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THE REGULATIONS FOR DRUG CLINICAL TRIALS IN GOVERNMENT OF INDIAN LAW

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YADAIAH.J COMMENTS ON THE REGULATIONS FOR DRUG CLINICAL TRIALS IN GOVERNMENT OF INDIA LAW MAKES AN ATTEMPT TO BALANCE OF PHARMACY INDUSTRY DEVELOPMENT AND WITH PUBLIC HEALTH, IN THIS REGARDS

ABSTRACT

The development of a new drug is a long process. Once the promising compound is identified, it has to be investigated in laboratory studies and be tested on laboratory animals. After years of work the newly developed drug is ready for clinical trials, or the testing on human volunteer. Clinical trials with safeguards are necessary for the introduction of new drugs for a country like India considering its disease burden and emergence of new variants of diseases. It is the only way of establishing the safety and efficacy of any new drug before its introduction into the market for human use.

The major ethical risks detected in clinical research were related to errors in the methodology of obtaining informed consent, monitoring the participant's safety during the clinical trial, and falsifying collected data.

A few famous cases of ethical misconduct were found and analyzed, and methods to decrease the risk of the re-appearance of such problems have been listed. Finally, this review is an invitation to explore the complexity of the methodology of clinical research and its ethical and legal risks, and to find new ways to mitigate the possibility of such risks related to the research process.

The Drugs and Cosmetics Act, 1940, and the Rules made thereunder-as also the New Drugs & Clinical Trials Rules, 2019-form the legal basis for these regulations.

MATERIALS AND METHODS A search of two electronic databases was performed using the terms malpractice OR ethical issues OR methodological errors OR legal issues AND clinical trials OR pharmacological research OR drug research OR psychopharmacology.

Keywords: clinical trial, volunteers, informed consent, vulnerable population, pharmacological agents, psychopharmacology, and ethical misconduct.

INTRODUCTION

Clinical research is an essential component of the broader paradigm of evidence-based medicine concerned with ensuring scientific progress in the healthcare field. While the evolution of medicine is a worthy goal, it always should be remembered when discussing clinical trials that the ultimate objective is to enhance the quality of services provided for

patients and their prognosis and chances for resuming a normal life.

To refer only to the field of psychiatry, the developments recorded in psychotropics in the last six decades represent a veritable revolution that allowed changing the nosological paradigm of psychiatric disorders. Due to this shift, which demonstrated that there is a biological basis for mental illnesses and that pharmacological agents may alleviate their symptoms, the stigmatization and the propensity to institutionalize patients diagnosed with such disorders decreased and are foreseen to decrease further in the near future.

The importance of clinical research is underlined by the high number of trials identified by searching the International Clinical Trials Registry Platform, a World Health Organization database, that reported the existence of 10606 depression studies in 2024. A total of more than 530000 studies are registered in the US National Library of Medicine database for clinical trials, ClinicalTrials.gov, out of which over 200000 are for studying a drug or a biological product, regardless of the pathology they are targeting, at the beginning of 2025.

India is the second most preferred destination to conduct clinical trials by the big pharmaceutical companies. In India, Drug Controller General of India (DCG) is the main authoritative body for approving clinical trials as well as marketing and manufacturing of the drug.

The clinical trial industry in India is pegged at over rupees 3500crore and is growing at 10-12% annually.4 India is the only country with the genetic diversity of the population where the clinical trials are on the easier track. One major advantage of getting involved in the world clinical trials is that it places us in the benchmark position to negotiate for a cheaper price tag when such drugs are sold in India; the regulatory framework is quite weak as there is a need of specific regulatory framework that should take the proper monitoring mechanism and a rigid administration.

The growing financial force and the growing effect of advances in science influence many researches on human subjects in recent years to unethical paths which have affected the human life on a great scale. Human beings are easily exposed in various types of trials, especially people with mental disability, especially the children's, prisoners, people suffering from several illnesses, etc.

These are the few of the numerous breathtaking human rights violations that have been seen in the field of clinical trials.

CONSTITUTIONAL PROVISIONS :

Clinical trial is a must for the approval of the drug to ensure the safety and efficacy of the drug. The Constitution of India has various provisions to protect the safety and health of the patient and makes sure that the rights of patients or participants in clinical trials should not be violated.

Article 19(1)(a): Article 19(1)(a) of the Constitution of India particularly provides all the citizens Freedom to Speech and Expression.

The Supreme Court of India in various cases including Bennett Coleman & Co. &Ors v. Union of India1 and Indian Express Newspapers (Bombay) Pvt. Ltd. v. Union of India2 has held that Right to Know is a fundamental right under Article 19(1)(a). It is also available to the patients and participants of Clinical.

Article 21: Article 21 confers the Fundamental Right of Right to Life and Personal Liberty. This is the most prized fundamental right of Indian Constitution and has been given very wide interpretation by various Supreme Court judgments.

It encompasses a lot many rights within its ambit. Right to life doesn't include mere existence but it implies living a dignified life. So nobody shall be forced by any means to take part in any Clinical Trial.

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Article 21 also ensures Right to Privacy to every individual and if any private information of the clinical trial participants is leaked without their consent it will amount to infringement of Article 21.

In case of Jacob Puliyel v. Union of India3 Supreme Court has opined that bodily integrity is protected under Article 21 of the Constitution and no individual can be forced to be vaccinated.

Further, personal autonomy of an individual, which is a recognised facet of the protections guaranteed under Article 21, encompasses the right to refuse to undergo any medical treatment in the sphere of individual health.

However, in the interest of protection of communitarian health, the Government is entitled to regulate issues of public health concern by imposing certain limitations on individual rights.

CLINICAL REGULATION LAWS IN INDIA

Regulations in India: Regulations are mechanisms to ensure that the quality and integrity of data collected in clinical trials are maintained, and also to ensure that the rights, safety, and welfare of research participants are protected.

Types of regulatory mechanisms

1. Law: A rule of conduct enforced by a controlling authority e.g., Drugs and Cosmetics Act 1940 and Rules 1945.

2. Regulation: An interpretation of how to put into place a law schedule e.g., Y schedule is the Indian regulation for clinical research issued by CDSCO, headed by DCGI, FDA Bhawan, Delhi.

3. Guideline: An interpretation of the regulations which has no legal binding and may not be universally accepted. It is accepted as Industry Standards e.g., Indian Council of Medical Research [ICMR] guidelines, Indian GCP guidelines.

There are various laws, regulations, and guidelines to be followed when planning and monitoring trials in a fair and ethical manner for conducting clinical trials in India.

The Drugs & Cosmetics Act, 1940 : It contains powers for regulating and ensuring quality, safety and efficacy of drugs and clinical trials and the necessary rules, procedures and guidelines have been framed under the Drugs and Cosmetics Rules, 1945. Rules for conducting clinical trials in India are prescribed under Rule-122DA, 122DAA, 122DAB, 122DAC, 122DD, 122E and Schedule Y to the Drug and Cosmetics Rules, 1945.

New drug advisory committees: The DCGI has constituted 12 New Drug Advisory Committees consisting of experts from the government medical colleges and eminent institutions from all over the country to ensure transparency in approval of proposals for conduct of clinical trials for drugs.

All fresh applications of proposals of new drug substances for clinical trials excluding investigational new drugs have to be evaluated by these Committees. For INDs, two separate expert committees have been constituted and there are six Medical Device Advisory Committees (MDAC) for evaluation of medical devices.

Since the Drugs & Cosmetics Act, 1940 did not have specific provisions for regulating the conduct of clinical trials and that the Act also does not have penal provisions, therefore, specific provisions for the purpose were proposed in the Drugs & Cosmetics (Amendment) Bill, 2007 introduced in the Rajya Sabha on 21.8.2007.

The previous bill has been replaced by the Drugs & Cosmetics (Amendment) Bill, 2013 introduced on 29.8.2013, which contains more comprehensive provisions for the purpose.

Newer initiatives by the CDSCO :

DCG1 has recently issued direction in November 2013 that an audio video of the informed consent process of an individual subject including the procedure of providing information to a subject and his understanding

of such content, shall be maintained by the investigator for record.

Another amendment proposed in Schedule-Y specifies that clinical trials are required to be conducted at sites that have their own Ethics Committee.

It has been also been recommended that clinical trials should be carried out in sites where the sites, investigators and the Institutional ethics committee are competent and have been accredited by a Central Accreditation Council (CAC) to carry on such studies.

REGULATORY CHANGES IN INDIA'S LANDSCAPE: 2005–2016

This amendment, issued on 20th January, 2005, had dramatic changes that sought to bring India on par with internationally prevalent regulations. Some of the key changes related to defining a clinical trial, allowing trials in India to be conducted in the same phase of drug development as elsewhere in the world, demarcation of clear roles and responsibilities of the sponsor, investigator and ECs, emphasizing the importance of informed consent, requiring studies in special populations and mandating that protocol amendments need approval from the office of the DCGI. Over the next 10 years, a slew of changes and reforms dotted the regulatory landscape as

Approval by Institutional Ethics Committee

• All clinical trials must obtain approval from the IEC

• A recent regulatory change regarding IISs is that studies with 'new drugs' conducted by academicians no longer require approval of the DCGI for conduct of the trial and approval by IEC would suffice. This is provided these studies are not intended for generating data to make a regulatory submission.

• In case it is perceived by the IEC that the academic and regulatory purposes of the trial may overlap, the office of the DCGI should be informed. If the IEC does not hear from the DCGI within 30 days, it should be presumed that no permission is needed from the licensing authority.

• Registration of the clinical trial with the Clinical Trials Registry of India The CTRI is a free, online portal that allows both investigator-initiated and regulatory studies to be registered. It is recommended that all studies are registered at a public portal. However, for Regulatory Clinical Trials, registration in CTRI is mandatory from June 2009.

• This is important, as registration needs to take place before the first participant is enrolled in the study

•\tRegistration is important from a publication standpoint point as editors of many Biomedical Journals will not accept papers that have interventional studies not registered with a Clinical Trials Registry

Obtain informed consent from participants

• Investigators are required to obtain written, informed consent from every participant in a clinical trial.

• For trials that involve vulnerable participants [children or mentally challenged patients for example] and involve a new chemical entity or a new molecular entity, the investigators in addition have to ensure audio visual recording of the informed consent process [gazette notification dated 19th November, 2013].[18]

Reporting of serious adverse events occurring during a clinical trial

• An SAE is defined as an untoward medical occurrence during a clinical trial that is associated with death, in patient hospitalisation (if the study was done on outpatient basis), prolongation of hospitalisation (if the study was conducted on in-patient basis), persistent or significant disability or incapacity, a congenital anomaly or birth defect or is otherwise life-threatening. The timelines for reporting SAEs are given below

• The investigator should report all SAEs to the DCGI (for regulatory studies), the sponsor and

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the IEC within 24 h of their occurrence. For academic studies, these should be reported only to the IEC within 24 h.

- If unable to do so, the reason for delay in reporting the SAE along with the report should be submitted to the DCGI

- Send SAE report to DCGI after due analysis. Also send to Chairman of IEC and the Head of the institution where the trial has been conducted within 14 calendar days of occurrence of the event

- IEC should submit its report on the SAE, after due analysis, along with its opinion on the financial compensation (if any) to be paid by the sponsor or his representative, and to the DCGI within 30 calendar days of occurrence of the event

Understand that compensation for trial related death and injury is now required and the implications of compensation particularly when academic studies with 'new drugs' are carried out

Compensation in a clinical trial is needed both in the case of death and in cases of injury related to a clinical trial. The formulae for the compensation of both are described below. Interventional studies in Anaesthesia that are not "drug trials Clinical studies/trials that are investigator-initiated and involving procedures as interventions, e.g., comparison of effectiveness of two different techniques of brachial plexus block, would require approval of Institutional Ethics committee and registration with CTRI.

PROBLEMS FACED DUE TO CURRENT CLINICAL REGULATION LAWS

The current Clinical Regulation laws are not fully prepared to handle big pharmaceutical companies that often engage in clinical trials. Countless health activists criticized the outsourcing of clinical trials due to the fact that pharmaceuticals conducting the said trials could opt to pay less attention to ethics. Pharmaceuticals often target developing countries like India because these countries lack uniformity in the accessibility to healthcare amongst the general population. This provides the false idea that clinical trials act like the availability of healthcare amongst the poverty-stricken population, who may not have the literacy to make an informed decision. Large pharma companies can exploit this due to the disparity in the judiciary about moral liability held by clinical researchers and sponsors. More so, patients are also acquired through the prospects of a last-resort treatment. Large pharmaceuticals will often set up a network with doctors and hospitals, who will in turn recommend to their terminally ill patients to join the clinical trial. The prospects of experimental treatment are the only option as current Western medication has reached its limit. These patients are often not in the right state of mind to decide as they may be still grappling with their mortality. The shortage of proper specialists in Ethics Committees and regulatory laws allows pharmaceuticals to pay less attention to the moral duty they owe to participating members. Besides that, monetary desperation is one of the reasons people tend to take part in clinical trials. In countries such as India, large pharmaceuticals have traditionally conducted clinical trials on patients who usually are from low-income groups. Large pharmaceuticals will often offer money to these patients, incentivizing them to participate in clinical trial research. These people participate because of their need for money to sustain their livelihood and often convince other family members to partake as well. The concerned citizens might not be in a position to make an informed and educated decision, thereby allowing large pharmaceutical companies to acquire patients at a lower cost.

Examples of famous cases when ethical and legal violations of clinical research were detected One of the first cases of ethical misconduct after the Nuremberg Trials, which brought to the general interest the dangers of experiments without ethical restraints, was related to the MKUltra studies (1955–1967) . These involved ,mind-control techniques using

LSD-25, and were sponsored by the CIA . Many of the subjects were given LSD and other psychoactive substances without consent, and some were subjected to psychological manipulation; also, not all of the ,investigators were healthcare specialists, but they came from very diverse professional backgrounds, e.g., one of them was a magician, i.e., a student of Harry Houdini, while another was a CIA consultant with a shady history; tragically, this so-called experiment for mental illnesses became Medical torture not very unlikely to the Nuremberg Trials. Various reports describe the impact of such experiments on mental health, including the Veterans Health Initiative Report in 2003. Study 329 (1994–2001) investigated the use of paroxetine and imipramine in adolescents, and this research was found to have serious ethical and scientific flaws subsequently, including selective reporting of results. An independent reanalysis of data from Study 329 -the RIAT initiative-showed that acute and longer-term paroxetine and imipramine were associated with harm and were ineffective in major depression in adolescents . In the original study, paroxetine proved itself well-tolerated and effective in that population on multiple outcomes, i.e., the Hamilton Depression Rating Scale (HAMD), Schedule for Affective Disorders and Schizophrenia for Adolescents-Lifetime version (K-SADS-L), and Clinical Global Impression (CGI), while the withdrawal rates due to adverse events were 9.7% vs. 6.9% (paroxetine vs. placebo) . The RIAT analysis showed several ways in which the presentation of safety data in clinical trials may influence the apparent tolerability of a drug, e.g., the use of an idiosyncratic coding system, failure to transcribe all adverse events from clinical records to an adverse event database, or filtering data on adverse events through statistical techniques . This is an interesting case because it represents an argument to make it available for independent analysis of all primary data available from a clinical trial.

The Ranbaxy Case, 2006-2008, was a major Indian pharmaceutical company involved in a significant controversy related to drug safety, more specifically to the quality of various generic drug products including gabapentin and the antibiotic ciprofloxacin. Ranbaxy was accused of falsifying data in clinical trials, including trials of generic drugs, related to the purity, strength and quality of these generics, and the case resulted in the company being fined $500 million by the US Department of Justice for selling counterfeit drugs and submitting false data to the FDA.In 2006, an FDA inspection detected incomplete testing records and inadequate programs focused on the assessment of the stability characteristics of drugs in the Paonta Sahib facility.

CONCLUSION

The Indian medical industry has been drawing eyeballs from around the world for its booming pharma industry, especially in the private sector. India's regulatory reforms have been a key factor in attracting foreign attention and becoming a hub for human trials in recent times. The initiative to accept more clinical trials can play out to be beneficial for increased collaboration and the foundation of group bolster.The failure to have judicial precedent, despite making reforms over the years to the Clinical Regulatory laws, has held the legislation from making monumental changes towards bettering of the regulation laws. Loopholes in clinical regulations have resulted in many inefficiencies and infringements of human rights. Non-existence of standardized regulations within the state has led to haphazard conducts by the likes of the Ethics Committee.

In the last few years, we continually see the dramatic increase in the number of clinical trials. There is a need for proper structure regulating the clinical trials as India lacks a proper mechanism in the clinical trial industry. With experienced clinical professionals and technological advances, India is sure to give its best as a major favourite destination for the clinical researches in the near future. The academic investigator needs to be up to speed

in reading, understanding, and applying regulations and work in tandem with the pharmaceutical industry for greater patient benefit. The ECs now have a larger than ever onus need to appreciate and understand risk – benefit and to empower themselves through repeated training and use of standard operating procedures given that it is known that the quality of IEC review across the country remains variable.

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