

CLINICAL TRIALS WATCH

This is the third factsheet collating data on clinical trials in India. The first and second factsheets were published in the October 2009 and April 2010 issues of the journal respectively. The cut-off date for the data collated for the first factsheet was June 15, 2009, coinciding with the Drugs Controller General of India's mandate for compulsory registration of clinical trials with sites in India. While the first factsheet contained data on two registries, it was decided to restrict data collection to the Indian registry Clinical Trials Registry-India (CTR-I, www.ctri.in).

In the six month period from June 15, 2009, when registration was made compulsory, to December 31, 2009, when data for the second factsheet were collated, the Indian registry, ctri.gov, recorded a marked increase in registration of clinical trials, from 324 to 689. A similar marked increase - to 1,078 trials - is seen in this third factsheet that records data on all registered trials as of June 30, 2010. As with previous factsheets, the majority (666/1,078) are drug trials.

Methods

CTR-I yielded 1,078 registered trials on June 30, 2010. The information on each registered 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".

Total number of trials registered	Clinical trials registry - India, N = 1078					
	Year missing	2006 & prior	2007	2008	2009	2010
Number of Trials	4	64	111	229	425	245
Recruitment status	Year missing	2006 & prior	2007	2008	2009	2010
Completed	1	38	30	44	73	8
Not yet recruiting	1	15	24	57	109	79
Recruiting	1	9	51	123	235	127
Terminated	1	2	5	5	6	
Temporary halt or suspended			1		2	
Total	4	64	111	229	425	214
Type of study	Year missing	2006 & prior	2007	2008	2009	2010
Behavioral		5		2	7	1
Device		3	4	8	11	7
Dietary supplement		1	3	5	11	6
Drug	3	31	73	142	285	132
Procedure		3	4	17	11	3
Radiation		2			2	4
Biological	1	16	21	43	79	78
Gene transfer						
Other		3	6	12	19	14
Total	4	64	111	229	425	245
Disease conditions	Year missing	2006 & prior	2007	2008	2009	2010
Bacterial infections, intestinal infections, STDs	1	4	10	19	45	50
Neoplasms		10	29	37	44	24
Endocrine, nutritional, and metabolic		6	5	30	55	27
Mental and behavioral diseases		3	2	4	25	8
Diseases of the nervous system		4	10	18	29	7
Diseases of the circulatory system		2	10	29	46	25
Diseases of the respiratory system	2	2	3	12	25	7
Diseases of the digestive system		4	13	11	20	20
Diseases of the musculoskeletal system and connective tissue		3	5	6	28	15
Diseases of the eye and adnexa		4	2	7	14	6
Diseases of the genitourinary system		3	4	8	22	15
Diabetes						
Pregnancy, Childbirth and the puerperium		4	5	7	3	4
Double disease condition	1	9	5	12	15	3
Other		4	7	27	48	32
Disease conditions not known		1	1	2	7	2
Total	4	63	111	229	426	245
Sponsor Ownership	Year missing	2006 & prior	2007	2008	2009	2010
Public		20	21	27	39	21
Private	4	32	63	156	343	191
Non-profit		2	6	16	9	9
Public, private		2		2	11	4
Non-profit, public				1		1
Non-profit, private		1	3	1	3	2
Mixed						
Individual investigator		3	3	10	7	6
Individual investigator, public		1	2	1	2	1
Individual investigator, non-profit		1	1	1		
Sponsor ownership not known		2	12	14	11	10
Total	4	64	111	229	425	245
Sponsor Profile	Year missing	2006 & prior	2007	2008	2009	2010
Institution/Agency		33	37	62	63	47
Pharma	4	29	62	151	350	186
Both						
Sponsor profile not known		2	12	16	12	12
Total	4	64	111	229	425	245

Phases	Year missing	2006 & prior	2007	2008	2009	2010
0						
I		1		7	33	20
II	2	9	23	46	66	30
III	2	25	43	99	200	111
IV		8	10	32	51	26
I/II		4	1	5	10	5
II/III		4	14	12	17	13
III/IV		2	7	2	8	5
not applicable		11	13	23	37	35
Phase not known				3	3	
Total	10	64	111	229	425	245
Sampling	Year missing	2006 & prior	2007	2008	2009	2010
Cross sectional						
Non-randomised		3	4	5	6	8
Prospective						
Randomised	4	50	91	162	327	171
Cluster				3	1	1
Other		7	12	33	35	26
sampling not known		4	4	26	56	39
Total	4	64	111	229	425	245
Assignment	Year missing	2006 & prior	2007	2008	2009	2010
Crossover	1	2	2	5	24	9
Factorial			3		2	2
Parallel	3	51	90	162	305	168
Single group		4	3	25	54	39
Other		7	12	36	39	27
Assignment not known			1	1	1	
Total	4	64	111	229	425	245
Control	Year missing	2006 & prior	2007	2008	2009	2010
Active		25	31	68	148	96
Placebo	3	20	46	74	121	46
Uncontrolled		4	3	25	54	39
Multi-arm		6	13	20	36	26
Crossover	1	2	2	5	24	9
Other		7	12	33	35	26
Control not known			4	4	7	3
Total	4	64	111	229	425	245

Clinical trials registry - India						
Total number of drug trial settings N = 4292						
	Year missing	2006 & prior	2007	2008	2009	2010
Number of drug trial settings						
Drug trial settings by states (in alph. order)						
Andhra Pradesh	1	14	51	88	216	74
Bihar		1	2	8	16	9
Delhi	1	14	47	60	141	65
Gujarat		11	18	46	210	132
Haryana		1	3	6	18	8
Karnataka	3	13	64	120	321	96
Kerala	1	2	20	50	62	17
Madhya Pradesh		3	5	20	63	32
Maharashtra	4	29	98	215	531	239
Punjab	1	4	11	21	32	7
Rajasthan	1	3	13	42	83	44
Tamil Nadu	1	13	51	89	176	59
Uttar Pradesh		1	10	28	67	36
West Bengal		3	16	30	45	32
Others	11	1	11	19	30	32
	24	113	420	842	2011	882
Drug trial settings by cities/towns (in alph. order)						
Ahmedabad		10	14	34	139	67
Aurangabad				5	34	9
Bangalore		3	41	82	215	52
Bhopal			3	5	12	6
Chandigarh		1	5	8	13	6
Chennai		5	21	44	94	37
Cochin		1	7	22	20	5
Coimbatore	1	3	5	16	31	5
Hyderabad	1	13	46	68	160	45
Indore		3	2	14	43	24
Jaipur	1	3	11	38	79	27
Kolkata		3	16	29	43	20
Lucknow			8	12	32	18
Ludhiyana	1	2	6	15	21	4
Madurai		2	3	11	22	3
Mangalore		2	12	13	61	14
Manipal		2	3	5	11	3
Mumbai	1	17	51	89	176	112
Mysore		3	3	13	18	7
Nagpur			5	22	59	24
Nasik				10	52	26
New Delhi	1	15	47	68	146	60
Patna		1	1	7	13	4
Pune	3	11	41	79	189	38
Surat		1		1	16	16
Trivandrum		2	11	18	31	6
Vadodara		1	2	7	28	16
Vellore		2	23	13	18	4
Vijayawada				7	13	6
Visakhapatnam		2	2	10	21	10
Others	83	6	37	77	186	148
	92	114	426	842	1996	822

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