AN INFO-BOOKLET

The Basics of Clinical Trials and its Processes in India

Sama
Resource Group for Women and Health

The information provided in this toolkit is for wider dissemination, and may be used with due acknowledgement to Sama.

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Introduction

Over the last decade India has become the venue for a large number of industry sponsored clinical trials. In 2008 India had 757 registered clinical trial sites and an annual clinical trial growth rate of 19.6%.[1] The industry was valued at US$ 400 million in 2010, up from US$ 230 million in 2008 and is expected to touch US $ 1.09 billion by 2014.[2]

The growing industry around clinical trials in India comprises of pharmaceutical companies, contract research organizations (CRO), data processing centres, recruiters and affiliated private and public hospitals and clinics. Contract research in the Indian pharmaceutical industry is already robust, and was estimated by the Chemical Pharmaceutical Generic Association to be worth between $100 and $120 million in 2005, while growing at 20 to 25 per cent per year. Currently, there are more than 150 CROs in India, out of which 20 comply with ICH-GCP guidelines. An increasing number of pharmaceutical companies have started moving drug trials to contract research organizations.

Another sub-set in this category would be the physicians who actually conduct the trials, though in the Indian context they have a relatively marginal presence compared to the CROs in setting the infrastructural and regulatory agenda for research.

There are many examples of clinical trials that have taken place without proper protocols of consent, or regard for participant rights. Without adequate and necessary regulatory jurisdiction or systematic review, the reliability and validity of medical research is jeopardized. This is particularly critical in the context of drug and vaccine trials, placebo controlled trials and genetic studies, that are often in violation of both, the Declaration of Helsinki as well as the principles laid down in the Indian Council of Medical Research's (ICMR) ethical guidelines for biomedical research. India requires more substantial regulation, awareness and vigilance, and effective implementation that can institutionalize the highest standards of independent inquiry, good clinical practice, protocols, monitoring and follow up, so that a strong policy framework can be put in place that brings together both medical science, and a pro-people impulse.

The main aim of this information booklet is to generate awareness and build capacities of communities about different aspects of clinical trials, including the regulatory frameworks and mandated protocol and participant rights. This booklet – drawing from both, existing regulatory mechanisms as well as from Sama's[3] on-going research on participants' perspectives on Clinical Trials – is an attempt to provide participants and targeted communities a handbook called the 'The Basics of Clinical Trials and Its Processes in India' describing 'what they must know before participating in a clinical trial'.

What are Clinical Trials?

According to Schedule Y of Drugs and Cosmetics Act, clinical trial is a "systematic study of pharmaceutical products on human subjects – (whether patients or non-patient volunteers) – in order to discover or verify the clinical, pharmacological (including pharmacodynamics/ pharmacokinetics), and/or adverse effects, with the object of determining their safety and/ or efficacy".

Clinical trials look at new ways of preventing, detecting, or treating disease. These may include new drugs or new combinations of existing drugs, new surgical procedures or devices, and new ways of using existing treatments. These experiments are at the core of all medical research and provide valuable information about how diseases progress. The goal of clinical trials is to determine if a new test or treatment works and if it is safe.

Some common reasons for conducting clinical studies include:

- Curative medicines: Evaluating one or more interventions (for example, drugs, medical devices, approaches to surgery or radiation therapy) for treating a disease, syndrome, or condition

- Preventive medicines: Finding ways to prevent the initial development or recurrence of a disease or condition. These can include medicines, vaccines, or lifestyle changes, among other approaches.
- Diagnostics: Examining methods for identifying a condition or risk factors for that condition
- Comparative diagnostics; Evaluating one or more interventions aimed at identifying or diagnosing a particular disease or condition
- Improving quality of care: Exploring and measuring ways to improve the comfort and quality of life of people with a chronic illness through supportive care.[4]

a) Idea–Protocol–Actors

The need for conducting a clinical trial, often originates in the laboratory. After researchers test new therapies or procedures in the laboratory and through animal studies, the most promising experimental treatments are moved to the next stage, that is, clinical trials amongst humans.

Major Actors

- Pharmaceutical companies
- Contract Research Organizations
- Indian Council of Medical Research/ Ministry of Health and Family Welfare
- NGOs/ Humanitarian Organizations
- Public Health Institutions/ Medical Colleges
- Private Hospitals/ Medical Research Institutes
- Individual Medical Practitioners
- Para-medical and Administrative Staff/ Agents/ Field/ outreach workers
- Participants
- Ethics committees
- Regulatory authorities

Clinical research is conducted according to a plan known as a protocol. The protocol lays out the details regarding the following:

- who is eligible to participate in the trial (inclusion/ exclusion criteria)
- details about tests, procedures, medications, and dosages to be administered before and during the trial
- the length of the study
- the kind of information that will be gathered

Clinical trials are sponsored or funded by various organizations or individuals, including physicians, foundations, medical institutions, voluntary groups, and pharmaceutical companies, as well as government agencies and bodies such as the Indian Council of Medical Research (ICMR) and the Ministry of Health and Family Welfare (MoHFW). All clinical trials must be approved by the Drug Controller General of India (DCGI) which acts as the licensing authority in this case following the grant of approval by the ethics committee. A clinical trial is led by a principal investigator (PI) who is often a doctor. It may be conducted in a variety of research and health care institutions.

b) Types of trials

Clinical trials are of different types and are classified on the basis of various criteria. One way of classifying clinical trials is by the way the researchers act.

- In an **observational study** the investigators observe the subjects and measure the outcomes of the medicine or the intervention. The researchers do not actively manage the study.
- In an **interventional study** the investigators give the research subjects a particular medicine or other intervention. Usually, they compare the subjects who receive treatment to subjects who receive no treatment or standard treatment. Then the researchers measures and assess how the health of the subject changes as a result.

Clinical trials can also be classified on the basis of the purpose they serve. The U.S. National Institutes of Health (NIH) groups trials into five different types:

- **Natural history studies** provide information about how disease and health progress.
- **Prevention trials** look for better ways of preventing a disease in people who have never had the disease or of preventing the disease from returning. These methods may include medicines, vaccines and lifestyle changes.

- **Screening trials** test the best way of detecting certain diseases or health conditions.
- **Diagnostic trials** identify better tests or procedures for diagnosing a particular disease or condition.
- **Treatment trials** test new treatments, new combinations of drugs, or new approaches to surgery or radiation therapy.
- **Quality of life trials** (or supportive care trials) explore and assess ways of increasing the comfort and improving the quality of life of people with a chronic illness.

Phases of Trials

Clinical trials are conducted in "phases". Each phase has a different purpose and helps researchers answer different questions. CDSCO DC&A explains the phases as follows:

Phase I: Human/Clinical Pharmacology trials

The objective of phase I of trials is to determine the maximum tolerated dose in humans; pharmacodynamic effect, adverse reactions, if any, with their nature and intensity; and pharmacokinetic behaviour of the drug as far as possible. These studies are often carried out in healthy adult volunteers using clinical, physiological and biochemical observations. At least 2 subjects should be used on each dose.

Phase I trials are usually carried out by investigators trained in clinical pharmacology and having the necessary facilities to closely observe and monitor the subjects. These may be carried out at one or two centres.

As per Indian laws Phase I trials for new drugs can only be conducted for those drugs discovered in India.

Phase II: Exploratory trials

In phase II trials a limited number of patients are studied carefully to determine possible therapeutic uses, effective dose range and further evaluation of safety and pharmacokinetics. Normally 10-12 patients should be studied at each dose level. These studies are usually limited to 3-4 centres and carried out by clinicians specialized on the concerned therapeutic areas and having adequate facilities to perform the necessary investigations for efficacy and safety.

Phase III: Confirmatory trials

The purpose of these trials is to obtain sufficient evidence about the efficacy and safety of the drug in a larger number of patients, generally in comparison with a standard drug and/or a placebo as appropriate. These trials may be carried out by clinicians in the concerned therapeutic areas, having facilities appropriate to the protocol. If the drug is already approved/marketed in other countries, phase III data should generally be obtained on at least 100 patients distributed over 3-4 centres primarily to confirm the efficacy and safety of the drug, in Indian patients when used as recommended in the product monograph for the claims made.

Data on Adverse Drug Reactions (ADRs) observed during clinical use of the drug should be reported along with a report on its efficacy in the prescribed format. The selection of clinicians for such monitoring and supply of drug to them will need approval of the licensing authority under Rule 21 of the Drugs and Cosmetics Act.

Phase IV: Post Marketing Trials

Studies performed after marketing of the pharmaceutical product. Trials in phase IV are carried out on the basis of the product characteristics on which the marketing authorization was granted and are normally in the form of post-marketing surveillance, assessment of therapeutic value, treatment strategies used and safety profile. Phase IV studies should use the same scientific and ethical standards as applied in pre-marketing studies.

After a product has been placed on the market, clinical trials designed to explore new indications, new methods of administration or new combinations, etc. are normally considered as trials for new pharmaceutical products.

Other Important Concepts: Typically, clinical trials compare a new product or therapy with another that already exists to determine if the new one is as successful as, or better than, the existing one. In some studies, participants may be assigned to receive a **placebo** (an inactive product that resembles the test product, but without its treatment value). However, placebos can only be used in the cases where the disease for which the drug is being tried is self limiting and where no other proven preventive, diagnostic or therapeutic method already exists. The participant must be informed (both verbally as well as through the consent form) about the use of a placebo and is eligible to receive compensation or free medical management or treatment in the case of any adverse event or death caused by the placebo. ***Randomization*** is the process by which two or more alternative treatments are assigned to participants by chance rather than by choice. This is done to avoid any bias in the assignment by investigators of participants to one group or another. The results of each treatment are compared at specific points during the trial, which may last for years. When one treatment is found superior, the trial is stopped so that the fewest number of participants receive the less beneficial treatment. In ***single*** or ***double-blind studies,*** also called single- or double-masked studies, the participants do not know which medicine is being used, so they can describe what happens without bias. "Blind" (or "masked") studies are designed to prevent members of the research team or study participants from influencing the results. This allows scientifically accurate conclusions. In single-blind ("single-masked") studies, only the patient is not told what is being administered. In a double-blind study, only the pharmacist knows; members of the research team are not told which patients are getting which medication, so that their observations will not be biased. If medically necessary, however, it is always possible to find out what the patient is taking or receiving/ being given.

Source: http://www.nih.gov/health/clinicaltrials/basics.htm

Apart from clinical trials there are hundreds of **Bio Availability (BA) and Bio Equivalence (BE) studies** that are going on at any given time in the country at different clinical research centres. BA/BE studies which take about three months time, are conducted for finding the bioavailability and bioequivalance of a drug, especially the generic drugs and the combination drugs which are already in the market.

According to ICMR Guidelines for Biomedical Research on Human Participants, for all new drug substances and for new dosage forms administered for systematic absorption which are approved elsewhere in the world, bioequivalence studies with the available formulation should be carried out wherever applicable. Data on the extent of systematic absorption may be required for formulations not meant for systematic absorption. Evaluation of the effect of food on absorption following oral administration should be carried out if the food absorption data is not submitted.

BA/BE (bioequivalence) studies are also clinical studies conducted most often in normal volunteers. Hence, all safeguards to protect participants must be in place, including ethical review of protocol, recruitment methods, compensation for participation, evidence of non-coercion and consent procedures. It is in such studies that volunteers often participate at short intervals and may participate at different centres within less than the prescribed period of three months between two studies.

Who participates in a Clinical Trial?

All clinical trials have guidelines about who can participate, called Inclusion/Exclusion Criteria. These criteria are based on factors such as age, gender, type and stage of a disease, previous treatment history, and other medical conditions. Before joining a clinical trial, a participant must qualify for the study. Some research studies seek participants with illnesses or conditions that will be studied in the clinical trial, while others need healthy participants.

a) Healthy Participant

A healthy participant is a person with no known health problems who participates in clinical research studies designed to test a new drug, device, or intervention. Research procedures involving healthy participants are designed to gain new knowledge or to advance existing knowledge, not to provide direct benefits to study participants.

Special Groups:

- **Pregnant or nursing women** should in no circumstances be participants in any research study unless the research study carries no more than minimal risk to the fetus or to the nursing infant and the objective of the research study is to obtain new knowledge about the fetus, pregnancy and lactation.
- **Children** should not be involved in research studies that could be carried out equally well with adults unless the purpose of the research study is to obtain knowledge relevant to the health needs of children and that too only with additional safeguards in place.
- Adequate justification is required for the involvement of participants such as prisoners, students, subordinates, employees and service personnel who have **reduced autonomy as research participants,** since the consent provided by them may be under duress or because of various other compelling reasons.
- **Vulnerable Groups -** Efforts should be made to ensure that individuals or communities invited to participate in research studies are selected in such a way that the burdens and benefits of the research are equally distributed.

b) Patient Participant

A patient participant has a known health problem and participates in the research study so that researchers are able to better understand, diagnose, treat, or cure that particular disease or condition.

What one needs to know before participating in a Clinical Trial?

Before obtaining an individual's consent to participate in the research study, the investigator must provide the individual with the following information in a language that she/he is able to understand and which should not only be scientifically accurate but should also be sensitive to and/or adaptive to the individual's social and cultural context.

Potential Risks	Potential Benefits
♦ There may be unpleasant, serious, or even life-threatening side effects to experimental treatment.	♦ Play an active role in their health care.
♦ The study may require more time and attention than standard treatment would, including visits to the study site, more blood tests, more treatments, hospital stays, or complex dosage requirements.	♦ Gain access to new research treatments before they are widely available.
	♦ Receive regular and careful medical attention from a research team that includes doctors and other health professionals.

- The aims and methods of the research study and the expected duration of the individual's participation in it.
- The benefits that might reasonably be expected as an outcome of the research study to the participant or to the community or to others.
- Any alternative procedures or course of treatment that might be as advantageous to the participant as the procedure or treatment to which she/he is being subjected.
- Any foreseeable risk or discomfort to the participant resulting from participation in the research study and the degree of harm that may result from such participation.
- The right to prevent the use of her/ his biological sample (DNA, cell-line, etc.) at any time during the conduct of the research study.
- The extent to which the confidentiality of records will be maintained, that is, the limits to which the investigator will be able to safeguard confidentiality and the anticipated consequences of a breach of confidentiality.

Available safeguards to protect the rights of Participants:

a) Ethical Guidelines Laws

The goal of clinical research is to advance knowledge that improves human health or that increases understanding of human biology. People who participate in clinical research studies make it possible for this to take place. However, narratives of the exploitation of these participants have existed for some time is a matter of concern. Hence, ethical guidelines, legal provisions and regulatory mechanisms have been put in place to protect participants and to preserve the integrity of scientific and medical research. In India, the relevant safeguards are described in the ICMR document – Ethical Guidelines for Biomedical Research on Human Participants, in the Schedule Y of the Drugs and Cosmetics Act and in the Good Clinical Practices (GCP) for clinical trials.

Statement on Principles of Research

Any research study using human beings as participants shall follow the principles given below –

- Principle of essentiality.
- Principles of voluntariness, informed consent and community agreement
- Principles of non-exploitation
- Principles of privacy and confidentiality
- Principles of precaution and risk minimization
- Principles of professional competence
- Principles of accountability and transparency
- Principles of the maximization of the public interest and of distributive justice
- Principles of institutional arrangements
- Principles of public domain
- Principles of totality of responsibility
- Principles of compliance

Source: _http://icmr.nic.in/ethical_guidelines.pdf

b) *Informed Consent*

Informed consent is the process whereby a potential participant is provided with the information pertaining to the clinical trial and learns the key facts about the clinical trial before deciding whether to participate. In all trials, freely given informed written consent is required to be obtained from every participant. The investigator must provide information about the study verbally as well as through the use of the patient information sheet, in a language that is non-technical and is understood by the participant.

The participant's consent must be obtained in writing using an 'informed consent form'. The participant must be given a copy of this form along with a copy of the patient information sheet.

In the eventuality that the participant is unable to give informed consent (for example, an unconscious person or a minor or an individual with severe mental illness or disability), the same may be obtained from a legally acceptable representative (a legally acceptable representative is a person who is able to give consent for or authorize an intervention in the patient as provided by the law(s) of India). In a case where the participant or his/her legally acceptable representative is unable to read or write, an impartial witness is required to be present during the entire process of obtaining informed consent and must also sign the form.

The process of obtaining informed consent should include the following essential elements:

- Statement that the study involves research and explanation of the purpose of the research
- Statement about the expected duration of participation
- Description of the procedures to be followed, including all invasive procedures
- Description of any reasonably foreseeable risks or discomforts
- Description of any benefits to the participant or to others reasonably expected from the research. If no benefit is expected, the participant should be made aware of this
- Disclosure of specific and appropriate alternative procedures or therapies available to the participant

- Statement describing the extent to which the confidentiality of records identifying the participant will be maintained and indicating who will have access to the medical records of the participant(s)
- Trial treatment schedule(s) and statement indicating the probability for random assignment to each treatment (for randomized trials)
- Statement about compensation and/or treatment(s) available to the participant in the event of a trial-related injury
- Statement about whom to contact for information about trial-related queries, the rights of the participant and the procedure to be followed in the event of an injury
- Statement about the anticipated prorated payment, if any, to the participant for participating in the trial
- Statement about the responsibilities of the participants regarding his/her participation in the trial
- Statement that participation is voluntary, that the participant can withdraw from the study at any time and that refusal to participate will not involve any penalty or loss of benefits to which the participant is otherwise entitled
- Any other pertinent information

c) Ethics Committees

It is mandatory that all proposals on biomedical research involving human participants should be cleared by an Ethics Committee, duly registered with the Drug Controller General of India as per Rule 122 DD of the Drugs and Cosmetics Rules. It is the responsibility of the ethics committees which reviews and approves a trial protocol to safeguard the rights, safety and well being of all trial subjects. The Ethics Committee should exercise particular care to protect the rights, safety and well-being of all vulnerable subjects participating in the study, for example members of a group with a hierarchical structure (for example; prisoners, armed forces personnel and staff and students of medical, nursing and pharmacy college/ institutions), patients with incurable diseases, unemployed or impoverished persons, patients in emergency situations, members of ethnic minority, homeless people, nomads, refugees, minors or others incapable of personally giving consent.

Thus the onus is on the Ethics committee to review every clinical trial proposal, to evaluate the possible risks to the participants, to access the expected benefits and to determine the adequacy of documentation for ensuring privacy, confidentiality and justice. The Ethics Committee is required to document its 'standard operating procedures' and also to maintain a record of its proceedings. The Ethics Committee is open to inspection by the officers authorized by the Central Drugs Standard Control Organization and must comply with the requirements of Schedule Y, the Good Clinical Practices Guidelines and other applicable regulations, for safeguarding the rights, safety and well-being of the participants in the clinical trial or the research study.

d) Compensation

The Drugs and Cosmetics Rules, governing clinical trials in India incorporate safe guards for all participants in the form of financial compensation and medical management. The recentnotification by Ministry of Health and Family Welfare on 30th January 2013 now states that in case of any injury to the participant, medical management will be provided to the participant free of cost. Further it also states, that in case of an injury (or death) occurring during the clinical trial, due to the reasons described below, the participant (or a nominee in the case of death) will be entitled to financial compensation:

- Adverse effect of the product being tried
- Violation of the approved protocol, scientific misconduct or negligence by either the sponsor or the investigator
- Failure of the product to provide the intended therapeutic effect
- Use of a placebo in a placebo-controlled trial
- Adverse effects resulting from the use of other medicines apart from those mentioned in the approved protocol
- Injury to a child/ foetus in-utero in the womb because of the participation of the parent in a clinical trial

The expense for either the financial compensation or the medical management will be borne by the sponsor and will follow the processes of reporting and verification as prescribed in the law.

Process of Payment of Financial Compensation

- The investigator must report all adverse events (including deaths) to the Licensing Authority to the sponsor and to the Ethics Committee within 24 hours of the occurrence of these events.
- The sponsor must then submit its report on the analysis of the adverse event to the Licensing Authority and to the Ethics Committee within 10 days of the occurrence of the event. In the case of death, the Expert Committee will be constituted by the Licensing Authority and the sponsor will be required to send its report to this Expert Committee as well.
- Within 21 days of the occurrence of the event the Ethics Committee is required to send its report analysing the event along with its opinion on the awarding of financial compensation to the Licensing Authority, and to the Expert Committee in case of death.
- In case of death the Expert Committee will give its recommendations to the Licensing Authority for the purpose of arriving at the cause of death within 30 days of receiving the report from the Ethics Committee. In case the death is found to be related to the clinical trial the Expert Committee will also recommend the amount of the compensation
- In case the injury or death is found to be related to the clinical trial the Licensing Authority will determine the amount of compensation to be paid by the sponsor and pass orders within three months of receiving the reports of the event
- The sponsor will then be required to pay the requisite amount of compensation to the participant within 30 days of receiving the order from the Licensing Authority.

The compensation should be paid irrespective of whether or not the participant freely consented to participate; whether or not the injury was caused by the investigational product. The recent "Guidelines for determining quantum of financial compensation to be paid in case of clinical trial related injury or death dated August 3, raises lot of concerns. A lot many trial participants are children, women or people who are not earning. For such unemployed people the trial compensation maybe nil or almost nil, if it is based on this formula. It is seen that in poverty ridden conditions in India, people are willing to become trial participants for a little amount of money, or free treatment. In such a scenario, it is not appropriate to compensate victims based on their income capacity.

What are the questions the Participants/ Communities/ Activists should ask?

If you are offered a chance to participate in a clinical trial, the following are some of the questions that you as a participant should ask:

The Study

- What is the purpose of the study?
- Why do researchers think that the approach they have adopted may be effective?
- Who will fund the study?
- Who has reviewed and approved the study?
- How will the study results be checked?
- How will the safety of participants be checked and guaranteed?
- How long will the study last?
- What will the responsibilities of the participants be?

Possible Risks and Benefits

- What are my possible short-term benefits?
- What are my possible long-term benefits?
- What are my short-term risks, such as side effects?
- What are my possible long-term risks?
- What other options for treatment do people with my disease have?
- How do the possible risks and benefits of this trial compare with those options?

Participation and Care

- What kinds of therapies, procedures and /or tests will I have to undergo during the trial?
- Will these therapies, procedures and/ or tests hurt? If so, for how long?
- How do the tests conducted as part of the study compare with those I would have outside of the trial?
- Will I be able to take my regular medications while I participate in the clinical trial?
- Where will I have/ receive my medical care?
- Who will be in charge of my care?
- Can I consult my family/ general physician and/ or members of my family and/ or friends?

Personal Issues

- How will being part of this study affect my daily life?
- Can I talk to other people participating in the study?

Economic Impact

- Will I have to pay for any part of the trial such as tests or the study drug? If so, what are the charges likely to be?
- Is there an insurance cover during the drug trial period?
- Will I get any reimbursement for travel/ food/ loss of pay?
- Who will pay compensation if there is any trial related injury or death? Whom should we report?

Glossary

1. Pharmacokinetics: Characterization of a drug's absorption, distribution, metabolism and excretion. Although these studies continue throughout the development plan, they should be performed to support formulation development and determine pharmacokinetic parameters in different age groups to support dosing recommendations.
2. Pharmacodynamics: Depending on the drug and the endpoints studied, pharmacodynamic studies and studies relating to drug blood levels (pharmacokinetic/ pharmacodynamic studies) may be conducted in healthy volunteer Subjects or in patients with the target disease. If there are appropriate validated indicators of activity and potential efficacy, pharmacodynamic data obtained from patients may guide the dosage and dose regimen to be applied in later studies.
3. Adverse effects: Any untoward medical occurrence (including a symptom / disease or an abnormal laboratory finding) during treatment with a pharmaceutical product in a patient or a human volunteer that does not necessarily have a relationship with the treatment being given.
4. Serious Adverse Events: An AE that is associated with death, inpatient hospitalisation (in case the study was being conducted on out-patients), prolongation of hospitalisation (in case the study was being conducted on in-patients), persistent or significant disability or incapacity, a congenital anomaly or birth defect, or is otherwise life threatening.

Abbreviations

1. DNA - Deoxy Ribonucleic Acid
2. GCP - Good Clinical Practices
3. DCGI - Drugs Controller General of India
4. ICMR - Indian Council of Medical Research
5. AE: Adverse Event
6. BE: Bioequivalence
7. CDSCO: Central Drugs Standard Control Organization
8. CRO: Contract Research Organization
9. CT: Clinical Trial
10. SAE: Serious Adverse Event

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[3] Sama is a Delhi based NGO that has been working on issues related to women and health since 1999. It has been involved with issues related to the ethics and governance of clinical trials in India since 2009. Sama conducted an investigation of HPV Vaccine "Demonstration Projects"conducted by PATh in collaboration with Andhra government in Bhadrachalam in 2010 and organized a National Consultation on Regulation of Drug Trials in 2011.Currently, Sama has been engaged in a national level research on Participants' Perspectives in Clinical Trials.

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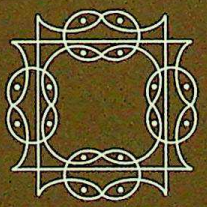
[5] PharmaBizNews. (2012). *Health ministry's efforts to make registration of BA/BE studies mandatory with CTRI stuck in red-tapism*. February 06, 2012, 0800 IST.

Sama is a Delhi based resource group working on issues of women's health and rights and locates concerns of women's health in the context of socio-historical, economic and political realities and finds linkages of women's well being with livelihoods, food, violence and other larger issues that affect their lives. Sama believes that equality and empowerment can be ensured only when multiple forms of discrimination based on caste, class, gender religion, ethnicity, sexual orientation and many others are structurally challenged.

The word 'Sama' means 'equality' while the logo symbolizes balance and equality. These are an intrinsic part of Sama's philosophy and vision.

Sama engages with community based organizations, Non Governmental Organizations, women's groups and collectives, health networks and coalitions, autonomous bodies like the National Human Rights Commission (NHRC), National Commission for Women (NCW), UN bodies, youth, health care providers, medical professionals and the media, through capacity building, policy monitoring and advocacy, action research, knowledge creation and dissemination.

Current work areas/ issues include Public Health, Right to Health and Health Care; Women's Rights, Reproductive and Medical Technologies; Adolescent Sexual Reproductive Health and Rights (SRHR); Clinical Trials: Human Rights Violations and Governance Issues; Population Policies; Bioethics; and Violence as a Health issue.



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