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REGULATORY FAILURES

The dark underbelly of India's booming clinical trials business

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NEW DELHI

In 2004, doctors at the Bhopal Memorial Hospital and Research Centre (BMHRC), established exclusively for treating the victims of the 1984 gas leak, recruited unsuspecting survivors for clinical trials without their knowledge or consent; 14 participants died during the course of the trials.

Together with the episode in Indore's Maharaja Yashwantrao Hospital (that *Mint* reported on 10 October), where 32 people have died in clinical trials between 2005 and 2010, this incident highlights irregularities and ethical violations in some trials conducted by clinical research firms and pharma companies—the dark underbelly of the booming clinical trial business in India.

In 2005, India introduced patent protection laws. Since then, it has become a global hub for clinical trials, drawing companies because of its ethnically diverse pool of potential test subjects, while bringing down research and development (R&D) costs by nearly 60% in phase II and III trials, according to lobby group Confederation of Indian Industry.

Sayeed Farooqui/Mint

Seeking relief: *Protesters outside the Bhopal Memorial Hospital and Research Centre.*

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A phase II trial establishes the protocol for testing and a phase III one is the final testing prior to approval.

Regulatory failures have marred the clinical trial business in India, experts said, pointing to lapses in the functioning of so-called ethical committees that are required by law for each trial, contract research organizations (CROs) and the Central Drug Standard Control Organization (CDSCO).

A parliamentary panel in May found CDSCO to be in collusion with drug companies and doctors, and approving at least one drug every month without conducting clinical trials or seeking expert medical opinion. Concerns over the conduct of clinical trials prompted the same panel to look into the rapidly growing industry, and the international and domestic pharmaceutical companies sponsoring them.

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Clinical Trials.