

# Clinical trials zoom in India

Rema Nagarajan  
TIMES INSIGHT GROUP

५२०

## TRIALS REGISTERED

If India is becoming a favourite destination for clinical trials, Maharashtra is the hub with Mumbai and Pune accounting for the largest number of clinical trials in the country. Maharashtra alone accounted for well over a quarter of all the clinical trials registered with the clinical trials registry of India till 2010. A study of the trials recorded in the registry, done by the Centre for Studies in Ethics and Rights, Mumbai, and published in the Indian Journal of Medical Ethics, reveals that the number of trials has been growing at an astounding 36% annually, from 2006-07 to 2010-11.

Even this may be an underestimation. This is despite the fact that the clinical registry could be an underrepresentation of the trials happening in the country as registration was made mandatory only in June 2009. Also, it is not mandatory to register trials that look into the rate at which or the degree to which a drug is absorbed by the body or becomes available at the site in the body where it is needed, explained Deepica Ravindran from the Centre for Studies in Ethics. She added that the study had shown that the increase

Disease conditions	No. of trials till Jun 2010	% of trials registered
Neoplasms (cancers)	144	13
Infectious diseases	129	12
Endocrine, metabolic diseases	123	11
Diseases of circulatory system	112	10
Diseases of nervous system	68	6

Drug trial setting by state	No. of trial settings till Jun '10	% of total trial setting
Maharashtra	1,116	26
Karnataka	617	14
Andhra Pradesh	444	10
Gujarat	417	10
Tamil Nadu	389	9
India	4,293	-

in clinical trials had no correlation to the disease scenario in the country.

The largest proportion of the drug trials is for cancer drugs, at 13.4% of all trials. Cancer is not among the top ten killers in India. But it is definitely among the top ten in developed countries. Trials on peri-

natal conditions, a major cause for deaths in India, constitute just 2.9%. Similarly, though tuberculosis is a major reason for morbidity and mortality in the developing countries, only 0.6% of the clinical trials or seven in number are TB related, said Ravindran presenting the results of the study at the National Bioethics Conference in Delhi. Only 16 out of 1,078 clinical trials were on lower respiratory tract infections though they are among the biggest killers both in India and other developing countries.

The bulk of the small proportion of trials on infectious diseases and on perinatal conditions is funded by institutions and mostly by Indian sponsors, notes the study. The study also reveals that most trials by foreign sponsors and pharmaceutical companies are for cancer and circulatory system related illnesses. Most of the trials take place in cities and states with good infrastructure to conduct such research, like Mumbai, Pune, Bangalore and Hyderabad, which are also the seat of most of the contract research organizations. They have a ready network of doctors and institutions, which feed them the patients required for the various trials, explains Girish Ingle, one of the researchers who conducted the study.

Clinical trials.