CLINICAL TRIALS INDUSTRY IN INDIA: A Systematic Review

Swadhin Mondal
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Swadhin Mondal
Dinesh Abrol

ISID
Institute for Studies in Industrial Development
4, Institutional Area, Vasant Kunj Phase II, New Delhi - 110 070
Phone: +91 11 2676 4600 / 2689 1111*; Fax:* +91 11 2612 2448
E-mail: info@isid.org.in; *Website:* http://isid.org.in

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CLINICAL TRIALS INDUSTRY IN INDIA: A Systematic Review

Swadhin Mondal[*] *& Dinesh Abrol*[**]

[***Abstract:*** *This study shows that many global clinical trials organisations have relocated their clinical trial (CT) research units to India. The Indian CT industry has become one of the most cost-efficient destinations in the world. It is growing fast and has emerged as a popular destination for global clinical trials. However, the process followed by the pharmaceutical companies for conducting CTs has raised some critical issues. First of all, the Indian CT industry has not been able to ensure rapid technological transformation and the building of capabilities required for development of new drugs despite receiving help from the internationally acclaimed CROs in India. Although the CT industry has been able to take advantage of financial gain from the global clinical trial activities conducted in India, capability-building for development of new drug is not occurring in a manner that can help the country tackle public health challenges. Second, over the past few years, the CT industry has come to face regulatory challenges. It is confronted with some serious ethical issues on account of its conduct with regard to containing deaths. Between 2010 and 2012, around 2500 people died because of adverse effects of drugs under trial. But, only a few participants received compensation in case of injury sustained or death. The authors of this paper argue that the Government of India needs to establish a policy framework for the Indian CT industry to provide for easy access to affordable drugs developed through adaptive clinical trials and create a regulatory environment capable of ensuring the conduct of clinical trials without violation of humanitarian ethics and other social norms.*]

Keywords: Economics, Clinical Research, Ethics, Regulation, India
JEL Classification: I18-Government Policy, Regulation, Public Health

1. Introduction

In 2005, India became fully compliant to TRIPS. Since then the policymakers have been trying to make changes in the policy framework and regulatory environment in order to promote clinical trials in India. These changes are known to have encouraged the international Clinical Research Organisations (CROs) to expand their clinical research

[*] The author is an Assistant Professor at ISID, New Delhi.
[**] The author is a Professor at ISID, New Delhi.

programmes in India. India hosts nearly a fifth of all global clinical trials with a huge potential for financial and scientific gains (*The Lancet*, 2007; Bavdekar, 2008). CROs are taking advantage of getting large pool of patients, highly skilled medical investigators, lower drug development costs and timely completion of clinical trials in India (Kaur, 2006; Bhat, 2004; Singh, 2008).

Recently, pharmaceutical companies that are involved in clinical trials are being trailed by a growing concern over the clinical research ethics followed in India. Global pharmaceutical companies are outsourcing their projects to India for several reasons: enhancing profit, cutting the cost of drug development and speeding regulatory approval, and, fostering a less hostile environment among the world's impoverished ill. Clinical trials are more than 50 *per cent* cheaper in India compared to developed countries (Jayaraman, 2004; Singh. 2008; Bigoniya *et al*., 2010; Bajpai, 2013).

The reasons for low cost of drug development are cheap human resource, low recruitment cost and lower rate of compensation for any injury sustained or death during the research process. In fact, CROs even recruit patients without any formal assurance of compensation because a large proportion of participants in India are illiterate and lured into trials by offers of free healthcare and financial inducements. However, they are often unaware of the benefits and risks of taking part in a trial, and many may not even be able to distinguish between treatment and research. Also, the concept of informed consent before enrolling in a trial is not very clear.

An important ethical question being raised in the debate is: Will the new drugs tested in India actually be of benefit to the local patients, and will these drugs be made available to them at reasonable prices? With 25 *per cent* of the Indian population living below poverty line, it is unlikely that these drugs will be "affordable". Another important issue in this context is compensation for clinical trial related injury or death. Over the past five years, more than two thousand people have died because of clinical drug trials and amongst them, only a few have received compensation (*The Economic Times*, 2013).

The Government of India continues to invite multinational companies for conducting clinical trials in order to attract foreign investments for financial and technological gains in this sector. The central ideology of clinical research is that it should be of wider benefit to society. There cannot be two societies—one that takes risks whilst the other reaps the benefits. Will India be able to bridge the gap between two societies, i.e., minimise risk and maximise benefit? Is the clinical trial practice of benefit to public health in general and to the pharmaceutical industry in particular? This study addresses the issues of benefit maximization and risk minimization by reviewing the progress of clinical trials industry in a systematic way. It has attempted to generate an evidence-based assessment to help policymakers shape future policies for development of the clinical trials industry. It also makes an attempt to direct the attention of the Indian policy-making apparatus to the legal and ethical questions being raised by researchers and civil society groups on the process of conducting trials involving human subjects.

2. Materials and Methods

In this study, we have used the following secondary level data sources: Clinical Trials.gov and CTRI (Clinical Trials Registry – India) dataset. ClinicalTrials.gov is a registry and results database of publicly and privately supported clinical studies of human participants conducted across the world; it is maintained by the National Institutes of Health (NIH), USA. This service currently lists all type of intervention (Drug and biological, behavioural, surgical as well as medical devices) and observational studies. Currently, 191,171 studies have been registered with locations in all 50 states in the US and in 190 countries. We have collected disease-wise clinical trial studies for 7 countries and analysed their data.

The other source, CTRI dataset, is regularly published by the Indian Council of Medical Research (ICMR). The Drug Controller General of India (DCGI) has made trial registration with the CTRI mandatory before enrolment of first participant for any kind of intervention such as drugs, surgical procedures, preventive measures, lifestyle modifications, devices, educational or behavioural treatment, rehabilitation strategies as well as trials conducted in the purview of the Department of AYUSH.

We also review the report and analyse the FDI factsheet data which is regularly published by the Department of Industrial Policy and Promotion (DIPP) under Ministry of Commerce and Industry, Government of India. DIPP regularly publishes sector-wise as well as country-wise FDI equity inflows of all manufacturing and service sector industries in India. We have separated the total FDI inflow for drug and pharmaceuticals, hospitals and diagnostic centres, and, medical and surgical appliances. We estimate the contribution of these drugs, pharmaceutical and healthcare industries to the total FDI inflows into the country over the past decade.

This study also describes the relative position of the country in terms of cost-effectiveness, availability of native patients, availability of medical professionals and technicians, and regulation. We have used the A.T. Kearney testimony data (A.T. Kearney: Wang, 2005) to reanalyse and represent it by using different statistical tools. Apart from the above-given data sources, we have collected evidence from various clinical study reports.

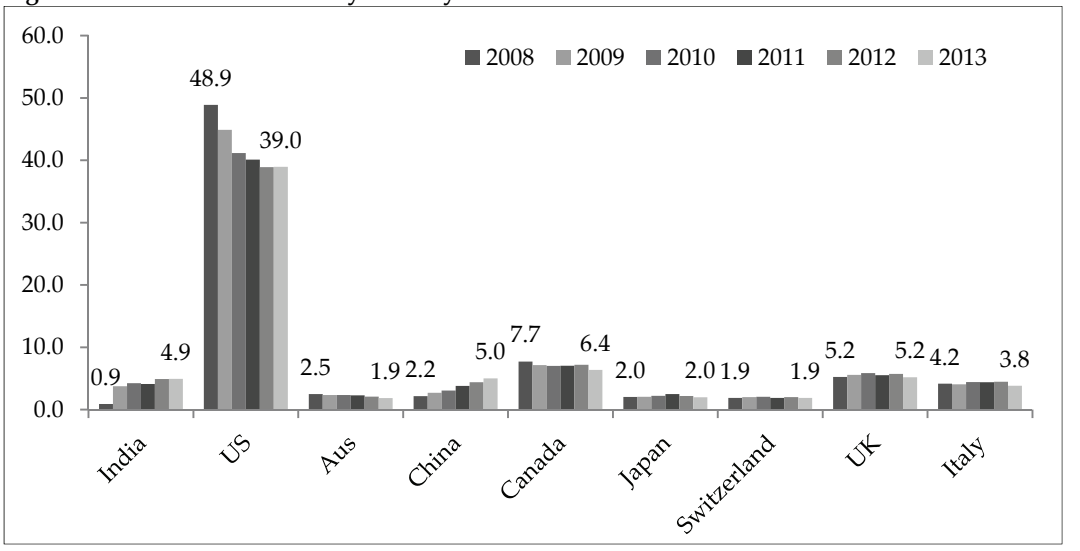
3. Results

3.1 Why and How India Became a Favourable Destination for Clinical Trials?

Global share of CTs in India grew from 0.9 *per cent* in 2008 to 5 *per cent* in 2013 (*Figure 1).* Like India, China also experienced the same growth path. On the other side, the share of CT activities in the United States and other developed countries is declining. Global pharmaceutical companies are relocating their clinical research operations to India and other developing countries because of the various advantages offered by them (developing countries): large patient pool, low cost of doing business, availability of

expert researchers, and, huge market opportunities. The pharmaceutical companies can access approximately three billion potential new clinical trial volunteers in this location (BRIC CT Report, 2011). Analysis of the empirical observations shows that various factors are taken into account prior to the beginning of any clinical trial, for example, the location of institutional partner, infrastructure, internal facilities and prospect of future product launches. Cost saving (35 to 60 *per cent*) and emerging market are also important factors for conducting clinical trials. Revenue implications are equally attractive. Timeline including recruitment process, timely completion of trials that translates into faster drug launch, a faster return on investment, a potential edge over the competitor and large patient pools are also very encouraging factors for conducting clinical trials in India.

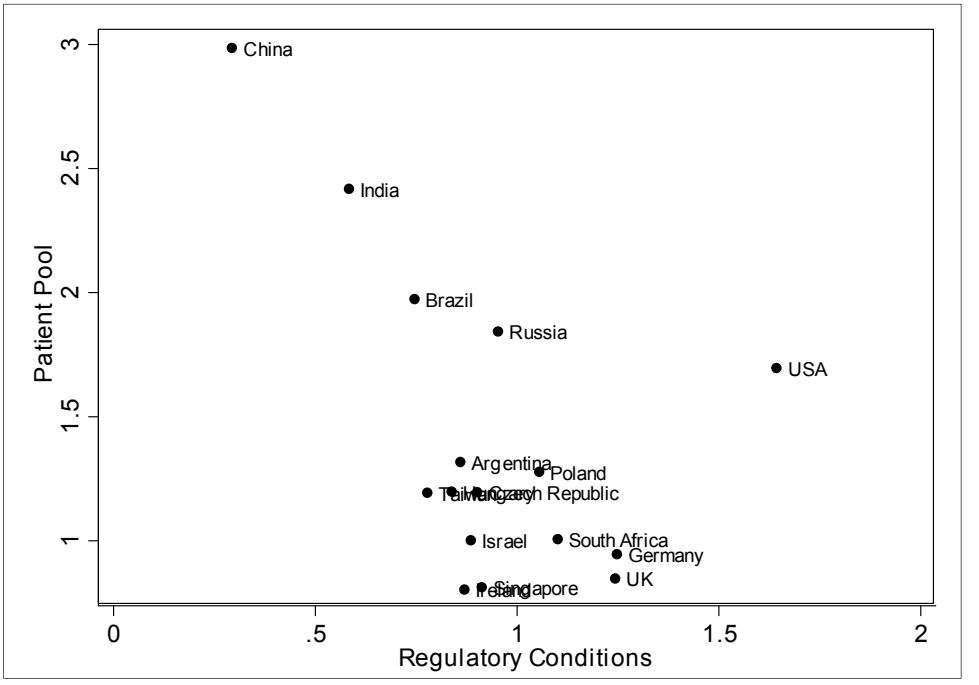
Figure 1: Global *S*hare of CTs by *C*ountry



Source: Clinical Trials.gov

India is home to more than 17 *per cent* of world population and around one-fifth of the global burden of disease (Bosworth and Collin, 2008; Haub, 2012; Horton, 2013). The country also has the greatest burden of maternal, newborn and child deaths in the world (WHO, 2013). India is facing dual burden of communicable and non-communicable diseases (Government of India, 2005). According to 2012 WHO report, non-communicable diseases (NCD) are responsible for two-thirds of the total morbidity burden and about 53 *per cent* of total deaths in India. Also, due to financial constraints, the sick and the suffering poor cannot undergo medical treatment. As a result, India offers these native patients for CTs. McKinsey estimated that India accounted for one of the highest scores in terms of offering patients for clinical trials compared to the other favourable nations. According to their estimates, India stood second (after China) in terms of patient pool for CTs (*Figure 2*).

Figure 2: Relative Position of the Country in terms of Patient Pool and Regulatory Conditions

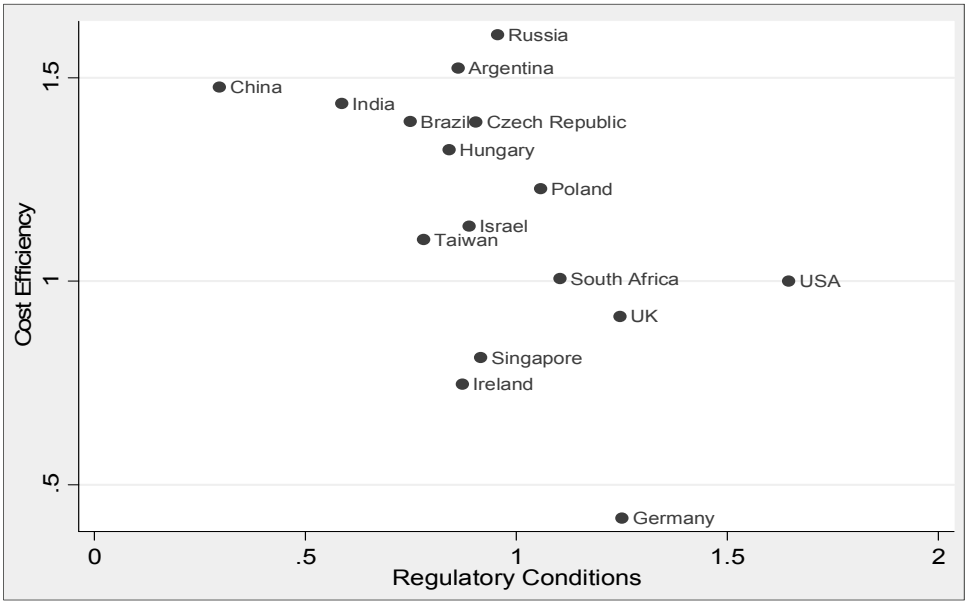


Source: Authors calculation from A.T. Kearney analysis.

Another important factor that makes India an attractive destination is lower unit cost for conducting trials. India ranks fourth after Russia, Argentina and China respectively in terms of clinical cost-minimization (*Figure 3*). Cost for clinical labour (clinical professionals, nurses, etc.) is reasonably low compared to the other destinations. It has been seen that if the overall clinical trial cost in USA is 1unit, then in India it would as low as 0.11 units (A.T. Kearney: Wang, 2005). We also observed that in case of the expenditure incurred by CROs, India's index value is lowest (0.11) compared to other countries.

The relevant expertise for conducting CTs depends on certain other factors: (i) presence of top 12 CROs in the country, the availability of local supply market, and, the number of CTs conducted in the country which indicates the level of experience. Another important indicator of expertise is the availability of relevant skilled professionals**,** which includes the availability (number) of physicians, nurses or clinical research assistants, number of clinical practitioners holding first rank in mathematics or computer science or engineering disciplines, and availability of a diverse talent pool. The availability of physicians can be measured through suitable proxies to doctors/physicians for CTs. Similarly, first rank holders in mathematics or computer science or engineering disciplines were measured through proxies to statisticians in the country.

Figure 3: Relative Position of the Countries in terms of Patient Pool and Cost-efficiency



Source: Authors calculation from A.T. Kearney analysis.

Further, our analysis shows that India, too, can offer a large number of skilled professionals for CTs. India ranks fourth in position after the US, China and Russia in providing physicians and nurses as well as in terms of the presence of CROs in the country (*Table 1*). India only lags behind in providing statisticians for the study of clinical trials.

Table 1: Availability of Relevant Skilled Professionals

	CRO presence	*Volume of clinical trials*	*Organisation Expertise/Experience*	*Relevant killed labour pool*
USA	5.00	4.81	5.887	2.587
Argentina	2.92	1.91	2.898	0.292
Taiwan	2.5	1.57	2.445	0.318
Singapore	2.5	1.36	2.316	0.319
South Africa	3.33	1.87	3.122	0.325
Ireland	0.83	1.07	1.141	0.348
Israel	2.5	1.74	2.541	0.357
Czech Republic	2.92	1.61	2.717	0.404
Hungary	2.92	1.68	2.759	0.42
Poland	4.17	2.18	3.807	0.543
UK	4.17	2.77	4.163	0.768
Brazil	1.67	2.05	2.227	0.793
Germany	4.58	2.79	4.424	1.251
India	3.75	0.86	2.766	1.328
Russia	2.08	1.97	2.432	1.791
China	2.92	0.86	2.266	3.049

Source: Clinicaltrials.gov; Physician Index Annual; WHO/EIP/HRH; NSF; A.T. Kearney analysis.

Therefore, on the basis of cost-effectiveness, availability of patient pool, availability of expert clinical professionals, and the presence of CROs, India has become a popular destination for clinical trials. However, many researchers and civil societies raise concern over the process of trials in India because most of the foreign pharmaceutical companies enter the clinical research market in India through mergers and acquisitions. So, in the next section, we discuss how foreign companies invest their resources and get involved in clinical research in India and its effect on the Indian pharmaceutical industry.

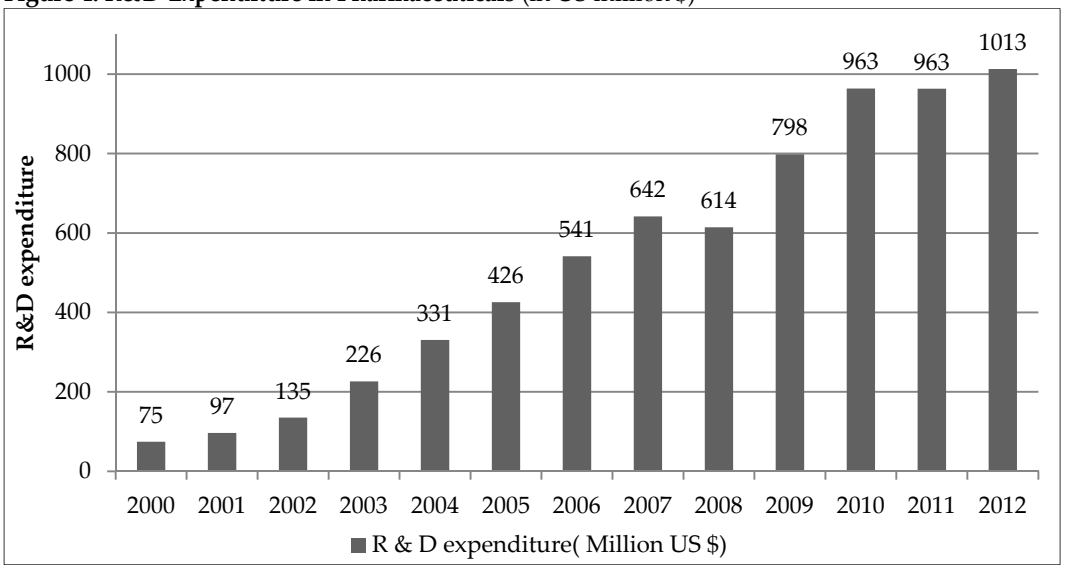
3.2 Effect of Foreign Investment in Clinical Trials on the Indian Pharmaceutical Industry

Foreign pharmaceutical companies can set up their businesses in India in two ways: (i) commence operations as an incorporated entity by forming a company under the Companies Act 1956 through joint ventures or wholly owned subsidiaries, and (ii) as an unincorporated entity through liaison office or project office. Such offices can undertake activities permitted under the Foreign Exchange Management (Establishment in India of Branch or Office or Other Place of Business) Regulations, 2000.

In pharmaceutical sector, foreign companies can invest and conduct clinical research through two alternate routes: (i) Automotive route – where 100 *per cent* FDI is allowed without government intervention. FDI through this route does not require any prior approval from the government or RBI (Reserve Bank of India). The investors are only required to notify the regional office concern of RBI within 30 days of receipt of inward remittance and file the required documents with that office within 30 days of issue of share to foreign investors. (ii) Government route – FDI in activities not covered under automotive route requires prior approval from the government and is considered by the foreign investment promotion board (FIPB) under Ministry of Finance.

However, India allowed 100 *per cent* FDI in clinical trials, which attracted many foreign companies to relocate to India for CTs. Therefore, R&D expenditure in pharmaceutical industries increased from 75 million US$ in 2000 to 1013 million US$ in 2012 (*Figure 4*). Clinical trials industry also experienced a significantly higher rate of growth (44 *per cent*) between 2003 and 2009 (*Table 2*). Many foreign companies also spent on R&D for clinical trials following collaboration with Indian companies. The clinical trials industry has gained substantial capital through CTs which can be invested in building infrastructure in this sector. Government run hospitals, too, can use this capital to better equip themselves with relevant infrastructure.

Figure 4: R&D Expenditure in Pharmaceuticals (in US million $)



Source: Prowess CMIE database.

Table 2: Analysis of Pharmaceutical FDI: Number of Projects by Activity

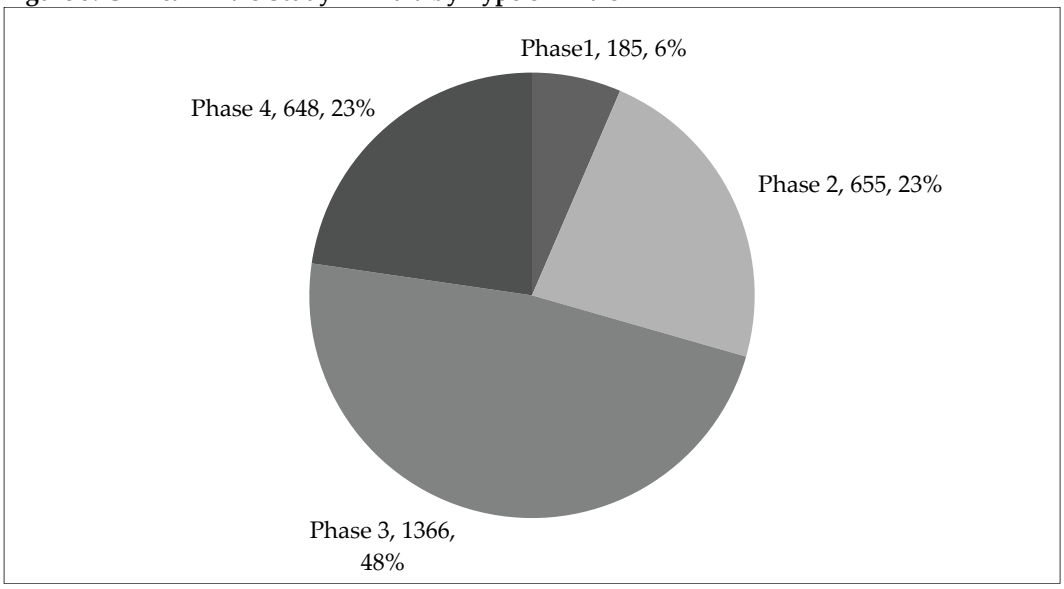
Business Activities	*2003*	*2004*	*2005*	*2006*	*2007*	*2008*	*2009*	*Total*	*Average annual Growth (%)*
Research and Development	2	4	10	5	8	5	2	36	44.5
Manufacturing	3	8	6	3	3	5		28	NA
Sales, Marketing and Support		2	2	3	1	1	1	10	NA
Design, Development and Testing		1	1		2	1		5	NA
Business service			1					1	NA
Headquarters				1				1	NA
Logistics, Distribution and Transportation					1			1	NA
Retail		1						1	NA
Overall Total	5	16	20	12	15	12	3	83	NA

Source: Abrol, 2014.

3.3 Clinical Trials and Technological Spill-over Effect on the Indian Pharmaceutical Industry

There is an ongoing debate on whether India has gained from scientific and technological developments in the pharmaceutical industry. We have tried to understand the nature of clinical trials and technological spill-over in India. India hosts 5 *per cent* of global clinical trials and out of these, 60 *per cent* trials are Phase III trials[1], while only 5 *per cent* trials are Phase I trials[2] (*Figure 5*). Phase I trials are allowed only when a country that originally developed the drug or new chemical entity first tests the drugs on its own populations and then outsources clinical trials to other countries. This is so because Phase I trials have more risk of adverse reaction.

Figure 5: Clinical Trials Study in India by Type of Trials



Source: CTRI, 2013.

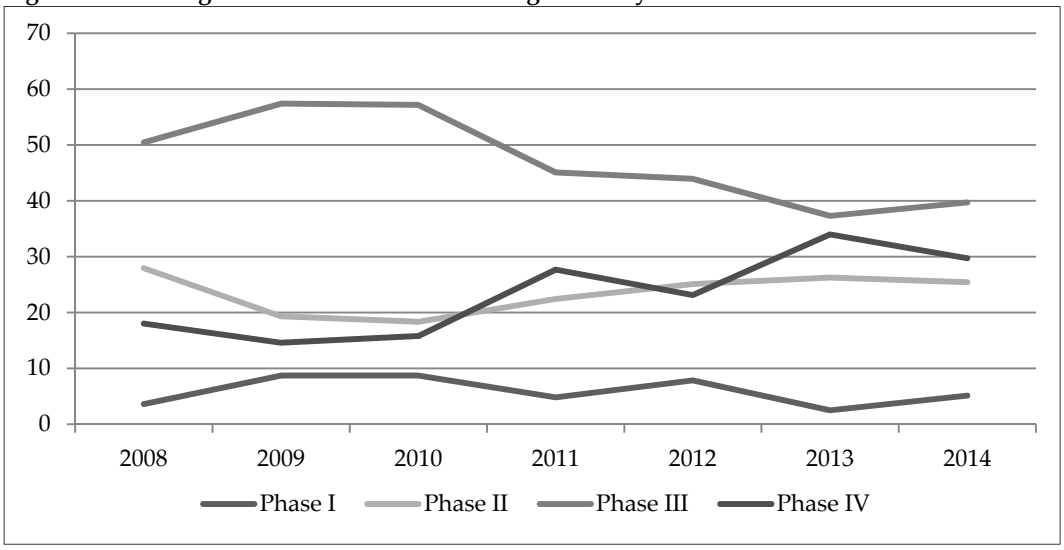
So, while Phase I trials are conducted to test new drugs and new forms of treatment but only in the country where the drug is originally developed, Phase III trials test the efficacy and therapeutic dose of the drug on a much larger group of people. So, drug development technology is not involved here. *Figure 6* shows that the Indian clinical trials industry has been mostly concentrating on Phase III trials since 2008. Very few firms undertake Phase I trials. This means that the technological spill-over effect has

[1] Phase III trial determines the efficacy and therapeutic dose of the drug on a diverse group of at least 1000 to 2000 patients.

[2] Phase I trial determines whether the new drug is safe to be tested on humans; it is tested on a small group of 20 to 100 patients. Since Phase I trial has huge risk of adverse reaction, it is only allowed to be carried out in the country that originally developed the drug.

not been felt in India. However, this may have long-term diffusion effect on the Indian pharmaceutical industry.

Figure 6: Percentage of New Clinical Studies Registered by Phase



Balancing Clinical Trials and Public Health Interest

There is another debate on whether the pharmaceutical companies conducting clinical trials in India exploit the poor and vulnerable population of the country. In order to address the foregoing issue, in this section we will analyse whether and how the Indian healthcare sector is benefiting from clinical trials.

India is not only facing the double burden of communicable and non-communicable diseases, but is also suffering in terms of loss due to disability-adjusted life year (DALY) (*Table 3*). India accounts for 21 *per cent* of the global burden of disease. The burden of communicable diseases—e.g., TB, Malaria, HIV, and, waterborne and vector-borne diseases—in the country is very high, especially among children and mothers, which poses serious health problems. Similarly, the burden of non-communicable diseases like cancer, diabetes, mental health disorders, and cardiovascular disease (CVD) is also high, and is the leading cause of functional impairment and death. However, knowing that the country accounts for a high percentage of burden of disease, the Indian public healthcare system is very weak. The biggest challenges facing the public healthcare system are inaccessibility to and unavailability of medicines, lack of advanced laboratory services and equipment, and, low level of investment in healthcare.

However, the issue is that clinical research organisations in India, mostly concentrate on trials in non-communicable diseases (*Figure 7*), which though is of great relevance to the country, yet leaves much that is undone. That is, while development of drugs to treat non-communicable disease such as cancer, diabetes, CVD, chronic obstructive

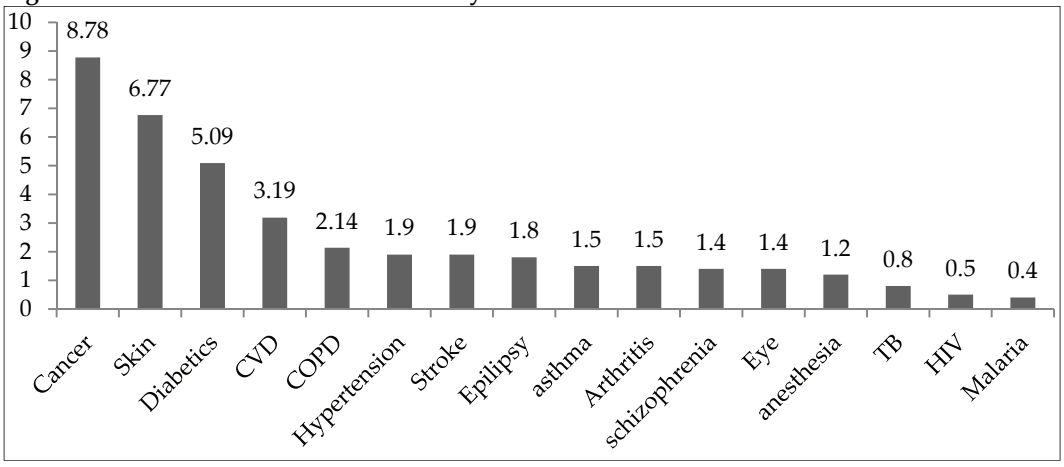
pulmonary diseases (COPD), etc., are of relevance to the country, there is an equally important need to develop drugs for communicable diseases in order to maintain a fair balance. Also, 7 *per cent* of the pharmaceutical companies are involved in developing drugs for skin conditions, including cosmetic products, which, though essential, is not an area of critical need.

Table 3: Health Conditions and Disability Adjusted Life Years Lost in India

Disease/Health Conditions	*DALYs Lost*	*Share in the total Burden of Disease*
Communicable diseases, Maternal and Prenatal conditions		
TB	7577	2.8
HIV	5611	2.1
Diarrheal	22005	8.2
Malaria and Vector-borne	4200	1.6
Leprosy	208	0.1
Childhood	14463	5.4
Otitis Media	475	0.1
Maternal and Pre-natal conditions	31207	11.6
Others	49517	18.4
Non-communicable		
Cancer	8992	3.4
Diabetics	1981	12.1
Mental	22944	8.5
Blindness	3699	1.4
Cardiovascular	26932	10.0
COPD and Asthma	4061	1.5
Oral Disease	1247	0.5
Injury	45032	16.7
Others	68319	25.4

Source: WHO, Global Burden of Disease 2010.

Figure 7: Disease-wise Clinical Trials Study in India



Source: CTRI, 2013.

CTRI data shows that between 2007 and 2009, out of 116 foreign companies, 110 concentrated on non-communicable diseases (Abrol *et al*., 2011). This was so because of a high demand for NCD medicines in India and other developed countries. Further, Indian pharmaceutical companies, too, mostly concentrated on manufacturing drugs to treat diabetes, cancer, metabolic disease, hepatitis, cardiovascular disease, influenza, infectious disease, inflammatory disease, allergy, and respiratory disease (*Table A1*). Resultantly, the cost of NCD medicines placed considerable burden on household income. This result has wider implications for access to medicines in India, that is, if all of these drugs are developed and marketed at reasonable prices in India, then the country can expect to gain benefits.

In view of the above, it can be said that India's healthcare sector needs radical changes. However, this is not to say that India has not benefited from clinical trials. Most of the trials conducted in India are Phase III trials that involve testing of already "well-tested" drugs. Hence, not only is the risk minimal, but also participants gain access to new treatments before they are widely available.

Having said this, India has yet to cover a lot of ground. Clinical trials are the need of the hour because they allow access to better medicines in the future, thus resulting in significant medical advances. Also, ensuring proper compliance with regulatory norms will ensure that India continues to reap the benefits of clinical trials. But, it is of utmost importance that for the purpose of research the poor and vulnerable population is protected against exploitation.

3.4 Legal and Ethical Issues in Recent Clinical Research

It is true that India can provide a huge patient pool for CTs. However, the process of recruiting patients for CTs is questionable. Many a time, drug manufacturing companies prefer to recruit patients through local recruiters/agencies. A case study undertaken by Dateline shows that a pharmaceutical company paid $12 per patient for voluntary involvement in clinical trials (NBC, 2012). Most of the patients are very poor and their average earning per day is 50 cent only (Hansen, 2012). Also, due to their economically poor background and lack of education, the patients are not aware of their involvement and the possible risk of injuries. Many a time they ignore the side effects like feeling weak or having body ache only because they are "monetarily compensated" for it. The payment works as an inducement. In fact, the patient can earn up to $400 depending on the length of study and this payment outstrips their general income (Dateline NBC, 2012).

The unethical practice of financial inducement—though seemingly an incentive—leads to enrolment of volunteers in more than one study at a time. This not only puts their lives in danger, but can also skew the accuracy of test results that pharmaceutical companies and regulators rely on to judge a drug's safety. Until now, many people have fallen sick and several deaths have occurred. The Indian government reports that across the country

more than 2500 people have died in clinical trials since 2005, many participating in studies for Western pharmaceutical companies. But it is unclear that how many people died or were injured due to their involvement in clinical trials because in many cases there are no proper systems of documentation of death registration.

According to an affidavit filed by the Health Ministry in the Supreme Court in response to a petition by healthcare NGOs, there were 80 deaths due to clinical trials between January 2005 and June 2012. Further, between July 2012 and August 2013, nine more such deaths were reported (Biswas, 2013). However, compensation was paid only in 82 cases. The Ministry of Health and Family Welfare also acknowledged that 2,644 people died during clinical trials of 475 new drugs between 2005 and 2012; and, 11,972 due to serious adverse events (excluding death) and out of which, 506 were said to have been caused by clinical trials (Biswas, 2013).

There are several controversies regarding the number of deaths and injuries in CTs because different sources reported different numbers. According to the DCGI, there were 2,031 deaths during clinical trials between 2008 and 2011. Out of these, 668 had taken place in 2010, of which 22 were directly related to clinical trials. In these cases, the companies conducting the trials had paid varying compensations, but the DCGI was not aware of the amounts (Jain, 2013).

Narayan (2013) has reported that since 2005, more than 2,800 patients have died during CTs and out of these, only 89 or about 3 *per cent* of the deaths occurred mainly due to the effects of the drugs under trial. Of these, 70 victims received compensation ranging from ₹1,80,000 ($3,000) to ₹4,20,000 ($7,000). A study by *The Tribune* (2013) also reported that 666 deaths occurred alone in 2010; of these, 22 cases were attributed to deaths on account of clinical trials and the rest were attributed to past medical history of the trial participants. In 2011, this number reduced to 438, of which only 22 victims were paid compensation on account of clinical trials. In 2012, 436 deaths were recorded during clinical trials but compensation is yet to be paid with the government still ascertaining the number of deaths that have occurred due to trials (*The Tribune*, 2013).

Table 4: Number of Deaths, Injuries and Compensation Received by the Kin
(as reported by various sources)

Sources	*Year*	*Number of deaths*	*Number of injuries*	*Location*	*Compensation received*
Swasthya Adhikar Manch	2005–2012	89		All India	82
Ministry of health and family welfare	2005–2012	2,644	11,952	All India	NA
DCGI	2008–2011	2,031	NA	All India	NA
DCGI	2010	668	NA	All India	NA
Narayan (2013)	2005–12	2,800	89	All India	70
Bhatnagar (2013)	2004	14	NA	Bhopal, India	0
Bhatnagar (2013)	2005–10	32	NA	Indore, India	0

During clinical trial, a patient can die because of several reasons: life threatening diseases like cancer, cardio-vascular diseases like heart failure/stroke and other serious diseases that the participant may have be suffering from in the past. Death can also occur due to adverse effects of the trials. However, there is no standard protocol for post-mortem mechanism to investigate it (Biswas, 2013). The pharmaceutical companies conduct investigations only to ascertain the cause of death: whether it was the result of a clinical trial or simply because of a pre-existing disease. Compensation is to be given only if a death is said to have been caused due to clinical trial. Also, the amount of compensation varies across different companies. But now, the government is in the process of fixing a minimum compensation amount in case of death or injuries sustained during the course of the trials. The Ministry of Health and Family Welfare has authorised DGCI to determine the amount of compensation to be given in case of death or injuries sustained during trials (*The Tribune*, 2013).

Another unethical practice is the simultaneous conduct of Phase II and Phase III trials by CROs. Clinical trial laws were amended in 2005 to help familiarize India with international clinical research activities as well as allow for Phase II and Phase III trials to be conducted concurrently. Before 2005, Phase II and Phase III trials were allowed with a phase lag—that is, after their gross safety aspects were somewhat known abroad (Srinivasan, 2013). These concurrent clinical trials may have a serious adverse effect on the trial participants, for instance, causing disability or permanent damage or death.

3.5 Government Regulation on CTs

Over the past few years, pharmaceutical industry has experienced a tremendous growth and government has allowed 100 *per cent* FDI with limited regulation. Indian pharmaceutical sector exports 32 per cent of drugs, of which 90 per cent is generic and marketing growth is about 20 per cent per annum (Sharma *et al*., 2008). India is able to produce low cost generic drugs and the Indian drug makers' account for 40 per cent of generic drug imports to the US (based on volume) and 39 per cent of the total generic drug approvals by the Food and Drug Administration (FDA), an agency of the US federal government (Silverman, 2014). However, the process of drug development in India is rather controversial (Dieppe *et al*., 2004).

The issue of unethical practices in clinical trials is placed at the top of the list. This controversy arises because of complicated regulatory policies and contradictory norms implemented by government agencies. As a result, many people have died or are severely injured due to clinical trials but have not been compensated properly. Only very few have received compensation and the amount of compensation is also very low. For example, in 2004, doctors at Bhopal Memorial Hospital and Research Centre recruited Bhopal gas tragedy survivors for clinical trials without taking informed consent (Bhatnagar, 2013) and it is reported that 14 participants died during the course of the trials. Similarly between 2005 and 2010, 32 people died at an Indore-based hospital because of clinical trials (Bhatnagar, 2013).

A pharmaceutical franchise company has reported that many of the clinical trials that are carried out in India do not meet international standards. Just how many people may have been killed or seriously harmed by clinical trials remains uncertain. The government has testified that between 2005 and 2012, around 2,644 people died during clinical trials for new drugs, of which 80 deaths were directly attributed to the items tested. A further 500 suffered serious adverse reactions (Buncombe, 2013).

Clinical trials are regulated by the government under the Drug and Cosmetics Act 1945, which is amended from time to time. Civil societies and many social activists complained to the court that Indian citizens are being used as guinea pigs during the course of drug development. Accordingly, the Supreme Court has ordered the government to make audio-video recording of informed consent mandatory for companies intending to conduct clinical trials. It also mandates them to inform patients about the possible adverse health effects of the drug under trial. According to the new guidelines, a manufacturer, before requesting an individual to participate in clinical trial of a new drug, must inform the individual of any reasonably foreseeable risks or discomforts as well as of the possible benefits.

For further regulation, the Department of Health and Family Welfare has appointed an expert committee for setting guidelines for CTs. The committee produced and published its report in July 2013. It suggested that clinical trials can only be carried out at accredited centres. Both the principal investigator of the trial and the ethics committee of the institute should be accredited. Only those trials conducted at such centres should be accepted by the Drugs Controller General of India (DCGI) (Ghooi, 2014). An informed consent from each participant is a prerequisite for a clinical trial. In circumstances where informed consent has to be obtained from special groups of people who have diminished capacity to protect their interests or give consent for themselves, the consent given by the guardian should be witnessed by an independent person who also has to sign the informed consent document. Audio-visual recording of the informed consent process should be undertaken and the documents preserved, adhering to the principles of confidentiality.

The audio-visual recording of informed consent process and other related documents should be safely preserved after the completion of the study for at least a period of 5 years (Government of India, 2014). If any adverse effect or serious adverse effect occurs during a clinical trial, the sponsor investigator should be responsible for providing medical treatment and care to the patient at his own cost and also provide proper compensation for disability or death of the participant.

Roy Chaudhury report (Ghooi, 2014) also recommended that the Central Drugs Standard Control Organisation (CDSCO) is responsible for providing written assurance to the pharmaceutical house or investigator seeking approval for a clinical trial that if all the papers needed for the review are complete, then a decision, either interim of full, will be given within three months. For all new chemical entities (NCEs) that are developed and

marketed in India, all trial phases (Phases I–IV) will have to be carried out in India. In case of NCEs developed outside India, which is of relevance to our population, it is presently not always necessary to carry out Phase I trials in our country, provided Phase I trials have either been done or are being done in the country of origin. All NCEs undergoing clinical trials in any country can also undergo parallel Phase II and Phase III trials in India, after testing for "safety" in Phase I trials. However, Phase I trials should have been done in the country of origin if the disease is prevalent there.

However, it is yet to be seen whether or not the new regulations will deter the clinical trials industry from continuing its operations in the long run. It has been seen that the number of clinical trial studies drastically reduced to 19 in 2013 as compared to 500 in 2011. The decision of many of the biopharmaceutical companies to stop operations and move to other destinations ultimately affects the drug development process. New regulations also incur additional cost, which may force domestic companies to go abroad for conducting trials. The Indian Society of Clinical Research reported that earlier, at the global level, the average time for approving a new drug for the purpose of sale was around six months. It has now increased to over three years. Many big pharmaceutical companies like Biocon are planning to move their clinical research to Malaysia, Singapore or other favourable destinations for trials. They mention that video recording of large trials involving 10000 patients or more will be extremely difficult.

4. Discussion

The rationale for relaxation of regulations is that the drugs will be made available post-trial. But there is no supporting international treaty or domestic legislation which can ensure the provision of this benefit. However, since policymakers believe that clinical tests can prove beneficial in many more ways, thus regulations are being relaxed with the aim to create an open environment for international research on drugs relevant to the host country. Claims are being made that the participating physicians get first-hand experience while experimenting with new drug as well as receive extensive training on it. Less equipped public hospitals can get funds and build up necessary infrastructure. Many trials conducted in government hospitals are, in fact, the last resort for poor patients (Srinivasan, 2004; Kumar, 2013). It is also argued that patients can receive benefits in view of the fact that in addition to getting free medicines, they will undergo focused and more frequent medical supervision during the trial (Kumar 2013). Many patients can't afford such treatment because of financial reasons but they can access it free of cost through clinical trials.

Of course, it is important to note that it is not just the multinational companies that are conducting clinical trials, but Indian firms, too, have started conducting trials. Indian firms not only focus on clinical trials for developing new drugs, but are also open to innovation for discovering new drugs. India offers huge patient pools to CROs because the country has a large urban population; also, the disease prevalence rate is too high.

India alone accounts for one-fifth of the global burden of disease. Since India has a large population divided into multiple ethnic groups, it is home to all types of diseases. Due to high level of poverty and low capacity to pay for healthcare, the country has a wide variety of treatments for the native population. The native people suffer from various diseases but do not seek treatment because of financial reasons. Also, since the government is unable to provide healthcare services to all of them, it leads to market failure. In such case, while India can offer these vulnerable populations for CTs, on the other side, CROs can offer drug or medical testing services under clinical trials at zero cost.

However, one should not forget that most of the big CROs are keen to relocate to India because clinical research is 60 per cent cheaper than in the US or UK. Russia, Argentina and China are also cost-efficient locations but India, in addition, can provide a large patient pool for trials. In India, CTs are inexpensive because labour and other professional costs are relatively low. Also, Patent law is now very flexible and favourable to drug producers. Foreign companies can collaborate with domestic firms and easily enter the Indian pharmaceutical industry. Collaboration with domestic companies also reduces the cost of drug testing because they can readily utilize Indian laboratories, hospitals and other infrastructure.

Another important factor is recruitment cost and time, which is also very low compared to other destinations. Many a time CROs recruit patients through local agencies to avoid legal and financial hassles. As most of the patients are very poor, illiterate and economically vulnerable, the recruitment agency or CROs can easily persuade them to sign the informed consent form without proper information—this ultimately reduces the recruitment cost as well as the time required to involve patients in trials. Poor people also do complaint because of for the monetary compensation that they receive for participating in trials. Another important reason for India becoming a favourable destination for CTs is the availability of skilled medical professionals. Apart from the US, China and Russia, India, too, provides a large pool of skilled labour for clinical research projects.

However, the clinical research industry in India is facing new challenges due to government's desire to "control and regulate" clinical trial operations. In the last few years, though a large number of participants have died and many are injured, only a few have received compensation. Civil societies have also raised some ethical concerns over the working of CTs, the recruitment process, the process of taking informed consent, etc. As mentioned earlier, the Supreme Court has mandated the audio-video recording of the informed consent process. Under this guideline, it is mandatory for the drug manufacturer to inform the volunteer of the possible risks or benefits of participating in a trial. However, even after the introduction of new guidelines, the pharmaceutical industry is facing severe crisis because a number of clauses are not clear, which has given rise to a lot of uncertainties. Many of the pharmaceutical companies have withdrawn their applications or suspended their trials prematurely or are planning to move to other

countries because they are not in a position to restore the entire video recording information. Regulations may have an adverse impact on the CT industry.

Another important issue that we need to discuss is how and to what level the country has gained from clinical trial operations over the past few years, both from the point of view of public health and industry. The present experience shows that the Indian population is prone to both communicable and non-communicable diseases, thus pointing towards the high prevalence of these diseases in India (*Table 3*). This means that a large percentage of the population is suffering from any of the above-mentioned diseases; therefore, India should allow clinical trials on these diseases. In 2012, the share of CTs to the total trials on cancer, diabetes, CVD, asthma and COPD is 12.71, 10.62, 3.23, 2.30 and 2.41 *per cent* respectively. CTs on communicable diseases such as HIV (.77%), TB (.66%) and malaria and other vector-borne diseases (.77%) are extremely low (*Figure 7*). The main reason is that most of the CROs concentrate on trials on non-communicable diseases (cancer, diabetes, CVD) for political and business motives or profit making. The demand for cancer, diabetes, and CVD drugs is high both in developed and developing countries.

But, communicable disease is identified as a developing country phenomenon. So, the drugs for non-communicable diseases constitute a larger market as well as higher demand in western countries as compared to that for communicable diseases. Thus, pharmaceutical companies basically concentrate on producing high-demand drugs (high value also) at low-cost destinations. However, on the other side, the burden of communicable diseases such as TB and vector-borne diseases is also very high. Out of 1,00,000 people, 176 people in India are suffering from TB; this disease is basically concentrated among the poor. However, very few clinical trials have been conducted on developing drugs for TB. Pharmaceutical companies have scant interest in clinical trial for TB because it is one of the major public health problems and also because the government is already taking measures to control and prevent the spread of this disease.

Consequently, a moot question is: How can India benefit technologically as well as build capacity for future R&D and innovation in the pharmaceutical sector? There was an expectation that India could gain financially and scientifically through CTs. Further, medical professionals and clinical technicians, too, could gain from new techniques as well as scientific exercises undertaken during trials and that learning will be useful for future R&D and innovation. During 2011 and 2012, India received FDI in drug manufacturing sector. These foreign funds were used to set up many research laboratories as well as to expand/upgrade the existing infrastructure for CTs. Also, in collaboration with foreign companies, many of the domestic companies have spent money on R&D and creation of new chemical entities. Indian medical professionals also got an opportunity to learn through these scientific exercises so as to enhance their capabilities. However, as the Indian CT industry mostly concentrates on Phase III trials—which is only to 'examine and determine' the therapeutic dose of medicines—this exercise is not closely related to technology and innovation of new drugs or NCEs. So, in India there is a lesser chance of technological transformation in pharmaceutical industry.

5. Conclusions

The review concludes that the clinical trial industry in India has great potential to become the most favourable destination in the world because of low cost of doing business, the availability of skilled professionals, and, the availability of **a** large and diverse patient pool. Many global CROs relocate their research units to India for drug development activities. Though the CT industry has been taking advantage of the huge financial gains, technological transformation for development of NCE is not happening. Also, the Indian public health industry only partially benefits from CTs. The Government of India needs to establish a policy framework for the Indian CT industry to provide for easy access to affordable drugs developed through adaptive clinical trials in India. There is also a need to create a regulatory environment capable of ensuring the conduct of clinical trials without violation of humanitarian ethics and other social norms.

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Appendix Table

Table A1: Disease Type-wise Product R&D Activities of Domestic Firms Active in India, 1999–2009

Domestic Companies	*1999–2001*			*2002–2004*			*2005–2007*			*2008–2009*			*Total*
	Disease Type												
	I	*II*	*III*	*I*	*II*	*III*	*I*	*II*	*III*	*I*	*II*	*III*	
Orchid Pharmaceuticals Limited				2			6			2			10
Sun Pharmaceutical Limited							2			7			9
Ranbaxy Laboratories Limited	2						2	1		3			8
Shantha Biotech							3		2	10	1		16
Matrix Laboratories										3			3
Biocon Limited				2			4			6			12
Glenmark Pharmaceutical limited				1			5		1	7			14
Bharat Biotech Limited								1	1	3		2	7
Alembic Limited													0
Dr. Reddy's Laboratories limited				7			2	1		15			25
Lupin Limited	1				1		4	4		4		1	15
Cadila Healthcare Limited							3	1		9			13
Piramal Healthcare limited							7			5			12
Wockhardt Limited							1			2			3
Ipea Laboratories Limited										2	2		4
Aurobindu Pharmaceutical Limited													
Torrent Pharmaceutical Limited										1			1
Ajanta Pharma										7			7
Netco Pharma										2			2
Granules India Limited										1			1
SMS Pharmaceuticals										10			10
Panacea Biotech												2	2
Total	3			12	1		39	8	4	99	3	5	174

Source: Abrol, 2014.

Note: Disease Type I: Diabetes, Cancer, Metabolic disease, Hepatitis, Cardiovascular, Influenza, Infection disease, Inflammatory disease, Allergy, Respiratory disease.
Type II: HIV/AIDS, TB, Malaria.
Type III" Leishmaniasis, Trypanosomiasis, Lymphatic Filariasis, Leprosy, Diarrheal.

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ISID

Institute for Studies in Industrial Development
4, Institutional Area Phase II, Vasant Kunj, New Delhi - 110 070
Phone: +91 11 2676 4600 / 2689 1111; Fax: +91 11 2612 2448
E-mail: info@isid.org.in; Website: http://isid.org.in