



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

Hi,

### [Apex committee on clinical trials gives approval to 33 proposals of clinical trials](#)

The Apex Committee on clinical trials, constituted by the Union health ministry on the directive of the Supreme Court to monitor the clinical trial sector in the country, has cleared a total of 33 proposals, 18 proposals of global clinical trials (GCTs) and 15 in other areas, after these were approved by Subject Expert Committees (SECs) and thereafter the Technical Committee, another high-level committee constituted by the ministry on this purpose on the directive of the Supreme Court.

Source: <http://www.pharmabiz.com/NewsDetails.aspx?aid=85059&sid=1>

### [EMA rejigs biosimilar guidelines to help developers avoid repeating trials](#)

Reference drugs in biosimilar trials now only need to be “representative” of a product cleared in the EEA not approved themselves under guidelines issued by the EMA this week.

Source: <http://www.biopharma-reporter.com/Markets-Regulations/EMA-rejigs-biosimilar-guidelines-to-help-developers-avoid-repeating-trials>

### [US FDA to issue UFI System for Drug Establishment Registration norms, Indian pharma lauds move](#)

US FDA is expected to issue a guidance on the specification of the Unique Facility Identifier (UFI) System for Drug Establishment Registration. The draft of this guidance has been circulated to the industry which has commented and provided their views on the move.

Source: <http://www.pharmabiz.com/NewsDetails.aspx?aid=79240&sid=1>

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

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