JOURNAL OF CLINICAL RESEARCH BEST PRACTICES

Vol. 2, No. 1, January 2006 "Can You Handle the Truth?"

A Knowledge-based Process for Offshoring Clinical Trials

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Globalization of clinical research means that clinical trials are increasingly being "offshored" to multiple countries, each with its own medical, regulatory, oversight, legal, infrastructure, language, and cultural environment.

In the case of clinical research, potential cost benefits may be less important than ready access to potential research subjects, requirements for marketing approval by the country's regulatory authority, and even superior data quality. These benefits can be lost, however, unless a consistent approach is taken to manage the inconsistent situations in multiple countries.

The Global Marketplace

Like other industries, some countries will emerge as preferred offshoring locations; others will be too difficult or costly to be competitive in the global marketplace. However, just as some clothing is still manufactured in high-cost countries, some clinical trials will be conducted in almost every country, but only for compelling reasons such as a unique genetic population.

The clinical research global marketplace is rapidly evolving. The current "flavor of the month" quality will subside as the market stabilizes over the next few years. Some countries will make clinical research a key long-term national objective. Others will take an early lead and then impose new restrictions or cumbersome procedures that drop them back in the pack. Eventually, as in any industry, the leaders with staying power will emerge and move down the learning curve to become ever stronger. Countries that become interested in the market later will find it difficult to catch up.

Global Knowledge

Because personnel "on the ground" have the required local expertise, it is easy to delegate the management of a multinational trial to independent managers or CROs in each country. What can get lost, however, is the sharing of knowledge across countries. Knowledge that is hard-won in one country is often applicable to others. Lessons learned on one trial are useful for the next. Expertise by an employee or CRO is lost when that person moves on, even to another position in the same company.

Knowledge management – the structured and methodical management of knowledge in an organization – ensures that knowledge is captured, made available, and built upon in a global collaborative effort. Like any other management discipline, there are right ways and wrong ways to run a knowledge management system. The details are beyond the scope of this article. However, the following characteristics are essential:

- The system must be simple to learn and use in a consistent manner.
- The benefits of using the system must significantly outweigh the costs for each participant.

Knowledge management systems take many forms. They can be a hugely complex database or a few simple spreadsheets. In general, it is better to start with something simple. As the system gains momentum and accumulates knowledge, more sophisticated technology can be brought in to maintain order and ease access.

Table 1 presents a categorized checklist of considerations for multinational trials. The following simple, repeatable process employs this checklist:

1. Complete the spreadsheet for the home country, e.g., the United States.
2. Select candidate countries for the trial.
3. Identify expert(s) for each country.
4. Have each expert complete the spreadsheet for his/her country, noting differences to the home country.
5. Consolidate the spreadsheets.
6. Compare the entries for each country to prioritize countries for participation and identify open issues and questions.
7. Pare down the list of candidate countries.
8. Obtain answers to open questions for remaining candidate countries; document within the spreadsheet.
9. Discuss remaining issues in more depth, as required; document the substance of the discussion and the participants in the spreadsheet.
10. Make final country selection
11. Proceed with study.
12. Identify variances from the spreadsheet as the trial progresses; document in the spreadsheet.

Table 1. Offshoring Considerations

Area	Issue
Regulatory	• Regulatory authorities, requirements & process • GCP • Informed consent • Subject stipends
Legal	• Clinical trial agreements • Service provider agreements • Jurisdiction & governing law • Enforceability of contracts • Attitudes towards contracts & dispute resolution • Intellectual property • Privacy
Language	• Translation of study documents • Subject education • Translation of site entries • Translation of subject entries • Adverse event management • Investigators meeting • Training of site personnel
Medical	• Standard of care • Infrastructure • Structure of medical enterprise • Third-part payors
Ethical	• Ethics boards • Doctor/patient relationship • Cultural milieu • Stipends
Operational	• Standard of care realities • Subject logistics, e.g., travel • Source documentation/medical records • Data security • Personnel qualifications, availability, location, language • Training (availability, method, language, location, cost) • Insurance • Facilities • Electrical power • Storage of test article, documents • Suitability of standard metrics • Culture, e.g., punctuality, frankness
Shipments, Travel & Communications	• Shipments to country – carrier, frequency, customs • Shipments from country – carrier, frequency, customs • Equipment • Meetings • Monitoring • Internet & computers • Telephone • Fax • Time zone
Quality	• Training • Site monitoring • Data queries
Timing	• Regulatory approvals • Oversight approvals • Site selection • Staffing • Subject recruiting • Data collection

13. Conduct a study "post mortem" and clean up spreadsheet with final results.
14. Maintain a copy of each version of the spreadsheet in case future questions arise.
15. For the next study, repeat the process, but starting with knowledge from the previous study.

The above process assumes a series of sequential trials. In the real-world, multiple trials start, add/delete countries, and end in parallel. Interim versions of the spreadsheet can be shared across studies. Periodically, spreadsheets from multiple studies can be compared and consolidated.

Conclusion

A haphazard, ad hoc approach to multinational clinical research will yield inconsistent, inferior results. A more methodical, knowledge-based approach will yield more consistent results that improve over time. The approach does not need to be complex and burdensome; all that is required is a simple way to capture, reuse and evolve the knowledge that is – or should be – employed on each study anyway.

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