



## Lotus Labs; why India's No 1 CRO??

Hi %BASIC:FIRST\_NAME%,

### US FDA norms on Clinical Pharmacogenomics may provide clear rules for new drug devpt

The US Food and Drug Administration (FDA) has now issued the guidance for Industry on Clinical Pharmacogenomics which refers to a Premarket Evaluation in Early-Phase Clinical Studies and Recommendations for labelling.

The guidance is intended to assist the pharmaceutical industry and other investigators engaged in new drug development in evaluating how variations in the human genome, specifically DNA sequence variants, could affect a drug's pharmacokinetics (PK), pharmacodynamics (PD), efficacy, or safety.

Source:

<http://www.pharmabiz.com/NewsDetails.aspx?aid=73665&sid=1>

### Govt forms panels to frame guidelines & SOPs for approval of new drugs, trials, banning drugs

The Union health ministry has constituted two expert committees to formulate policy guidelines and standard operating procedures (SOPs) for approval of new drugs, clinical trials, banning of drugs and Fixed Dose Combinations (FDCs).

Source:

<http://www.pharmabiz.com/PrintArticle.aspx?aid=73666&sid=1>

### Health Min notifies rules for granting permission, conducting inspections of clinical trials

Close on the heels of notifying the rules on giving compensation to the victims of clinical trials, the Union Health Ministry has now amended the Drugs and Cosmetics (D&C) Rules to set conditions for giving permissions to the trials and inspection of sites, looking to further streamline the sector

Source :

<http://www.pharmabiz.com/NewsDetails.aspx?aid=73609&sid=1>

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**About us:** : Lotus Labs is a Clinical Research Organization working towards widening the frontiers of Medicine through services of the highest Quality that conform to International Standards, combining speed, accuracy and reliability and aims to be the most admired Clinical Research Organization from India

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