

Asia becoming important Phase I player

17/07/2007 - Phase I development in Asia is becoming very important, delegates heard at the recent Drug Information Association (DIA) meeting in Atlanta.

Asia has been witnessing a rise in clinical trial activity in the late phases as companies are drawn to the region's large treatment-naïve patient populations in order to achieve faster and cheaper drug development.

Phase I research in Asia, however, has been fairly limited and mainly consists of bridging studies providing local pharmacokinetics (PK), pharmacodynamics (PD), efficacy and safety data that most Asian countries, such as [China](#), South Korea, [Japan](#) and India, require in order to have any foreign-developed drugs approved there. Dose requirements for these populations are often much lower than those for Caucasian populations, for example.

Slowly though, a trend is emerging towards sponsors conducting trials that are global "*right from the start*," with more and more Asian sites starting to be involved in early-phase studies simultaneously with western sites, said Shirley Suresh, Singapore Clinical Research operations manager at Société Générale de Surveillance (SGS) Life Science Services.

"I think it is very important to involve Asian countries in the early phase of drug development and more sponsors should be discussing this approach with regulators."

She quoted a statistician from the Food and Drug Administration (FDA) as saying: "*data from global studies is more efficient than bridging studies because everything is considered [for the specific populations involved] right from the beginning.*"

Doing so could also open up faster access for drug companies to the huge Asian markets and help close the "drug-lag" in these regions.

Singapore has been attracting a lot of international interest in the early-phase area of late as it takes a viewpoint that is "*quite different*" from its Asian neighbours, in that it actively promotes first-in-man studies, said Suresh.

"This is because the country has only a very small population [4m] and is not suitable for larger phase studies."

The country's Biomedical Sciences initiative has been key in encouraging and enabling international companies to set up dedicated [Phase I](#) centres in Singapore to conduct their Asian drug development programmes, she added.

A further advantage for Singapore is also the fact that it has a large mixture of populations from neighbouring Asian countries and so some of the data that is required for the regulatory submissions in these neighbouring countries can also be generated in Singapore. South Korea, in particular, accepts PK data from studies conducted on South Koreans who are living outside the country, as does Japan in some cases.

It also has no barrier to the import and export of biological samples as some other Asian countries do.

Meanwhile, other Asian countries are also attracting foreign early-phase focus, not least of all, China, with its huge patient population and market potential.

Any new drug that is not already approved in another county requires Phase I-III studies on Chinese populations before it can be approved in China. If the drug is already approved

elsewhere only PK and Phase III studies are needed.

There are problems with operating in China. Only hospitals that are approved by the country's State Food and Drug Administration (SFDA) at specific site with specific specialisations can be used in the trials; in addition, the export of whole blood/DNA is restricted or prohibited and every drug import has to be inspected and undertake a quality control check, which takes 15-30 days.

As a result of all these requirements, firms are starting to set up China-specific drug development programmes, which function as an effectively self-contained unit, doing everything from trials to lab testing and pilot manufacturing from within the country.

Japan, the world's number two drug market, is another country gaining prominence in early-phase research. Despite its market size, it suffers from an incredible drug-lag - taking an average of 3.5 years longer for a drug to reach the market than in the US and Europe.

Some of this has to do with the fact that it is very sensitive to having have PK/PD study data (generated from at least single-dose safety and pharmacokinetics study) on its own population first before any other studies in the country can begin.

Regulatory hurdles, another major cause of the drug lag, are now starting to be lowered by the Japanese regulators and it is expected that in the next year or two sponsors will begin more regularly involving Japan in global studies from the start.

India, too is an important location in the region and also requires data in its own populations before marketing approval can be granted, although as yet, its rules state that for new drugs discovered in other countries, Phase I data generated outside India is required before any clinical trials in India can begin, then Phase I and/or II trials need to be conducted in local populations, after which Phase III studies may then be conducted concurrently with other global studies.

So at this stage, the country is not amenable yet to being involved in global studies from the beginning, although regulatory changes that will relax its rules for research on foreign molecules are expected within the next two years, at which point, the country may become an important player. The fact that the import and export of study-related materials is not generally a problem, like it is in China, is also an advantage.

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