Facts about clinical trials

The Supreme Court has put a spotlight on clinical trials by asking the government for details on deaths linked to them. A clinical trial involves the testing of a medicine for its safety and efficacy on a sample group of volunteers and patients before the medicine is commercially launched in a market. The apex court's directive will help streamline and strengthen the existing law and bring greater transparency to the way clinical trials are conducted in the country.

WHY INDIA

Besides the obvious reason of being roughly 40 per cent less expensive than Western countries as a destination to conduct clinical trials, India holds out two other major attractions for drug majors.

The local population comprises several gene types (Caucasoid, Mongoloid and Australoid), unlike other countries that have homogenous populations. Also, people in India are reported to be "treatment naive", that is, less exposed to medicines.

Even though the Indian clinical trial industry was projected to touch revenues of $1.5 billion by 2010, it is at present barely over $400 million. And while this could partly be attributed to the global economic slowdown, it has also been impacted by the adverse publicity every time a trial goes awry.

INFORMED CONSENT

Clinical trials in the country are covered by the Drugs and Cosmetics Act, and a drug company wanting to recruit volunteers or patients to participate in a trial is mandated to, among other things, get their "informed consent".

The situation gets complicated when people are not literate or do not understand the language in the form. To address this, forms are prepared in different languages and participants are asked to explain back to the recruiters what they have understood.

But the situation is still far from satisfactory, as a trial involving the testing of cervical cancer vaccines on tribal girls in Andhra Pradesh and Gujarat indicated. Though a government investigation gave the trial an all clear, it did not explain who gave the consent on behalf of the girls.

Why clinical trials are needed

- To check if a new drug or device is safe and effective.
- To compare existing treatments and determine which is better.
- To study different ways to use already existing treatments to make them more effective and easier to use, and/or to decrease side effects.
- To learn how best to use a treatment in a different population, such as patients in whom the treatment was not tested previously.

Phases of clinical trials

Phase 0

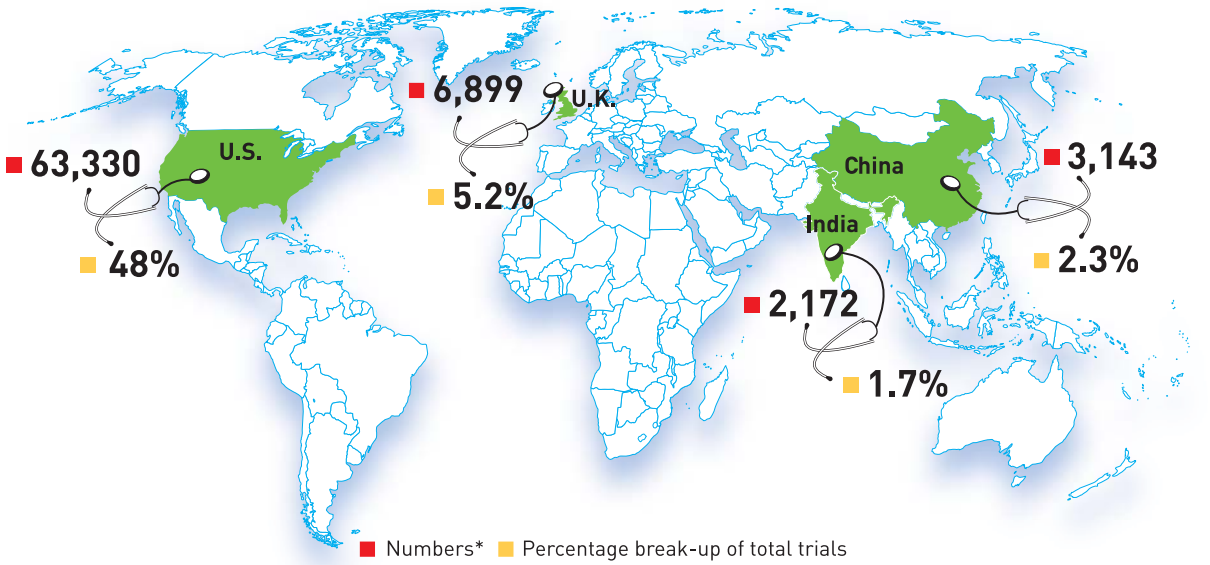
Exploratory study involving very limited human exposure to the drug, with no therapeutic or diagnostic goals (for example, screening studies, microdose studies).

Phase 1

Studies that are usually conducted with healthy volunteers and that emphasise safety. The goal is to find out what the drug's most frequent and serious adverse events are and, often, how the drug is metabolised and excreted.

Compiled by P.T. Jyothi Datta; Infographics: V. Srinivasan

Clinical studies—a comparison



*Cumulative number of trials since the inception of the Clinical Trials Registry as on October 4, 2012

Total trials across 178 countries: 1,31,167

POSSIBLE BENEFITS

Clinical trials are allowed in a country so that medicines can be tailored to the diseases of the local population. They also expose researchers in the country to global scientific practices. And patients, for instance those with advanced cancers for whom no other medicine may work, could opt to participate in the trial of a new medicine that is close to being launched in the market.

So while trials can bring benefits to the local population, the government will have to ensure that volunteers and patients are protected, and compensated in the event of an adverse outcome.

- **Of 10,000 substances identified as potential drugs, only about 10 make it to the human testing stage, and out of these, only one may finally be launched in the market.**
- **India has 17 per cent of the world's population and 20 per cent of the global disease burden. However, less than 2 per cent of the global clinical trials are conducted in India.**
- **Not only are lifestyle diseases growing in India but it also has diseases that are unique to this part of the world, such as filariasis, leishmaniasis and rabies. It is, therefore, important to do research on Indian populations to find cures for many of these diseases.**
- **China has overtaken India in terms of share of new trials, which rose from a 1:1 China-to-India ratio in 2008 to a 2:1 ratio in 2011.**
- **The clinical research market in India earned revenues of $485 million in 2010-11 and is estimated to cross $1 billion in 2016.**

Phase 2

Studies that gather preliminary data on effectiveness (whether the drug works in people who have a certain disease or condition). For example, participants receiving the drug may be compared with similar participants receiving a different treatment, usually an inactive substance (called a placebo) or a different drug. Safety continues to be evaluated, and short-term adverse events are studied.

Phase 3

Studies that gather more information about safety and effectiveness by studying different populations and different dosages and by using the drug in combination with other drugs.

Phase 4

Studies occurring after the drug regulator has approved a drug for marketing. These include post-market requirement and commitment studies that are required of or agreed to by the sponsor. These studies gather additional information about a drug's safety, efficacy, or optimal use.

Sources: Indian Society for Clinical Research; U.S. Food and Drug Administration; ClinicalTrials.gov; U.S. National Institutes of Health; Boston Consulting Group; Frost & Sullivan.