

Hi %BASIC:FIRST\_NAME%,

### [Indian clinical trial approvals see early spike in 2014](#)

The approval of clinical trials in India is rebounding in 2014 after a year in which the country's regulations were in constant flux.

Source: <http://www.outsourcing-pharma.com/Clinical-Development/Indian-clinical-trial-approvals-see-early-spike-in-2014>

### [FDA offers new draft guidance on informed consent process](#)

For the first time since 1998, the US FDA is offering draft guidance on what it expects from IRBs (institutional review boards), clinical investigators and sponsors regarding informed consent.

Source: <http://www.outsourcing-pharma.com/Clinical-Development/FDA-offers-new-draft-guidance-on-informed-consent-process>

### [EMA delays policy on clinical trial data transparency](#)

The Management Board of the EMA (European Medicines Agency) has postponed the formal adoption of its policy on publication of clinical trial data, though the agency stopped short of revealing exactly why.

Source: <http://www.outsourcing-pharma.com/Clinical-Development/EMA-delays-policy-on-clinical-trial-data-transparency>

### [US FDA to set more specific GMP regulations for outsourcing facilities](#)

Until final regulations are finished, the US FDA has released draft guidance describing the agency's expectations for outsourcing facilities and the cGMP requirements for them.

Source: <http://www.outsourcing-pharma.com/Contract-Manufacturing/US-FDA-to-set-more-specific-GMP-regulations-for-outsourcing-facilities>

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