"I was lucky to get into a study, so I could survive financially."

The Globalization of Clinical Trials:

Testimonies from Human Subjects

"I asked the trial officials some questions but they said explaining everything would take too much time."

"I totally trust what the doctors are telling me."

wemos

In this book, the Wemos Foundation presents the testimonies of people participating in clinical trials in Poland, Russia, the United States, China and India. Wemos would like to clarify the reasons why these people choose to participate and the way in which they are being treated.

Contents

Foreword

Since 2006, Wemos has been following trends in the globalization of clinical trials, particularly the shift of many clinical trials away from the West towards countries in Eastern Europe, Asia and Latin America. Together with our partner organizations in Europe, India and Latin America, we have documented cases of unethical trials, most of which involve Western pharmaceutical companies. We have confronted politicians and policymakers with our findings, and we have urged them to improve the protection of vulnerable trial subjects. We have generated considerable societal support for 'fair' drugs. The backing of medical ethics experts, health and human rights organizations, health workers, medical students and other concerned citizens has lent enormous weight to our advocacy work.

Our efforts are paying off. The European Medicines Agency (EMA) has promised to improve supervision regarding compliance with ethical guidelines in clinical trials conducted outside the European Union. In short, the EMA will work harder to ensure that only 'fair' drugs enter Europe. This is only part of the solution to unethical trials, but it is an important part.

Continued pressure – at the European level as well as in the countries where the trials take place – is necessary in order to ensure that the rights of trial subjects are no longer being violated. Wemos is constantly searching for ways to demonstrate that the present situation is far from acceptable. It is for this reason that we have prepared this book, which differs from our prior publications. Instead of presenting examples of unethical trials and policy measures that require political action, we focus on human interest stories. In collaboration with local journalists, we have documented testimonies from trial subjects in Poland, Russia, the United States (US), China and India.

By collecting and publishing testimonies from trial subjects, their relatives and others investigating the issue, Wemos hopes to clarify how the right to health – the departure point for all activities of Wemos – is being respected or undermined. It also provides a voice to those who are seldom heard, allowing them to speak for themselves about their decision to participate in clinical trials, as well as about their experiences.

In the following chapters, we refrain from singling out specific companies or individuals for criticism, making interpretations or drawing conclusions. We leave that to the trial subjects and the journalists with whom we worked, as well as to you, the reader of this book. To help you, we have included a chapter on the most authoritative document dealing with the ethical principles of medical research on human subjects, the Declaration of Helsinki.

Michelle Smith, the journalist with whom we worked in Poland, writes that the trial subjects she interviewed came from all walks of life – from an imprisoned single mother, to a homeless man, to a student and a wealthy business owner. In her interpretation, this indicated that “vulnerability, be it economic, physical or emotional, can be a decisive factor in both an individual’s decision to participate in a clinical trial and in the recruitment strategy of the companies”. I was particularly interested to note that well-educated, affluent people in such countries as Poland and the US (for example, Ania and her husband, Jolee and Robb Mohr) have so much trouble obtaining the right information and receiving justice from the authorities, doctors and companies involved. How much more difficult it must be for poor, illiterate people taking part in clinical trials in less developed countries.

The global clinical trials industry is rapidly expanding. In this light, Wemos’ call to engage in action to demand ethical clinical trials is more urgent than ever. Please join us and hundreds of others by signing the ‘Call for Ethical Clinical Trials in Developing Countries’ at www.FairDrugs.org.

Annelies den Boer, MSc.
Wemos Project Coordinator for Medicines

Methodology

When we initiated this project in November 2009, we listed several countries that we knew to be emerging clinical trial hubs: China, Russia, India, Brazil, Poland and South Africa. From the perspective of the pharmaceutical industry, these countries are attractive clinical trial destinations for a number of reasons. Compared to the traditional research areas in the West:

- It is less expensive to conduct clinical trials in these countries.
- Regulatory constraints are either less stringent or less actively policed.
- It is easier to find trial subjects, as participation in a trial is often the only treatment option or because it offers the chance to earn some money.
- The large populations of these countries make it easier to find patients suffering from specific diseases, even in the case of relatively rare diseases.
- Trial subjects have less frequently already been exposed to medicines, and this improves the reliability of the test results.

The governments of these countries are also interested in the economic benefits of allowing clinical trials to be conducted in their countries.[1]

[1] See ‘A Bitter Pill’ (2007) by Wemos, available at www.FairDrugs.org.

We added the US, as we had heard of trials being conducted on vulnerable groups, including migrants and (former) prisoners. For each country, we conducted preparatory research to determine whether unethical clinical trials were truly an issue, whether there had been much media scrutiny and activism and which challenges were associated with accessing trial participants and trial information. We also considered the availability of opportunities for research collaboration. Based on our findings and available means, we compiled a short list of focus countries, consisting of China, India, Russia, Poland and the US. Throughout 2010, we collected the testimonies and worked on this book.

We paid the journalists with whom we worked in Poland, the US and China. We did not pay any of the trial subjects interviewed in these countries. In the case of India and Russia, the testimonies were generously made available to us free of charge by the French-German television network ARTE and Studio Indigo in Russia. These organizations had just finished producing documentaries on unethical clinical trials, proceeding from a human-interest approach that is similar to our own. To our knowledge, ARTE and Studio Indigo did not pay their respondents either, although ARTE did provide reimbursements for transport and food. Wemos has done everything it can to verify the quality and integrity of the journalism.

The trial subjects from Poland, China and the US gave us permission to use their names (in the case of Poland, only first names) and to publish their experiences on the internet and in a printed book. In the case of China, we chose to change the names of the interviewees for reasons of security. We also chose not to disclose the identity of the Chinese journalist who worked with us on this project. For Russia and India, permission for filming, broadcasting and communications was already obtained by the documentary makers.

Because of the approach taken by ARTE, the Indian stories in this book follow a different format. They are told by documentary film maker Paul Jenkins, but include quotes that come directly from trial subjects or their relatives.

Declaration of Helsinki

The first ethical guidelines for clinical trials date from 1947 and the Nuremberg Code. The Declaration of Helsinki is currently considered the most authoritative document.[2] The Declaration deals exhaustively with the ethical principles of medical research on human subjects, detailing the importance of voluntary, informed consent; the fact that the interests of the subject outweigh those of the research; the need for special protection of vulnerable research populations; and the requirement that patients have post-trial access to treatment.

The following are key statements from the Declaration. Please note that "The Declaration is intended to be read as a whole and each of its constituent paragraphs should not be applied without consideration of all other relevant paragraphs".[3] The full version is available on the website of the World Medical Association (WMA).

3. It is the duty of the physician to promote and safeguard the health of patients, including those who are involved in medical research.

6. In medical research involving human subjects, the well-being of the individual research subject must take precedence over all other interests.

9. Medical research is subject to ethical standards that promote respect for all human subjects and protect their health and rights. Some research populations are particularly vulnerable and need special protection.

11. It is the duty of physicians who participate in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects.

15. The research protocol must be submitted for consideration, comment, guidance and approval to a research ethics committee before the study begins.

16. The responsibility for the protection of research subjects must always rest with the physician or other health care professional and never the research subjects, even though they have given consent.

[2] For an overview of all relevant legislation, please see the Wemos publications 'A Bitter Pill' (2007) and the 'Call for Ethical Clinical Trials in Developing Countries' (2009) that are both available at www.FairDrugs.org.
[3] Source: http://www.wma.net/en/30publications/10policies/b3/index.html, last consulted on November 10, 2010.

17. Medical research involving a disadvantaged or vulnerable population or community is only justified if the research is responsive to the health needs and priorities of this population or community and if there is a reasonable likelihood that this population or community stands to benefit from the results of the research.

20. Physicians may not participate in a research study involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed. Physicians must immediately stop a study when the risks are found to outweigh the potential benefits or when there is conclusive proof of positive and beneficial results.

22. Participation by competent individuals as subjects in medical research must be voluntary.

24. In medical research involving competent human subjects, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal. Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information. After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject's freely-given informed consent, preferably in writing.

31. The physician may combine medical research with medical care only to the extent that the research is justified by its potential preventive, diagnostic or therapeutic value and if the physician has good reason to believe that participation in the research study will not adversely affect the health of the patients who serve as research subjects.

33. At the conclusion of the study, patients entered into the study are entitled to be informed about the outcome of the study and to share any benefits that result from it, for example, access to interventions identified as beneficial in the study or to other appropriate care or benefits.

1. Poland

Barbara

Barbara is a **30-year-old mother of two**, currently serving a prison sentence in a Warsaw jail for drug offences. She is separated from her alcoholic husband and her mother is taking care of her two sons as she serves out her term in detention. Having been fired from her last job as a cleaner and receiving no financial contribution from her estranged husband, money is extremely tight for the young family. To add to her difficulties, Barbara's eight-year-old son Marek suffers from an attention deficit disorder and requires regular medical assessments. Despite the constant presence of a prison guard and the security cameras, Barbara was willing to share her experiences and explain how she and her son became involved in a clinical trial.

Actually my son Marek is not really sick, he is very well physically, but he has a sort of behaviour disorder which makes it hard for him to sit still and pay attention. Earlier this year our doctor told us about a new drug which sounded a bit like Prozac. He said that if we agreed to let Marek take part in a trial they would pay me PLN[4] 200 (approximately 51 Euros). I really needed the money, my husband drank all our money away, so there was nothing left for the boys.

On the day of the trial we had to take the bus to a private clinic in Warsaw and discuss the trial with some people that I guessed were doctors. They took some blood samples from Marek and explained that the drug might make him feel sleepy or hungry. I was asked to sign a contract but it was really too long to read it all properly, around 60 pages, and it was written in a style of Polish I couldn't understand. I could feel that they were in a rush, so I didn't ask too many questions and anyway, they said the contract was more concerned with payment they would make to me for taking part.

After about five weeks on the trial, there was a big change in Marek, he was calmer and sleeping much better. I was much happier and life was easier for all of us. However a short time later, my doctor told me that the trial was finished and that the new drug would no longer be given to Marek. He explained that the contract I had signed clearly stated that the trial would only be for a certain period of time, and after that, the drug would be withdrawn.

I was angry and panicked. How was I supposed to pay for this kind of drug once it came onto the market? I couldn't even pay for my mother to take care of the boys, so how could I pay for their medicines? I started shouting at the doctor, feeling angry at myself for not realising all the facts. I should have paid more attention, and I should have understood what I was signing. That's true. But then again, that contract was impossible. Nobody could understand it without help, and if those people in that office wouldn't help me, who would?

I can't believe I signed my son up for this trial without really understanding what I was agreeing to. I was blind. I realise now that people taking part in clinical trials should have the right to ask questions and be spoken to like human beings, not just guinea pigs.

"I realise now that people taking part in clinical trials should have the right to ask questions and be spoken to like human beings, not just guinea pigs."

[4] Polish Zloty, Poland's currency. Rate on October 27, 2010. Source: International Currency Converter.

Wojciech

Wojciech is a **24-year-old homeless man** currently living in a church-run shelter on the outskirts of the Polish capital Warsaw. Wojciech is a father of two, but his downwards spiral into life on the streets has led to his estrangement from his young family. His unkempt beard, dirty clothes, and weathered face are testament to the hardship of life on the streets. Poor diet, exhaustion and heavy smoking are also having a detrimental impact on his fragile health and contributing to his chronic bronchitis. Wojciech explained how he became involved in a clinical trial for a flu vaccine.

Last year, I was standing outside a shelter that provides a free meal every day – it's not great, just rice or noodles, vegetables, but it's hot and it's something. Anyway, one day I was standing outside, waiting for the place to open, when three men walked up and started talking to the people waiting in line. They told us that they would pay us PLN 50 (approximately 13 Euros) in cash for taking two injections for a new flu vaccine which a drug company was testing here in Poland.

A lot of the guys were interested in this offer, PLN 50 is a lot of money right? I was getting a bit of money from the government, PLN 300 per month (approximately 76 Euros), and a bit of income from begging, but getting paid to take part in a clinical trial seemed like easy money to me.

"I asked the trial officials some questions but they said explaining everything would take too much time."

On the day of the trial, I had to go to a private clinic outside of Warsaw and sign a contract. I didn't really understand it, it was around 50 pages long and the language was difficult to understand. I asked the trial officials some questions about it but they said explaining everything would take too much time. They told me there would be no side effects. I didn't tell them about my bronchitis and they didn't ask.

So I took the two vaccines and got my money. I have no idea what the name of the drug was and have no idea if it is now available in Poland. All I care about is making easy money. I did what I had to do and got paid. I have seen those three guys again and they have offered me another chance to take part in another trial for money. Lots of guys like me have done trials and still want to.

Ania

Ania is a 34-year-old stylish and successful **businesswoman**, running an upmarket bakery and café in Warsaw. She married her husband, a doctor specializing in paediatrics, eight years ago and the couple have been trying unsuccessfully to have a baby ever since. Despite Ania's good health, she has miscarried and been undergoing fertility treatment for the past five years. In 2009, her gynaecologist offered her the chance to take part in a five-month clinical trial for a fertility drug manufactured by a US pharmaceutical company. The couple related their experiences.

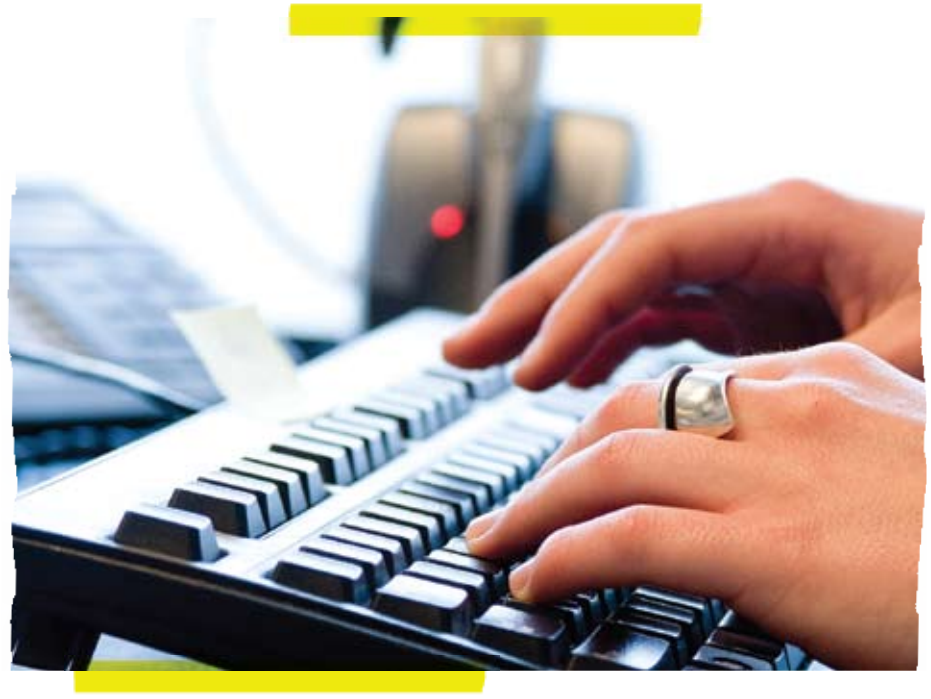
After many different attempts to get pregnant, my gynaecologist offered me the chance to take part in a trial for a fertility drug which involved a new combination of the drugs clomiphene and gonadotropin. Although we were already familiar with these two drugs from other treatments, this trial was different because it used a variation of gonadotropin which triggered the ovaries to release eggs. I signed a contract and I was paid, but I don't want to reveal how much. I also cannot reveal the name of the US pharmaceutical company for legal reasons.

The clinic running the trial seemed very diligent. I had to go every two weeks for blood tests and for examinations to see how my body was reacting to the injections. To my amazement, I did fall pregnant but unfortunately I miscarried and lost the baby at six weeks, just before Christmas. But the fact I had fallen pregnant at all made me think that this new drug could be the answer for us and that it was worth trying again. So, we went back to the clinic and asked to enrol again in three months' time.

Meanwhile my husband, being a doctor, was curious to know why our baby had died and requested an autopsy from the medical authorities. This was unusual in Poland as miscarriages in the first trimester are common, so people rarely think to find out what happened. To our horror, the toxicology report showed the foetus contained high levels of poisonous substances and was severely deformed. My husband had a strong suspicion that this deformity had been caused by the trial fertility drug. I also then remembered that two of the other woman on the same drug trial had both lost their babies as well. As a result, we decided against taking part in any further trials for this drug. Despite a lack of proof, I could not risk carrying an ill and deformed baby to term.

However, the Contract Research Organization (CRO), acting on behalf of the pharmaceutical company, was very reluctant to let us get out of the contract for the second trial. They said the agreement could only be annulled if we signed a separate document stating that we would not talk to anyone about the pharmaceutical company, the CRO, the fertility drug, the clinical trial, or the autopsy results. They said that if they allowed us to get out of the contract, then we would have to keep quiet and if we ever said anything, or anything showed up in print or in the media, they would sue us. So this is why we are now in a legal battle with them. We want to be able to do whatever we want with the information we have. We want to tell others and warn them.

Before I felt so sad about the miscarriage but I really thought I'd found an answer to all my prayers for a baby. Now I don't have the words to express how I feel. I just feel so angry and so used.



"I just feel so angry and so used."

Adam

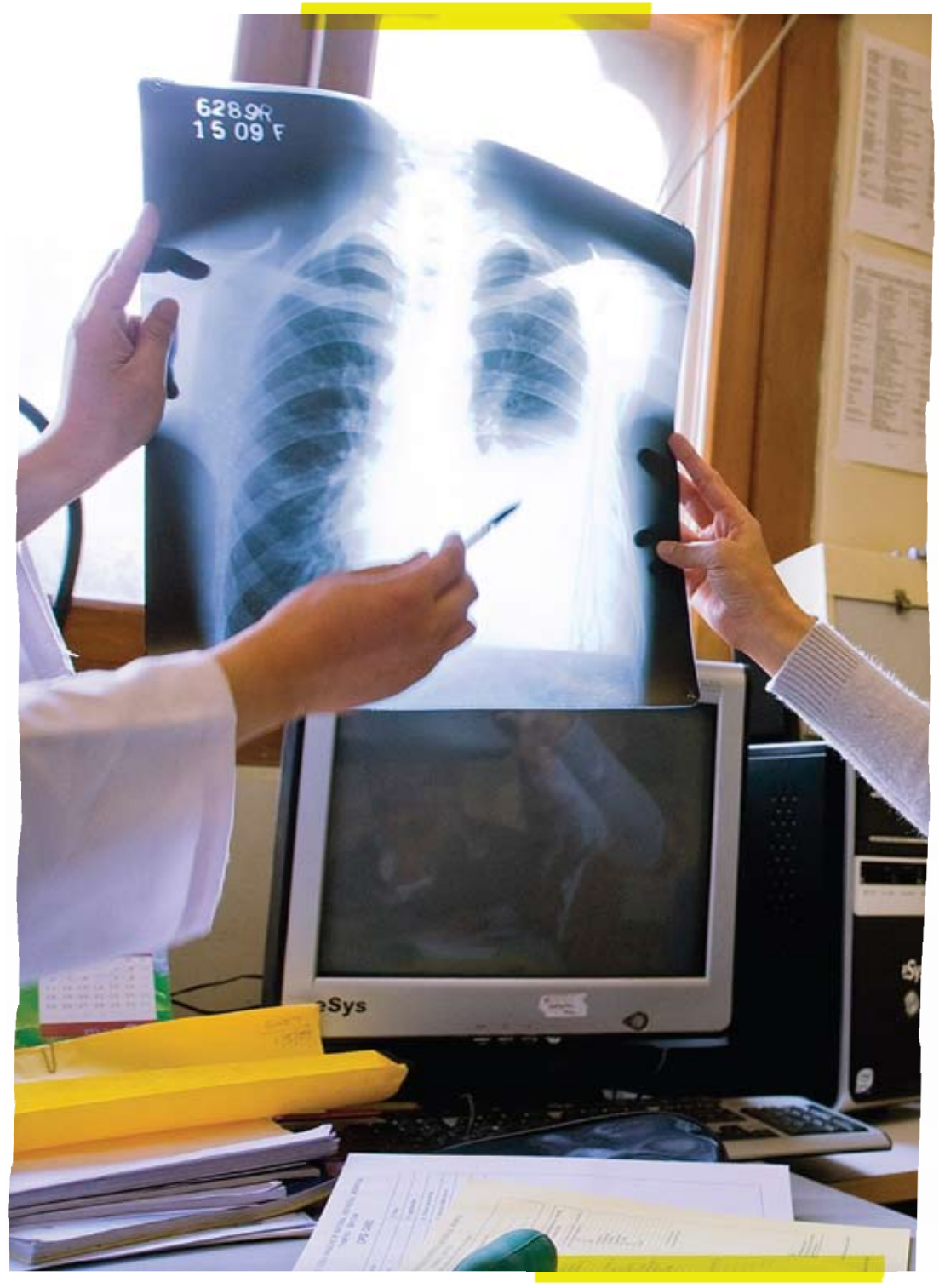
Adam is a **25-year-old student** at the University of Warsaw. Despite looking young and healthy, Adam suffers from Hepatitis C after contracting it through a routine dental procedure two years ago. The illness causes him extreme fatigue and he often breaks out in rashes. Last year Adam took part in an eight-month clinical trial for a new Hepatitis C drug. He explained how he was recruited to take part in a clinical trial.

Last year, I was at the hospital having some routine tests and getting my regular treatment for Hepatitis C. I went outside to have a cigarette and a doctor, whom I had never seen before, approached me and starting talking about a new drug for my condition. He told me it was much more effective in slowing down the damage to the liver and would take effect in a shorter time than my usual treatment. He then offered me the chance to take part in a trial if I wanted to and I accepted. It wasn't for money, in fact I didn't realise at the time that you could be paid for taking part in medical trials.

Anyway, I signed up to this trial which involved taking a pill every day and getting an injection every week for eight months. I signed a contract, which was about 50 pages long. I was fully aware of the possible side effects, such as hair loss, depression and fever. Although these kinds of side effects were not mentioned in the contract, they just warned me about them verbally. The hospital staff was very good at keeping an eye on me for those eight months, they always took blood samples and checked my hormone levels. I always had the option to stop the trial if things were not going well.

After the eight months were up, I was taken off the new drug and put back on my usual treatment. I am still suffering from Hepatitis C, I'm not cured. I had no follow up information about the trial, so actually I have no idea if that new drug is available in Poland now. I probably couldn't afford to buy it anyway, unless it was covered by state medical insurance.

"I had no follow up information about the trial, so actually I have no idea if that new drug is available in Poland now. I probably couldn't afford to buy it anyway."



Bio: Michelle Smith

Michelle Smith has been working in journalism for over nine years. Originally from Canada, Michelle is now based in Warsaw, Poland, where she has been Editor-in-Chief of three different titles and currently runs her own writing and editing business. Having worked with many Polish journalists and lived and worked in the country for many years, Michelle has an in-depth knowledge and understanding of Polish politics, business, culture and society.

Aside from the business and corporate aspects, issues relating to the clinical trial industry are rarely covered in the Polish media. Before discovering through Wemos that Poland was becoming a popular place for the outsourcing of clinical trials, I had never read or heard anything about it. After doing more research, I found it incredible that such an important and widespread issue, which was affecting Polish society in so many ways, could be kept so secret. I enlisted the help of a Polish journalist to do some initial research into the issue and we immediately came up against a number of obstacles.

We started with the official channels and approached an organization whose mandate was to protect the rights of clinical trial patients in Poland. It emerged that the interviewees presented to us had all signed confidentiality agreements with the various pharmaceutical companies, so it was therefore very difficult to have frank discussions with them. After a strategy re-think, I tapped into my local contact base and started rather lengthy research with the assistance of charities and small Non-Governmental Organizations (NGOs) working with poor and vulnerable people in the Warsaw area.

Both the NGO workers and the trial participants we met were initially suspicious of getting involved and were reluctant to go on the record. But, having lived in Poland for a long time, I had expected this. A widespread and deeply ingrained mistrust of authority is a relic of the former communist era. Plus, in Poland, every single person who voluntarily undergoes a clinical trial cannot have their personal data and experience used or published in any form – even if they give their permission. If they have signed an agreement about the trial, they are 100% protected and forbidden from giving any interviews and talking about their experiences.

When we finally gained their trust and started talking to the interviewees, it was immediately obvious that these people were all vulnerable and in desperate need of either money or medical assistance. It was disturbing to see how trusting these people were and it was clear they had all been recruited for trials precisely because they were desperate and willing to try anything.

Another surprising aspect was that the people taking part in the clinical trials came from all walks of life – from a single mother, to a homeless man, to a student and a wealthy business owner. That to me reflected that vulnerability, be it economic, physical or emotional, can be a decisive factor in both an individual's decision to participate in a clinical trial and in the recruitment strategy of the companies.

I hope that by publishing these testimonies, these people will have a voice and that greater awareness about the ethical issues relating to clinical trials both in Poland and around the world can be raised.

"Vulnerability, be it economic, physical or emotional, can be a decisive factor in both an individual's decision to participate in a clinical trial and in the recruitment strategy of the companies."

2. Russia

Mrs Adamova

Mrs Adamova is a **retired grandmother** who lives in the industrial city of Volgograd, southern Russia. Mrs Adamova was recently featured in an investigative documentary about the blossoming clinical trial industry in Russia after her one-year-old granddaughter Vika was entered into a trial without the knowledge or consent of her mother. Mrs Adamova explains how a number of other parents became caught up in a similar situation and how she tried, in vain, to ensure that the foreign pharmaceutical company involved was brought to account for their unethical recruitment practices.

My little granddaughter Vika needed to get her routine childhood inoculations, so her mother, my daughter, recently took her to our usual health clinic to get vaccinated against measles, mumps and rubella (MMR). However, for reasons my daughter didn't understand, the doctor at the clinic explained that she would have to take the child to another clinic in a neighbouring town.

So my daughter left the clinic and took a bus to the neighbouring town. By the time they arrived, Vika was fast asleep, but the doctors woke her up immediately and told my daughter that the inoculation needed to be given as quickly as possible as time was short. The doctor produced a form which my daughter was asked to sign. She didn't really read it and, having seen a copy of it later, it was written in a style of language which was very difficult to understand. And anyway, my daughter didn't suspect anything out of the ordinary, she just thought Vika was getting a routine injection.

A few days after receiving the vaccination, Vika suddenly started to become unwell and weak. She developed an itchy rash, her lymph nodes became swollen and she had difficulties in breathing. Then her legs started to become weak and she experienced painful spasms which hindered her movement. We decided to take her back to the same clinic to find out what was wrong.

The doctor at the clinic gave her a quick check-up and said there was nothing for us to worry about. He said it was most likely an allergic reaction to food and didn't examine her further despite her serious symptoms. Whilst at the clinic, my daughter met a parent whose child had received the same inoculation a week before Vika. This child also had similar problems with her legs and this is when our suspicions were aroused.

A few weeks later, the clinic called my daughter and asked if she could bring Vika back for a second injection. I told my daughter to wait because my instincts were telling me that this vaccine may not be safe. But my daughter was very concerned about making a fuss. She is in a secure job and did not want to damage her reputation.

So, the next day, I called a contact of mine who is senior paediatrician at a hospital in Volgograd. He said he hadn't heard anything about it, so he also started to look into it through the Department of Public Health. It soon transpired that these vaccines were in fact clinical trials being carried out by foreign pharmaceutical companies on Russian citizens without official permission from the local health authorities. It also emerged later in the criminal investigation that the doctors involved in the trial were being paid a kind of commission for every child they referred for the inoculation.

I did some more research and managed to find out which pharmaceutical company was behind these clinical trials. It was a major one from Europe and I wrote several letters to their representative offices in Moscow, but never received a reply. I telephoned a high-ranking hospital official and she warned me to stop investigating the company, saying that very influential people were involved and that I, as a nobody, would achieve nothing.

But I wanted to carry on and find out what was going on. I managed to contact some of the other parents who had received the same vaccine. We later found out from the investigation that, despite this clinical trial being designed for healthy participants, 56 out of the 113 children already had some form of neurological disorders when they were given the experimental vaccine. It was therefore difficult to prove that these problems had arisen as a result of the vaccine, but my suspicions were only further fuelled when I received letters from parents whose healthy children had been physically disabled after receiving the inoculation. Plus, given that Vika and the other children had not been examined properly, there was no official record of any side effects.

A criminal case was brought against the company but no-one was punished and I believe these and other similar trials are still going on. But what can we, as ordinary people, do in the face of a big corporation? I believe this company should pay for the treatment of our sick children but they will not. Most parents involved in this can't afford medical care or even the recommended high-calorie diet. We have no health insurance and Vika is still very ill.

"What can we, as ordinary people, do in the face of a big corporation?"

Bio: Sergey Nadejdin

Sergey Nadejdin is Russian investigative journalist and documentary filmmaker based in Moscow. He has worked for a number of Russian broadcast and print outlets and was head of the special reportage unit at Russia's Channel Three TV station for eight years. Sergey is now director of the Indigo documentary film company which works within the investigations department of Russia's semi state-owned Channel One. Sergey recently produced a hard-hitting investigative documentary about the increase of multinational clinical trials in Russia which revealed, amongst other issues, cases of people being recruited into clinical trials without prior informed consent. The film entitled 'Death by Prescription' was broadcast on Russia's Channel One in October 2010.

I thought it would be interesting to look more closely at the issue of clinical trials in Russia as no investigation of any real depth or quality has been done on this issue. It's still a very secretive subject and the general public know very little about it. I first got the idea to start looking into this after seeing a number of documentary films from Europe and the US about the expanding clinical trial industry. I thought it would be interesting to look into what was happening in Russia. In recent years, a growing number of major pharmaceutical companies have been keen to carry out more and more trials in our country because it's cheaper and easier to recruit people.

Before we started the research, I knew we would come across some complex and challenging issues when investigating this subject. We were able to track down and interview people and families involved in clinical trials through our own local contacts, through the internet, and also through the local press after we advertised for people taking part in clinical trials to contact us.

But, in terms of the background research, it was very difficult to establish 100 per cent the exact laws governing clinical trials in Russia. There are very few experts in national clinical trial law and those who did have an expertise were reluctant to speak to the media. In addition, a lack of hard data and statistics on trial patients and adverse events made the research very challenging and no doubt has been one of the reasons why the Russian media have not looked into this matter more closely.

It was quite alarming to learn that such unethical and bad practices were still going on in Russia, particularly in relation to patient's rights and protection measures which are still lagging way behind those in Europe. It became evident that the clinical trial monitoring systems and legislation in Russia are still very weak and I hope that this film will be useful in drawing attention to the failings in the current system.

On a positive note, there has been some movement on this issue over the past year, for example the matter of compensating doctors for recruiting trial patients has recently been debated in the Russian Parliament. So I believe the more attention that is raised, the greater the pressure will be for the government to tighten up existing legislation.

FILM 'Смерть по рецепту'
English title: 'Death by Prescription'

Production: Studio Indigo, Russia, 2010
Scenarists: Sergey Nadejdin, Olesya Shakhbazova
Director: Mihail Elkin
Producers: Sergey Nadejdin, Natalya Elisova
http://www.1tv.ru/anons/id=162563
http://www.youtube.com/watch?v=q6iCxQY9Xws

3. United States

Robb Mohr

Until she died during a clinical trial, **Jolee Mohr** was a vivacious **36-year-old secretary** and doting **wife and mother** to husband Robb and five-year-old daughter Toree. The family lived in Taylorville, Illinois where Robb worked for a retail farm service centre. Despite having rheumatoid arthritis for over 16 years, Jolee had been able to enjoy an active, busy life with little discomfort thanks to various conventional arthritis drugs. When she told her doctor that her right knee still bothered her at times, he suggested that a new experimental gene therapy drug might help her. He was so enthusiastic about the possible benefits of the drug that Jolee didn't think twice when he asked her to sign a consent form enrolling her in a clinical study of the experimental therapy. Robb and Jolee thought the study could be an opportunity to help reduce the swelling in her knee. After consenting to take part in the clinical trial, Jolee became a test subject in an early-phase study that wasn't designed to test whether the therapy worked - but whether it was safe.

We were optimistic about the new gene therapy and thought it would help the arthritis in Jolee's knee. Before the trial started the doctor asked her to sign a consent form that was 15 pages long. She didn't really read it in that much detail. How many people would with the doctor sitting right there in front of you? Anyway, the doctor explained that Jolee would receive two injections; the first one could contain either the experimental drug or a placebo. The second injection would definitely be the trial product. I don't think Jolee was aware of the risks involved. She was a very trusting person and had total faith in her doctor so she went ahead and signed up for the trial.

After her doctor injected her right knee the first time, she seemed to be ok. However, just a day after the second injection, which contained the experimental drug, Jolee started to feel sick. She had a fever and headache. Doctors thought she just had the flu. Then she began to vomit and have terrible abdominal pain and had to be hospitalized. Her doctors discovered that she was bleeding into her stomach and her liver was failing. Within days they had to put her on a life support machine. Just before she died, they discovered that the cause of her bleeding was a fungal infection, histoplasmosis, which had attacked her liver, lungs, spleen, kidneys and brain. She died three weeks after her doctor had injected her with the drug that we had hoped would help her.

My wife had been in good health before the clinical trial, so I had strong suspicions that her death could be linked to the experimental drug. I voiced my concerns and was shocked to learn that the manufacturer didn't report Jolee's symptoms to the US Food and Drug Administration (FDA).[5] The drug company claimed the reason they didn't report her illness was that there wasn't enough evidence to prove that their drug caused her symptoms. But after she was transferred to another hospital, not connected to the clinical trial, doctors there intervened and filed a 'serious adverse event' report with the FDA. That was four days before she died. Even then, the company conceded that her condition was only 'possibly' due to the treatment.

The company claims that since Jolee was taking an immunosuppressant drug for her arthritis along with the study drug, there was no proof that the experimental had drug caused her infection. But the experimental drug they gave Jolee was a powerful immunosuppressant and what makes me really angry is that the label on the arthritis medicine she was taking before the study – and that they told her to continue during the study – specifically warns that it shouldn't be given with another immune suppressing drug. Despite this, her doctor enrolled her in the study and the FDA allowed it.

Now I'm left to pay all the hospital bills because the company still says there isn't proof that the drug caused her death. But the consent form stated that volunteers would not have to pay for medical costs. This to me is a failure of the safety net, which is supposed to protect people who are injured during medical experimentation.

I discovered later that Jolee's doctor might have had a reason – other than her best interest – to encourage her to enrol in the clinical trial: He was receiving payments from the manufacturer to recruit volunteers and conduct the study. This clinical trial was not what Jolee thought it was. I think people should see two independent doctors before they enrol in any study and we should have had our own lawyer look at the consent form beforehand.

[5] The FDA is an agency of the United States Department of Health and Human Services, responsible for public health and the supervision of medical products and vaccines.

Robert Helms

Robert Helms is a 53-year-old **former painter and decorator** living alone in south Philadelphia. With painting work now scarce, Robert, a former union activist, lives on unemployment benefits and devotes his time to writing and campaign organizing. Robert spent eight years as a research volunteer for clinical trials before he became too old to enrol in many studies. He explains how and why he decided to become a so called 'professional guinea pig'.

I used to sign up for clinical trials on a regular basis for about eight years. It was a quick way to make cash to fund my writing and activism activities. My antecubital vein was my financial pipeline. In a good year, I could usually make around USD[6] 15,000 (approximately 10,856 Euros) just from doing trials.

The term *volunteer* is not really correct. People do these trials for the money. But the money isn't really that great. The time it takes to participate in a study, sometimes weeks at a time, makes it virtually impossible to hold down a full-time job. Because of this, many clinical trial subjects in the US are often former prisoners, students or unemployed people. Once I took part in a clinical trial at a testing site called Neptune. It reminded me of a boot camp because the officials had to search us for guns before we went in. Half the guys at that testing centre had been in jail.

For sure I was aware of the risks of taking part in clinical trials, but I wasn't too concerned. Working as a painter, I spent most of my days climbing ladders and working up on rooftops. Painters regularly fall and end up paralyzed or dead. So I wasn't too concerned about any danger from clinical trials. But I did hear of things going wrong. Once I had to 'babysit' a friend of mine, a fellow guinea pig, who was working as a test subject in a study of the interactions between an allergy drug and an antidepressant. My friend had no history of psychosis, but during the study he became frankly psychotic. In the end, a few of us guinea pigs got together to fight to get medical attention for him because the drug company said they were not responsible for his condition. So yes, I was aware of the risks and always stayed clear of trials for drugs such as antidepressants.

Although I was never too concerned about the risks I was taking, I still find it disturbing that most test subjects don't get any health insurance even though they are volunteering their bodies for the benefit of science. In my eight years taking part in clinical trials, I was never once offered any insurance. Because of my background as a union activist, a few years ago I started up a magazine for clinical trial volunteers called *Guinea Pig Zero* which aims to represent the views and voice the similar concerns of clinical trial 'guinea pigs'.

I used to think to myself: If I'm doing this for altruistic reasons and volunteering my body so other people can get better medical care, but I'm not getting any medical care, then I'm just a loser who gets cr*p. The humanity I referred to doesn't apply to me. In my opinion I am not considered human unless I get healthcare coverage.

"My antecubital vein was my financial pipeline."

[6] United States Dollar (USD), America's currency. Rate on October 27, 2010. Source: International Currency Converter.

Dave Onion

Dave Onion, 38, lives alone in Philadelphia where he works as a **website developer**. In his late twenties, Dave became a serial participant in clinical trials. In 2003, after both experiencing and witnessing many aspects of the clinical trial industry, he wrote an article for 'Guinea Pig Zero' magazine questioning the unfair pay and working conditions of trial participants. Despite no longer taking part in clinical trials, Dave was keen to share his concerns and observations about the industry.

I signed up for my first clinical trial around the age of 27 after hearing about it from other people who were volunteering. I had to go to a testing site in New Jersey which belonged to one of the leading drug companies. Security checks were tight and we were forbidden from taking photos.

Taking part in clinical trials did turn out to be a really quick way to make money. I did about 12 trials in all, but haven't done any for the past few years. The best money I made was USD 7,000 (approximately 5,066 Euros) for a trial which lasted a few weeks. I wasn't scared at all and didn't really think about the risks. I read the consent forms, but they were mostly considered as bureaucratic bullsh*t by many doctors. I used to scan through the form to check for information about any effects of the drug on previous test subjects or animals.

The money you could earn was easy but the amount wasn't always that great. The 'professional guinea pigs' I met were usually scrabbling around for money to pay the rent and buy food. Sometimes people were so desperate to get into a study that they would lie about existing illnesses or illegal drug use. Lying is very widespread in this industry.

"Lying is very widespread in this industry."

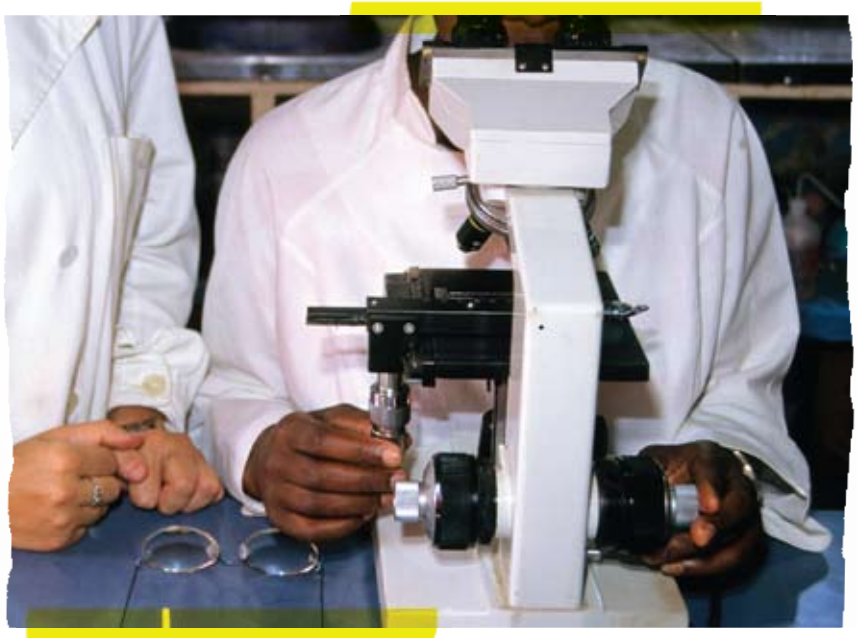
Another thing that concerns me is that many volunteers lie about the side effects of the drugs they are given so they can be allowed to complete the trial. I once had a bad experience where I was pushed to the limit with the dosage increases. My head felt like mush and I wanted to get off the drug.[7] But the research official threatened to withhold my USD 1,000 (approximately 724 Euros) if I didn't complete the trial. Luckily a nurse intervened and allowed me to stop without forfeiting my payment. Desperate people who choose to ignore the side effects are endangering themselves and also compromising the scientific results.

[7] Mr Onion was enrolled in what is known as a 'dose escalation' or Phase I study in which a drug is tested for safety through continuous, small increases in drug dosage until side effects are too strong to safely continue.

Jamie Graham

Forty-year-old **Jamie Graham** is currently employed as **social worker**. As a young college student at the University of Virginia, Jamie was arrested and sent to prison for minor drug offences. Despite his subsequent release a year later, the consequences of that one criminal incident stayed with him for over 20 years and affected his ability to find regular employment. As a young adult living day-to-day and desperate to earn an income, Jamie decided to find work as a 'professional guinea pig', renting out his body to doctors for medical research. He recalls his experiences.

I was living in an abandoned house when I first started taking part in clinical trials. A fellow prisoner told me about the work. He told me there were only two jobs that ex-convicts could get without being asked questions about whether you have a prison record. The two jobs? Be a drug dealer – or a guinea pig. I didn't want to deal drugs, so I decided to become a guinea pig for medical experiments. Throughout the time I was doing clinical trials, about one in five of the subjects I met were ex-convicts.



We were always given a consent form to sign, which I tried to read carefully. They did use a lot of complicated terms like cardiac arrhythmia. Not everyone knew what words like that meant. A lot of people went in and took a release that was several pages long and would just flip right to the back page without reading the consent and sign.

The trials I did never came with any health insurance and I was never tested for pre-existing illnesses like HIV or Hepatitis. I assumed I would be tested for everything, I wish they had told me these kinds of checks were not included, because all that time I assumed that I didn't have any of those conditions and then I found out that they never tested me for them.

I was aware of the risks. But I used to put LSD into my body, so why would I be worried about a study? I was usually able to spot the riskiest drugs and avoided them. I decided to stop doing trials a while back. I miss the easy money but I don't miss the job.

"Throughout the time I was doing clinical trials, about one in five of the subjects I met were ex-convicts."

Bio: Jeanne Lenzer

Jeanne Lenzer is a US medical investigative journalist based in New York. Throughout her career, Jeanne has published a number of articles about the ethical aspects of clinical trials for respected publications such as the British Medical Journal (BMJ), Discover Magazine and The Atlantic. The focus of her US-based investigations has ranged from issues of informed consent, the suitability of trial participants, and how financial conflicts of interest and the drive for profit can potentially lead to biased reporting of study results. In 2003, Jeanne also published a powerful report in the BMJ about the unethical practices of multinational pharmaceutical companies conducting clinical trials on children in Nigeria.

As an investigative journalist, I have been looking into the issue of clinical trials in the US for many years. I was therefore able to tap into my contact network when I was approached by Wemos to work on this project. As a first step, I approached someone who had worked as a test subject in numerous studies in return for payment. He was able to introduce me to a number of volunteers who, often desperate for money, had enrolled in multiple clinical trials. This was my introduction to the world of people who call themselves 'professional guinea pigs'.

Despite having covered the clinical trial industry extensively, it still remains a real challenge to actually get access to the people being recruited. The pharmaceutical companies and the CROs hired to manage the trials are supremely well organized and go to great lengths to ensure media scrutiny and access to participants is limited.

A number of excellent articles on the clinical trial industry have been published and there are several websites devoted to the monitoring of the ethical issues, but I think the American public are generally still unaware of how financially compromised many doctors and trial researchers can be and how poor the oversight of clinical trials still often is.

It was very interesting to learn about the lives of people who volunteer for clinical trials and understand what motivates them to do so. It's always surprising to me, that despite some significant risks, many of the participants don't consider trials as particularly risky – or at least not in comparison to the other job choices available to them. The issue of choice and a lack of alternatives are important factors to consider when looking into this issue.

It's of course important to remember that many people taking part in clinical trials have very positive experiences that trial research can benefit us all. But it's also important to remember that problems and failings still exist, both in a developed country like the US and in developing countries where the clinical trial industry is beginning to flourish. It's not an easy problem to solve but there are some innovative ideas that should be examined and the public should be more involved in the process.

"The pharmaceutical companies and the Contract Research Organizations hired to manage the trials are supremely well organized and go to great lengths to ensure media scrutiny and access to participants is limited."

4. China

Mr Zhang

Mr Zhang is a 35-year-old professional **journalist** and the doting **father** of his 18-month-old baby son. To the dismay of Mr Zhang and his wife, their baby boy was born with a congenital heart defect and initially only given 20 days to live. Desperate to give their son a chance of life, Mr Zhang, who lives in Guizhou Province in the southwest of China, gathered together all the family's private financial resources, arranged leave from his job, and managed to get the baby into a Beijing hospital for lifesaving open heart surgery. A first operation on the baby's left heart valve was successful and, two months later, the little boy was deemed strong enough for a second round of surgery. It was at this point that the family was offered the opportunity to take part in a clinical trial for an international pharmaceutical company.

When our little boy was born, the doctor told us that he had a serious problem with his heart and that he would die within a month. Some of my wife's family told us that we should just give the baby away to the cleaner, so she could drown him and we would be free from the burden of a sick child. But of course there was no question of that, I knew my little son was a fighter and we could save him. Fortunately my wife and I both work, so we were able to pay for the first operation on his heart, and this seemed to go well. Afterwards, he was very weak and still dependent on the ventilator, so he stayed in the hospital in Beijing for two months and then we were told he would need a second operation.

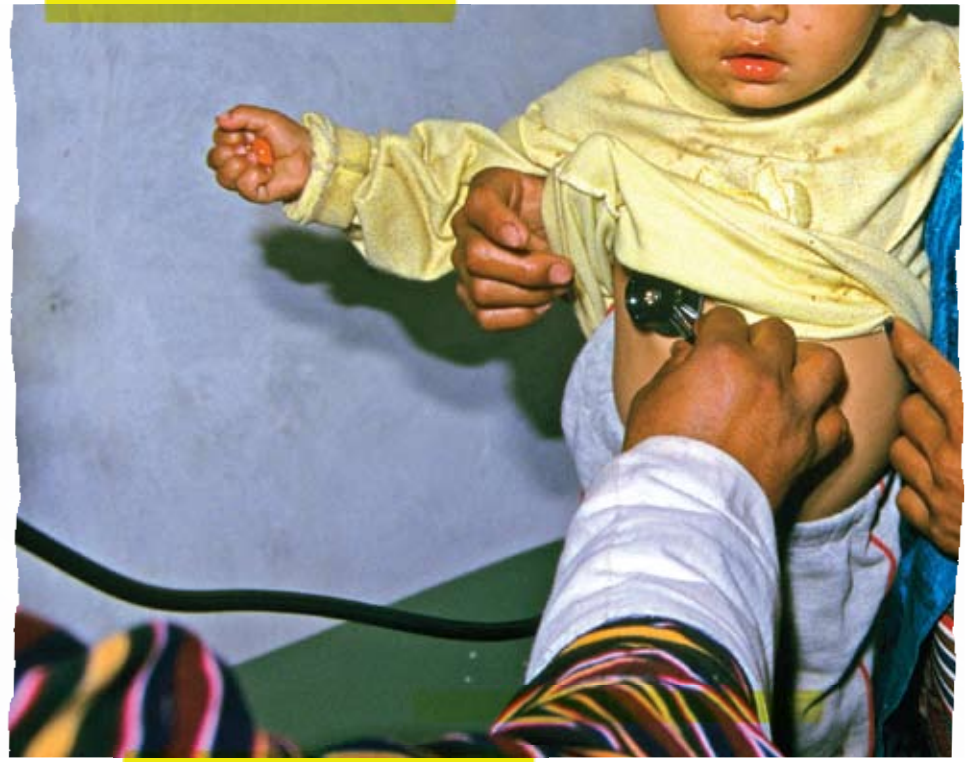
Before the second operation, the doctor explained that because of a problem with my son's left heart valve, there was a risk that the blood would not be able to circulate properly and could clot. To try and prevent this, the doctor said they would insert a tube to try and help the blood flow more easily. He also said that ideally they needed to try and thin his blood. We were told that for adults this could be done with aspirin or specialist blood-thinning drugs. However, the doctor told us that blood-thinning drugs for babies and small children were not yet available on the market in China.

"It felt a bit like gambling."

We were feeling very worried and despondent about our son and the upcoming operation, but then the doctor mentioned that a big pharmaceutical company from Europe was carrying out clinical trials for a blood-thinning drug for children in the very same hospital in which our son was being treated. We were told by the doctor that an adult blood-thinning drug was already on the market, both in China and all over the world, and that the company now wanted to see if this same drug was safe to use on babies and young children.

I asked the doctor if taking part in the trial would be risky for my son and he told me that in all honesty he could not be 100% sure. But then he continued to say that he thought the risk would be low because the adult version, already on the market, had proven to be safe. Given the urgent situation, I didn't feel that I had any choice, so my wife and I agreed to enrol our son in the clinical trial.

We were told that we would receive the drug for free which immediately sounded alarm bells in my head. As a journalist, I know there is no such thing as getting something for free in China, and I wondered if there was some other motive behind it.



Whilst we were enrolling, it turned out that there were quite a number of other parents taking part in the same trial as our son. Many of them were clearly from poor backgrounds, a few were unable to even read. They just seemed to be happy to be saving money and getting free treatment. I was the only parent asking any questions.

The doctor gave us some information about the drug company and about the nature of the drug and the dosages involved. I was also asked to sign a consent form which I carefully read and tried to find out exactly what safeguards were in place to protect my son should anything go wrong. I noticed that the form stated clearly that if doctor's orders were not obeyed throughout, neither the hospital nor the drug company would pay for any subsequent illness or injury. This to me sounded quite useless and open to manipulation. But again, I felt like I had no choice but to sign the form because my son needed the surgery. It felt a bit like gambling.

We were also told that, as parents of the trial subjects, we would not be allowed to have any direct contact with the pharmaceutical company and that we were only allowed to talk to the hospital staff involved in the trial. I remember once trying to talk to a delivery man who came from the pharmaceutical company. He told me that he was under strict instructions not to talk to any of the patients.

So my son, given the number 001 because he was the first baby in the trial, was given the experimental drug to thin his blood and then underwent the second heart operation. It seemed to go according to plan, although there were some complications when closing up his chest after the surgery. A few days later my son suddenly developed a very serious lung infection and weeping, itchy sores all over his head. I was concerned by this and I asked the doctor if this was a side effect from the experimental drug. To my frustration, he refused to give me an answer and no one seemed to be able or willing to give me any information. There was no one to make a complaint to, it was obvious that I was expected to keep quiet and just trust the doctor and the hospital.

My little boy was still very weak from the operation and the lung infection. He was kept in the Intensive Care Unit for a week and we were very worried. Even though I couldn't prove my son had been directly affected by the clinical trial, I was powerless to even ask questions or get any clarification.

This all happened very recently and my son is still in the hospital and still in a serious condition. We are waiting to see what happens next. I realize now that there really should be an independent third party to mediate in cases of clinical trials, but in China this doesn't seem to happen.

This incident has made me think about clinical trials. I understand that clinical trials are important for medical development, but why does a developed country need to run trials in countries with many poor people like China? I would like to know if this company is doing the same trials on children from European countries. The human rights of children all over the world should be respected. In China we need to make sure that parents like me get access to all the information before and after the trial takes place.

Hao

Hao is a 23-year-old **estate agent** currently living with his girlfriend in Beijing. Hao's job selling property is commission-based and therefore not a guaranteed source of stable income. Hoping to get married next year, Hao is in desperate need of extra money and has been a regular participant in clinical trials for the past two years. Despite being recruited on the basis of being a healthy volunteer, Hao looked underweight and gaunt with yellowed eyes. Hao explained how a friend had introduced him to the clinical trial industry.

A friend of mine told me about clinical trials a few years ago and said it was an easy way to make some quick money. I don't earn much money in my job and I also have a lot of time on my hands when we don't have any clients. So I gave my information to a patient recruitment agent and started taking part in clinical trials. The agent usually rings me whenever a new trial opportunity comes up. I usually do trials for foreign companies whom, I'm told, just want to make sure their drugs are not harmful to Chinese people.

Normally there are around 20 of us selected to take part in a trial. The doctor explains what will happen and then we have to sign a form to say we agree to take part. I think the form is usually about six pages long. So far, the drugs I have tested have already been approved in countries outside China. That's what they tell me anyway but I have never checked that out for myself. Sometimes I do think about the risks and wonder about what would happen if there were some bad side effects. I could not afford to pay for medical care myself and I don't have insurance. Of course accidents can happen, but I think China has been running these kinds of clinical trials for some years now and so far it seems ok.

There are many people willing to take part in clinical trials and there is a big business around it. For example, there are agents like mine whom I suspect get paid a fee by the hospitals to find people.

The longest I ever stayed in the hospital for a trial was 29 days and I was paid RMB[8] 5,000 (approximately 539 Euros), which was good money for me. But now I heard the amount of money we can get is going down because so many people are signing up. Of course, most people in China are taking part in trials for the money. If we didn't get paid, we wouldn't do it, nobody would go. It takes up your time and you are at risk of taking something which could be poisonous to your body.

"Sometimes I do think about the risks and wonder about what would happen if there were some bad side effects."

[8] Renminbi (RMB), China's currency. Rate on October 27, 2010. Source: International Currency Converter.

Mrs Liu

Mrs Liu is a 47-year-old **farmer**, who owns a small plot of corn field in a village about an hour south of the Chinese capital Beijing. Three years ago, during a severe winter, Mrs Liu started to feel sick and started coughing up blood. Her illness got steadily worse and her local doctor diagnosed her with lung cancer. Having little faith in the local health service, Mrs Liu and her adult son went to a hospital in Beijing. Having no savings or insurance, the family was forced to meet the upfront costs of the consultation by borrowing money from her son and other family members. Mrs Liu's husband, a former electrician, can no longer work due to failing eyesight and general ill health, so the couple is dependent on their son's salary and money is extremely tight. The tumour on Mrs Liu's lung recently spread to her brain, so she went back to the hospital in Beijing to seek further treatment. It was at this point that she was offered the opportunity to take part in a clinical trial for an anti-tumour drug for a Chinese company manufacturing traditional herbal medicine. Now back at her sparse, rural home, Mrs Liu is visibly in pain with one side of her face being badly swollen and her eyes constantly weeping. She explained how she had become involved in a clinical trial.

I knew something was wrong when I started to get pains in my head and I started vomiting. The doctor in Beijing told me the tumour had moved onto my brain. I told him that we were a very poor family with no savings and that I would not be able to pay for any treatment. He then told me that I would be a suitable candidate for a clinical trial for a drug to help shrink the tumour. I didn't really understand anything but he said I could have the treatment for free which was a good thing. I do not really understand what a clinical trial means, but we are poor farmers and the most important thing for us is saving money.

There were many of us wanting to take part in the trial, so the hospital set up a kind of lottery system. We all had to draw lots to see if we could get a place. I was lucky and given the chance for the free treatment, everything like the radio therapy, the blood tests, CT[9] scans and the check-ups would all be free of charge.

Neither I, nor my husband, understood what a clinical trial was or what it would involve. We didn't ask the doctors anything. I didn't think about any risks, I just wanted the free benefits and to save some money. They didn't ask me to sign anything, I don't remember any kind of contract or agreement, and I just told them I agreed to take part. There was one form which recorded the types of drug I was taking, but I couldn't understand it, I have no idea what the name of the drug even was. The doctor told me it would stop my dizziness and make me feel better. I had the treatment a few months ago but I have no idea if the medicine has worked or not, I am still very ill and waiting for another check-up.

Now that I know more about clinical trials my husband is angry and upset. He said that if we were a rich family we would not have to take part in these clinical trials and face such risks.

"I do not really understand what a clinical trial means, but we are poor farmers and the most important thing for us is saving money."

[9] Computed Tomography.

Lifen

Lifen is a 23-year-old **student** from the northwestern province of ChingHai. Lifen currently lives in Beijing where she recently graduated from university and is now keen to stay on in the capital to pursue further studies. However, given her status as a student, her finances are limited and she feels too ashamed to ask her parents for any more funding. Two years ago, Lifen discovered that pharmaceutical companies, both Chinese and foreign, were paying healthy volunteers to take part in clinical trials. Believing this to be an easy way to earn income, Lifen has so far taken part in five clinical trials and continues to do so.

I started to take part in clinical trials about two years ago when I was still completing my studies. There were posters around the university campus calling for volunteers to come and take part for money. I called the number and made contact with a girl, another Chinese student, whom I guessed was working as the recruiting agent for the companies. I later learnt that hospitals in China seem to have a regular list of trial participants to call upon and they also use recruiting agents like the girl I deal with.

The agent explained that the drugs I would be testing were already on the market in other countries and that the pharmaceutical companies, mainly foreign ones, just needed to do the trials here in China, to make sure the same drugs were not harmful to Asian people. I did not think there would be any risk at all. I still don't. I don't worry about the side effects because I know that the drug has already been tested on people and animals.

I really was getting desperate for money, I knew I wanted to study more but I am now too old to ask my parents to help me financially. I knew this extra income would be an easy way to help with my studies. So far, I have taken part in five clinical trials for foreign pharmaceutical companies and it has usually followed a similar process.

"I totally trust what the doctors are telling me."

Before the trial starts, all people taking part are given a consent form and an information booklet explaining about the drug. The longer the trial will take, then the longer the agreement paper I need to read and sign. Normally it's around four to five pages and the doctor goes through it with me and I can ask any questions. I totally trust what the doctors are telling me. I never know which company the drug is being trialled for, but I am always aware of what the drug is supposed to cure. So far, I've done trials for drugs which regulate the heartbeat, for tuberculosis and also one to help with swollen joints. The drugs either come in the form of pills or as an injection and so far, I have always stayed in the hospital for a few days.

The money is good, although recently I've noticed the payment rates have been going down. I think this is because there are more and more volunteers coming forward. The money we receive is determined by the number of days you need to stay in the hospital. The average amount for a trial is around RMB 5,000 (approximately 539 Euros) for a couple of days in the hospital. If a drug trial is deemed to be a bit more risky and could result in physical harm, you can be paid an additional fee on top of the basic payment. I heard about one trial which paid volunteers over RMB 50,000 (approximately 5,388 Euros) for less a month's work but with the risk that the drug could leave the patient with painful lesions on the body.

I don't worry about the risks and so far I have had no serious side effects from taking part in clinical trials. I have heard that some bad things have happened to other people, but the worst thing I suffered was mouth ulcers. I'm not sure what would happen if something went really wrong, I don't think compensation is included in the consent form.

I think foreign pharmaceutical companies are doing trials in China because it's easy to find volunteers. We have a very big population and unemployment is high. I think if you are extremely poor and in urgent need of money, people will take part in clinical trials and not care about the risks. I don't tell my parents that I'm doing this because I know they would be really worried and try to stop me from doing it.

Bio: Jessica Sallabank

Jessica Sallabank is a British journalist currently based in Geneva, Switzerland. She has been a professional journalist for over eight years working in both print and television covering issues in Asia, the Middle East and Europe. In 2006, Jessica joined the TV station Al Jazeera English where she worked on the investigative programme 'People and Power'. She has also worked on documentaries for BBC Television and most recently with the French/German channel ARTE, on an investigative documentary about the clinical trial industry in India.

Having spent two months in India working on the ARTE documentary, I had already done a lot of background research into the global clinical trial industry. So when I was approached by Wemos to investigate the situation in China, I thought it would be a good opportunity to see whether the issues and challenges we had encountered in India would arise in a Chinese context. The issue of globalization and the outsourcing of services in general has become a dominant issue of the past decade and has brought up lots of questions about the advantages and disadvantages for people in developing countries. The increasing trend by the pharmaceutical companies to outsource their clinical trials to countries such as China is an issue which merits much more media scrutiny than it currently receives.

Before even arriving in China, I knew that it was going to be difficult to find both a Chinese journalist to work with me and to get access to the people taking part in clinical trials. I made contact with around 10 different Chinese journalists, working both inside and outside of the country, but the majority of them were reluctant to undertake this kind of research due to their own legitimate safety concerns. In addition, the only reporting taking place on clinical trials in China seemed to be linked to the business aspects so the journalists I spoke to had very little to go on in terms of leads and background information.

After over a month of searching, I finally made contact with a young Chinese journalist, who we can obviously not name for security reasons. She had a background in media and communications and had spent the past few years working with various foreign TV news crews covering stories in China. She was willing to help with the research and spent 10 days on the ground in Beijing researching and seeking out possible people for us to meet and interview. She was incredibly smart and resourceful in her approach to the research, spending hours sitting around hospital waiting rooms and standing outside hospitals talking to people. She also followed up on the trial recruitment posters which were posted around university campuses advertising for trial volunteers. It was as a result of both her resourceful investigative techniques and a few strokes of luck that we managed to get to access to our interviewees.

It was indeed an interesting and rewarding project to be involved in and I hope that these testimonies will inspire other journalists and also NGOs and governments to start scrutinizing more closely the potential problems that can arise from carrying out clinical trials in less developed countries. The onus should not just be on the pharmaceutical companies to ensure their practices are ethical but also on governments to tighten up trial regulations and invest more in their national healthcare and welfare systems. That would ensure that people are not tempted into things simply through desperation and lack of alternatives. Clinical trials are a crucial and necessary aspect of medical research but the highest standards of ethics should be applied at all times, in all countries.

"Clinical trials are a crucial and necessary aspect of medical research but the highest standards of ethics should be applied at all times, in all countries."

5. India

Surender Kolagani

Surender Kolagani was a healthy 25-year-old man living near the southern Indian city of Hyderabad. About to be married and unable to find work, Surender secretly started to volunteer for clinical trials in return for payment. His participation in so called 'bioequivalence studies', trials which test the efficacy of an existing drug already on the market with the same drug of another company, became regular and enabled him to earn enough money to survive whilst trying to find full-time employment. But things took a turn for the worst just days after Surender took part in a trial to monitor a drug called felodipine which was already on the market to treat high blood pressure. The trial was being managed by a local based CRO which was tasked with finding and recruiting patients on behalf of the pharmaceutical companies operating in the city. The sudden death of Surender, nine days after taking the first dose of the drug, and the secrecy around it, attracted the attention of a local journalist from his hometown of Warangal who tried, in vain, to access the police report and Surender's post mortem result. The CRO involved told the media that Surender had been taking part in several clinical trials at the same time and there was therefore no evidence to prove the young man had died as a result of that particular trial. The many unanswered questions attracted the attention of investigative documentary filmmaker Paul Jenkins and his ARTE team. They travelled to the remote rural town of Warangal to meet the family of the dead man. Paul explains what was revealed.

After coming across Surender's story in the local press, we managed to make contact with the journalist who had initially reported his death and knew how we could find his parents. The village where the Kolagani family lived was very remote and very poor and it was clear that the presence of foreigners was initially making the family very nervous and suspicious. Eventually Surender's parents and his younger brother opened up to us – once it was clear we were not working for the pharmaceutical industry or any other organization that could influence their attempts to try and get answers. Surender's father, Babu, told us that his son had kept the fact he was working as a clinical trial volunteer a secret. The family was under the impression that Surender was working in a laboratory and saving up for his upcoming wedding and married life. It was only when the family was informed that their son had died following a clinical trial that they learnt about his secret life and that he had received around INR[10] 150 (approximately 2 Euros) per day to volunteer for the drug study, which involved two stays of about three days of observation at a time.

Almost two years on, there has been no real conclusion to the case of Surender Kolagani. The Kolagani family tried in vain to get more information about what had happened. At the time of writing, no one, including Surender's parents, has been able to see a copy of the autopsy report and efforts to claim any form of compensation have been in vain. *"Why did they give those tablets and cheat a young boy? What a bastard company!,"* Surender's father said to us.

The CRO denied all responsibility and refused to reveal any details about the nature of the trial and the pharmaceutical company that had sponsored it. *"If Surender was participating in trials with other CROs*," the head of another leading CRO in Hyderabad told the local newspaper, *"then the CRO should have taken enough care in his case since this particular drug would react with other drugs administered to him by other CROs."*

[10] Indian Rupee (INR), India's currency. Rate on October 27, 2010. Source: International Currency Converter.

Baby Lakshimi

In November 2008, three-month-old **baby Lakshimi** died just a week after receiving the third in a series of vaccinations for a Phase III clinical trial at a leading hospital in Bangalore, India. The trial was to test an advanced vaccine for pneumococcus, a bacteria that causes serious infections in adults and children, including pneumonia, blood infections, and meningitis. The vaccine trials, sponsored by a leading US pharmaceutical company, were intended for healthy babies only and involved the testing of the new advanced vaccine against the already approved version of the vaccine. Baby Laskhimi was injected with the approved version but, after receiving a third vaccination, became very ill and died just a week later. The death of baby Lakshimi, whom it was later revealed, had a pre-existing cardiac disorder, resulted in the first ever investigation into clinical trials by the Indian government and generated a significant amount of media attention in both the national and international press. After successfully tracking down the bereaved parents of baby Lakshimi, Paul Jenkins was able to piece together the events leading up to the baby's death. He explains the background to the story and his experience of meeting the family.

From our initial research, we knew that the Indian government's investigation into this particular case had revealed that the baby girl had a pre-existing heart condition and should therefore never been accepted onto this trial in the first place. There was no way of proving that the baby had died as a direct result of the drug trial, but there were still many ethical questions about the way this baby had been recruited and why a sick baby had been involved in a trial designed for healthy infants only.

The Bangalore story had sparked the interest of the national media and, with the assistance of local journalists, we decided to look into the story further. With the help of a resourceful Bangalore city crime reporter we were able to obtain a copy of the baby's death certificate and track down the address of the baby's parents. The family lived in a slum area outside of Bangalore and were initially confused and very wary of meeting foreigners. Eventually they agreed to talk to us and explain what had happened to their baby. The parents, father Parameshvaraiah and mother Pushpalatha, were still clearly very upset about the death of the baby and were shocked to be told that their case had become the subject of national media scrutiny. They were also unaware that the Indian government had launched an investigation into the case and said no one from the government's investigation team had ever approached them as part of a follow up investigation. We found this quite disturbing and wondered how comprehensive this government audit had actually been.

The couple recounted how Lakshimi, named after the Indian goddess of wealth, had already been ill with a cough and diarrhoea at the time of the trial and, like an earlier deceased sibling, had been born with an enlarged heart. The local family doctor, who referred the baby for this trial, was well aware of Laskhimi's fragile health, but according to the parents no further checks or chest x-rays were carried out on Laskhimi before she was given the vaccine as part of a Phase III global trial. *"We were told we would get the injection and treatment was free,"* Parameshvaraiah told us. *"The hospital said the medicine came from abroad. They said it was good for children's health. We gave him all the (health) details. He's always been our family doctor and been with us through good and bad times. How could he do this knowing the full history?"*

Although it was extremely difficult to prove that baby Lakshimi's death had been directly linked to the vaccine, it was very clear that mistakes had been made at the recruitment stage. The Ethics Committee charged with overseeing the protocol of the trial had approved the study on condition that the babies involved were in good health. What also became apparent from the Bangalore case was just how unclear the lines of responsibility were in the chain of command. The pharmaceutical company had outsourced the trial management to a local CRO, who in turn had handed over responsibility to local doctors. So where in fact did the blame lie for the death of this baby girl? And would better monitoring at all levels have prevented such an incident from happening?

With the launch of the government investigation, all testing for the vaccine trial was suspended for six months across India, but was then subsequently resumed. Lakshimi's parents have still had no contact with the government investigators and received no real answers or any compensation for the death of their daughter.

The Diamond Workers

The western Indian state of Gujarat has traditionally been a major centre for the global diamond manufacturing industry. But, with the onset of the recent financial crisis, global demand has dropped and many Indian diamond workers are finding themselves out of work. With few other employment alternatives available, many of these unemployed diamond workers are volunteering for clinical trials in exchange for payment. This is particularly true in cities like Ahmedabad, the capital of Gujarat, where CROs, which manage trials on behalf of the pharmaceutical companies, are establishing themselves in large numbers and recruiting test subjects for the many trials which take place in the state every year. Paul Jenkins heard the stories of **two young unemployed diamond polishers** now earning a regular income by participating in clinical studies.

The local press in Ahmedabad had already carried a number of stories about the crisis in the diamond worker sector and highlighted this growing trend of the unemployed workers signing up to take part in clinical trials. So, we flew out to Ahmedabad to meet the local journalist who had been looking into this.

Despite being a prosperous state in terms of business and industry, Gujarat has high levels of poverty and it was clear from what we saw in the slum areas and on the streets, that life was very difficult for many people.

According to the press reports, over 85,000 diamond workers across the region had been made jobless in the space of three months and, according to one report, become 'easy victims' for CROs recruiting for clinical trial units in and around the capital of Gujarat. The trials could reportedly get them anything between INR 7,000 (approximately 113 Euros) to INR 20,000 (approximately 323 Euros) per week depending on their physical condition and on the number of days required for the trial.

"I was lucky to get into a study, so I could survive financially."

We interviewed a number of young men who preferred to remain anonymous. One told us that many unemployed workers were turning to trials as a last resort. *"I had a close friend who committed suicide because he was in the diamond business," he told us. "He had no other choice to earn an income. I was lucky to get into a study, so I could survive financially."* Another young diamond worker, who had so far taken part in four studies said: *"We don't know anything about the names of the drugs. If you talk about health, I don't notice anything right now, but when we grow old, we'll notice because I already have pains in my body. I feel pains in my legs and knees, plus a feeling of weakness."*

One worker also told us how the CROs would often send buses to collect the volunteers in the middle of the night and transport them to various testing sites across the state. Another told us how he would use fake identity cards so as to be able to do more trials in a shorter space of time, with clearly little understanding of the impact this could have on his own health and also on the validity of the scientific data.

It was very difficult to get an idea of the scale of this recruitment drive as the CRO offices were heavily guarded and representatives were often very reluctant to speak to the media. We did however track down an agent, hired by the CROs to recruit willing trial participants. He was initially reluctant to speak to us and refused to give his real name, but he explained how the CROs would call him with specific criteria such as age and weight of trial subjects. *"They give us the money we want. I get seven euros per person on condition that we keep all this secret. Work as an agent is totally illegal. It mustn't be done. If, in the future, there are any side effects (from the trials), and the police and government take steps to stop this, agents like me will be caught."*

Bio: Paul Jenkins

Paul Jenkins is a British documentary film maker with twenty years of experience in the field of investigative journalism. He has produced and directed documentaries for high-profile organizations such as Channel 4, BBC Television and most recently ARTE, the respected Franco-German network. His most recent film, broadcast on ARTE, focuses on the booming clinical trial industry in India and provides a rare insight into the lives of Indian people taking part in medical trials for both international and local pharmaceutical companies. The film 'Cobayes Humains' also examines the commercial aspects of the trial industry, documenting the work of Indian doctors and CROs involved in patient recruitment and trial oversight.

I initially became aware of the international clinical trial industry after reading a book called 'The Body Hunters' by Sonia Shah. Shah's book provided a useful and alarming introduction to the rising trend of clinical trial outsourcing to developing countries by major pharmaceutical companies. When I was approached by ARTE to investigative this issue in India, I knew this could be a good opportunity to investigate whether these trials were being carried out in an ethical, fair and safe way.

We were prepared for the fact that as a film crew working in a country such as India, we would come up against a number of bureaucratic and logistical problems. We were also acutely aware that very little investigative work had been done in this area by the local media. So our initial starting point for the research was the handful of Indian NGOs and activists who had only recently started to monitor the clinical trial industry. With very little to go on, we followed up on the small number of trial-related stories which had appeared in the local English-language press and in doing do, were able to expand on stories in Bangalore, Hyderabad and Ahmedabad.

Overall, the field research for this documentary proved extremely challenging. Getting access to the trial subjects was incredibly difficult, not least because the public relations machines of pharmaceutical companies are powerful and suspicious. We kept a low profile to avoid doors being closed in all directions. Safety issues were also a concern. Whilst we were working on a case in Hyderabad, an Indian member of our crew was attacked in his hotel room. Journalist Jessica Sallabank, working with me on the film, was tailed by people we suspect were working for the Contract Research Organization we were investigating.

We scaled down our visibility and took an alternative route, working with an activist from an NGO focusing on welfare issues in slums in Ahmedabad. To his, and our surprise, through basic word of mouth, many people came forward to talk about their experiences and it emerged that volunteering for clinical trials has become a popular means of income for many people in the slums we visited.

In Bangalore, Jessica tracked down a resourceful and well-connected local crime reporter. This reporter shrewdly persuaded a hospital staff member to photocopy the death certificate of the baby involved in a case which enabled us to get access to the family concerned. Through a mixture of good fortune, good connections and good instincts, we were able to document a number of interesting cases in the film.

I hope this film will highlight the potential pitfalls of outsourcing medical research to countries with less stringent legislation and ethical oversight. There are of course many positive aspects to clinical trials and their contribution to the development and economy of countries like India. But, as we are still in the early days of this new industry, the media and civil society should play more of a role in ensuring everything is being done in line with the principles enshrined in the Helsinki Declaration and other international guidelines.

“The media and civil society should play more of a role in ensuring everything is being done in line with the principles enshrined in the Helsinki Declaration and other international guidelines.”

FILM ‘Cobayes humains – Au coeur de l’industrie pharmaceutique’ English title: ‘Body Hunters’

Documentary by Paul Jenkins (France, 2010, duration 78 minutes)
Coproduction: ARTE France, TelFrance
Documentary department: Pierrette Ominetti, Christilla Huillard-Kann
http://www.arte.tv
http://www.artepro.com
http://www.arte.tv/cobayes-humains

What you can do

Sign the ‘Call for Ethical Clincial Trials in Developing Countries’
The ‘Call for Ethical Clinical Trials in Developing Countries’ has been formulated out of concern about the shift in many clinical drug trials away from the richer nations and towards developing countries, and the associated ethical violations. It represents a call to action for policy makers, regulators and pharmaceutical companies to protect vulnerable trial subjects and it has been signed by leading figures in the field of medicine and ethics, and other concerned parties. The call was drafted by a worldwide coalition of health and human rights organizations and experts led by the Wemos Foundation. You didn’t sign the ‘Call for Ethical Clinical Trials in Developing Countries’ yet? Add your online signature: go to www.FairDrugs.org and click on ‘Sign on’.

Demonstrate your support
What can you do to support the work on ethical clinical trials in developing countries, other than signing?

- Become an ambassador for the ‘Call for Ethical Clinical Trials in Developing Countries’ by inviting others to sign;
- Post a banner on your website (available in English and Dutch on www.FairDrugs.org);
- Report cases of unethical clinical trials to us;
- Raise attention about the issue of unethical testing in developing countries among politicians, policymakers and the media in your country;
- Make a donation to support Wemos’ work on ethical clinical trials.
  Please earmark your donation as ‘FairDrugs.org’. Your bank can transfer money to the account of Stichting Wemos in Amsterdam, the Netherlands. For international transfers BIC/Swift and IBAN codes are necessary. Transfers to our bank account 42.65.727 at ING Bank Amsterdam:
  Beneficiary: Stichting Wemos, Amsterdam, the Netherlands
  IBAN: NL25 INGB 0004 2657 27
  BIC/Swift: INGBNL2A

More information
Would you like to stay informed about Wemos?
Please visit www.wemos.nl for more information.

FairDrugs.org

About this publication

The Wemos Foundation is an Amsterdam-based non-profit organization that advocates for the right to health of people in developing countries.

This publication is an initiative from the Medicines project of Wemos. The testimonies contain the work of journalists and not of Wemos per se. Wemos has done everything it can to verify the quality and integrity of the journalism.

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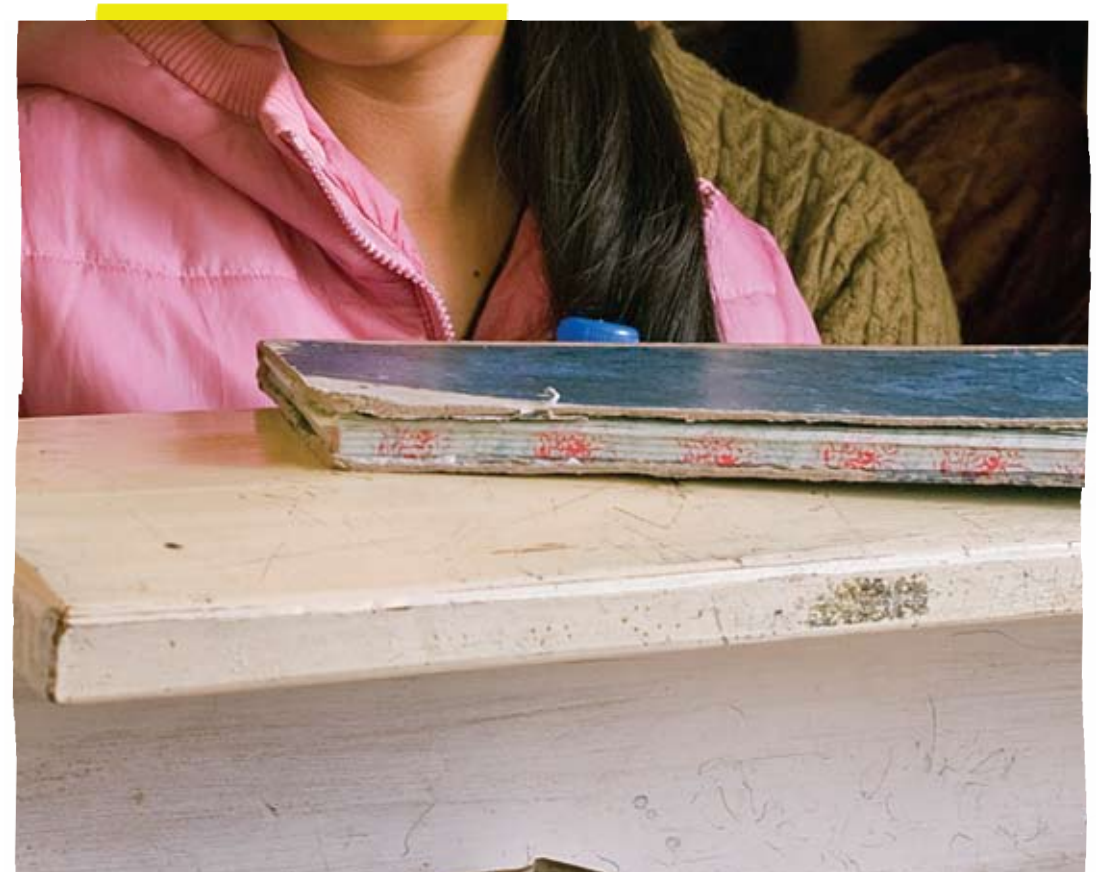

"I do not really understand what a clinical trial means, but we are poor farmers and the most important thing for us is saving money."

Wemos works to promote 'fair' drugs

Wemos Foundation
Ellermanstraat 15-0
P.O. Box 1693
1000 BR Amsterdam
The Netherlands
T +31 (0)20 435 2050
F +31 (0)20 468 6008
E info@wemos.nl
www.wemos.nl

"Sometimes I do think about the risks and wonder about what would happen if there were some bad side effects."