Five times the cost, twice the time, double the complexity. These are the dynamics of the Clinical Trials industry – a segment within the CRO sector. Shifting trends, new international growth and a fragmented industry create new opportunities...

ALLEXIAN
GLOBAL HEALTH CARE ADVISORS

Clinical Trials -- Big Opportunity?

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Industry Overview

The development cost of a single drug has risen to $1.3 billion, a five-fold increase from 1991. Total procedures per clinical trial, an indicator of drug and trial complexity, have increased over twofold since 1999 and the length of a trial has almost doubled in time. An average trial today lasts about 800 days.

"$8 billion industry projected to grow annually at 9%"

Clinical drug development is not only expensive; it is also a highly complex process lasting 10-15 years. Clinical trials in humans begin 3-6 years after drug discovery and can take 6-7 years before the FDA grants approval for general drug distribution.

Pharmas' research and development expenditure globally is just under $120 billion. The drug development component is a little less than 45% of this, approximately $52 billion. The outsourced drug development expenditure is approximately $18 billion.

"Today, the critical needs of the Pharmas--quality, timeliness and compliance--are generally not well met by the Clinical Trial industry."

Clinical Trials, as distinct from CROs, include the recruitment of patients, trial implementation and trial reporting. It is a fragmented $8 billion industry projected to grow annually at 9% trial sites in the US today including physicians' offices, hospitals, academic medical centers and dedicated research sites. The Clinical Trial industry remains highly fragmented with no one company having more than a 1% share. A well run Clinical Trial company can have EBITDA margins in excess of 25%.

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Pharma Needs

Today, the critical needs of the Pharmas--quality, timeliness and compliance--are generally not well met by the Clinical Trial industry.

As a result, US Pharmas are moving clinical trials overseas to contain costs and improve patient recruitment. However, overseas trials create major operating problems for Pharmas: quality of trial, local regulatory and cultural risks overshadow many of the benefits of lower costs.

A US based Clinical Trial company can take advantage of these global trends by establishing a global, multi-site, market leading growth business, significantly improving on current industry practice, increased patient recruitment, timely trial completion and ultimately lowering costs.

According to the *Contract Pharmas Outsourcing Survey*, the critical needs of both Pharmas and CROs are as follows: Trial completion in a timely manner, patient enrollment, protocol quality and adherence, therapeutic and management practices, reliable Principal Investigators, cost-control and geographically dispersed sites.

Critical to Quality

Revenue per trial ranges from $500 per patient to $10,000 per patient. Total revenue per trial varies based upon the number of trial participants ranging from 3-4 patients up to 40-50 patients, and number of patient visits (trial duration) ranging from 1 visit to 25+ visits over multiple years. Another factor that influences the revenue value of each trial is the trial complexity.

To favorably compete, clinical trial sites need to win more studies through international coverage, enroll more patients and provide a timely study.

In general, Pharmas are not very well served by the Clinical Trial industry. The factors most often causing trial delay are: Contract and budget negotiation, patient recruitment, protocol design and implementation, legal and IRB review.

International Growth Shift

In the last few years the Clinical Trial industry has shifted towards Asia — to lower costs — from the US. The US is expected to retain 40% of trials globally after 2012.

India has the highest growth in trials. Japan is showing promise and in the long term China is a viable location. There has also been an increase in trial in Africa, Eastern Europe and parts of South America. Quality control, language or regulatory barriers hamper each country's short-term growth potential.

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"While trial outsourcing clearly reduces costs and improves quality, only 7% of trials currently reach patient enrollment on schedule"

Allexian delivers operational improvement and strategy focused on bottom line and value creation.

As former CEOs we assist health care companies with planning and execution.

We are experienced in performance improvement, strategy, M&A due diligence, interim management and technology planning and organizational change.

The US has historically provided most of the trial testing services globally. There is a growing shift toward trials in Asia and Europe and away from the US. The US allocation is decreasing from 60% in 2006 to 40% in 2012.

India is demonstrating rapid growth; Population of just over one billion, fluent in English and a 'treatment naïve' patient population. India has undergone regulatory and structural changes that have made India eligible to be a global player. In addition, India offers a 50% cost advantage over the US.

Japan is demonstrating promise but slower growth; Largest market for drugs after the US. Japan's ability to run simultaneous drug trials is slowed by their language barrier, lack of infrastructure to deliver on-time data and lack of motivation for physicians to participate

China is demonstrating growth but has structural barriers; Enormous market and 'treatment naïve' patient population. China has a need for accreditation of clinical test sites, needs to meet ethical requirements and must improve on quality and availability of experienced and trained staff.

While trial outsourcing clearly reduces costs and improves quality, only 7% of trials currently reach patient enrollment on schedule.

According to *Tufts Center for the Study of Drug Development*, trials miss the planned FDA submission date by 93 days.

Conclusion

In order to favorably compete, grow and maintain strong margins, Clinical Trail companies need to expand internationally, taking advantage of easier patient recruitment and lower costs to deliver the trial, thereby delivering trial studies on a timely basis.

Allexian has developed an in-depth analysis and investment thesis of the Clinical Trial industry.

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