

## Book Review

### **When Experiments Travel: Clinical Trials and the Global Search for Human Subjects**

**Adriana Petryna, Princeton University Press, 2009**

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Adriana Petryna's second book, *When Experiments Travel*, is a timely addition to the understanding of offshore clinical trials. Employing an anthropological perspective the book explores the organisational settings that enable these trials, the complex networks of interests they maintain and in which they unfold, and the ethical and legal tensions present within these settings. Continuing the investigative strategies developed in her study on how Chernobyl's exposed populations negotiate health care access (2002)<sup>2</sup>, Petryna's new research explores the impact made by pharmaceutical trials in Eastern Europe and Latin America. Her argument relies on data collected through extensive fieldwork in Poland, Brazil and the United States.

The author sets the scene for the examination of global drug trial development by looking at the ways in which clinical trial evidence is constituted and experimental subjects are identified. 'Treatment saturation', characterised by a shrinking pool of available human subjects in the West for the pharmaceutical industry, an increasing demand both for new markets and for human research subjects in general, are identified as factors in the offshoring of clinical trials. Petryna shows how in the last 20 years the sites of research have shifted from academic to contract research organisations (CROs), which are typically subcontracted by pharmaceutical sponsors to collect the evidence required for drug approval by the FDA (Federal Drug Agency in the USA) or the EMEA (the European Agency for the Evaluation of Medical Products). Such CROs are competitive trans-national businesses that run trials not only for the pharmaceutical industry but also for bio-technological products and medical devices. Their projected growth is faster than that of the pharma industry.

Responsible for locating research sites, patients, local experts and ethical review boards and on occasions for drawing up study design and performing analyses, the CROs may work with primary healthcare facilities such as hospitals and consortia of medical specialists. Some even have centralised institutional review boards to review protocols and subject recruitment to ensure the safety of trial volunteers. Alongside more permissive national legislative environments, factors such as population disease profiles, mortality rates, patient trial costs and potential for future marketing of the drug to be approved are essential in identifying new clinical trial sites. Petryna's analysis illustrates how regulatory requirements, both in terms of patient safety and standardised scientific protocols, are made sense of by local actors in different ways.

The offshoring of clinical trials equally needs to produce convincing scientific evidence for each drug's adoption and various strategies are presented by clinical trial

experts in relation to the inclusion/exclusion criteria for the selection of patients and the ways in which these impact upon the collected evidence. Issues of competition, economic profit, risk, transparency and ethics are weighted individually and collectively through a constant comparison between different countries and locations to illuminate further aspects of the complex dynamics created by various interests, actors and agencies.

Petryna develops the concept of “experimentality” defined as a “distinct *modus operandi*”, “decentralised and diffused” which supports the global drug market. Her analysis suggests that experiments are more than simple hypothesis-testing instruments, “they are operative environments that redistribute public health resources and occasion new and often tense medical and social fields”. In this process “the line between what counts as experimentation and what counts as medical care is in flux”. Furthermore, the ethics of offshore clinical trials remain, despite strict scientific protocols (and occasional scandals), a malleable “workable document”. One instance of such malleability is the “expedient experimentality” presented by public health crises in African countries, where international ethics codes can easily be overlooked in favour of immediate access to valuable, yet vulnerable subjects. In order to present experiments as ethically standardised, the complex ethics surrounding the clinical trials placebo is addressed by providing equivalent medication or the best local treatment available. As the research aims to keep costs low, clinical trial locations are chosen so that the best local treatment is hardly better than placebo, for instance, vitamin C. Other examples on the offshoring of clinical trials to Eastern Europe and Brazil depict poignantly ethical conundrums regarding what happens in the aftermath of the trials both to patients and to health care systems.

Yet, the issue of whether such trials are a public good or exploitative mechanisms remains complex. Petryna shows how in different ailing healthcare systems the opportunity of clinical trials seems attractive both to clinicians and administrators, who have few resources but great entrepreneurial spirit. Moreover, these trials may offer a glimpse of hope to patients with little access to medication. At the same time, as the trials unfold, they become powerful marketing tools for specific drugs, instrumental in the reorganisation of healthcare priorities and in the production of a pharmaceuticalization of health care in specific regions of the world (i.e. an increasing dependency on particular, expensive, but not necessarily cost-effective drugs, often introduced through clinical trials). In Brazil, for instance, patient groups mobilise public opinion to lobby for treatment access from the state to drugs previously on trial. Such developments raise further questions from regulators, governments, researchers, other medical practitioners and patients themselves, regarding the continuity of treatment and control over the patients’ trial data - matters that are neither part of the initial clinical trial contract or of the consent form, but emerge in the aftermath of the trials. Furthermore, such clinical trials can also provide opportunities for clinicians not only to distribute trial drug resources to patients, but also to carry out further research for the benefit of such patients and in the interests of their own national healthcare systems. It is here, argues Petryna, that a critical assessment of the localised impact of the drug trial political economy is undertaken.

Combining scientific rigour with the need to inform public opinion and support government healthcare decisions, researchers continue to monitor the use of clinical trial drugs in order to expose the shortcomings of organisational cultures in securing the integrity of scientific research and patient safety.

To conclude, Petryna's argument provides a rich, detailed and compelling account of the many economic and political interests, complex moral issues and cultural settings of offshore clinical trials. The book will be of particular relevance to scholars in sociology, anthropology and health studies, interested in the dynamics of pharmaceutical markets and their impact on less developed countries, and the production of scientific and clinical evidence.

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<sup>2</sup> Petryna, Adriana. 2002. *Life Exposed: Biological Citizens after Chernobyl*. Princeton: Princeton University Press.