(b) whether any all India helpline number for blood banks operation will be considered so that in emergency/night time blood can be provided to the patient immediately?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI ASHWINI KUMAR CHOUBEY): (a) No, Sir. Public Health and Hospitals being State Subject, States are free to plan their own transfusion services as per needs aligned with National Blood Policy.

(b) E-raktkosh under NHM is an Integrated Blood Bank Management Information System which connects all the blood banks of public health facilities into a single network. Integraed Blood Bank MIS deals with acquisition, validation, storage and circulation of various live data and information electronically regarding blood donation and transfusion services.

Guidelines for clinical trials

2966. SHRI MD. NADIMUL HAQUE: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Government has devised guidelines for clinical trials by pharmaceutical companies;

(b) if so, the details thereof;

(c) the details of the total number of cases resulting in deaths or permanent disabilities of patients due to clinical trials in the last three years, year-wise;

(d) the details of the compensation paid by Government and pharmaceutical companies for cases of deaths and permanent disabilities due to clinical trials in the last three years, year-wise; and

(e) the details of clinical trial sites, IECs (Institutional Ethics Committees) and principal investigators being accredited in the last three years?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI ASHWINI KUMAR CHOUBEY): (a) and (b) 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. The detailed requirements and guidelines for permission to conduct clinical trials are specified in Schedule-Y of Drugs and Cosmetics Rules, 1945.

Draft New Drugs and Clinical Trials Rules, 2018 were published on 01-02-2018 for inviting public/stakeholder comments.

(c) and (d) Serious Adverse Events (SAEs) of death/injuries/disabilities in clinical trials may occur due to various reasons like life threatening disease, cancer, cardiovascular diseases, side effects of the investigational products etc. Such SAEs may or may not be related to clinical trials. The number of Serious Adverse Events (SAEs) of deaths, clinical trials related deaths and compensation paid since 2016 is given in the Statement-I (*See* below) and in respect of permanent disabilities is given in the Statement-II (*See* below).

(e) There is no provision under Rule 122DD of the Drugs and Cosmetics Rules, 1945 for accreditation of clinical trial sites, IECs (Institutional Ethics Committees) and Principal Investigator.

However, there are provisions for registration of Ethics Committee. As per Rule 122DD, no Ethics Committee shall review and accord its approval to a clinical trial protocol without prior registration with Central Drugs Standard Control Organisation (CDSCO).

Detailed guidelines and requirements for registration of Ethics Committee are specified in Rule 122DD and Appendix-VIII of Schedule-Y of the Drugs and Cosmetics Rules, 1945. The number of Ethics Committees registered under the said Rules during the year 2016, 2017 and 2018 are 136, 578 and 345 respectively.

Statement-I

Number of Serious Adverse Events (SAEs) of deaths, clinical trials related deaths and compensation paid since 2016

Sl. No.	Year	No. of Serious Adverse Events (SAEs) of Death reported	No. of Serious Adverse Events (SAEs) of Death related to Clinical Trial based on available status of examination done.	No. of cases in which compensation was paid related to Serious Adverse Events (SAEs)	Total amount of compensation paid by the applicant/ companies/ sponsor to Serious Adverse Events (SAEs) Death cases till date (INR).
1.	2016	378	27	25	1,62,14,668
2.	2017	345	27	18	1,19,59,933
3.	2018	339	5	1	4,87,270

Statement-II

Details in respect of permanent disabilities

Year	Total Nos. of Permanent disabilities reported	Total Nos. of SAE-Permanent disabilities Established to be related to Clinical Trial	Compensation paid to related SAE Permanent disabilities cases	Amount Paid by the sponsor to the legal heir/nominee of the subject
2016	Nil	Nil	Nil	Nil
2017	1	1	1	47,49,996
2018	Nil	Nil	Nil	Nil

Rise in number of patients suffering from diabetes

†2967. SHRI REWATI RAMAN SINGH: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that the number of diabetes patients has been increasing constantly in the country, day-by-day;

(b) if so, whether any report of World Health Organisation has come out in this regard; and

(c) the steps being taken by the Government for proper treatment of diabetes patients?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI ASHWINI KUMAR CHOUBEY): (a) and (b) As per the International Diabetes Federation (IDF), the estimated cases of diabetes in India in the age group of 20-70 years were 65.0 million, 66.8 million and 69.1 million respectively in 2013, 2014 and 2015, which is estimated to have risen to 73 million in 2017.

As informed by Indian Council of Medical Research (ICMR), ICMR-INDIAB Study) estimated 62.4 million people with diabetes (>20 years of age) in 2011 and 73 million are projected to have diabetes in 2018. The study is completed in 21 States.

The World Health Organization WHO) reports also indicate increasing trend in diabetes prevalence.

†Original notice of the question was received in Hindi.