## GOVERNMENT OF INDIA MINISTRY OF HEALTH AND FAMILY WELFARE DEPARTMENT OF HEALTH RESEARCH

## LOK SABHA UNSTARRED QUESTION NO. 3965 TO BE ANSWERED ON 24<sup>TH</sup> MARCH, 2023

### CLINICAL TRIALS REGISTRY INDIA

#### 3965. DR. SANJEEV KUMAR SINGARI:

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

- (a) the details of the activities undertaken by the Clinical Trials Registry India (CTRI);
- (b) whether it is a fact that the CTRI is not a permanent project;
- (c) if so, the details thereof and the reasons therefor;
- (d) whether the Government proposes to give the CTRI a permanent structure/status;
- (e) if so, the details thereof and if not, the reasons therefor; and
- (f) the total budgetary allocation made and funds spent on CTRI in the last three years?

# ANSWER THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (DR. BHARATI PRAVIN PAWAR)

(a) to (f): The Clinical Trials Registry India (CTRI), hosted at the ICMR's National Institute of Medical Statistics (NIMS), New Delhi is a free and online public record system for registration of clinical trials conducted in India. Trial registration in the CTRI has been made mandatory by the Drugs Controller General (India) (DCGI).

Any researcher who plans to conduct a trial involving human participants, of any intervention such as drugs, surgical procedures, preventive measures, lifestyle modifications, devices, educational or behavioural treatment, rehabilitation strategies etc. registers the trial in the CTRI before enrolment of the first participant.

Trial registration involves public declaration and identification of trial investigators, sponsors, interventions, patient population etc. before the enrolment of the first patient. Submission of Ethics approval and DCGI approval (if applicable) is essential for trial registration in the CTRI. Multi-country trials, where India is a participating country which have been registered in an international registry, are also registered in the CTRI. In the CTRI, details of Indian investigators, trial sites, Indian target sample size and date of enrolment are captured.

Rs. 2.73 crore has been spent on CTRI for the period from April, 2020 till February, 2023.