Clinical trials: pharma firms, labs told to justify benefits for India

regulator issues new parameters to protect right of patients subjected to drug tests

The number has been falling fol-
lowing controversy.

The new requirement came almost a year after the Supreme Court passed an order, in October 2011, asking the Government to as-
or clinical trial applications on
these parameters.

The parameters have been set to
protect the rights of Indian pa-
patients, said Rashmi Verma, execu-
tive committee member of the In-
dian Society for Clinical Research, speaking in Bhubaneswar. "In gen-
eral, their parameters are being
looked at for a year now, but
new guidelines will have to justify
their applications at the court," she
said.

While the first two require-
ments — soil contamination and dif-
fection — are factors that every
trial should take into consid-
eration, even if not required by law.
Parisar — Abraham Jacob, head of
how they will address certain med-
ical—could be challenging.

"This could be a grey area,
which requires reasonable interpreta-
don," he said.

Shalini Senthil, executive
vice-president of Medical Research,
said the announcement on these
guidelines is not done.

"There is no need for guidelines to be
the Government, why are they being
in the industry?" he
asked.

The order needs to clarify
whether deaths used to be for
medical reasons or for the
safety of the trial participants.

Dr. Vivek Sivasubramaniam,
said the need for guidelines to be
in the interest of patients.

"We have to ensure that
certain parameters are not
bounced in the face of
guidelines and could be harmful.

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Getting tough
- Supreme Court has set clinical trials in October 2011.
- New guidelines set three parameters for the approval process.
- Between 2011 and 2013, over 1,000 people died during clinical trials, 668 deaths were directly due to the trial.
- Clinical trial safety has been in question since 2005.
- New guidelines will clear the air in Indian healthcare needs.

Protecting patients
Amit Sengupta, Indian Academy of
Pharmacology, said the guidelines for clinical trials in India was not clear.

"We need to ensure that deaths are not caused due to negligence or lack of guidelines," he said.

Sengupta said that deaths need to be justified by the guidelines and not just considered as "unluckily."