

The Clinical Trials Market Opportunity: Action Steps

I. Summary

Demand for clinical trials has exploded over the past decade, with the need for patients and clinical investigators growing at 15 to 20% a year, and spending expected to increase at 10 to 15%. With R&D per drug exceeding \$500 million and lasting seven years, pharmaceutical companies experience huge pressure to complete trials quickly and safely.¹ Each day of delay in trials costs an estimated \$1 million in lost revenues.²

Puerto Rico brings competitive advantages to enable major pharmaceutical companies to conduct trials for new drugs quickly and cost effectively. Companies like Merck and American Home Products could build on extensive existing operations in Puerto Rico, which produce over \$20 billion in new drugs annually including eight of the ten highest grossing drugs in the U.S.

Puerto Rico offers rapid patient recruitment and low operating costs, with the protections and regulatory standards of the United States. Unlike in any foreign country, U.S. pharmaceutical firms are now eligible for the federal research and development tax credit for R&D conducted in Puerto Rico.

A public / private partnership guided by local business leaders in Puerto Rico and the Puerto Rico Industrial Development Corporation (PRIDCO) would most effectively market the clinical trial opportunity to U.S. pharmaceutical companies.

II. The Market Opportunity

Pharmaceutical companies invest \$7.75 billion annual on clinical trials, a third of all R&D spending.³ Clinical trial spending is expected to increase at 10% for the foreseeable future. Pharmaceutical companies face huge pressure to bulk up their pipeline of new drugs to meet sales forecasts through 2005.

Costs of conducting trials have escalated rapidly, driven by increasing procedural complexity, regulation and difficulty of patient recruitment. Since the early 1990's, trial costs have increased at 10%

¹ Boston Consulting Group, The Contribution of Pharmaceutical Companies: What's at Stake for America, September 1993; DiMasi, J.A., "New Drug Development: Cost, Risk, and Complexity," Drug Information Journal, May 1995.

² CenterWatch, 2001.

³ Pharmaceutical Research and Manufacturers Association, *Pharmaceutical Industry Profile*, 1999, Figure 2-5.

annually.⁴ The overall costs of drug development have also increased to an estimated \$500 million per drug.

Given huge upfront costs and long development time, pharmaceutical firms face intense pressure to reduce the time drugs are in development. Most drugs require between eight and twelve years of development before the company can hope to gain a return on its investment. CenterWatch estimates that each day of delay in clinical trials costs the drug company \$1.3 million, including both the additional trial costs and lost selling time.⁵

Failure to recruit patients on time costs the industry up to \$500 million annually. 75% of trials are not completed on time due to patient recruitment difficulties.⁶ Most Phase II and Phase III trials still take four times longer to complete than the patients' actual participation in the trial.⁷ As Dr. Spilker of the Pharmaceutical Research and Manufacturers of America observed, recruitment "is the No. 1 reason why trials fail, and it's the No. 1 area where increased efficiency is possible."⁸

III. Why Puerto Rico?

Given the increasing demand for clinical trials, Puerto Rico represents a relatively untapped market opportunity. As competitive advantages, Puerto Rico offers pharmaceutical companies already on the island rapid patient recruitment, competitive operating costs, well-trained clinical personnel, and an extensive health infrastructure.

Due to decades of manufacturing focus by pharmaceutical firms and federal tax exemptions that discouraged any R&D by mainland firms, few clinical trials are now conducted in Puerto Rico. With a public / private collaboration, a quick and effective marketing effort could promote and sell the opportunity to the big pharmaceutical companies, which already have extensive experience and existing manufacturing operations on the island.

- **Rapid patient recruitment**

A combination of factors makes Puerto Rico an attractive location for rapid patient recruitment and management: a large, heavily concentrated patient population; strong resident interest, reflected in rapid historical patient enrollment; and significant patient populations in key disease areas (diabetes, cancer, HIV, etc.). Puerto Rico also offers pharmaceutical firms

⁴ Harold E. Glass, "Clinical Grant Costs - A Case for Management," Scrip Magazine, April 1995.

⁵ CenterWatch, 2001. www.centerwatch.com.

⁶ John Hosken, "Re-engineering the clinical trial recruitment process," e-Health Europe 2001, Maastricht, the Netherlands.

⁷ Dorland's Biomedical.

⁸ *Hartford Courant* interview, December 20, 2000.

quick access to a concentrated population of Hispanics, the fastest growing ethnic group in the U.S. Developing the clinical trial market in Puerto Rico would both help companies to speed time to market and cut costs, and expose the U.S. citizens of Puerto Rico to new, cutting edge medical treatments.

Large concentrated population. Clinical research centers in Puerto Rico can draw on a sizeable resident population of almost 4 million U.S. citizens, all concentrated in a thousand square mile area. This proximity makes patient recruitment and follow-up far easier and less costly than in locations with more dispersed populations. Because of lower per capita incomes, reaching potential patients through advertising is less costly.

Patient interest. Because few clinical trials have historically been conducted in Puerto Rico, there is strong pent-up demand among residents for up-to-date health care treatments. This strong interest is reflected in a record of rapid patient recruitment for trials at the University of Puerto Rico hospitals and elsewhere. While many clinical centers face a diminishing untreated patient population on the mainland, Puerto Rico offers a source of untreated patients eager for better treatment. Because of lower wages and salaries, the cost of paying any patients is significantly lower than on the mainland.

- **Educated, experienced personnel**

Puerto Rico also offers a large and well-educated workforce of clinicians. With 10,000 physicians, Puerto Rico has more physicians per resident than the U.S. as a whole - 26.2 per 10,000 compared to 24.1 in the U.S. The total medical labor force is estimated at 31,300 and growing rapidly.⁹ Over 150 researchers now receive federal funds to conduct clinical research on the island.¹⁰

- **Lower labor costs**

Within a U.S. regulatory environment, Puerto Rico offers medical labor costs at about half the mainland U.S. rate. Given that labor costs contribute 40% of the typical clinical research budget, lower costs in Puerto Rico would alone reduce the overall clinical budget by 16%.

Hospital wages. Hourly wages at Puerto Rico hospitals are estimated at \$9.32, less than half the cost in the average U.S. hospital, \$18.80.¹¹ In

⁹ Alfaro and Riz-Calderon, "Rediscovering the customer," Caribbean Business, May 13, 1999.

¹⁰ Community of Science database on federally funded research, May 1999.

¹¹ HCFA Case-Mix Index File, Proposed for FY 2000. Of hospitals receiving Medicare funds. Medicare records The file indicates that the types of operations performed by Puerto Rico hospitals is not significantly different from those performed by Medicare-funded hospitals nationwide.

fact, compared to high cost states like Massachusetts (\$21.98 per hour) and New York (\$23.23 per hour) where many trials are conducted, wage costs in Puerto Rico are about 60% lower. Even the most expensive research hospital on the island, the University of Puerto Rico Hospital at Rio Piedras, has wage costs of \$16 per hour, comparable to Mississippi, and a fraction of wage costs at major mainland research hospitals.

Hospital wage index. The wage index estimated for every hospital in the Medicare system confirms the cost savings of doing business in Puerto Rico. The average wage index for all Puerto Rico hospitals, 0.4573, is less than half of the average for all U.S. hospitals, 0.9280. Please see table below.

Table: Hospital Wage Costs in Puerto Rico and the United States

State / Territory	Wage Index	Average Hourly Wage
Puerto Rico	.4573	\$9.32
Mississippi	.7544	\$15.18
New York	1.152	\$23.23
Massachusetts	1.131	\$21.98
U.S. Hospital Average	.9280	\$18.80

Note. Wage index and hourly wage for average hospital by state. Health Care Finance Administration databases, May 1999.