Chapter 13
Institutions and Co-Creation of Value in the Service Ecosystem of Clinical Trials for the Development of New Medicines

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ABSTRACT

The pharmaceutical sector has outsourced R&D value chain activities, leading to the emergence of a new population of companies called clinical-trial Contract Research Organisations (CRO), focused on offering clinical-trial services to pharmaceuti-

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cals. They grew and quickly set up themselves as multinationals, proving global ecosystems of clinical-trial service. This chapter analyses in an exploratory way the relationship between regulatory institutions for clinical trials, national culture practices, and the cocreation of experience and value in clinical trial ecosystems in Brazil. The research was based on an inductive approach. We characterised the formal regulatory institutions, cultural practices and conducted in-depth interviews with coordinators of clinical trials in 8 CROs in Brazil, collecting primary data on their experience. Data were analysed using categorical thematic analysis. The result shows that national cultural practices and regulation influence the experience and value co-creation in the provision of the CROs' clinical trial service.

INTRODUCTION

Why should we care about the cocreation of value in the service ecosystem of clinical trials of new medicines? In capitalist systems, governments have the obligation to promote the quality of life of their citizens related to health but do not generally invest directly in the development and manufacturing of new medicines. This leads to a mutual dependence between the government and the pharmaceutical sector in a context of conflicting interests: Governments must guarantee safety and quality in the development of new medicines by applying strict control over clinical trials, but this increases the costs and time needed for pharmaceutical companies to introduce their new products to the market; governments must make innovative medicines available (e.g. by reducing side effects and increasing efficiency and effectiveness of existing medicines), but this requires investment from pharmaceutical companies; and governments must meet the needs of small population groups by making medicines available for rare and population-specific diseases, such as those related to ethnicity, geographical regions, and age, but pharmaceutical companies must concentrate on large consumer markets so that the price they charge can be lower and their turnover higher.

Another concern that arises and adds to this context of conflicting interests is the relationship between government bodies and social actors because the commercialization of new drugs depends on government approval and the clinical trial processes must obey government specifications since governments have discretionary power; that is, their decisions as public agents have the effect of law. However, government bodies have been associated with a democratic deficit in their relationships with social actors, leading to questions of legitimacy (Maman, 2022).

Some questions arise from this situation. How is it possible to attract long-term investment for the development of innovative new medicines? What are the constraining and driving factors behind clinical trials in the regulation of new