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

RAJYA SABHA
UNSTARRED QUESTION NO. 216
TO BE ANSWERED ON 5TH FEBRUARY, 2019

DEATHS IN CLINICAL TRIALS

216. SHRI HUSAIN DALWAI:

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

(a) the State-wise, year-wise number of clinical trials registered since 2015;

(b) the State-wise, year-wise number of deaths and Serious Adverse Events (SAEs) reported in these trials since 2015;

(c) whether compensation has been paid in each case of death and SAE, if so, the State-wise, year-wise details of compensation claimed, paid and due, since 2015, if not, the reasons therefor;

(d) the State-wise number of Ethics Committees operating currently and the number of clinical trials approved by each Committee, State-wise, year-wise, since 2015; and

(e) the number of complaints of violations of clinical trials rules recorded, State-wise and year-wise since 2015?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(SHRI ASHWINI KUMAR CHOUBEY)

(a): Central Drugs Standard Control Organisation (CDSCO) grants permission to conduct clinical trials in the country without any State specific permission. However, the details of the clinical trials registered are available on the website of Clinical Trials Registry--India (CTRI).

The year-wise distribution of clinical trials as registered in CTRI from 2015 is given below:

S.No.	Year	No of trial
1	2015	859
2	2016	873
3	2017	2516
4.	2018 (till 28th November, 2018)	3869

Contd……..

Details of State-wise sites of clinical trials as available in CTRI is enclosed as **Annexure-A**.

The count given in the table above and that in the State/UT wise list may vary as many trials are multi centric studies conducted in multiple sites across the country.

(b) & (c): 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 & compensation paid since 2016 is enclosed as **Annexure-B**.

(d): As per Rule 122 DD of Drugs and Cosmetics Rules, 1945, no Ethics Committee shall review and accord its approval to a clinical trial protocol without prior registration with Central Drugs Standard Control Organisation (CDSCO). List of the Ethics Committee registered since 2015 to 2018 are enclosed as **Annexure-C**.

As per the rule, the Ethics Committees are required to maintain the details of clinical trial protocol approved, overseen, etc. However, such information is not available with CDSCO.

(e): Some complaints against clinical trials were received by CDSCO. They have conducted investigation and taken action as per the provisions of Drugs and Cosmetics Rules, 1945.

…….

Annexure-A

No of trials by state and year wise

State Name				
	2015	2016	2017	2018
JAMMU & KASHMIR	9	3	9	20
HIMACHAL PRADESH	15	6	32	34
PUNJAB	39	20	59	99
CHANDIGARH	81	76	161	221
UTTARAKHAND	3	3	15	71
HARYANA	24	46	65	94
DELHI	225	225	627	673
RAJASTHAN	83	73	202	218
UTTAR PRADESH	151	88	280	334
BIHAR	19	15	48	55
SIKKIM	3	0	2	1
ARUNACHAL PRADESH	0	0	1	1
NAGALAND	0	0	0	0
MANIPUR	1	0	0	2
MIZORAM	1	0	1	0
TRIPURA	1	0	2	1
MEGHALAYA	0	0	2	5
ASSAM	22	10	32	24
WEST BENGAL	148	102	232	263
JHARKHAND	2	0	13	15
ORISSA	44	26	72	68
CHHATTISGARH	6	6	6	24
MADHYA PRADESH	16	17	14	35
GUJARAT	319	272	494	432
DAMAN & DIU	0	0	0	0
DADRA & NAGAR HAVELI	0	0	0	0
MAHARASHTRA	485	381	914	802
ANDHRA PRADESH	283	160	349	337
KARNATAKA	346	299	786	1037
GOA	8	4	8	6
LAKSHADWEEP	0	0	0	0
KERALA	49	64	146	173
TAMIL NADU	178	146	431	458
PONDICHERRY	38	60	134	117
ANDAMAN & NICOBAR ISLANDS	0	0	0	3
TELANGANA	0	0	2	10

Annexure-B

S.No	Year	No. of Serious Adverse Events (SAE) of Death reported	No. of Serious Adverse Events (SAE) 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 (SAE)	Total amount of compensation paid by the applicant/companies/sponsor to Serious Adverse Events (SAE) Death cases till date (INR).
1	2015	381	18	18	2,05,94,866/-
1	2016	378	27	25	1,62,14,668
2	2017	345	30	18	1,19,59,933
3	2018	339	13	1	4,87,270

Annexure-C

S.No	States	Registered Ethics Committees in 2015	Registered Ethics Committees in 2016	Registered Ethics Committees in 2017	Registered Ethics Committees in 2018
1	Andhra Pradesh	8	13	47	19
2	Assam	3	2	3	4
3	Andaman & Nicobar	0	0	1	0
4	Bihar	0	1	3	1
5	Chattisgarh	3	2	2	3
6	Delhi	3	9	32	11
7	Goa	1	2	3	1
8	Gujarat	13	17	69	34
9	Himachal Pradesh	1	0	0	1
10	Haryana	1	4	11	6
11	Jharkhand	1	0	1	1
12	Jammu and Kashmir	0	1	0	1
13	Karnataka	13	17	68	28
14	Kerala	7	8	31	20
15	Maharashtra	33	20	137	81
16	Madhya Pradesh	3	1	7	7
17	Manipur	0	0	0	2
18	Meghalaya	0	0	1	0
19	Odisha	0	2	10	4
20	Punjab	4	2	7	11
21	Puducherry	0	2	3	4
22	Rajasthan	3	5	22	17
23	Sikkim	0	0	0	1
24	Tamil Nadu	15	15	55	30
25	Telangana	3	8	7	6
26	Tripura	0	0	1	0
27	Uttarakhand	3	0	3	2
28	Uttar Pradesh	9	6	26	25
29	West Bengal	3	7	29	10
Total		**130**	**144**	**579**	**330**