The Keys to Success
For Cost-Efficient Late Phase Studies
Phase 4 Health Inc.

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Phase IV clinical trials represent the fastest growing area of clinical spending.[1] Three sets of factors are fuelling this trend:

1. The need to keep approved drugs up-to-date with the market as new product introductions decline.
2. Regulatory pressures demanding peri-launch and post-launch research.
3. The strategic value of Phase IV studies in support of earlier market entry.

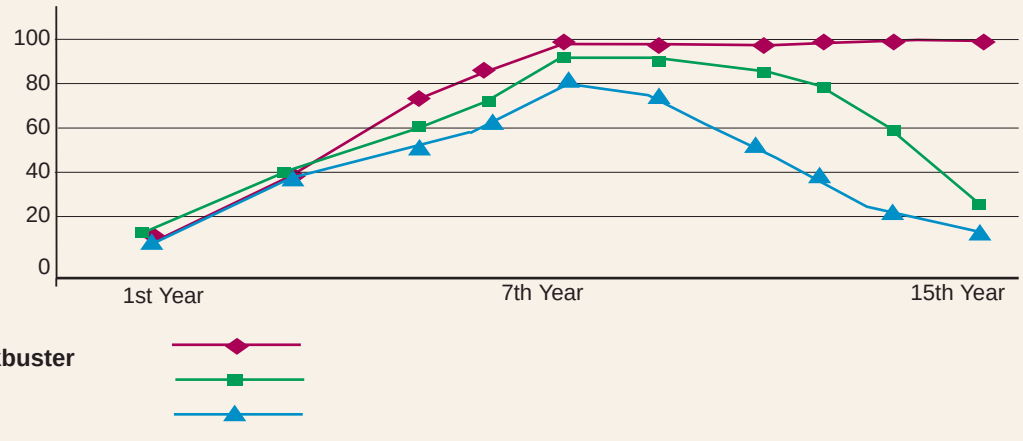
As Figure 1 illustrates, now more than ever before, shortened product lifecycles generate the need for creative medical marketing to optimize market share.

Considering the scope of investment required for Phase IV studies, astute pharmaceutical managers will want to consider some key success factors in optimizing budget allocations. Listed below are the points to consider.

1. **Proper needs assessment.** This will ensure that a worthy and rewarding study objective is defined. Indeed, many trials waste funds because physicians are not consulted in the design phase. Consider that earlier research phases (I to III) have been conducted over the last five to 10 years and that they may not reflect current or future market needs. Taking the pulse of your target physicians could mean the difference between a sound investment and a futile exercise.

2. **Planning is key**. The efforts, consultations, and compromises achieved in drafting a study plan ultimately equips you with alternate scenarios. The final plan is often not exactly what happens, but variants on anticipated scenarios will represent reality. Limit expensive, unforeseen situations by devoting time to elaborating "what if" scenarios. Your readiness to manage the unexpected will only be enhanced.

Figure 1. The Product Life Cycle.



3. **Think strategically**. Increasingly, regulatory authorities approve products on a conditional basis, requiring that sponsors conduct post-approval surveillance. Strategic managers should consider securing an earlier launch in return for post-launch research. This approach could reposition pharmacovigilance departments as profit contributors instead of necessary evils.

4. **Simplicity rules**. The constraints of our health-care system on the medical community are such that little time can be devoted to other initiatives. Simple study designs and methods save money, as they are understood and implemented efficiently by study sites.

5. **Look at ROI, not just cash outlay**. Strategic managers assess all returns on investments of a study, during and after the study. A pure cost minimization approach will not capture new attitudes towards a drug or new prescription behaviours.

6. **One can only improve what is measured**. This adage holds true for study managers who include measures of performance against benchmarks in areas, such as recruitment rates and time targets. Use actual results of past studies to project key benchmarks. Consider the lessons of other affiliates who conducted similar studies.

7. **Master technology or it will master you**. Investigator meetings are increasingly conducted over the Internet. Despite limitations, remote data entry has become a common data management paradigm. Regulatory authorities are supporting e-submissions. Personal digital assistants can collect diary data with more credibility than paper ever will. Fax-scanning technologies can automate labour-intensive tasks. Those who scan the environment and select technologies that directly support their study objectives will save time and money.

8. **Leverage opportunities**. Take advantage of symposiums and conferences to hold your investigator meeting. Exploit natural physician networks, as they harbour close peer relations. It is easier for a physician to drop out of a group of unrelated physicians than it is to leave an initiative supported by his peer network. Your study should have profiles of potential sites and existing alliances among them.

9. **Entice physicians with performance data**. Compare their results with their cluster of peers, their region, their province, and the country. Integrate data quality and timeliness standards. Make these comparisons available to the rest of the study participants. Patient recruitment costs and speed of recruitment will be favourably affected.

10. **Think like your physicians.** Physicians want to practice according to evidence-based data and disease-specific guidelines. Consider including those in your study design, either as a research topic or as an item to further develop. Physicians will embark on endeavours that reflect their practice concerns, thereby optimizing site recruitment. Pharmaceutical managers may ask themselves how their study advances physicians' practice, while saving time and improving care.

Throughout, three common themes prevail:

1. The need for open channels of communication between the sponsor and the medical community.
2. The necessity to plan, execute, measure, and improve.
3. Medical marketing strategy and the study goals must converge in every detail of the execution of the Phase IV trial.

Pharmaceutical managers able to master this web of skills and conditions will maximize their potential to implement cost-effective medical marketing initiatives.

Phase 4 Health Inc (P4H) is a leading out-sourced commercialization partner to the biopharmaceutical industry. The P4H multi-disciplinary team's proven experience and know-how help clients bring products to market faster and improve their performance throughout their product life. CPM

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Reference
1. Centre for Business Intelligence, 3rd Annual Phase IV Clinical Trials Conference. Sept. 23, 2002.