

## Press Release Details

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#### **National Institute of Science Technology and Development Studies in New Delhi**

Even if such a system becomes established-which is doubtful-India must still address issues of quality and regulations, analysts say. The heavy expense of gaining regulatory approval in biogenerics and the spending needed to reassure doctors about product safety remain barriers. "Not many Indian companies have the resources to cross these hurdles," says Prasantha Ghosh, head of biotech at Cadila Pharmaceuticals in Ahmedabad.

While the generics producers are testing the waters in regulated markets, India must still create monitoring mechanisms and develop adequate clinical practice standards to attract outsourced clinical trials. Government reluctance to grant exclusivity of clinical trial data may also scare away companies, analysts say. And even if implemented successfully, the \$2.5-billion-per-year business model-ironically built on high disease prevalence and a billion-plus, genetically diverse and economically weak population-has its critics.

By putting emphasis on services instead of innovation to become competitive, DBT's biotechnology development strategy is likely to spawn "clones of companies doing contract research, clinical trials and validation studies for multinationals [MNCs]," says Srinivasan Visalakshi, an industry analyst at the National Institute of Science and Technology Studies in New Delhi. She foresees an army of biotech "coolies" laboring alongside the ones doing computer programming for their masters in California's Silicon Valley. Instead, suggests Samir Brahmachari, director of the Institute of Genomics and Integrative Biology in New Delhi, India could create a substantial fund for buying intellectual property rights from small and medium enterprises around the world and turn them into higher value products in collaboration with MNCs.

Visalakshi's study of 229 Indian biotech companies concludes that 20 years after setting up DBT, India still has no clear definition of biotech. "Everything from fermentation to aquaculture and sericulture to bio-fertilizer is clubbed under biotech, resulting in subcritical funding," she told Nature Biotechnology. Visalakshi also finds the preproduction stage to be the weakest link in the commercialization of biotech in India as venture capitalists "shy away from risk, and lack understanding or capability to assess biotech projects." The conclusion of a recent study "Dynamics of Biotechnology Research and Industry in India" by the Organization for Economic Cooperation and Development in Paris is similar. India needs "to set priorities in the R&D; work program," it says, and should "urgently address problems arising out of a large number of agencies dealing with biotech, which has led to duplication of research funding and a lack of coordination."