

**GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE**

**LOK SABHA
UNSTARRED QUESTION NO. 3236
TO BE ANSWERED ON 13TH MARCH, 2020**

CLINICAL TRIALS

3236. DR. UMESH G. JADHAV:

Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

- (a) the number of clinical trials conducted in the country in the last three years and the current year;
- (b) whether there has been a decline in the clinical trials being conducted in the country during the said period;
- (c) if so, the details along with the reasons therefor; and
- (d) the measures taken by the Government in this regard?

ANSWER

**THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND
FAMILY WELFARE
(SHRI ASHWINI KUMAR CHOUBEY)**

(a) to (d): Clinical trials of new drugs are regulated under Rules 122 DA, 122DAB, 122DAC, 122DD, 122E and Schedule-Y of the Drugs and Cosmetics Rules, 1945. Central Drugs Standard Control Organization (CDSCO) grants permission for conduct of clinical trials under the said Rules.

The number of clinical trial permissions granted by CDSCO during the last three years are as under:-

Year	Total permissions
2017	213
2018	196
2019	258
2020 (As on 04.03.2020)	44

The data above shows that there is no declining trend in the clinical trials being conducted in the country.

Further, various measures have been taken for streamlining the regulatory provisions in respect of clinical trials which include amendments in the Drugs & Cosmetics Rules, 1945.

The New Drugs and Clinical Trial Rules, 2019 have been notified on 19.03.2019 for regulation of clinical trials, bioavailability and bioequivalence (BA/BE) study of new drugs and investigational new drugs, which contain various provisions for improving transparency and accountability of the approval process of new drugs and clinical trial and for promoting research and development of new drugs in the country.

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