VPI PARTNERS LLP

Improved Effectiveness for Clinical Research

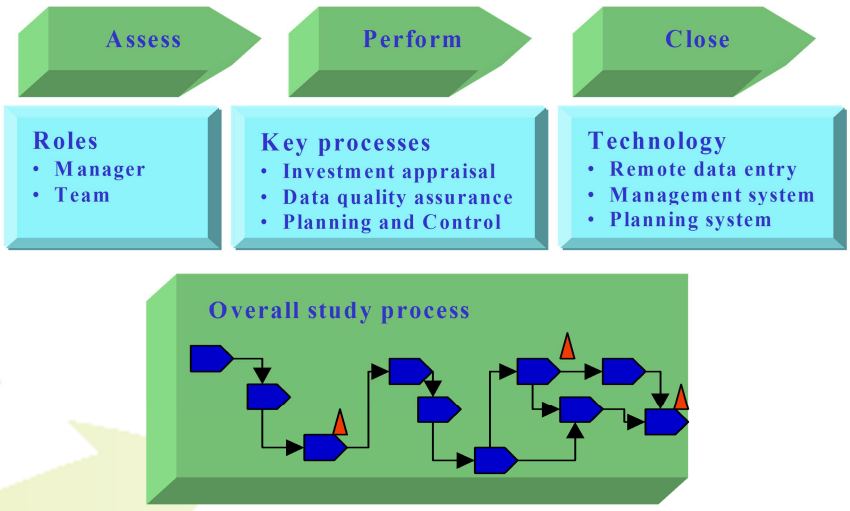
Improve the value from clinical research through excellence of process and efficient management

How do we achieve real value in good time from our huge investment in Clinical Research? This is a common demand from pharmaceutical senior management who are often confronted with very complex decision scenarios. There are huge risks involved, together with long timescales and high costs. The payoffs can similarly be huge, whether through bringing to market new drugs or providing improved evidence of efficacy or safety for current products. There also remains the overall concern as to whether the substantial investments in R & D will deliver the necessary returns to sustain the growth required by the pharmaceutical sector.

The management of clinical research can be greatly assisted by improving the focus of the activity on real marketing needs and increasing the efficiency of performing trials. This improvement can yield great rewards when faced by an ever-increasing number of trials, real difficulties in obtaining patients and competent investigators and the need for trials to cross national and continental boundaries.

The key components of our recommended approach are shown below. These consist of a rigorous process to enable a client to assess both the relative and specific business value of proposed studies and a set of roles and detail management processes for their efficient performance. There is an overall study process to apply in a common manner throughout an organisation to ensure effective working by different groups, such as international teams and different disciplines such as medical and marketing.

An effective approach to achieving value from clinical studies

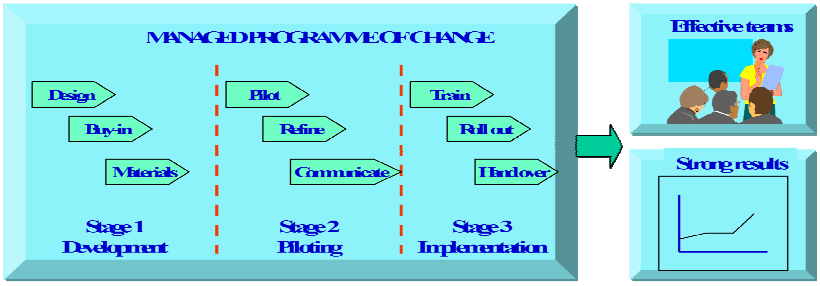


Too often, there is insufficient investment in good decision-making processes, efficient study management and effective support technology to complement the essential focus on clinical excellence.

The principles for these components have been developed from best practice in the industry and experience in real application on live studies. From this basis, one can improve significantly upon current practice, to provide an effective approach that is suitable for the specific and individual needs of an organisation and its culture.

Implementing the improvements through a managed change programme

VPI Partners have worked with pharmaceutical clients to help them develop more effective management processes through a programme of change.



Develop a process to match the business culture

At VPI Partners, we understand that the critical business processes must be compatible with the culture and demands of an individual client. This means best practice developed intelligently and with sensitivity. Clearly the clinical research process must satisfy ICH/GCP guidelines and a company's SOPs. Beyond these mandatory demands, our approach is to support the client to improve practices in a real and practical way to achieve substantial gains in the business value of their investments.

At the conclusion of an important change programme, we ensure an effective handover to allow for ongoing improvements and support.

Evidence of value for the service

We have experience of implementing major change programmes in many of the leading pharmaceutical companies. We can also deliver technology solutions for aspects such as data collection and management systems. Our efforts to improve the clinical research function have added real value for our clients for product development and post-launch marketing support.

The principles we follow are to employ experienced consultants, with a deep understanding of the industry, who can work directly with clinical research staff to develop and apply new processes that are effective in practice. This combined with excellent communications, ensures acceptance of the essential changes involved.

Why improve the clinical research function?

Each organisation will have different requirements for improving the clinical research function. There may be the need for:

- a common and effective management processes throughout the organisation
- clinical data more widely available or of more robust quality
- study teams that can be established rapidly to meet demanding timescales
- increased capacity to manage more trials with the available staff

The support from our consultants can ensure our clients satisfy these requirements.