Original article:

A study on status of clinical trials in India, 2011

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Abstract:

The Clinical Trials Registry–India is an online, primary register of the WHO's International Clinical Trials Registry Platform. It was launched on 20 July 2007, and is now open to the prospective registration of clinical trials of any intervention conducted in India involving human participants.(Ctri.nic.in)Trials are registered by the pharmaceutical, biotech or medical device company (Sponsor) or by the hospital or foundation which is sponsoring the study, or by another organization, such as a contract research organization (CRO) which is running the study.Public disclosure of all 20 items in the WHO Trial Registration Data Set is mandatory for a valid registration number to be allocated.(Pandey A)This number is required if the results are to be published in journals that endorse the International Committee of Medical Journal Editors. Objective of the work is to find out trial status, therapeutic area, and phase of clinical trial maximum, study design.India included in the central repository of the WHO's International Clinical Trials Registry Platform search portal. In addition to the 20 items, the Clinical Trials Registry–Indiaalso requires mandatory disclosure of details of ethics committee and regulatory clearances. The present study is based on database of the clinical trial register in India in the year 2011. The present study clarifies the major players participating for conducting clinical trials, source of funds to conduct clinical trials, therapeutic area in which maximum trials conducted, ratio of completion of clinical trials, study design of clinical trials. Clinical trials are mainly sponsored by pharmaceutical industry, academics, hospitals, clinics, government funding agency, biotech company, CRO, others (self-funded, nil).Major therapeutic areas are cancer, neuro, dermal, ortho, diabetes, pregnancy, baby care, respiratory, Parkinson, HIV. Major trials are in phase 3 & 4. Clinical trials are maximum completed but some are open to recruitment or not completed. The data extraction was done by internet.It was found in the study that industry and academics domain were the major sponsors, the major therapeutic areas were cancer, diabetes, ortho, GIT diseases, dermal diseases, maximum number of trials were completed, study design for maximum trials was randomized and phase 3 trials were mostly conducted

.**Keywords:** CTRI, Therapeutic Area, Sponsors, Clinical Trials, Tools

Introduction:

A clinical trials registry is abbreviated as CTR. Itis an official platform and catalog for registering aclinicaltrial.Some countries require clinical trials being conducted in that country to be registered, Clinical Trials Gov., run by the United StatesNational Library of Medicine (NLM) was the first online registry for clinical trials. (www.cdsco.nic.in.) It is the largest and most widely used today.Clinical trials are conducted to allow safety and efficacy data to be collected for health interventions (e.g., drugs, diagnostics, devices, therapy protocols). There has been a push from governments and international organizations, especially since 2005, (Pandey A) to make clinical trial information more widely available and to standardize registries and processes of registering. The current study is based on to find out major

players participating for conducting clinical trials.Source of funds to conduct clinical trials, therapeutic area in which maximum trials conducted, Ratio of completion of clinical trials, Study design of clinical trials(Pandey A).

THE CLINICAL TRIALS REGISTRY–INDIA

Shortly after the launch, the WHO's International Clinical Trials Registry Platform (WHO ICTRP; http://www.who.int/ictrp) designated the CTRI as a primary register in its network of registers thus ensuring that data regarding trials registered in the CTRI will be displayed in the WHO ICTRP search portal.(www.icmje.org)Currently, there are3 other primary registers in the WHO ICTRP network: The Australian New Zealand Clinical Trials Registry; the Chinese Clinical Trials Register (launched on 25 July 2007) and the International Standard Randomized Controlled Trial Number Register. Although not a primary register, data from ClinicalTrials.gov will also be included in the WHO search portal. As a WHO primary register all trials that are fully registered in the CTRI will also meet the registration requirements of the International Committee of Medical Journal Editors (ICMJE), which recently supported the efforts of WHO to provide a one-stop search portal for those seeking information about clinical trials. This endorsement by the ICMJE of the WHO registry platform is important since their policy, initiated in 2004, requires prospective registration and full disclosure of all 20 items in the WHO Trial Registration Data Set (Table I) before enrolment of the first participant, as a mandatory prerequisite for the trial's results to be considered for publication by many major international journals. The CTRI will accept registration from individual registrants.(www.icmje.org)

Need of a clinical trials registry:

The need of a clinical trials registry is to provide transparency & accountability,

easy access to clinical trials, made the results (whether +ve or –ve) available to the public & the participating volunteers, prevent occurring of same trials at two different sites strengthen the validity and value of the scientific evidence base.(www.cdsco.nic.in/clinical_trial)

Material & methods:

Material (Tools):

Data collection:-in the data collection some parameters were covered from the ctri data seat of 2011 i.e.

1. ctri no
2. registered on
3. study design
4. title
5. therapeutic area
6. sponsor
7. type of funding
8. no. of sites
9. intervention
10. sample size
11. phase
12. status

Method:-The data collections are done with the help of internet and data was entered from the website www.ctri.nic.in

Sponsor type: sponsor in clinical trials were industry 340(45%),institute 265(35%), other 75(10%) government 41(6%), biotech 20(3%), cro 8(1%)

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Table 1- Sponsor Type

SPONSOR TYPE	NUMBER OF TRIALS
INDUSTRY	340
INSTITUTE	265
OTHER	75
GOVERNMENT	41
BIOTECH	20
CRO	8

Table 2-Type of pharmaceutical industry

TYPE OF PHARMACEUTICAL INDUSTRY	NO.
GLOBAL COMPANIES	186
INDIAN COMPANIES	154

Table 3- Phase of clinical trials

PHASE	NO.
1	19
2	59
3	162
4	72
N/A	46

Table 4- STATUS

STATUS	NO.
Completed	269
Open to Recruitment	39
Not Yet Recruiting	10
Other (Terminated)	11
not-Completed	8

Table 5- STUDY DESIGN

STUDY DESIGN	NO.
Randomized, Parallel Group Trial	226
Single Arm Trial	65
Other	35
Non-randomized, Multiple Arm Trial	12

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Table 6- Therapeutic Area

THERAPEUTIC AREA	NO.
AIDS	5
Dermal	30
NEURO	32
CANCER	60
OPTHALMIC	8
RESPIRETORY	25
DIEBITIES	50
ORTHO	18

Table 7- Therapeutic Area

THERAPEUTIC AREA	NO.
G.I.T.	15
Dermal	11
NEURO	32
CANCER	22
Cardio vascular	20
RESPIRETORY	20
DIABITES	12
ORTHO	18

Table 8- Phase

PHASE	NO.
1	16
2	57
3	51
4	56
N/A	118

Table 9- Status Of Trials

STATUS	NO.
Completed	152
Open to Recruitment	88
Not Yet Recruiting	24

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Table 10-Study Design

STUDY DESIGN	NO.
Randomized, Parallel Group Trial	186
Single Arm Trial	36
Other	35
Non-randomized, Multiple Arm Trial	11

Table 11- Therapeutic Areas

THERAPEUTIC AREA	NO.
AIDS	1
Dermal	2
NEURO	2
CANCER	2
ULCER	3
RESPIRETORY	2
CARDIO	2

Table 12- Study Design

STUDY DESIGN	NO.
Randomized, Parallel Group Trial	15
Single Arm Trial	3
Other	1
Non-randomized, Multiple Arm Trial	1

Table 13-Status

STATUS	NO.
Completed	18
Open to Recruitment	1
N.A.	1

Table 14- Phase

PHASE	NO
1	4
2	5
3	8
4	6
N/A	1

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Table 15- Therapeutic Area

THERAPEUTIC AREA	NO.
Dermal	12
NEURO	8
CANCER	2
OPTHALMIC	4
RESPIRETORY	10
DIEBITIES	6
ORTHO	7
Dental	4

Table 16- Phase

PHASE	NO.
1	3
2	11
3	5
4	11
N/A	48

Table 17-Study Design

STUDY DESIGN	NO.
Randomized, Parallel Group,Trial	41
Single Arm Trial	14
Other	16
Non-randomized, Multiple Arm Trial	3

Table 18- Status

STATUS	NO.
Completed	49
Open to Recruitment	18
Not Yet Recruiting	7
Other (Terminated)	1
not-Completed	2

Table 19-Therapeutic Area

THERAPEUTIC AREA	NO.
CARDIO VASCULAR	1
Dermal	1
NEURO	1
RESPIRETORY	1
DIABETES	1
HYPER-LIPIDMIA	1

Table 20- Study Design

STUDY DESIGN	NO.
Randomized, Parallel Group,Trial	4
Single Arm Trial	1
Other	3

Table 21- Status

STATUS	NO.
Completed	6
Open to Recruitment	1
Not Yet Recruiting	1

Table 22- Phase

PHASE	NO.
3	5
N/A	3

Table 23- Therapeutic Area

THERAPEUTIC AREA	NO.
AIDS	1
DERMAL	5
NEURO	5
CANCER	3
OPTHALMIC	4
RESPIRETORY	4
DIABETES	6
PREGNANCY	3

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Table 24-Phase

PHASE	NO.
2	12
3	9
4	10
N/A	11

Table 25- Study Design

STUDY DESIGN	NO.
Randomized, Parallel Group Trial	35
Single Arm Trial	3
Other	3
Non-randomized, Multiple Arm Trial	1

Table 26- Status

STATUS	NO.
Completed	7
Open to Recruitment	17
Not Yet Recruiting	5
Other (Terminated)	2

Result:

In the project the result which are obtain was that major sponsor involve in the clinical trials are pharmaceutical industry mainly global company are maximum 55% in comparison of Indian pharmaceutical company other sponsor are academics, research institute government or privet hospitals, biotech company, government funding agencies and some others as cosmetics company medical device manufacturing company are involve. In case of pharmaceutical industries

Sponsor type in global company which are registered are maximum then Indian company

The no of clinical trial registered status complete are more than open to recruitment and some are which are not yet recruiting or terminated. Maximum trials of industry were in 3 and 4 but some are in phase 1 & 2 also. Major therapeutic areas are cancer diabetes neuro disorder, ortho, dermal & dental problem on which maximum trials are conducted.

Conclusion:

It was found in the work, that trials were sponsored by pharmaceutical industry, academic research institute, hospitals, government funding agencies, Biopharmaceutical Company other industry and self-funding, CRO but maximum trials are sponsored by global pharmaceutical industry then Indian pharmaceutical company. Clinical trial registered on ctri web site in 2011 in phase 1, phase 2, phase 3, phase 4, and some are not applicable but maximum trials are in phase 3 and phase 4 and not applicable few trials are in phase 2 and phase 1.

Study designs for clinical trials are mainly randomised, single arm, non-randomised and other but maximum trials are randomised parallel group.

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