File No. 12-01/14-DC Pt.47
Central Drugs Standard Control Organization
Directorate General of Health Services
Ministry of Health & Family Welfare
FDA Bhawan, Kotla Road, New Delhi-110002

Dated: 03.07.2014

ORDER

SUBJECT: Limiting Number of Clinical Trials an Investigator can undertake at a time- regarding

The Ministry of Health & Family Welfare had constituted an Expert Committee under the Chairmanship of Prof. Ranjit Roy Chaudhury to formulate policy and guidelines for approval of new drugs, clinical trials and banning of drugs. The Expert Committee submitted its report to the Ministry of Health & Family Welfare. The actions proposed to be taken on the recommendations of the Expert Committee were finalised by the Ministry of Health & Family Welfare.

Pursuant to above, it has been decided that the number of clinical trials an Investigator can undertake should be commensurate with the nature of the trial, facility available with the Investigator etc. However, under no circumstances the number of trials should be more than three at a time.

In view of above, all Sponsors / clinical trial applicants are hereby directed to ensure that the above recommendations are implemented and the Investigators are not involved in conduct of more than three clinical trials at a time.

(Dr. G. N. Singh)
Drugs Controller General (India)

To:

IDMA / IPA / OPPI / ISCR / ACRO

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US (D), Ministry of Health and Family Welfare