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In clinical trials fiasco, patients worst affected

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All these factors and the uncertainty and unpredictability of regulatory direction has led to a hesitancy and lack of confidence in biopharma companies, academic and teaching institutions and not-for-profit organizations doing clinical research in India.

For many thousands of patients, participation in a clinical trial can provide early access to new therapies including for debilitating and life-threatening conditions. For patients who have run out of other options, clinical trials are often the last option. There is a need to create a sound clinical research ecosystem that encourages local research and innovation. There are several biopharma companies, not-for-profit organizations, and teaching and medical institutions in the country doing a lot of valuable research in diseases that affect our populations. We need to encourage such innovation and not deter the scientific and medical community from continuing in the quest to find safer and more effective treatment for our disease burden.

Ms Suneela Thatte feels that the declining number of clinical trials in India does not augur well for a country with an increasing healthcare burden. "Considering that India has 16 percent of the world's population and 20 percent of the global disease burden and does less than 2 percent of global research, the country's responsibility towards the health of its citizens is critical in creating an enabling environment for clinical research and drug innovation," said Ms Thatte.

Dr Jitendra Verma, managing director, Lifecare Innovations said, "Clinical trials and field trials of biotech and bio-pharma products consume most of the patent life, depriving return on investments in R&D and thus discouraging R&D for developing new drugs or products."

Dr Verma believes that there should be funding of trials for crucial diseases, done especially by small companies. "Clinical trials by innovators for translational research must be encouraged by timely approvals and funding support by the government," he told BioSpectrum.