CLINICAL TRIALS WATCH

Total number of trials registered	Clinical trials.gov, N = 1040							
	Year missing	2003 & prior	2004	2005	2006	2007	2008	Jun-09
Number of trials	21	103	79	118	183	226	225	85
Recruitment status								
Active, not recruiting	3	18	8	16	41	44	33	
Completed	8	68	57	63	81	67	23	
Enrolling by invitation					1	3	8	2
Not yet recruiting	2				2	5	4	27
Recruiting	3	14	7	26	50	90	154	54
Suspended						4		
Temporarily not available								1
Terminated		3	7	13	8	12	2	
Withdrawn						1	1	1
Recruitment status not known	5							
Total	21	103	79	118	183	226	225	85
Type of study								
Behavioural	1	6	3	2	3	4	3	1
Device		2	1	6	10	12	8	2
Dietary supplement		1		2		2	7	2
Drug	10	70	65	87	146	176	173	59
Procedure	3	7	3	7	8	4	5	6
Radiation		1		3		1	1	
Biological		3	1	5	10	20	17	9
Gene transfer			1					
Other		4	1	2	2	4	5	3
Not given	7	9	4	4	4	3	6	3
Total	21	103	79	118	183	226	225	85
Disease conditions								
Bacterial infections, intestinal infections, STDs	7	25	6	20	24	31	28	11
Neoplasms	5	23	14	24	43	44	44	12
Endocrine, nutritional, and metabolic								
Mental and behavioural diseases		2	5	9	4	12	7	2
Diseases of the nervous system			9	4	11	20	11	2
Diseases of the circulatory system		7	8	14	19	29	28	13
Diseases of the respiratory system		9	6	4	7	6	6	8
Diseases of the digestive system		4	4	6	8	10	3	6
Diabetes		6	4	9	28	17	46	16
Double disease condition	1	10	6	7	4	16	5	3
Other	3	17	17	21	35	41	47	12
Disease conditions not known	5							
Total	21	103	79	118	183	226	225	85
Sponsor nationality								
Indian	2	23	19	26	34	32	34	20
Non-Indian	13	67	54	81	139	183	180	61
Indian and Non-Indian	1	13	6	11	10	11	11	4
Sponsor nationality not known	5							
Total	21	103	79	118	183	226	225	85
Sponsor ownership								
Public	8	28	12	16	21	17	21	12
Private	5	54	55	72	148	185	188	67
Non-profit		4	5	10	3	6	4	
Public, private	1	3	1	5	2	9	3	2
Non-profit, public		2	1	4	1	1	1	
Non-profit, private		1		1	1	1	2	
Mixed	2	11	5	10	7	7	6	4
Individual investigator								
Individual investigator, public								
Individual investigator, non-profit								
Sponsor ownership not known	5							
Total	21	103	79	118	183	226	225	85
Sponsor profile								
Institution/Agency	11	59	28	45	47	46	43	19
Pharma	5	43	49	68	136	177	178	64
Both		1	2	5		3	4	2
Sponsor profile not known	5							
Total	21	103	79	118	183	226	225	85

Clinical trials registry - India N = 324				
Year missing	2006 & prior	2007	2008	Jun-09
3	27	67	129	98
	8	8	10	4
	17	14	7	2
		2	20	26
	2	43	91	66
			1	
3				
3	27	67	129	98
	2		2	1
	2		2	1
			2	
	18	59	104	85
	2	4	14	6
	1			
	2	4	5	5
3				
3	27	67	129	98
	3	7	12	10
	2	21	20	14
	1	1	19	11
		3	11	5
	2	5	12	14
		3	10	10
	3	5	6	6
	6	4	11	4
	10	16	28	21
8				
8	27	65	129	95
	20	44	75	45
	5	13	41	49
	1		3	
28				
28	26	57	119	94
	7	15	19	9
	12	31	79	78
	2	5	12	3
				1
			1	
		2		1
	3	2	8	2
		1		
		1		
30				
30	24	57	119	94
	17	26	42	14
	8	31	77	80
29				
29	25	57	119	94

Clinical Trials Watch

The launch of the Clinical Trials Registry-India (CTR-I) provides an opportunity for one-point registration and tracking of clinical research activity in India. However, this resource has remained unexplored ever since the launch of CTR-I on July 20, 2007.

The objective of this new column, Clinical Trials Watch, is to employ CTR-I for regular monitoring of clinical research activity in India. It will therefore publish information on select indicators extracted from CTR-I on a regular basis.

Clinical Trials Watch will also publish parallel information on Indian clinical trials extracted from www.clinicaltrials.gov, a registry managed by the National Library of Medicine at the United States National Institutes of Health. This information is being included to broaden the database for monitoring clinical research in India.

We also hope that publishing parallel indicators from a relatively more established registry enables a comparative evaluation of the functioning and operational aspects of CTR-I. With the current Drugs Controller General of India (DCGI) mandating registration of all clinical trials, it may be only a matter of time before the registration of trials catches up on CTR-I. That however will be an issue to examine for the next factsheet of Clinical Trials Watch, which will appear in the April 2010 issue of *IJME*.

Methods

For clinicaltrials.gov, a search was conducted for all trials with the keyword "India". This yielded 1,040 search results on June 15, 2009. The results were downloaded from www.clinicaltrials.gov in excel and xml format. The excel spreadsheet of 1,040 clinical trials, automatically generated from the website, contained the following fields in the columns: National Clinical Trials Identifier (NCT ID); brief study title; recruitment status; disease conditions; intervention type; sponsor type; phases; study start date and study design. The xml files contained the same fields but also contained many text-heavy fields that included study objectives, rationale, inclusion and exclusion criteria, disease characteristics and study locations. From the xml files, a second excel spreadsheet was generated by extracting only the NCT ID, study location, city and state information. The data from the two excel spreadsheets were merged.

The Indian registry yielded 324 registered trials on June 30, 2009. Trial information pertaining to each registered clinical trial was manually exported into an excel spreadsheet using a template. The fields of information exported were CTR-I ID, brief study title, study status, trial location, ethics committee details, sponsor, disease condition, trial start date, DCGI approval and study type.

	Year missing	2003 & prior	2004	2005	2006	2007	2008	2009
Phases								
0							1	
I	1	6	3	3	5	4	7	3
II	3	11	11	26	28	43	41	12
III	5	46	34	54	105	123	120	28
IV	1	11	10	13	11	18	14	19
I/II		1	3	1	1	7	7	5
II/III	1	5	3	4	7	9	8	3
III/IV								
not applicable								
Not given	10	23	15	17	26	22	27	15
Total	21	103	79	118	183	226	225	85
Sampling								
Cross sectional						1		
Non-randomised	3	6	11	15	21	29	18	7
Prospective		2	2	6	9	3	10	11
Randomised	11	80	61	92	148	185	170	57
Retrospective			1					
Convenience		1	1					
Defined population		1	2	1	1			
Cluster								
Other								
Not given	7	13	1	4	4	8	27	10
Total	21	103	79	118	183	226	225	85
Assignment								
Crossover		6	3	4	12	5	4	4
Factorial		7	1	5	3	1	3	
Parallel	9	61	51	81	134	183	171	55
Single group	5	10	17	18	24	32	33	14
Other								
Not given	7	19	7	10	10	5	14	12
Total	21	103	79	118	183	226	225	85
Control								
Active	5	44	22	40	71	79	55	16
Case control				1		3	4	2
Cohort		1	2	3	7		3	7
Cross sectional		1	2	1	1		1	
Dose comparison		4	3	1	4	7	5	1
Historical				1	3	4	1	
Longitudinal		1	1					
Placebo	3	18	23	33	45	50	59	12
Uncontrolled	3	4	10	11	13	15	14	4
Multi-arm								
Crossover								
Other								
Not given	10	30	16	27	39	68	83	43
Total	21	103	79	118	183	226	225	85
Total number of drug trial settings	N = 3884							
		2003 & prior	2004	2005	2006	2007	2008	Jun-09
Number of drug trial settings	29	231	229	443	854	904	994	200
Total number of drug trials	N = 786							
		2003 & prior	2004	2005	2006	2007	2008	Jun-09
Number of drug trials	10	70	65	87	146	176	173	59
Top drug trial settings by cities								
Mumbai	2	33	31	54	101	99	103	12
Bangalore	2	25	34	57	83	99	118	15
Delhi	6	29	27	52	58	83	85	15
Hyderabad	1	21	27	47	79	81	73	16
Pune	3	13	15	28	71	71	73	13
Others	15	110	95	205	462	471	542	129
Top drug trial settings by states								
Maharashtra	5	50	46	87	206	197	226	37
Karnataka	2	29	42	76	122	141	175	23
Tamil Nadu	5	33	25	56	100	90	105	27
Andhra Pradesh	1	23	28	60	103	110	100	21
Delhi	6	29	27	52	58	83	85	15
Others	10	67	61	112	265	283	303	77

Year missing	2006 & prior	2007	2008	2009
			4	9
	2	16	26	14
	13	25	53	40
	5	5	17	19
	2		3	6
	1	9	6	5
		4	2	
	4	8	18	5
3				
3	27	67	129	98
	1		3	2
	21	56	96	80
			1	
	3			
35		7	17	2
35	25	63	117	84
	2	2	4	6
		1		
	19	53	92	74
	2	3	12	14
	3	7	17	2
11				
11	26	66	125	96
	10	17	38	38
	8	28	44	29
	2	3	12	14
	2	8	13	9
	2	2	4	6
	3	7	17	2
6				
6	27	65	128	98
N=1432				
	2006 & prior	2007	2008	Jun-09
	42	280	520	590
N = 266				
	2006 & prior	2007	2008	Jun-09
	18	59	104	85
	1	31	54	44
	1	12	50	56
	16	35	43	39
	6	18	46	45
	2	20	34	25
	16	164	293	381
	2	65	110	151
	6	36	87	90
	7	40	66	74
	5	21	60	53
	14	35	40	51
	8	83	157	171

All data were then exported to SPSS for analysis. Categories presented in the tables are as given in the original datasets. In some cases, the variables were recoded to ensure comparability across two data sets. Details of recoded variables are given in the notes.

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Notes: recoded variables

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. Clinicaltrials.gov provides a record of the study start date, the date on which information was first received on the registry, as well as the date of trial completion, "last updated", and "last verified" dates. The study start date was coded as the 'year' for each trial.

As the numbers were very small, trials starting in the year 2003 or earlier were combined into one category for the trials listed in Clinicaltrials.gov. Similarly, trials starting in 2006 or earlier were combined into one category for the trials listed in CTR-I.

Disease conditions: 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 in the ICD 10, including diseases of the nervous system, circulatory system and digestive system. To these categories, a new category, "double disease conditions", was added to include combinations of the disease conditions involved in the trial. After running the frequencies for all disease conditions, only the prominent categories were chosen for representation. The less significant categories were clubbed as a separate category named "other."

Type of study: In Clinicaltrials.gov, all trials were pre-coded according to the type of study as "drug", "behavioural", "device", "procedure", "radiation", and "other". The same classification was used to recode the trials listed on CTR-I after a careful reading of each study title.

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

Drug trial setting: This refers to the city or state where the site of a drug trial (as defined in "type of study") was located. An analysis of the locations of trials was conducted only for drug trials.