

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

**LOK SABHA
UNSTARRED QUESTION NO.1205
TO BE ANSWERED ON 28TH JUNE, 2019**

CLINICAL TRIALS

1205. 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 during the last three years;
- (b) whether there has been a decline in the clinical trials being conducted in the country during the last three years;
- (c) if so, the details thereof and the reasons therefor; and
- (d) the corrective 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 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
2016	129
2017	213
2018	196
2019 (As on 24-June-2019)	111

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 contains various provisions for improving transparency and accountability of the approval process of new drugs and clinical trial and to promote research and development of new drugs in the country.