

# APPLIED CLINICAL TRIALS

YOUR PEER-REVIEWED GUIDE TO GLOBAL CLINICAL TRIALS MANAGEMENT

Global Trials & Emerging Markets

Jena Jankosky, Ying Jiang, and Ted Farwell

## Grant Budgeting and Negotiating in India and China

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Industry must grasp the cultural  
nuances of these two burgeoning  
countries to find success there.  
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India and China offer attractive environments for clinical studies, with India emerging as a major market for clinical trials and China not far behind. Both countries provide huge and accessible treatment-naïve patient populations and cost-effective research opportunities with low procedure and professional fees. While these countries presently account for less than 1% of the total FDA-regulated clinical research,<sup>1</sup> forecasters estimate an expanding market for new clinical trials in both countries.

In this article, we describe why this rapidly developing market for clinical trials will create an industry wide challenge for researchers who have less than a complete understanding and experience with cultural issues and nuances of clinical trials in India and China. We focus on the key components of investigator grant budgeting and negotiating in these countries, detailing how clinical investigators can maximize their resources and enhance their trials in these rapidly expanding economies.

To construct budgets that reflect market conditions in both India and China, the industry must have access to current actual cost per visit and cost per patient numbers. These data ensure successful

budget negotiation and create a positive relationship between pharmaceutical companies and the clinical sites in these countries.

### What companies say

We contacted more than 30 sponsor companies to determine if they anticipated new clinical trials in China or India in 2007. The companies indicated that for 2007, nearly 4% of new clinical trial sites would be in India and 5% in China; by 2010, they expect this number to jump to 10% of new sites in India, and another 10% in Asia, especially China. These forecasts match A.T. Kearney's Overall Country Attractiveness Index,<sup>2</sup> which ranks India and China as the most attractive countries for clinical research after the United States. This index was constructed using five variables: Patient Pool, Cost Efficiency, Regulatory Conditions, Relevant Expertise, and Infrastructure and Environment.

### Clinical research in India

India provides an attractive setting for clinical research. Some of the benefits include:

- More than 500,000 English-speaking doctors, many trained in the United States or UK

- An enormous naïve patient population
- The highest number of FDA-approved laboratories outside of the United States.

The larger cities of Mumbai, New Delhi, and Chennai offer both large patient populations and better equipped research institutions, which have the capability of handling greater patient populations as well as more complex trials.

## Low cost budgeting for trials and the potential for significant cost savings in India's emerging market provide incentives for companies.

Some examples include the Adyar Cancer Centre in Chennai and the Tata Memorial Hospital in Mumbai. The major ongoing clinical trials in India are for cardiovascular diseases and diabetes.

In 2000, there were 60 unique 1572s filed; this number increased to 174 in 2004 (0.5% of the global 1572 filings). By 2010, the clinical research market is expected to surpass \$2 billion.<sup>3</sup>

### Investigator grant budgeting

Of course, low cost budgeting for clinical trials and the potential for significant cost savings in India's emerging market provide incentives for companies as they look for ways to contain expenses in the expanding clinical services industry.

In India, local offices build investigator grant budgets, which traditionally have been based on intangibles such as experience and gut feelings. Most contracts are two-party arrangements between the investigator and the hospital.

Most clinical grants in India have four main components: procedures, professional fees, site costs, and overhead.

**Procedures.** Procedures are activities done to or on a patient. Common procedures in most clinical grants are electrocardiograms (ECG), informed consent, and chest x-rays. Procedure costs are 21% of the U.S. costs. Some specific cost differences can be seen in Table 1.

**Professional fees.** Wages, salaries, drug preparation, and facility fees are examples of professional fees. Contracts do not include pharmacy fees, and the cost for dispensing the investigational product is already included in the principal investigator's salary. India does not include subject reimbursement in the initial budget, but this cost may be added to ensure that the study retains subjects.

On average, India's professional fees are half the cost of U.S. fees. Some examples are illustrated in Table 1. Physician fees are budgeted on a per visit basis and study coordinator fees are budgeted as monthly salaries. Principal investigators decide how many full-time salaried support staff (i.e. study coordinator, nurse, and dietician) are needed and what their compensation should be.

One of the cultural differences when negotiating site budgets in India is subject reimbursement. Oftentimes, a family member will have to accompany the patient to each visit; therefore, additional reimbursements may be included. This is not typically included in the initial budget presented to the site, but may be added in order to accommodate the sensitive needs of this population and their families.

**Site costs.** Site costs tend to be one-time fees, such as advertising, Institutional Review Board or Ethics Committee fees. India's enormous patient pool and the country's 13 official languages make an advertising campaign impractical. Rather, hospitals recruit patients directly, with each site determining

### Procedure and Professional Fees: India vs. the United States

Line Item Description	India	U.S.	% Difference
Blood draw, phlebotomy, routine venipuncture or finger/heel/ear stick for collection of specimen(s): Includes preparation and handling	\$3	\$28	-89%
Detailed office or other outpatient examination: Includes a detailed history, a detailed examination, and vital signs. Typically, 25 minutes are spent performing or supervising these services during the visit	\$32	\$145	-78%
Electrocardiogram, routine ECG with at least 12 leads (EKG), tracing, interpretation, and report	\$14	\$119	-88%
Inclusion/Exclusion criteria	\$10	\$52	-81%
Initial office or other outpatient examination: Includes a comprehensive history, physical examination, and vital signs. Typically, 60 minutes are spent performing or supervising these services during the visit	\$51	\$200	-74%
Nurse Per Hour	\$16	\$45	-65%
Physician Per Visit (Complex: e.g., initial visit, final visit)	\$102	\$175	-42%

Source: GrantPlan® Database.

**Table 1.** Both procedure and professional fees have a lower price tag in India compared to the United States, with professional fees costing on average 50% less.

## Procedure and Professional Fees: China vs. the United States

Line Item Description	China	U.S.	% Difference
Brief office or other outpatient examination: Includes vital signs, blood pressure, and weight/height. Typically, five minutes are spent performing or supervising these services during the visit	\$20	\$37	-45%
Urine pregnancy, gonadotropin chorionic (hCG) (BetahCG), qualitative	\$10	\$35	-71%
Blood count: complete (CBC), automated (Hgb, Hct, RBC, WBC, and platelet count), and automated differential WBC count	\$13	\$51	-75%
Electrocardiogram, routine ECG (EKG) with at least 12 leads, 12-lead ECG: Includes tracing, interpretation, and report	\$50	\$119	-58%
Physician Per Visit (Complex: e.g., initial visit, final visit)	\$128	\$175	-27%
Study Coordinator Per Visit (Complex: e.g., initial visit, final visit)	\$64	\$125	-49%

Source: GrantPlan® Database.

**Table 2.** Procedure and professional fees are also less expensive in China compared to the United States, where a study coordinator can cost almost 50% more per visit.

its fees for this service. Health Authority & Ethics committee fees are also predetermined.

**Overhead.** Overhead in India runs between 10% and 20%, which is applied for both procedures and professional fees. Some have questioned whether the overheads varied between public and private hospitals. Based on our analysis and survey results, the cost difference is not significant enough to warrant a comparison.

Once sponsors create a budget they believe represents market conditions, they submit it to the site for approval. At this point, a site may choose to negotiate certain aspects of the budget to reflect its own requirements.

### Investigator grant negotiation

Negotiating contracts in India always takes place directly with the principal investigator. Contracts are usually in English and the negotiating currency is in dollars; at times, the currency may be in euros or pounds.

## Investigator grant budgeting in China follows key practices that create a cost-friendly environment for clinical trials.

A smaller amount is paid at the initial visit to encourage investigators to retain patients. Typically, payments are made on a per visit schedule (i.e., cost per visit times total number of patients). Monthly site payments are used to provide wages and salaries for support staff.

When we consider all of the aforementioned costs, the total investigator grant on average ranges from 30% to 40% of the cost in the United States. The information in Table 1 is provided from the GrantPlan® Database,<sup>4</sup> which is the largest

database of current international clinical grant costs in the world. Most major pharmaceutical companies contribute data to, and access, GrantPlan® for clinical grant data.

### Clinical research in China

As with India, China represents a vast new marketplace for the clinical research community. The country offers:

- The largest urban, treatment-naïve patient population in the world
- More than 18,000 hospitals
- More than 1.5 million physicians, almost 2 million physician's assistants, and more than 1.6 million well-trained registered nurses and technicians, all working at significantly lower salaries.<sup>5</sup>

Some key clinical trials underway in China are primarily for lung cancer and infectious diseases. Beijing, Shanghai, and Guangzhou are three of the major clinical research cities. The Beijing Tong Ren Hospital and Peking Union Medical College Hospital are two examples.

In 2000, there were 26 unique 1572s filed; this number increased to 76 in 2004 (0.2% of the global 1572 filings). Experts predict that by 2010 China will become the fifth largest pharmaceutical market and the world's third largest market by 2020.<sup>6</sup> Simply put, China is the next frontier for pharmaceutical clinical trials and offers both opportunities and challenges for the pharmaceutical industry.

### Investigator grant budgeting

Similar to India, investigator grant budgeting in China follows key practices that create a cost-friendly environment for clinical trials. For example:

- Only public hospitals are allowed to participate in clinical research.
- Most contracts are solely between the investigator and the hospital.

- Budgets are built according to a local office's experience or sometimes according to headquarters' "gut feelings."
- Most budgets are built on a cost-per-visit basis, although the costs for some expensive procedures, such as biopsies, are disclosed to the investigator as individual line items.

**Procedures.** On average, procedure costs in China are 39% of the cost in the United States (examples can be seen in Table 2). Procedure fees are hospital specific and almost all public hospitals provide the procedure costs to the public either in the hospital or online. However, these publicly available prices do not represent clinical costs and can only be used as one of the sources of information to begin budgeting.

**Professional fees.** Physician fees are usually budgeted per visit. The principal investigator decides if additional staff should be hired and whether study coordinator fees are paid on a per visit basis or on a monthly salary. Subject reimbursement is provided for patients who travel from a long distance

## China and India represent what some have called "the industry's single biggest opportunity for growth."

and for invasive procedures. Pharmacy fees are often included in the contract with the hospital and include specific milestones. Infused medications are usually double or triple the cost for an oral or topical medication. On average, professional fees are 50% of the costs in the United States. Table 2 displays some specific examples.

**Hospital fees.** Administration fees are typical in hospital contracts. Hospital bed fees are used for surgical procedures. A "leading fee," in the form of a certain percentage, is applied for hospitals that are overseeing the study. Site costs are commonly included in the hospital contract.

**Overhead.** The investigator contract and the hospital contract may have two different overhead percentages. Overhead is applied to both the procedures and the professional fees (including both subject reimbursement and pharmacy fees) and can be presented as both overhead and administrative fees on budgets. Most contracts have an overhead of 10%.

### Investigator grant negotiation

In China, budgets are almost always negotiated directly with the principal investigator and signed by the principal investigator and the hospital official, and sealed or stamped by the hospital. Study managers or CROs negotiate the contracts locally; the common negotiating currency is the yuan, although occasionally contracts are in dollars or euros.

Communication is key in successful negotiation in China. Compared to India, English is not as widely spoken in China;

therefore, consistency and transparency are essential in presenting and negotiating the budgets.

### Conclusion

Clearly, China and India are burgeoning regions for the pharmaceutical industry and represent what some have called "the industry's single biggest opportunity for growth." But realizing the promise both countries hold will take a full understanding of their clinical market community and their approach to budgeting and negotiating clinical trial contracts.

The rapid growth of clinical trials in both of these emerging economies and the array of local standards that can affect the bottom line will make it increasingly difficult for companies to operate in these countries without expertise in negotiation and budgeting. These particular negotiations are specific to the phase and complexity of the study as well as the site's experience and ability to execute the trial.

The clinical research community will also need to understand fully the areas of patient recruitment, trial monitoring, data collection and management, and statistical analysis of data generated from clinical trials in both countries. And even with a full understanding of these factors, pharmaceutical companies will need to rely on an industry aggregate of prices that enables them to realize the savings and efficiency inherent in clinical trials in China and India.

All the prerequisites for success in China and India are available today, but the industry must prepare itself with thorough research and understand the nuances of health care in both countries before conducting clinical trials in these relatively new geographies.

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**Jena Jankosky**, \*MBA, is client manager at TTC, llc, 4548 Market Street, Suite M-20, Philadelphia, PA 19139, email: [jjankosky@ttc-llc.com](mailto:jjankosky@ttc-llc.com). **Ying Jiang and Ted Farwell** are also client managers at TTC, llc.

\*To whom all correspondence should be addressed.