Optimizing Global Clinical Trial Investments

Advanced Risk Modeling for Patient Enrollment Forecasting in 23 Country Phase III Trial Saves Company Millions.

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Introduction

Before a pharmaceutical company can bring a new product to market, it must conduct extensive clinical trials that take years and cost hundreds of millions of dollars to complete. While this process is underway, each day spent in development brings the product a day closer to the time when patents expire, presenting the innovator company with fierce competition from generic firms that can sell the product for a fraction of the original price.

Although the pharmaceutical industry has faced this development cycle for decades, new pressures have arisen in recent years that make the clinical research environment more challenging than ever. First, as a result of an increased focus on safety, regulators throughout the world want to see longer and larger trials than were required in the past. Further, with the number of trials escalating, sponsors face growing competition for patients and increased difficulty convincing researchers to participate. Indeed, many top-tier research institutions receive so many offers to participate in studies that they have either turned away new trials altogether or have become extremely selective about the ones in which they choose to participate.

In a November 2006 report, the U.S. Government Accountability Office summed up the situation as follows:

“On average, drug sponsors can spend over 13 years studying the benefits and risks of a new compound, and several hundred millions of dollars completing these studies before seeking FDA’s approval. About 1 out of every 10,000 chemical compounds initially tested for their potential as new medicines is found safe and effective, and eventually approved by (the) FDA, making the drug discovery and development process complex, time consuming, and costly.”

“Over the past several years it has become widely recognized throughout the industry that the productivity of its research and development expenditures has been declining; that is, the number of new drugs being produced has generally declined while research and development expenses have been steadily increasing.”

Industry figures underscore the point: Pfizer reports that 60% of total development budgets are spent on clinical trials, double the level required in the 1980s. With these facts in mind, it is clear that there is a pressing need for an effective and efficient clinical development process. This paper outlines a probability-based modeling approach we recently employed to reduce overall expenditures for a major cancer trial without sacrificing the likelihood of successful, on-time enrollment.

**The Assignment**

Value of Insight Consulting, Inc. (VOI), a life-sciences advisory firm, was hired by BBK Worldwide (BBK), the industry leader in providing clinical trial sponsors with global study enrollment services, products, and technology. The ultimate client for both VOI and BBK was a major multinational pharmaceutical company that needed to determine the relative suitability of 23 countries as locations for a phase III clinical trial of a cancer drug. For confidentiality reasons, the names of the client, trial, drug and the specific type of cancer are not disclosed. For the purposes of this document, the drug is referred to as “Drug X”, the specific cancer as “Cancer Y” and the clinical study as “Trial Z”. Similarly, where budget figures are cited, we have replaced our client’s proprietary figures with industry averages obtained through secondary research.

The majority of countries with meaningful abilities to conduct clinical research were included in the Trial Z evaluation set. These ranged from major research centers such as the United States, Germany and Japan to countries with emerging clinical trial infrastructures, such as China, India, Brazil and Russia.

The objective of our analysis was to determine the best countries in which to place Trial Z so as to ensure that a minimum total of 690 patients would be enrolled within the sponsor’s 26-month timeline. In addition to being diagnosed with Cancer Y, potential patients had to meet certain other criteria before they could be admitted to the trial. These inclusion criteria included the patient’s particular subtype of Cancer Y, how far the disease had progressed and prior history.

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2 [http://www.pfizer.com/research/clinical_trials/clinical_trials.jsp]
with various forms of therapy. In addition, since Cancer Y is a particularly malignant form of cancer with very limited survival rates, the relevant population for Trial Z was the number of people diagnosed annually (incidence) rather than the number of people ever diagnosed (prevalence).

The stakes involved in obtaining an accurate assessment were high. Consider, for example, that even in the United States — a country with an extremely advanced research infrastructure — up to 40% of the total labor involved in a cancer trial occurs before a single patient is enrolled. Countries with less developed clinical trial capabilities usually offer lower patient recruitment costs, but the upfront administrative burden associated with gaining approval, identifying sites and training investigators is considerably higher in these less-experienced countries. Placing Trial Z in countries where recruitment would ultimately fall short of target levels would result in unnecessary loss of patent life and divert scarce resources from productive to unproductive locations.

Although the primary objective of the assignment was to evaluate the likelihood of successful, on-time enrollment based on our client’s original plan, the analysis ultimately allowed us to make revisions that resulted in a substantially improved approach. This process is described below.

**Methodology**

VOI and BBK conducted extensive primary and secondary research to determine the characteristics of each market and how these might affect clinical trial enrollment. First, we evaluated the structural environment for clinical research in each country. Factors considered in this phase included: length of time required to obtain regulatory approval for trial initiation, motivations and incentives for physicians and patients to participate, cultural attitudes toward clinical trials and availability of the necessary human and technical resources.

Next, we collected information specific to Cancer Y in each country. For example, we examined epidemiological data including the annual incidence of Cancer Y and the percentage of Cancer Y

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patients meeting the enrollment criteria for this trial. We also considered diagnostic pathways for Cancer Y patients, the number of specialists treating the disease, the number of contacts each patient would have with investigators, investigators’ attitudes toward or prior experience with Drug X and its competitors and the likelihood that this particular group of patients would enroll in Trial Z.

With the results of our research in hand, we used the information to complete a model of the patient enrollment process for each of the 23 countries. BBK’s Enrollment Projection Model (EPM), a proprietary product for forecasting enrollment across the range of disease states, served as the foundation for this component of the project.

As a proprietary methodology, we are not able to elaborate on the nuances of BBK’s EPM. At a very general level, however, it is possible to say that there were four major steps employed to forecast patient enrollment for each of the Trial Z countries:

- **Step 1**: establish the number of Cancer Y patients diagnosed per investigator per month. Information used to arrive at this figure included the overall incidence of Cancer Y, the number of investigators involved in the trial and their monthly patient volume.

- **Step 2**: compare the national profile of Cancer Y patients against Trial Z’s inclusion/exclusion criteria to determine how many patients would be eligible for enrollment. Here we employed epidemiological data on the prevalence of specific subtypes of Cancer Y and the portion of patients diagnosed at each stage of disease progression. (Due to environmental factors and the quality of healthcare systems there was considerable variation in these figures from one country to another.)

- **Step 3**: determine the likelihood that eligible patients would be invited to participate and, if invited, would elect to enroll in Trial Z. Inputs for this step included availability of and satisfaction levels with existing therapies, investigator opinions about both Drug X and the design of Trial Z and cultural attitudes towards clinical research.

- **Step 4**: establish the schedule for patient enrollment and bringing all investigative sites online. This component was based on research into procedures and timelines required for regulatory and ethical approval, contract negotiations and investigator training.

The final product of the EPM was a model containing recruitment projections for each of Trial Z’s 23 countries. Each country-level model relied on data from 54 inputs; the model’s output was
a monthly estimate of patient enrollment. By incorporating a wide range of information about each country into a unified enrollment forecast, the EPM allowed us to analyze and compare the countries in a way that would not have been otherwise possible. When weighed against our client’s original enrollment targets, BBK’s EPM provides a method for determining the countries that are best suited to host the trial.

At this point in the process results are provided in the form of single figure, bottom-line projections that reflect what our research and modeling indicated to be the most likely number of patients recruited in each country each month. Deviations from the base-case estimates, whether caused by “real-world” variability within the model parameters or inaccuracies in the research, were not yet factored into the analysis.

Given that differences between the base-case forecast and actual outcomes could lead to unnecessary expenditures, delays in Trial Z’s completion and could even jeopardize the ultimate approval of Drug X, VOI and BBK wanted to gain a more comprehensive understanding of the likelihood of achieving enrollment objectives in each country. With this in mind, it was desirable to incorporate an additional forecasting step which could account for uncertainty. To accomplish this, VOI applied a risk-modeling technique known as Monte Carlo Analysis to the EPM.

**About Risk-Modeling with Monte Carlo Analysis**

A well-designed modeling approach based on reliable in-depth research, like the EPM for Trial Z, provides an excellent method for predicting future events and evaluating alternative actions. It is possible, however, to enhance forecasts by taking account of the inherent uncertainty in future events. Monte Carlo Analysis (MCA) is one of the leading techniques for accomplishing this and, as such, is increasingly being used in a variety of industries where important decisions involve substantial risk.

To employ MCA, the modeler begins by replacing single-point estimates with probability distribution functions, thereby allowing for incorporation of risk and uncertainty into forecasting models. Next, the model is calculated and recalculated hundreds or thousands of times, with each iteration having a different set of randomly generated values derived from the probability functions. As these randomly generated distribution values interact with each other, they ripple throughout the model. The end result is a forecast that includes a wide range of feasible outcomes and their probabilities of occurrence.
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As a simple example, assume that the goal is to forecast profitability for a product line. The standard modeling approach might be based on estimates that the cost of inputs will be $100, the average price per unit will be $125 and the demand will be 1,000 units. The result of this model would be a single profitability estimate of $25,000.

In contrast, the parameters for a Monte Carlo-based model might state that these estimates are normally distributed, so that the cost of inputs has a mean expected value of $100 with a standard deviation of plus or minus 5%, the average price will be $125 with a standard deviation of plus or minus 10%, and the demand will be 1,000 units with a standard deviation of plus or minus 20%. With these probability distributions in place, an MCA simulation would be executed, yielding an analysis of profitability across all feasible cost, price and demand possibilities.

In this example, the most likely profit level would remain $25,000. However, the forecaster would also find that there is a 97% probability of reaching breakeven, a 1% chance of losing more than $6,000 and an 80% confidence interval that profits will fall between $8,000 and $44,000. As we can see, MCA provides a more robust understanding of potential risks and benefits than would otherwise be possible. By comparison to this simple example, a major international clinical trial represents an opportunity to incorporate MCA in a far more complex and uncertain, high-stakes environment.

Applying Monte Carlo Analysis to the Trial Z Enrollment Model

With the original model for each of our 23 countries providing the framework, we employed Palisade Software’s @Risk program to conduct our Monte Carlo Analysis.

Broadly speaking, the model inputs used can be broken out into those with known and unknown or variable values. Known values are those that are controlled by the sponsor, such as target enrollment objectives, scheduled timeframe and the number of potential investigative sites per country. Of the 54 inputs in each of the 23 country-level models, seven fell into the known (client-controlled) category. These remained unaltered from the Enrollment Projection Model discussed above.

The remaining 47 model inputs had uncertain or variable values. These included such factors as the monthly incidence of Cancer Y, the number of patients seen by each investigator, the percentage of patients meeting Trial Z’s inclusion criteria and the percentage of physicians who...
would discuss the trial with their patients — in short, anything that was not directly controlled by the sponsor. Instead of single-point estimates, these were assigned probability distributions with the expected value from the original model serving as the mean. Although it is possible to incorporate any probability distribution into a Monte Carlo Analysis, we used a normal distribution for all variables, as this was believed to be the most representative pattern for our data.

The size of the standard deviation around the mean ranged from 5% to 20% for each variable. This was based on two factors: the first was the inherent variability of the underlying data (for example, the number of patients diagnosed within a month by each particular investigator is subject to greater variability than the epidemiologic profile of the Cancer Y population within each country); the second factor was an estimate of the reliability of the particular research finding in question (for example, findings based on large-scale studies were deemed to have a higher degree of accuracy than findings based on a small number of interviews). The upper range of standard deviation was assigned to model inputs with greater variability or lower reliability.

After changing our variables from point estimates to probability distributions, we used the Monte Carlo software package to run 10,000 separate simulations on each of the country-level models. As described below, the results were highly informative and created a substantial savings for our client while also providing an extremely high degree of confidence that Trial Z’s enrollment goals would be met on time.

**Interpreting the Probability Figures**

As noted, this analysis includes probabilities for reaching enrollment goals for each country and for Trial Z as a whole. The results are based on the 10,000 Monte Carlo simulations conducted and reflect the percentage of these trials that resulted in a higher or lower amount than the target value.

For example, if a country is forecast to have a 99% probability of meeting its target enrollment rate, then 9,900 of the 10,000 simulations resulted in a value equal to or greater than their target enrollment rate. If a country is forecast to have a zero chance of meeting enrollment goals, none of the 10,000 trials resulted in a value equal to or greater than the target enrollment rate. If a country is forecast to have a 50% probability of meeting enrollment, it means that half of the trials were equal to or above the goal and half were below.
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**Trial Z Results based on Original Plan**

The results of our Monte Carlo Analysis are summarized in Table 1. (Note that these figures are based on the countries, recruitment targets and number of investigative sites included in our client’s original plan.)

Barring major unforeseen circumstances, Trial Z is highly likely (94.7% probability) to meet its enrollment goal of 690 patients by the end of Month 26. In other words, when the results of the 10,000 simulations conducted in each of the 23 countries were summed, the overall trial enrollment goal was missed in only 5.3% of cases. Indeed, the most likely case is that 816 patients will be enrolled by the end of the recruitment period. Even in the lowest 10th percentile of trials — which might serve as a reasonable boundary for a “worst case scenario” — Trial Z enrolls approximately 712 patients, or 22 more than required, on schedule.

**Table 1 - Summary of Monte Carlo Analysis based on Original Trial Z Plan**

<table>
<thead>
<tr>
<th>Trial Total</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Target Patient Enrollment</td>
<td>690</td>
</tr>
<tr>
<td>Enrollment period (months)</td>
<td>26</td>
</tr>
<tr>
<td>Number of investigative sites</td>
<td>208</td>
</tr>
<tr>
<td>Probability of Achieving Target by End of Enrollment Period</td>
<td>94.73%</td>
</tr>
</tbody>
</table>

**Trial Z Enrollment at Month 26 (Results of 10,000 Simulations)**

| Minimum Enrolled Patients | 550.9 |
| Lowest 10th Percentile (fewer than X patients recruited) | 711.7 |
| Mean Enrolled Patients    | 816.3 |
| Median Enrolled Patients  | 809.4 |
| Highest 10th Percentile (more than X patients recruited) | 928.9 |
| Maximum Enrolled Patients | 1,306.3|
| Standard Deviation        | 86.8  |
| Standard Deviation (%)    | 15.8% |
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Figure 1 shows the combined (all countries) forecast for patient recruitment levels over the 26-month course of Trial Z. (Note that the inflection point around Months 3 to 6 is a result of trial sites coming online in the countries that have slower initiation processes.) Here we can clearly see that the lowest 10th percentile of simulations crosses the enrollment target sometime between Months 25 and 26. We can also see that, in the most likely case (defined by the 50th percentile of simulations), Trial Z will reach the target by Month 23 and in the highest 10th percentile, the enrollment objective will be met by Month 20.

Figure 1 - Trial Z Patient Accrual Forecasts based on Original Plan
Individual Country Results

Although the odds for successful enrollment of Trial Z are high, Figure 2 reveals that there is a great deal of variation within the individual countries; a finding that creates an opportunity for considerable reduction in the level of resources required for the trial. As indicated, five countries are virtually certain (probabilities well over 90%) to meet their enrollment objectives on schedule, while another five countries are virtually certain (probabilities near zero) to fail in this regard. Projections for the remaining 13 countries are less clear-cut (probabilities ranging from approximately 13% to 86%), but even in this middle group we can see that the odds of success are much greater in some countries than in others.

Figure 2 - Probability of Reaching Target Enrollment on Schedule based on Original Plan - Trial Z Total and Individual Countries
Producing an Optimal Plan for Trial Z

Looking at the forecast results based on the original plan indicates that the country list and national enrollment targets could be adjusted to the benefit of Trial Z and the sponsor’s bottom line. With this in mind, we continued our probability-based analysis to determine a mix of countries, enrollment targets and site rosters that would maximize the probability of success while minimizing the sponsor’s expenditure. This was accomplished by applying optimization software to our Monte Carlo-based model. (As mentioned, in the monetary figures below we have replaced our client’s proprietary budget information with industry-standard averages derived from secondary research.)

As shown in Table 2, this optimization process resulted in substantial benefits for the sponsor. Without changing patient recruitment goals or schedules, the analysis allowed reduction in the number of scheduled countries from 23 to 17, the number of total sites declined by 24 and the budget was cut by nearly $4.1 million, or 8.1%, of the total required under the original plan. Indeed, we estimate that the actual savings may be two or three times this level, as the administrative costs associated with trial approval, site initiation and ongoing oversight are not fully captured in the figures below.

The above savings were achieved with a miniscule, 0.5%, reduction in the probability of successful on-time enrollment. Put another way, the cost of purchasing an additional 0.5% probability of success is at least $4.1 million, a very inefficient use of funds.

Table 2 - Results of Recommended Optimization Plan for Trial Z

<table>
<thead>
<tr>
<th></th>
<th>Original Plan</th>
<th>Recommended Revised Plan</th>
<th>Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target Patient Enrollment</td>
<td>690</td>
<td>690</td>
<td>Unchanged</td>
</tr>
<tr>
<td>Number of Months</td>
<td>26</td>
<td>26</td>
<td>Unchanged</td>
</tr>
<tr>
<td>Number of Countries</td>
<td>23</td>
<td>17</td>
<td>-6</td>
</tr>
<tr>
<td>Number of Investigative Sites</td>
<td>208</td>
<td>184</td>
<td>-24</td>
</tr>
<tr>
<td>Total Budget in US$ (000)</td>
<td>50,307</td>
<td>46,232</td>
<td>-4,075</td>
</tr>
<tr>
<td>Probability of Achieving Enrollment Target on Time</td>
<td>94.7%</td>
<td>94.2%</td>
<td>-0.5%</td>
</tr>
</tbody>
</table>
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Conclusion

While there may be legitimate reasons for forging ahead with clinical studies in some of the countries where the trial will not reach its enrollment goals (for example, the need to cultivate investigators for future research or the potential for improving local approval chances), this analysis clearly shows that there are significant benefits to be gained from adjusting the number of countries involved in Trial Z.

We suspect that most global clinical trial initiatives would see similar advantages using this approach. Indeed, the advantages would likely be greater: Cancer Y, the focus of our assignment, tends to be substantially more prevalent in developed than in emerging countries. For this reason, the changes in our revised plan resulted in an increased level of activity in major markets; savings came primarily from a reduction in the administrative burden associated with initiating the trial in multiple locations. If the focus had been on another disease state that would have allowed us to shift more patients from high-cost developed markets to low-cost emerging markets, the savings would have been substantially higher.

Further, Trial Z had a very high probability of reaching its recruitment goals both in the original and revised plans. Thus, the opportunity costs associated with missing the enrollment deadline was not a major factor in our results. Most trials, however, are far less certain to meet their schedules, and an analysis similar to what we performed for Trial Z would therefore offer the additional benefit of either reducing trial length or identifying unrealistic timeframes.

As the preceding shows, risk-modeling with Monte Carlo Analysis provides decision-makers with valuable insights that would not otherwise be available. Considering this, it is somewhat surprising that it has not become a more widely-used tool. While the technique requires additional effort on the part of the modeler, the vast majority of the work takes place during the research phase: in this assignment, gathering accurate research and conducting the interviews necessary to establish the 1,242 bits of data needed for 23 country-models with 54 variables each took approximately 80% of the time, while the completion of both the original EPM and the Monte Carlo models consumed the remaining 20%. Since the research would have been conducted in any case, gaining a comprehensive understanding of the probabilities of success for Trial Z and the ability to reduce trial costs by approximately 10% was thoroughly worth the incremental effort.
Risk-modeling could be applied to a number of other aspects of the life-sciences industry as well. Valuation of licensing or M&A deals, determination of which pipeline projects to pursue, assessments of market entry potential and optimization of ROI in promotional allocations are just a few of the areas that require substantial investments in the face of uncertainty. In an industry that is arguably facing the most challenging period in its history, companies that incorporate risk-modeling into their decision-making process could provide themselves with a distinct and affordable advantage over their competitors.
VOI Consulting is a life sciences advisory and publishing company dedicated to providing pharmaceutical and biopharmaceutical clients with fact-based analysis and business intelligence to meet market challenges in today’s highly competitive global environment. By skillfully employing innovative research techniques and advanced analytical tools our services help clients minimize risks, cut costs and maximize commercial opportunities.

VOI translates to “Value of Insight” and plays on the statistical term “Value of Information,” which describes the difference between expected outcomes in the absence of information and expected outcomes in the presence of information derived through applied research techniques, sound analysis and experienced judgment. For our clients — including 17 of the top 25 pharmaceutical companies — this insight translates into measurable success.

VOI’s reputation as a leading publisher of pharmaceutical industry reference books and in-depth pharmaceutical market research reports has distinguished the company well beyond the competition as a trusted source of research and analysis.

Our services are global in reach, are relevant for any therapeutic category and span the entire range of the pharmaceutical lifecycle. Whether you are planning a clinical trial or need to assess the market for a generic drug, whether you operate in developed countries or are looking at emerging opportunities in countries like China, India, Russia, Turkey or Latin America, VOI can help you execute better, faster and cheaper. We invite you to contact us today to learn more about how VOI Consulting can be of service.

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GLOBAL CLINICAL TRIALS ANALYSIS

VOI was contracted to explore the suitability of 30 countries as locations for clinical trials with five compounds aimed at diseases in the oncology, endocrinology, rheumatology, nephrology and dermatology fields. The majority of countries with meaningful abilities to conduct clinical research were included in the evaluation set. These ranged from major research centers such as the U.S., France, Germany and Australia to countries with emerging clinical trial infrastructures, such as China, India, Brazil, Russia and South Africa.

GLOBAL BIOSIMILAR STRATEGIC OPPORTUNITY ASSESSMENT

Our client needed to evaluate a number of strategic options regarding possible entry into the biosimilar category. VOI performed a thorough analysis of clinical, manufacturing, intellectual property and marketing issues in both advanced (e.g. US, EU, Canada) and emerging (e.g. India, China, Latin America) markets. The developing legislative and regulatory frameworks in these markets were explored in-depth. In countries such as the U.S., where governing regulations are not yet in place, the implications of various scenarios (e.g. different lengths of data exclusivity, clinical trial requirements) were explored.

STRUCTURAL ANALYSIS OF INTERNATIONAL PHARMACEUTICAL MARKETS

Our client needed to understand the chain of influence in 11 international markets and how this affected the commercial prospects of their products. VOI examined the elements of the decision-making chain in these markets and determined the relative influence of each component (e.g. payers, prescribers, distributors, patients) on the product selection process.

about the author

Todd Clark is the President of VOI and the author of many pharmaceutical industry publications. During nearly 20 years experience in the life sciences field he has worked with leading companies to find solutions to a range of clinical development, regulatory and commercialization challenges. Todd has an MBA from the Kellogg School of Management and is an adjunct professor of business at two universities.