

**GOVERNMENT OF INDIA
CHEMICALS AND FERTILIZERS
LOK SABHA**

UNSTARRED QUESTION NO:2139
ANSWERED ON:29.11.2016
Clinical Research Hubs
Hansdak Shri Vijay Kumar

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

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- (a) whether the Government is considering on reducing processing and approval time limit and at the same time ensuring quality parameters, Contract Research Organisation (CRO) with Good Clinical Practice (GCP) standards in order to create clinical research hub in the country ;
- (b) if so, the details thereof;
- (c) whether some cities have been selected for setting up of clinical research hub in the country; and
- (d) if so, the details thereof ?

Answer

MINISTER OF STATE IN THE MINISTRY OF ROAD TRANSPORT AND HIGHWAYS; MINISTRY OF SHIPPING AND MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI MANSUKH L. MANDAVIYA).

(a) Yes, Madam.

(b) The Government has rationalised the processes involved in granting approval for applications relating to clinical trials, bringing higher degree of clarity in the rules, increasing the number of subject experts, online receipt, processing and approval of clinical trial related applications. The clinical trial sites are being inspected for ensuring conformity with Good Clinical Practices and provisions including payment of compensation have been made to ensure patient safety and welfare.

(c) No, Madam.

(d) Does not arise.
