

**THE PROFESSIONAL GUINEA PIG: BIG PHARMA AND THE RISKY WORLD OF HUMAN SUBJECTS.**  
**Abadie R. Durham: Duke University Press; 2010.**  
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The book portrays – and helps us reflect on – the human beings that work as professional research subjects in Clinical Trials [Phase I], paid to test drug safety, and HIV patients enrolled in Clinical Trials Phases II and III testing drug efficacy. As part of his study, Anthropologist Roberto Abadie (Health Sciences Doctoral Programs – Graduate Center – City University of New York) followed research subjects to test sites, documenting their experiences and routines in Philadelphia, a major hub for clinical trials activity.

In the research and development of new pharmaceutical drugs, after pre-clinic tests, compounds are preliminary tested on animals – usually mice and dogs, because they are cheaper – to assess drug toxicity. If approved, the compounds are then tested for security in Phase I (Clinical Trials) that involve, on average, a small group – 30 to 100 – of healthy research subjects to determine drug toxicity. If the drug or compound is found to be safe in Phase I Trials it is then tested in Phases II and III. These trials are generally multi-centric and involve hundreds and/or thousands of patients that display the clinical condition that the drug is supposed to address. These phases evaluate drug efficacy. Finally, Phase IV, or Post-Marketing, enables additional studies of drug security, quality and efficiency.

The development of a new pharmaceutical drug takes between 12 and 15 years of research and demands, on average, financial resources of 150 million dollars. When tested during Phase I, most compounds are abandoned due to their high toxicity. Only a small fraction of the compounds tested in each phase of Clinical Trials research are approved. These difficulties entitle large pharmaceutical companies to justify the high price commanded by new drugs. The whole process is closely regulated by governments that establish mechanisms for drug access, quality, pricing and rational utilization.

Until the mid 1970s, Phase I Trials were conducted on prisoners – theoretically volunteers – a very convenient proposition for the pharmaceutical industry, not only financially, but also from the point of view of the confidence on the results, produced in a totally controlled environment. After the use of prisoners in drug safety trials was banned in the United States, the North-American pharmaceutical industry had to find a new population of healthy subjects to test an increasing number of compounds. It was then that the industry started to recruit healthy paid human beings, creating a new informal economy in which some subjects volunteered on a regular basis and became dependent upon the trial income for their survival. As a result, a new profession emerged: *the professional guinea pig*.

The book is based on a year and a half of ethnographic research conducted in Philadelphia between June 2003 and December 2004. The study focuses on a group of poor, mostly white-male Americans that earn a livelihood as professional guinea pigs testing drug safety in Clinical Trials (Phase I). As a comparison, this work also involves poor African-American and Latino HIV patients testing drug efficacy in Phase II and III Clinical Trials. The author's main research goal is to describe the effects of financial rewards on the way volunteers perceive and deal with the risks they face as trial subjects.

In this context, the empirical study conducted by anthropologist Roberto Abadie, help us formulate a number of important questions:

Is there any difference related to the behavior and risk perception between healthy paid subjects – professional guinea pigs in Clinical Trials [Phase I] – and, volunteers testing HIV drugs in Phases II and III?

Is this new occupational category – professional guinea pigs in Phase I Clinical Trials, a new business in the informal economy – the result of social inequalities, exploitation and deregulation in the pharmaceutical industry?

Does financial compensation place human beings working as guinea pigs at risk? Do financial rewards influence the professional guinea pigs' perceptions of risks and benefits involved in clinical trials?

Is routine or continuous participation often involving long stays for human beings [guinea pigs] influencing subjects' perception of risks and benefits involved in clinical trials?

Is there an adequate ethical oversight to safeguard paid human beings [guinea pigs] in clinical trials [Phase I]?

Are the healthy paid subjects [guinea pigs] volunteering in clinical trials [Phase I] aware of the inherent risks involved in the studies they volunteer for?

Are there any rights for the paid healthy subjects [guinea pigs] volunteering in clinical trials [Phase I] or are they being exploited due to their vulnerable position at the bottom of the economic ladder?

To respond to these and other questions, it is absolutely necessary to read this book.

This publication contributes to strengthen the fight to protect healthy paid subjects through better regulation ensuring their labor rights while making sure that ethical principles guiding biomedical research are also followed.

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