

CLINICAL TRIALS WATCH

Clinical Trials Registry - India (www.ctri.in) Total number of trials registered

Number of Trials	N = 689				
	Year missing	2006 & prior	2007	2008	2009
	4	54	100	211	320
Recruitment status					
Active, not recruiting		16	17	29	19
Completed	1	25	17	16	8
Enrolling by invitation					
Not yet recruiting	1		2	21	72
Recruiting	1	12	62	142	219
Suspended					
Temporarily not available					
Terminated	1	1	2	3	
Withdrawn					
Temporarily halted/suspended					1
Recruitment status not known					1

Type of study

Behavioural		5		2	6
Device		2	4	8	8
Dietary supplement			2	4	4
Drug	3	30	80	155	233
Procedure		3	4	16	9
Radiation		2			2
Biological	1	9	7	16	45
Gene transfer					
Other		3	3	10	13

Disease conditions

Bacterial infections, intestinal infections, STDs	1	4	10	17	37
Neoplasms		10	28	34	38
Endocrine, nutritional & metabolic		4	5	30	38
Mental & behavioural diseases		3	1	4	18
Dis. of the nervous system		3	6	16	18
Dis. of the circulatory system		2	9	27	35
Dis. of the respiratory system	2	2	3	12	18
Dis. of the digestive system		4	11	10	14
Dis. of the musculoskeletal system & connective tissue		3	4	7	22
Diseases of the eye & adnexa		3	2	6	11
Diseases of the genitor-urinary system		2	4	5	16
Pregnancy, Childbirth & the puerperium		4	5	7	3
Double disease condition	1	6	4	12	11
Other		3	5	22	37
Disease conditions not known		1	3	2	4

Sponsor Profile

Institution/Agency		26	32	57	41
Pharma	4	27	57	140	270
Both					
Sponsor profile not known		1	11	14	9

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Sponsor ownership					
Non-profit			2	6	16
Public, private			2		2
Non-profit, public					1
Non-profit, private				3	1
Individual investigator			3	4	9
Individual investigator, public			1	2	
Individual investigator, non-profit			1	1	1
Sponsor ownership not known			1	10	14

Phases

0					
I			1		7
II		2	6	22	45
III		2	22	39	90
IV			7	8	27
I/II			4	1	5
II/III			4	13	12
III/IV			2	6	2
Not applicable			8	11	23

Sampling

Cross sectional					
Non-randomised			2	4	5
Prospective					
Randomised		4	43	81	152
Cluster					3
Other			6	10	29
Sampling not known			3	5	22

Assignment

Crossover			2	2	5
Factorial				2	2
Parallel		3	43	77	146
Single group			3	4	22
Other		1	6	14	37
Assignment not known				1	1

Control

Active			19	25	63
Placebo		3	19	43	71
Uncontrolled			3	4	22
Multi-arm			5	13	17
Crossover			2	2	5
Other		1	6	12	29
Control not known				1	4

Clinical Trials Registry - India (www.ctri.in)

Total number of drug trial settings

N=3138

	Year missing	2006 & prior	2007	2008	2009
Number of drug trial settings	13	119	452	917	1637

Drug trial settings by states (in alph. order)

Andhra Pradesh	1	16	55	105	167
Delhi	1	20	51	68	94
Gujarat		8	19	52	171
Haryana		2	3	6	14
Karnataka	3	14	72	141	249
Kerala	1	2	21	51	52
Madhya Pradesh		3	6	19	55
Maharashtra	4	26	97	228	458
Punjab	1	3	15	25	27
Rajasthan	1	3	15	40	74
Tamil Nadu	1	14	55	95	148
Uttar Pradesh		2	10	30	49
West Bengal		3	20	29	36
Others		3	13	28	43

Drug trial settings by cities/towns (in alph. order)

Ahmedabad		7	14	38	111
Aurangabad				5	31
Bangalore	3	5	40	100	172
Chandigarh		1	6	9	12
Chennai		6	21	47	77
Cochin	1		8	23	18
Coimbatore	1	3	6	18	29
Hyderabad	1	14	49	83	133
Indore		3	2	13	38
Jaipur	1	3	11	36	70
Kolkata		3	19	28	35
Lucknow		1	8	13	25
Ludhiyana	1	2	7	17	20
Madurai		2	4	11	19
Mangalore		3	10	11	44
Mumbai	1	15	53	97	145
Mysore		3	2	14	14
Nagpur			3	23	56
Nashik				9	47
New Delhi	1	21	52	76	102
Patna		1	1	7	12
Pune	3	11	39	84	163
Trivandrum		2	12	17	28
Vadodara		1	3	9	22
Vellore		2	25	15	16
Vishakapattinam		2	3	9	11
Others	0	8	54	105	187

This is the second fact-sheet of Clinical Trials Watch. CTW, which was first published in the October-December 2009 issue of *IJME*, aims to employ the Clinical Trials Registry-India (CTR-I) for regular monitoring of clinical research activity in India.

The fact-sheet initially presented information from two registries, the Indian Council of Medical Research's Clinical Trials Registry-India (CTR-I), www.ctri.in, and the US National Institutes of Health's registry, www.clinicaltrials.gov.

On July 1, 2009, the Drugs Controller General of India (DCGI) made registration of all drug trials being conducted in India mandatory. As a result, there was a twofold increase in the number of trials registered on www.ctri.in between June 2009 and December 2009. Thus, this database is now more representative of the clinical research scenario in India. For this reason, from this point on, we will be presenting data only from CTR-I. The data presented in this fact-sheet are updated up to December 31, 2009. All the registered trials on www.ctri.in were revisited and information was revised to ensure that changes made in the record of each trial in the registry were incorporated in the database.

Methods

The Indian registry yielded 689 registered trials on December 31, 2009. Trial information pertaining to each registered clinical trial was manually exported into an Excel spreadsheet via the copy-paste mechanism of Microsoft Office. The fields of information exported included CTR-I ID, brief study title, study status, trial location, ethics committee details, sponsor, disease condition, trial start date, DCGI approval and study type. This Excel spreadsheet was then exported to SPSS for analysis.

Definitions

Year: CTR-I provides a record of the last date on which the study was verified, the date on which the study was updated and the date of first enrolment for each trial. The date of first enrolment was coded as the "year" for each trial.

Study type: The trials listed in the CTR-I were classified according to the different types of studies as "drug", "behavioural", "device", "procedure", "radiation", and "other" after careful reading of the study title. These codes were in line with the classification for different types of trial intervention listed on Clinicaltrials.gov.

Disease condition: The disease conditions were coded according to the 10th revision of the World Health Organization (WHO) International Classification of Diseases (ICD 10). There were 18 categories including diseases of the nervous system, circulatory system and digestive system. An additional category for "double disease conditions" was created to include combinations of the disease conditions involved in the trial. After running the frequencies for all disease conditions, only the prominent ones were chosen for representation, while the less significant categories were truncated and labeled as a separate category referred to as "other."

Sponsors: Sponsors were categorised as: Indian and non-Indian; private, public and non-profit; and, lastly, institution/agency and pharmaceutical company.

Trials starting before 2006 were combined with trials starting in 2006 in CTR-I. All the data pertaining to phase, disease condition, sponsor, study type, recruitment status, and location (by cities and states) have been analysed by "year".

Drug trial setting: This refers to the institution where the trial site was located. The city/town in which this institution is located was coded. Similarly, the state in which this institution is located was coded. Each "drug trial setting" represents a single trial site. Thus, each trial can have multiple "drug trial settings". Likewise, the same city may be listed more than once for the same trial, depending on the number of institutions from that

city participating in that trial. This variable was coded only for those trials categorised as "drug trials" in study type.

In this factsheet, the data on drug trial settings has been reported in more detail. All cities/towns reporting more than 20 trials, over the entire period, have been listed separately. Likewise, all states reporting a significant number of trials have been listed. The remaining have been clubbed into a category called "others".

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Articles from the journal's previous titles, *Medical Ethics* (1993-1995) and *Issues in Medical Ethics* (1996 to 2003), are also indexed.