical trials meet patient recruitment but by doubling timelines
- 50 % of sites do not recruit any patient or do not meet recruitment goals

Thus, costly amendments are required. The median direct cost to implement a substantial amendment is[2]:

- 141,000 USD for a phase II protocol
- 535,000 USD for a phase III protocol

Thus, clinical trial budgets and timelines are often overrun. A well-founded feasibility study combined with a diligent selection of participating trial sites is essential for the success of a clinical trial.



[1]Tufts CSDD Report, 15 January 2013; [2]K. A. Getz et al. The Impact of Protocol Amendments on Clinical Trial Performance and Cost. Therapeutic Innovation & Regulatory Science 2016, Vol. 15 (4), 436-441.

What We Can Do for Our Customers

The PPH plus Feasibility Services team comprises medically qualified specialists with long-lasting expert knowledge in the conduct of feasibility studies. Our Feasibility Services team leads the clinical trial planning efforts and select professional investigative sites. Accurate clinical site and protocol evaluations relieve sponsors, investigators and patients of preventable, costly and time-consuming protocol amendments.

Our Feasibility Services enhance quality by design (QbD) with a team that efficiently communicates with sponsor units and trial sites to achieve feasible study protocols.

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PPH plus Unsurpassed Feasibility Services

- Review of study protocols to provide a medical-scientific assessment of their feasibility at local and international level with input from external sources
- Conveyance of scientific input from highly qualified and experienced investigators and/or key opinion leaders regarding protocol features which could possibly constrain the timely conduct of the clinical trial
- Preparation or review of specific feasibility questionnaires ensuring their suitability to assess investigators' interest, concerns and recruitment estimations
- Provision of detailed input to customer concerning regional clinical research infrastructure, availability and acceptance of therapies, local regulatory requirements and information about possible issues at country and site level
- Distribution, collection and evaluation of feedback from sites and clarification of concerns raised by investigators regarding the clinical trial protocol or trial-specific procedures
- Site assistance during the conduct of feasibility studies
- Provision of feasibility status reports, identified beneficial or inhibiting factors and recommendations for the setup and conduct of the clinical trial to the sponsor team on an ongoing basis
- Preparation of a final feasibility study report with all findings, results, predictable issues, and estimated cost, together with a sophisticated assessment of subject recruitment at country and site level
- Delivery of scientifically founded recommendations on how to avoid delays and inhibiting factors in the clinical study setup and conduct phase

Customer Benefit

The scientific qualification and expert knowledge of our Feasibility Services team together with excellent contacts to trial sites and investigators assure a reliable prediction of performance at site, country, and international levels. The selection of professionally working and committed sites speeds up your clinical trial, improves the data quality, makes the processes more efficient and, thus, saves costs. In consequence, your clinical development program is likely to be accomplished on time and on budget.