

**No. 04-01/2012-Misc.-159 (CT database)
Central Drugs Standard Control Organization
Directorate General of Health Services
Government of India**

**Food & Drugs Administration Bhavan,
Kotla Road, New Delhi**

Dated: 09.09.2015

**SUBJECT: IT ENABLED SYSTEM FOR ONLINE SUBMISSION OF APPLICATIONS
OF CLINICAL TRIAL-REG.**

The clinical trials on the new drugs are regulated under the provisions of the Drugs & Cosmetic Rules, 1945, amended from time to time.

In order to improve transparency, accountability and efficiency in processing of clinical trial applications and it's monitoring, CDSCO with the approval of Ministry of Health and Family Welfare, Government of India has taken initiative to create an IT enabled system for online submission and processing of application as well as monitoring of clinical trials in the country.

In the first phase, an IT enabled system for online submission of clinical trial applications has been created and made accessible to the stakeholder through <http://octams.gov.in>.

On trial basis, the applicants may now upload their clinical trial applications online through <http://octams.gov.in> for the purpose of feedback / suggestions only. The usual procedure of submission of application physically through hard copy shall continue till the system for online submission is made fully operational and adopted by CDSCO.

The suggestions/comments, if any, may please be forwarded to CDSCO through email at dcic@nic.in or phone at 011-23236965 for addressing the issues in consultation with NIC.

Office of DCG (I)