



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

Hi %BASIC:FIRST\_NAME%,

### US FDA issues rules on Electronic Source Data in Clinical Investigations; Indian CROs view it platform to prove proofs

US Food and Drug Administration (FDA) has issued the guidance for industry on Electronic Source Data in Clinical Investigations. This guidance provides recommendations to sponsors, Contract Research Organisations (CROs), clinical investigators, and others involved in the capture, review, and retention of electronic source data in FDA-regulated clinical investigations.

Source: <http://www.pharmabiz.com/NewsDetails.aspx?aid=78905&sid=1>

### EMA, US FDA issue responses to industry on 9 aspects of QbD for design space verification

European Medicine Agency (EMA) and the US FDA have issued their responses to the industry on nine aspects of Quality by Design (QbD) elements on design space verification. It would facilitate the implementation of QbD specifically on design space verification in both US and Europe.

Source: <http://www.pharmabiz.com/NewsDetails.aspx?aid=78764&sid=1>

### US FDA norms on electronic source data in clinical investigations seen to ensure transparency & traceability

The US Food and Drugs Administration (FDA) has issued norms on guidance for Industry on the Electronic Source Data in Clinical Investigations. It has clearly defined its recommendations to sponsors, Contract Research Organizations (CROs), clinical investigators, and others involved in the capture, review, and retention of electronic source data in FDA-regulated clinical investigations.

Source: <http://www.pharmabiz.com/NewsDetails.aspx?aid=78543&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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