

577 clinical trial sites inspected in India

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Singapore: The Indian Health Ministry has said that the regulatory authorities in the country have so far inspected 577 clinical trial sites in the last few years and notices have been issued in 235 cases.

The country's clinical trial sector has now come under the judiciary's scanner following which regulatory authorities intensified monitoring of the clinical trials.

Figures compiled by the Health Ministry show that notices were issued to the investigators/sponsors/ethics committees seeking clarifications in 235 cases.

With the increased scrutiny, the number of clinical trial approvals too experienced a sharp decline. The Drug Controller General of India (DCGI) has provided permissions to only 162 out of 285 clinical trial applications till the end of August this year.

The Indian government had formed an Apex Committee and Technical Committee to supervise clinical trials after the Supreme court passed an order in January this year. In September the Supreme Court placed a stay on the 162 approvals following petitions by health activists alleging irregularities.