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

LOK SABHA
UNSTARRED QUESTION NO. 2550
TO BE ANSWERED ON 04TH AUGUST, 2023

CLINICAL TRIALS FOR RARE DISEASES

2550. SHRI K. NAVASKANI:

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

(a) whether the Government agrees to the view that there needs to be more participation and ownership from the heads of Medical Institutions, Ethics committees, Patient advocacy groups, etc. to enable the conduct of clinical trials for rare diseases, communicable diseases, neurosciences and ophthalmology etc. in the country;

(b) if so, the details thereof and if not, the reasons therefor; and

(c) the initiatives taken/proposed to be taken by the Government in this regard and if so, the details thereof?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(PROF. S.P. SINGH BAGHEL)

(a) to (c) : The participation of relevant stakeholders in clinical trials is guided through New Drugs and Clinical Trial Rules, 2019 and National Ethical Guidelines for Biomedical and Health Research involving Human Participants, 2017. This also includes clinical trials for rare diseases.

The National Consortium for Research and Development on therapeutics for Rare Diseases and Rare Disease Registry have been established for improving coordination of research efforts, including clinical trials in India under the overall ambit of National Policy on Rare Diseases (2021). The approval for new drugs and decision related to trials continue to be provided by Drugs Controller General of India under the New Drugs and Clinical Trial Rules, 2019.

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