

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

**RAJYA SABHA
UNSTARRED QUESTION NO. 2016
TO BE ANSWERED ON 10TH MARCH, 2026**

CLINICAL TRIALS CONDUCTED IN THE COUNTRY

2016. SMT. JEBI MATHER HISHAM:

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

- (a) the data on clinical trials registered and conducted in the country over the last five years, along with outcomes;
- (b) the details of compensation paid to participants in clinical trials over the last five years, necessitated under the New Drugs and Clinical Trials Rules, 2019;
- (c) the steps taken to increase awareness among patients, particularly with rare or chronic diseases, about ongoing clinical trials;
- (d) whether mechanisms exist to make clinical trial registry information accessible and understandable to the public, the details thereof; and
- (e) the details of adverse events or side effects observed during clinical trials in the last five years and actions taken, State/UT-wise?

ANSWER

**THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY
WELFARE
(SMT. ANUPRIYA PATEL)**

(a) to (e): Clinical trials of drugs are regulated as per the provisions of New Drugs and Clinical Trials Rules, 2019. As per the said rules, every clinical trial shall be registered with the clinical trial registry of India (CTRI), an online registry, maintained by the Indian council of Medical Research (ICMR), before enrolling the first subject for the trail.

The details of clinical trials registered and conducted in the country over the last five years, along with outcomes is available on <https://ctri.nic.in>. An e-Module is available on the CTRI homepage to guide users and registrants. A comprehensive frequently asked question (FAQs) section is also available on CTRI website to assist both registrants and public in understanding the registration process and access clinical trial related information.

Further, the clinical trial permissions issued by Central Drugs Standard Control Organization (CDSCO) in Form CT-06 are regularly uploaded on CDSCO's website for public accessibility.

Clinical trials conducted are multi-centric, conducted simultaneously across many centres/ states across the country. Serious Adverse Events (SAE) may occur during clinical trials due to multiple reasons depending upon the study drug, conditions of patient, concomitant drugs etc. Each case of SAE reported during conduct of CT/BA-BE study is examined as per the provisions of New Drugs and Clinical Trial Rules, 2019 for payment of compensation and free medical management on case-to-case basis.

The number of clinical trial permissions granted, SAE reported and Compensation paid during last five years is as under:

Year	Number of Permissions granted	SAE Reported	Compensation paid (Amount Rs. in cr)
2021	268	1811	6.36
2022	219	2127	5.19
2023	249	2004	4.83
2024	213	1706	2.93
2025	284	2173	1.93
