Asian Century and clinical trials:

Issues for consideration by biotechnology companies

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As with many other industries, there is a prevailing belief that the 21st Century will be the Asian Century when it comes to drug development and the pharmaceutical industry. Already, markets such as China are predicted to overtake the US to become the largest pharmaceutical market in the world during the first half of this century. Together with already large pharmaceutical markets such as Japan, it is not difficult to see why Asia represents a block of great interest to global pharmaceutical giants. But what of the biotechnology industry? Should it participate more actively as Asia develops? Can it afford not to? This article addresses issues to consider for biotechnology companies contemplating an Asia strategy as part of planning product development.

Cost of drug development

It is well known that the world of drug development has been in a state of globalisation for some time. This is particularly true when it comes to clinical development where the traditional regions of North America and Western Europe are no longer the automatic default where large clinical trials are conducted. As Figure 1 indicates, more than 40% of clinical trials in Investigational New Drug submissions to the US Food and Drug Administration are now initiated outside the US. Among other reasons, this is partly related to the cost savings available in emerging markets such as Latin America, Asia and Eastern Europe. As the largest emerging market, Asia as a block stands to benefit greatly from the ever-increasing momentum in globalisation of clinical trials. The cost savings are particularly important for biotechnology companies, which typically have no revenues or earnings of their own. As any biotechnology executive will attest, the ever-present challenges of managing cash burn and raising fresh capital are as vital to their companies' future as the science that is being developed.

Access to patients

In the last two decades the total universe of clinical trials has not only greatly increased in number (see Figure 2), but become far more complex.]These twin factors of increasing volume and greater complexity are at least as important as cost considerations when assessing the Asian Century in the context of clinical trials. Far more people, and far more patients, live in Asia than any other continent. Combined with a relatively low base of clinical trials historically in the region, it is not difficult to see why Asia is of such importance to the pharmaceutical industry. Led predominantly by US-based biotechnology companies, the region is now also increasingly popular for biotechnology sponsored phase II and III clinical trials. This trend is likely to gather momentum, with the key being greater access to patients. In many therapeutic areas, the patient demographic and disease prevalence is

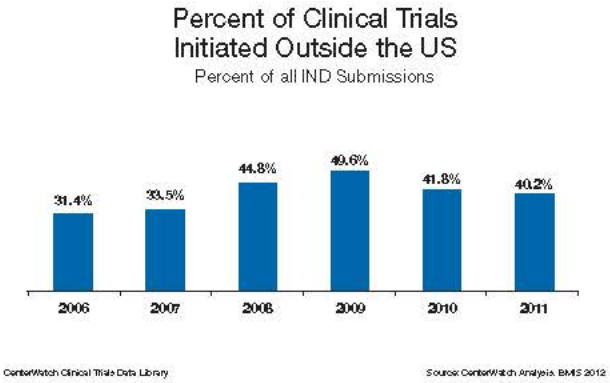

Figure 1 – Clinical Trial Initiations

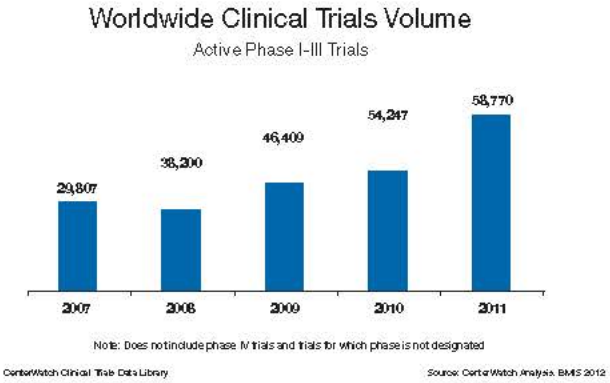

Figure 2 – Increasing numbers of clinical trials

comparable across the world, and this weighs heavily on the decision where to conduct larger pivotal studies. The factors influencing such decisions are largely the same for both pharmaceutical and biotechnology companies.

Regulatory considerations

With the widespread adoption of the international Good Clinical Practice guidelines around the world, regulatory hurdles around data acceptability for clinical trials conducted in far-off lands have been steadily coming down. Indeed a recent report by the European Medicines Agency indicated that more than a quarter of all patients enrolled in pivotal trials that were submitted to the Agency during the period 2005-2011 came from the rest of the world (ROW), represented predominantly by Asia and Latin America. Of greater interest is that this trend is increasing. So, whilst only 20% of all patients came from ROW in 2005, this number had risen to 37% in 2011. (Ref. Clinical Trials Submitted in Marketing Authorisation Applications to the European Medicines Agency – April 2013).

Commercialisation

When it comes to predicting the shape of the pharmaceutical industry in the 21st Century, the importance of the rise of Asian economies, led by China in particular, cannot be overstated. For the biotechnology industry this is particularly relevant. As the century rolls on, a number of pharmaceutical markets in Asia will gain increasing prominence when it comes to valuing biotechnology assets in development – be it in out-licencing transactions, or raising public or private capital to 'go it alone'. Currently, most Asian countries require local clinical trials as a condition of registration. Whereas in the 20th Century this did not weigh heavily on the location decision for conducting pivotal trials, today many drug developers seek to 'kill two birds with one stone' when it comes to making such decisions. Until such time that key Asian countries drop the requirement for local clinical trials as a condition of registration, this trend is likely to increase.

Execution

Global pharmaceutical giants have been present in one fashion or another in Asia for two decades or more. For a lesser period of time, so too have global contract research organisations (CROs). But what of biotechnology companies who are heavily dependent on CROs for execution of their clinical development programs, and who typically opt for smaller to midsize CROs for this work? This is an area where the region is currently lagging behind. Whilst there are a small number of regional CROs servicing the biotechnology industry in Asia, the number is not very large. Free markets being what they are however, the vacuum is likely to be filled the more the region develops.

In conclusion, the Asian Century promises exciting developments for biotechnology companies looking to accelerate their drug development programs and to 'go it alone' further down the pathway of development as they add value to their assets. As with any other region, the Asian frontier is certainly not without its pitfalls, and it's certainly not homogeneous. That said, the issues discussed here for consideration by biotechnology companies represent a compelling case to include the region in drug development planning.

