

VolREthics Initiative - Volunteers in Research and Ethics

Asia Workshop, September 23, 2022

“Focus on the risks of exploitation of healthy volunteers in biomedical research in Asia”

Meeting report

Meeting agenda:

→ **Introduction by the co-chairs. 10 minutes**

Chun Keat Chew (*Institute for Clinical Research, Malaysia*), Nandini Kumar (*Forum for Ethics Review Committees in India*)

→ **The VolREthics Initiative - Learnings from previous meetings. 15 minutes**

François Bompard (*Drugs for Neglected Disease initiative, Switzerland & Inserm, France*)

→ **How to protect healthy volunteers from exploitation: presentations on Asian perspectives. 1 hour**

- Juntra Karbwang (*SIDCER-FERCAP Foundation, Thailand*)
- Melvin George (*SRM Institute of Science and Technology, India*)
- Nicholas Leow Chun Wei (*Bioequivalence Centre & Ethics Committee Section, National Pharmaceutical Regulatory Agency, Malaysia*)

→ **Healthy volunteers' testimonies. 30 minutes**

→ **Open discussion with the audience: field experiences; identified risks of exploitation; recommendations. 25 minutes**

→ **Next steps and closure 5 minutes**

François Hirsch (*Inserm, France*)

Attendees: a total of 81 persons registered to attend the meeting, from 17 countries (Bangladesh, Belgium, Bhutan, Cambodia, Germany, India, Japan, Kenya, Laos, Malaysia, Nepal, People's Republic of China, Sri Lanka, Thailand, USA, Vietnam, and France) including 2 healthy volunteers from India and one from Malaysia.

Prior to the meeting, questionnaires sent to attendees to collect insights from Asian colleagues regarding cases of exploitation and harm they may have witnessed, and solutions they could propose to limit risks of exploitation. The answers (*verbatim* provided below) did not point at specific examples of exploitation but gave insights into attendees' areas of interest and expectations regarding the meeting:

I have had the opportunity to streamline our EC and likewise work towards developing SOPs as per the institute needs, in the capacity of member secretary. As an investigator, I have had the experiences of the decisions of the EC, which did not always fall within the SOPs. IN y experience there is need to reduce the subjectivity which occurs in decision making and hence auditing of the EC is more important so that the investigators are ensured the that their studies will be evaluated in the true spirit of ethics.
I am much concerned about post-approval Ethics process that relates to the actual conduct of the study, which often goes without getting duly monitored; and that the gains of a just and stringent Ethics review process goes in vain. The above is more grave given the fact that it facilitates and perpetuates 'pseudoscience'
I am a Chairman of EC. I am a Board member in CRO which deals with studies in Healthy subjects. We take extra precaution in Screening of subjects. Our screen failure ratio is as much as 50% .
My field of expertise is causality assessment of suspected SAE in healthy volunteer studies and issues like Clinical trial related compensation.
As a newbie in the clinical research domain, I would wish to learn more from the experienced researchers on the nuances of research ethics, especially how they have worked to maintain ethical practices in grey areas.
I will like to hear more on cases of exploitation of healthy volunteers from this webinar.
For this event, it is relatively new topic to me, hence I would like to take the opportunity to be an audience over the vast experience fellow researchers in field to learn more on needs to mitigate potential exploitation over healthy volunteers, thanks.
As I heard some of healthy volunteers participated in the trials partly/mainly due to monetary value offered by the sponsor. So, I would like to know to what extent does sponsor making sure that they are not exploiting the volunteers in their research? As I knew a few cases that the healthy volunteers participated due to the monetary value offered to them. I heard this experience from the volunteers in the developed countries.
Does monetary compensation in such studies especially in LMICs risk exploitation of healthy volunteers?
I am a physician involved in clinical trials including vaccine trials.
MY DOCTORATE OF PHILOSOPHY (PHD) IS IN HEALTH CARE MANAGEMENT AND HOSPITAL SERVICES TOURED ITALY, AUSTRALIA, SINGAPORE, ABU DHABI, AND KOLALAMBUR TO STUDY THE FUNCTION OF THE HOSPITALS AND CLINICAL RESEARCH ORGANIZATION. PROMOTED MBA HOSPITAL MANAGEMENT FOR DOCTORS AND NURSES.
To have understanding of exploitation of healthy volunteers
No specific experience sharing. Looking forward sharing by others.
Hope that this event will continue to drive awareness and the establishment of human rights & protection for all potential and research participants. Looking forward to this event. Thank you

During the meeting.

Insights on the realities of healthy volunteers' involvement in Asia were shared:

Reference was made to a paper written by Priyanka Pulla and published in "The Hindu" in 2017 entitled "Lured by blood money: serial volunteers set a disturbing trend", annexed to this report. This paper provided interesting insights in 2 broad categories:

- Risks of exploitation of volunteers: "Bioequivalence studies can pay up to ₹25,000 for a week-long commitment, during which a daily wage earner would have otherwise earned a tenth of the amount".
- Risks of harm to volunteers:
 - A 53-year old volunteer who lied about his age (he reported 38 yrs of age to be eligible for a bioequivalence trial) died suddenly 7 days after the end of the trial. The cause of death was not clarified, no autopsy performed, but before his death doctors diagnosed an arm thrombophlebitis and a compressed spinal disk. He had taken part in 8 previous trials with the same CRO. His family was unaware of his involvement in clinical trials.
 - A WhatsApp group called "Bloody money" with 250 members was reported to post around half-a-dozen advertisements for bioequivalence studies each day, with information on the name of the CRO running the trial, the amount of blood to be drawn, and the compensation.
 - A 32-year-old volunteer belonging to this WhatsApp group reported having been involved in over 40 studies. This volunteer said "it isn't uncommon for volunteers to break trial rules and lie. Even though CROs screen for infections such as HIV and hepatitis, and illnesses like anaemia and diabetes, they cannot catch everything. "People tell lies. They say I don't take any medicines. And then they pass the test".
 - A 25-year old reported having volunteered for over 20 trials in 2 years. He developed severe psychiatric symptoms but the relationship with tested medicines could not be assessed since he had destroyed all records of his participations in order to his this from his family.
- The bulk of studies involving healthy volunteers In India and Malaysia are bioequivalence / bioavailability studies (as opposed to first-in-man studies)
- In 2019, New Drugs and Clinical Trials Rules were released in India aiming at better protection of volunteers and patients in clinical trials. These regulations, however, have not led to mandatory measures to avoid over-volunteering, e.g. through a mandatory national registry. There are regional databases in India that are used across multiple states such as the Online Volunteer Information System (OVIS) used by CROs in the Northern Indian states and the Sentinel System by BlooMedha used by CROs in the Mid-Southern Indian States. Malaysia is the only Asian country which has set up a National Healthy Research Volunteer Register (NHRVR), managed by government authorities, details of which are provided later in this document.
- The 3 healthy volunteers who spoke (2 from India: a health professional and a teacher, 1 from Malaysia, a mechanic) did not report situations where they felt exploited or ill-treated. Their motivations included access to expensive vaccines (to travel internationally) or non-

available vaccines (COVID-19 vaccine to protect elderly relatives). The quality of health monitoring during the study was found attractive by one healthy volunteer. Information on potential studies came from friends and from social media, advertisements, etc. The cost of a vaccine needed for international travel was mentioned by a healthy volunteer as the primary reason why she enrolled into a meningococcal vaccine clinical trial.

Some key principles were highlighted

- The scientific soundness of a study involving healthy volunteers is key in assessing its ethical acceptability, as illustrated by examples of severe adverse events occurring during some First in Man studies.
- There is a need to ensure volunteers' confidentiality throughout the clinical research processes, including the post-study period. The example of Malaysia's National Healthy Research Volunteer Register (NHRVR) shows that volunteers' confidentiality can be ensured in such databases.
- Informed consent must be seen as a process, that is auditable, not merely a "tick box" routine task.
- There is a tension between the need to ensure freedom of volunteers to withdraw at any time without consequences, and the need to fairly compensate volunteers who complete all the study requirements.

Insights were provided in the following areas

Risks of possible exploitation:

- Healthy volunteers tend to follow the opinion of people who have authority over them, especially physicians, even more if the investigator is the person's treating physician
- Lack of vaccines during the COVID-19 crisis was a strong inducement for people to enrol in vaccine trials, even at the risk of being given a placebo.

Risks of possible harm to volunteers:

- Pressure to perform can expose volunteers to risks: there is a strong pressure on CROs, but also on investigators, to meet very aggressive timelines for recruiting healthy volunteers and completing studies. It was highlighted that all are in a competitive environment to "stay in business", which may lead them to minimise some risks, e.g. posed by "minor exclusion criteria" and the risk of concealed participation in multiple studies by some volunteers.
- Overworked ethics committees may wrongly assume that "routine" bioequivalence studies require less scrutiny than rarer first-in-man studies.
- Delegation of tasks: study protocols state very specific duties to be carried out by investigators and specifically the Principal Investigator. There are situations where investigators delegate tasks to people who are non-adequately qualified or trained, with the risk that some critical tasks are not properly performed.

Possible solutions proposed:

Information & education

- Informed consent:
 - o Proposal was made to create IC documents with 2 sections

- A simple one-page clinical trial summary that uses a pictorial format to highlight all key issues. This will ensure all trial participants read at least the core aspects of the trials such as purpose, risks benefits, brief procedure.
 - A more detailed document providing extensive the information needed to meet the regulatory and legal requirements.
 - The Strategic Initiative for Developing Capacity in Ethical Review (SIDCER) has developed 'Enhanced Informed Consent' principles and a developmental guideline, validated in several studies which suggest that participants comprehension of the study can be improved <https://pubmed.ncbi.nlm.nih.gov/27009426/>
- There is a collective responsibility to protect all stakeholders involved in clinical research. Several speakers expressed the need to inform/educate all stakeholders on the specificities of clinical studies involving healthy volunteers: the lay public, ethics committees, regulatory agencies, law makers, the volunteers themselves, etc. Consideration could be given to devote part of clinical trials' funding to fund these tasks.
- **Health authorities & ethics committee oversight**
 - Ensure that ethics committees are properly equipped (that is informed and trained on the specificities of studies involving healthy volunteers) to assess the scientific and ethical soundness of proposed studies.
 - Ethics Committees should be able to check that the protocol was truly executed. They should be authorized, and equipped, to perform surprise audits and review data.
 - Standardise requirements for all ethics committees: in India all ethics committees need to be registered. Initially the ethics committees of regulatory clinical trials were required to be accredited but now this is a not a mandatory requirement. Phase I and bioavailability / bioequivalence studies are conducted only if essential facilities are there as per New Drugs and Clinical Trial Rules for ethics committees to approve such studies.
 - Accreditation of clinical study sites (bioequivalence and First-In-Humans centres) is a legal requirement in Malaysia. Sites risk penalties and regulatory actions in case of non-compliance. Thailand currently relies on Ethics Committees to review the qualification of investigators and the suitability of research centres (for instance to ensure they have access to resuscitation services). A point was made that relying on ethics committees is an excellent first step but making appropriate qualification of investigators and of study sites a legal requirement, with the ability of governmental authorities to perform audits, could be desirable.
 - National healthy volunteers' registries: Malaysia set up in 2021 a National Healthy Research Volunteer Register (NHRVR) which use is mandatory for sites which plan to submit data to the National Pharmaceutical Regulatory Agency (NPRA). NPRA will not accept data originating from sites that do not comply with the NHRVR requirements.
 - National formulas for compensation of healthy volunteers for adverse events including types of SAEs have been formulated by Indian authorities. These formulas, however, do not extend to academic trials, for which decisions are made by local institutions and investigators applying for Grants. This should not be confused with compensation for participation which is often prorated for Pharma-sponsored trials. In Malaysia, compensation is based on the number of visits/admissions/time, potential travelling cost and inconvenience caused to the volunteers.

THE HINDU

Lured by blood money: serial volunteers set a disturbing trend



Priyanka Pulla

DECEMBER 30, 2017 01:15 IST

SHARE ARTICLE

A growing number of people are over-volunteering for clinical trials in order to supplement their income. Priyanka Pulla reports on a disturbing trend that is putting at risk the health of serial volunteers as well as the reliability of trial data

In late May 2017, about two weeks before he died, Nagaraju Vangaru, a 53-year-old father of three from Telangana's Karimnagar district, checked into a facility run by Lotus Laboratories, a Bengaluru-based clinical research organisation (CRO). Vangaru was taking part in a clinical trial for a sleep aid called melatonin. The trial was a bioequivalence study, designed to compare the biological behaviour of an unapproved formulation of melatonin with an older, approved formulation that was already available in the market. Vangaru would be paid ₹20,000 for participating, as would the 59 other volunteers in the trial.

On the morning of the trial, Vangaru ate a large breakfast, possibly of chicken, bread and eggs. Then he popped 2 mg of melatonin, so that the meal's effects could be tested on the medicine's concentration in his body. (These events are reconstructed from a document called an informed consent form, which Vangaru signed before the trial and of which he kept a copy.) Next, the investigators inserted a thin tube called a cannula into his vein to collect blood. Over a period of a day, the cannula remained in his

arm, and blood was collected 11 times. Finally, on May 27, the investigation ended, and Vangaru checked out of the facility. The first round of the trial was over. But Vangaru was to come back for a second one.

The Telangana resident then left Bengaluru for his home – a tiny, mosquito-infested brick house in the cotton fields of Karimnagar's Nagampet village. He lived there with his wife and three sons. Lotus Labs subsequently lost contact with him. So, the investigators didn't know when, on May 29, Vangaru grew feverish, with severe back pain and a swelling in his arm. Even though the informed consent form he signed states that volunteers could call the CRO if they felt unwell during the trial, Vangaru never did so. Instead, he visited several doctors near Nagampet, who diagnosed him with thrombophlebitis, an inflammation of the vein, which can occur due to intravenous cannulation. The doctors also said he had a compressed disk in his spine. Even as he began the prescribed treatment, on the evening of June 2, Vangaru suddenly collapsed in his home, dead.

The death set off a series of traumatic events for Vangaru's family. When they began sorting through his possessions, they discovered the form he had signed to participate in the Lotus Labs study. The family had no idea that Vangaru was a trial volunteer. All they knew was that he worked as a cook at weddings in Hyderabad, earning ₹300 a day. "We thought he was travelling around with catering companies. This was a shock to us," says 25-year-old Jagadeesh, Vangaru's youngest son and the only person in the family who has studied beyond high school.

There were more unhappy surprises when the local police station began investigating the case, seeking responses from Lotus Labs. The company revealed that the melatonin study was Vangaru's ninth such trial with them. More troublingly, Vangaru had lied to Lotus Labs to sign up for the trial. Even though he was over 50, the identity card he submitted to the company showed him to be 38 years old. This was a risky misrepresentation because the study was only for participants under 45

years of age, and the company discovered his true age only when newspapers reported his death.

Vangaru's case highlights the troubling trend of financially needy people serially volunteering for trials to supplement their income. This is a worldwide phenomenon, including in high-income regions like the U.S. and the European Union. The problem arises when volunteers who are desperate for money deceive investigators, lying about their age, health or other medications, just so they can participate. Such serial volunteers are an especially vulnerable class of people, because of their poverty and low levels of education, says Urmila Thatte, a clinical pharmacologist and bioethicist at Mumbai's Seth GS Medical College and KEM Hospital.

Under the Indian Drugs and Cosmetics Act, an independent body of doctors and laypersons, known as an ethics committee, must oversee a trial to make sure the rights of such groups are safeguarded. But bioethicists say this isn't happening. "There is a lot of scope for Indian ethics committees to directly supervise trials, which I don't think they do," says Thatte.

Protecting the vulnerable

In Vangaru's case, Lotus Labs concluded that his death wasn't due to melatonin, according to the company's response to the police. Melatonin has been safely used as a sleep aid for over 20 years now, and no published case report links its short-term use with death, they reasoned. Also, with a half-life of 3-4 hours, the drug would have cleared from Vangaru's body by the time he fell ill. While this reasoning may be correct, there are troubling hints that Lotus Labs and its ethics committee dropped the ball when it came to protecting Vangaru.

In any trial that relies heavily on vulnerable groups like daily wage earners, the ethics committee can choose to monitor subjects intensively, and counsel them on health risks, points out Thatte. There are several tools to do this — the committee can meet participants, or administer questionnaires to gauge their awareness. Shiela N. Rao, a veterinarian and the chairperson of the ethics committee in the melatonin trial, says that though her team did meet participants in some trials, they didn't meet anyone in the study Vangaru signed up for.

When asked if there was a lapse on the part of Lotus Labs in not identifying that he was 53 years old, Rao said she hadn't been informed by the company about this finding. And even though the Drugs and Cosmetics Act requires every trial death to be investigated, even if it is not related to the drug, no post-mortem was carried out on Vangaru's body. "Proving relatedness in a trial is a real challenge," says Thatte, "but at least the effort should be made." Rao says a post-mortem didn't happen because the company was unable to get information from the family about the death. Meanwhile, the results of a forensic investigation launched by the local police station near Vangaru's village haven't been released, seven months later.

The pervasiveness of serial volunteering and deception is not just a risk to participants but also taints the quality of data collected by CROs in bioequivalence studies. Volunteers from Hyderabad, Karimnagar and Mumbai interviewed by *The Hindu* admitted to participating in over 30 studies in a decade, and to have broken rules to make a quick buck. This included hopping from one trial to another without a three-month gap in between, drinking alcohol, and hiding one's health history. Such behaviour can distort trial data. To avoid this, France and the United Kingdom today have a national registry of volunteers, while the U.S. is contemplating one. India, with its lower levels of income and awareness, could benefit more from such a registry, but has none.

The trials that Vangaru and others participate in are called bioequivalence studies. When the patent on a drug expires, makers of generic versions must prove that these are metabolised by humans the same way as the patented drug. This year, the U.S. drug regulator, the Food and Drug Administration (USFDA), published a list of 267 off-patent drugs for which it was seeking generic versions. All drug-makers looking to address this market will need bioequivalence studies, opening up a large opportunity for Indian CROs. "It's a big business," says Thatte.



Yerram Devi Prasad, 33, a resident of Huzurabad, Karimnagar, participated in over 25 clinical trials between 2005 and 2009 for companies such as Dr. Reddy's Labs. About a year after he stopped, he began experiencing severe seizures and other mental symptoms. A government doctor told him his ailment could be due to the repeated participation in clinical trials. He displays his CT scan film. Next to him is his mother, who earns a living by selling home-made papad.

Unlike phase 2 and 3 trials that test for the first time if a drug is safe and effective in humans, bioequivalence tests involve medicines like melatonin that have already completed phase 2 and 3 trials and have a history of use in people. This makes bioequivalence studies relatively safer. On the other hand, participants in these studies receive no therapeutic benefit like phase 2 and 3 volunteers do, because bioequivalence studies are done on healthy people while the latter recruit patients. The assumption, therefore, is that a participant in a bioequivalence study is taking on the risk out of altruism.

It is important to remember that the risk of bioequivalence trials, while low, varies widely. A search of the Central Trials Registry of India, to which all regulated trials in India must be reported, shows that a range of drugs, including the breast cancer drug endoxifen, recombinant oral insulin, the hepatitis drug peginterferon alfa-2b, and anti-seizure drug phenytoin sodium, were tested on healthy volunteers in India in the last

few years. These drugs have dramatically different side effects. But a volunteer viewing such studies purely as a source of income is likely to paint them all with the same brush. “Many trials are probably associated with minimal risks. However, some trials could be associated with potential risks that require careful consideration before consenting. This distinction should not be blurred, as is inevitable when persons volunteer for trials regularly,” says Chittaranjan Andrade, the head of the department of psychopharmacology at Bengaluru’s National Institute of Mental Health and Neurosciences.

The higher the payment, the more likely that a volunteer will ignore the risks, argue some bioethicists. Bioequivalence studies can pay up to ₹25,000 for a week-long commitment, during which a daily wage earner like Vangaru would have otherwise earned a tenth of the amount. The Indian Council of Medical Research’s ethical guidelines for biomedical research on humans suggest that a company only compensate a participant for the inconvenience and loss of earnings due to the trial, and refrain from “undue inducement” or gratuitous payments that can influence decision-making.

Many payments do not fit this guideline. “These participants are not joining because of their dedication to medical science. We say there should be no undue inducement. But there is an inducement,” says Y.K. Gupta, the head of the clinical pharmacology department at New Delhi’s All India Institute of Medical Sciences.

Everybody lies

The large demand for volunteers and the supply of willing subjects has spawned a bustling marketplace for participation in bioequivalence studies. Dozens of groups on the instant messaging platform WhatsApp, with telltale names like “Anytime Money”, share information about ongoing studies.

The Hindu spoke to Kumar (name changed), a 32-year-old serial volunteer from Mumbai and a member of a WhatsApp group called Blood Money. He estimates that he has been in over 40 studies till date. Blood Money has 250 members, and its icon is a stack of currency notes atop a pool of blood.

Around half-a-dozen advertisements for bioequivalence studies turn up on the group each day, containing bulleted information that includes the name of the CRO running the trial, the amount of blood to be drawn, and the compensation. Some of the CROs whose calls for volunteers appeared on the group include the Mumbai-based Raptim Research and Watson Pharma, and the Ahmedabad-based Lambda Therapeutic Research Limited.

Kumar says it isn't uncommon for volunteers to break trial rules and lie. Even though CROs screen for infections such as HIV and hepatitis, and illnesses like anaemia and diabetes, they cannot catch everything. "People tell lies. They say I don't take any medicines. And then they pass the test," says Kumar.

Sometimes the cheating is driven by a family emergency. In 2014, when Kumar's two-year-old son was hospitalised for fever and seizures, he went from one study to another, to gather enough funds. The first trial, for "some brain drug," according to Kumar, was to pay ₹8,000, but with a delay. The second trial, for medicine for pediatric cough and cold, promised to pay within a week. That swung Kumar's decision. "That's the only time I did it. But others do it more often."

M.S. Swami Chowdhury, who participated in several clinical trials until 2015, when he stopped because he started experiencing chest pain, says volunteers take iron and folic-acid supplements to mask conditions like anaemia. Drinking liquor between two periods of a study isn't uncommon, even if it is often prohibited. It is not tough to game the system, according to Boga Rajesh, a serial volunteer from Jammikunta in Telangana. "You will be surprised at the things people do," he says with a smile.

When disaster strikes

Sometime in 2015, 25-year-old Ashok Chiluveri, a newspaper boy in Karimnagar, took off for Hyderabad to make his fortune from bioequivalence studies. He told his brother Shyamsunder Chiluveri that he had found a new job. "He would keep travelling back and forth," says Shyamsunder who puts up tents for weddings and other functions in his village. "But we had no idea what he was doing."



Shyamsunder Chiluveri (in photo) had no idea that his brother Ashok Chiluveri was participating in clinical trials. Ashok said in 2015 that he had found a new job, but no one in the family knew what this job entailed. Only when Ashok began having violent outbursts were his papers discovered. Before admitting Ashok to the Institute of Mental Health in Erragadda, Hyderabad, Shyamsundar and his mother took him to several dargahs and religious sites to pray for his health.

But Ashok's secret did not remain one for long. When he visited home in October 2017, he began having violent outbursts. He said he was hearing voices telling him to jump off a nearby hill. It was only when Shyamsunder noticed Ashok trying to burn some documents and seized them that he realised what was going on. One of the documents was an identity card from Lotus Labs, while the other was a payment cheque from the Bengaluru-based Apotex Research Private Limited. Upon being questioned, Ashok also named a third company, Syngene International in Bengaluru. In two years, he admitted, he had taken part in over 20 trials.

In December, Ashok was admitted to Hyderabad's Institute of Mental Health in Erragadda. K. Sudha Rani, a psychiatrist treating him, says he suffered a temporary episode of psychosis, a psychiatric condition in which the patient loses touch with reality. But she cannot say if the psychosis was due to the trials he took part in, because Ashok neither remembers the

medicines he took, nor retained any documents from these studies. A long list of drugs can trigger temporary psychosis, from alcohol and cannabis to some antibiotics, steroids and Parkinson's drugs. For now, Dr. Rani and her team are treating Ashok for his symptoms and expect him to be stable enough to leave for home soon.

To be fair to CROs, wilful deception by volunteers can be hard to flag, say bioethicists. But the problem is compounded by the cultural taboo surrounding trials. Volunteers often keep their families in the dark, leaving them without a safety net when they fall ill or are exploited.

The only way to tackle this trend in its entirety is through social campaigns to improve awareness. But ethics committees must keep up their end of the bargain. CROs have a clear conflict of interest when it comes to recruiting volunteers, says Thatte, because they need to fill studies quickly to earn their revenues. "The main responsibility lies with the ethics committee, because the CRO is totally conflicted. If they don't take up this mandate of continuous monitoring, who will?"

Too famous to volunteer

Thirty-year-old Suresh Boga looks depressed as he works in his footpath shop in the Jammikunta municipality of Karimnagar. The shop is 10 feet by 3 feet by 3 feet in size, enough to hold a man, a shelf full of tools like screwdrivers, and two dogs which come to nap on the floor in the afternoon. While petting them occasionally, Boga repairs portable gas cylinder stoves, a job that earns him ₹6,000 per month. It isn't enough. But his professional volunteering streak has come to an end, and this is his only source of income now.

Eleven years ago, when Boga was a high school graduate working as a serving boy for a Hyderabad-based catering company, he learnt about the money to be made in bioequivalence studies. He was earning ₹250 a day then. "Many of my friends were already doing it," he recalls. So he gave it a shot. He remembers that his maiden trial was with Hyderabad's Vimta Labs, but doesn't remember the name of the drug. "It was for skin blisters," he says falteringly, when I ask him what drug it was. "The kind that people say is due to the curse of goddess Poleramma."

For every clinical trial, the Drugs and Cosmetics Act requires participants to receive a copy of an informed consent form, which explains the trial protocol in great detail. Unless a company is convinced that the participant has understood the risks of the trial, they cannot recruit the patient. But Boga threw his copy of the form away. He didn't want anyone seeing it, for fear that they would disrespect him for selling his blood for cash.



Boga Suresh threw away the copy of his informed consent form. He feared that if someone saw it, they would disrespect him for selling his blood for cash. Boga has participated in over 20 trials for companies like MacLeods Pharma in Mumbai and the Hyderabad-based Axis Clinicals, Vimta Labs and GVK Biosciences.

Wasn't he worried about drug side effects? No, he says. "There are hundreds of side effects. But the company says you may get it, or you may not." One drug did give him a strong bout of nausea, while another gave several in his group a severe stomach ache. Yet another time, he recalls, the CRO told him to stop pretending, because he couldn't possibly have gotten the side effect he claimed he had. But the money was a good attraction and kept him going. In all, he has participated in over 20 trials for companies such as the Mumbai-based MacLeods Pharma and the Hyderabad-based Axis Clinicals, Vimta Labs, and GVK Biosciences.

But things went awry for the young man when Ashok Chiluveri, who lives in the same village as him, had psychotic episodes in October this year. Ashok's family blamed Boga for introducing him to trials, accusing him of being a pharma-company agent exploiting gullible young people.

Boga panicked. "I was afraid to go to jail," he says. So, he did the one thing he is comfortable with after ten years of volunteering for trials. With a five-millilitre syringe, he drew some of his own blood and squirted it in his mouth. Then he told onlookers that he had vomited the blood. When an ambulance rushed him to the hospital, he told doctors that the vomiting was a side effect of the trials he took part in. With the Nagaraju Vangaru and Ashok Chiluveri cases still fresh in the village's memory, the doctors believed him. "I was looking for sympathy," admits Boga. "I wanted people to know that I was only a volunteer, and not an agent."

The local police eventually saw through his pretence, and Boga confessed that he had put on an act. But by then his name had been splashed across all the local newspapers and television channels. CROs knew that he was a serial volunteer, as did his mother, who was ignorant till then. This brought his volunteering to an end.

Sitting on a cot in their cramped two-room home in Jammikunta, Boga's mother, who suffers from a kidney ailment, says she is glad he has stopped now. Boga looks on unhappily. He is too famous to take part in trials now. "But there are hundreds of others who are still doing it," he admits.