

## **BRAZILIAN CLINICAL TRIAL REGULATION IN A PERFORMATIVE APPROACH**

**RICARDO DE ABREU BARBOSA**

UNIVERSIDADE PRESBITERIANA MACKENZIE (MACKENZIE)

**WALTER BATAGLIA**

UNIVERSIDADE PRESBITERIANA MACKENZIE (MACKENZIE)

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**Abstract:** *The paper proposes redefining the regulation concept from a performative approach using the actor-network theory. It was discussed in a bill of law modelling the clinical trial regulation in Brazil. We used the cartography of controversies to follow the actants work. The regulation was recognised as a procedural and relational assemblage whose controversies and their performativity effects generate a zone of translation through which they passed and established contacts with new constituent elements of networks.*

**Key-words:** *regulation, performativity, actor-network theory, clinical trial*

### **1. Introduction**

This work proposes that the performative approach based on the actor-network theory can significantly contribute to a new signification of regulation, conceived here as a performative socio-material artefact.

Regulation is a broad term with an epistemological weakness which claims for new concepts. It has been associated with the divine (theology), homeostasis (biology), control (mechanics), power (political science) and normativity (sociology and law). Although its eclecticism, an epistemological fragility is recognised in the construct (PRÉVOST, 2000), reinforcing the antagonism about excess or deficiency of regulation, the conflicts between who regulates and what is subject to regulation as far as whether the regulation influences or is influenced by the activities it sets out to the control. Because of it, the notion of regulation, stabilising and controlling bias, can be revisited under a new paradigm. The construct will be seen as a dynamic artefact under a performative influence.

A performative mentality for studying regulation takes place from the actor-network theory perspective. The actor-network theory originates in the STS, which is based on materiality and procedural. As for performativity, whatever approach is adopted, it is relevant to notice that this is not a theory or a method but a mentality or a “mindset” that permeates various theoretical approaches (GARUD, GEHMAN, THARCHEN, 2018) and which is characterised by two essential aspects.

The first aspect is the idea that descriptions “add to reality” insofar as they “instantiate or affect their referent” and, therefore, “provoke a new situation or ontological agreement” (MUNIESA, 2014, p. 18). The second aspect is in its ontologically relational approach whereby its scholars are not interested in pre-existing things but in “things happening” and in the “relationships between things” (CABANTOUS, SERGI, 2018). These issues are evidenced in the version of performativity defended by ANT, according to Callon (2007), whose semiotic principle of relationality is not restricted to language or signs but applies to all types of materials (LAW, 1999).

The challenge of describing realities in motion lies in the fact that the reality of being explained is not only constituted by the deliberate action of a human actor but is constructed as an effect of networks between humans, non-human beings and their associations that arise from heterogeneous relationships, explained procedurally (LAW 1992; CALLON, 1986).

We do so through a case study of Brazilian clinical trial regulation involving a debate within a bill of law in progress in the Brazilian National Congress, which aims to create a regulatory framework for clinical trial with the promise of profound changes in the relations of the actors in the system.

We adopted the cartography of controversies, based on the works of Venturini (2010a; 2010b; 2015) and Hussenot (2008; 2014), consolidated by Tureta and Clegg (2021), as a technique to follow the Senate Bill (PLS) No. 200/2015 in progress, which was later converted into Bill (PL) No. 7082/2017, still pending approval. ‘PL7082/2017’, as it will be called from now on, contains several proposals sensitive to clinical trial activities, with emphasis on restructuring the process of regulation of the ethical instance of clinical trial by assigning new

status to the Research Ethics Committees (CEP) and National Committee on Research Ethics (CONEP), which are the bodies with ethical structure regulation in Brazil.

The cartography enabled a set of narratives built from the search to understand the relations that described the dynamics regarding (a) the meaning attributed to clinical trial and the regulation involved in it, (b) the controversies surrounding the ethical regulatory function (CEP-CONEP system) and (c) the legislative process that proposes a rearrangement of this regulatory dynamic, but also suffers performative effects in its construction.

Thus, our problem question is: "How to understand the regulation of the clinical trial segment in Brazil from a performative perspective?"

We outline the theoretical foundations of our argument, starting with an overviewing of the concepts of regulation to justify its study in a performative and relational paradigm. Afterwards, we review the different meanings of performative approaches, focusing on the performative thesis defended by Callon (1998), based on Actor-Network Theory (ANT), accompanied by the main concepts of this approach. Next, we describe the application of the performative view in the development of clinical trial regulation underway in Brazil. Finally, we demonstrate, through cartographic techniques, how the regulation was reassembled as a performative artefact, translated by narratives marked by a symmetrically distributed agency. This supported some contributions and final considerations.

## **2. Concepts of regulation**

The heterogeneous use of "regulation" henceforth shows the gap for its reviewing in a new paradigm. In the 18<sup>th</sup> century, the philosopher and mathematician Gottfried Leibniz offered the modern bases for the concept, attributing to God the role of preserving what he called "initial constants" with a function of conservation, restoration of closed systems or maintenance of balanced environments (CANGUILHERM, 1977). From the 19<sup>th</sup> century onwards, the notion of regulation evolved in a biological sense to seek a dynamic balance to improve transformation systems. This concept was exported to physics, contributing to the development of cybernetic theory, which is based on feedback relationships and, thus, the association of regulation with the notion of conservation or restitution has been expanded to become a function of compensation and adaptation (PRÉVOST, 2000).

In the economy, 'regulation' is a rule for disciplining individual actions and social interactions for controlling the productive activity carried out by a state authority. These rules seek to govern activities such as finance, transport, education, health, communications and even the functioning of the labour market (GUERRA, 2015). The economic concept of regulation was developed under the establishment of rules aimed at controlling social behaviour and maintaining or restoring a system's balanced functioning, which ensures the balance between the rights and obligations through the creation of state legal norms that will discipline the exercise of certain activities, predominantly of an economic nature, in the face of the presupposed denial of self-regulation by the invisible hand of the market (DI PIETRO, 2004).

Brazil followed the American traditions to create a regulatory agency model combining Executive and Legislative State powers (GUERRA, 2015). For this reason, several questions were raised about the normative power of this agency's regulation model concerning the hierarchical positioning of regulatory standards within the system, the problem of the profusion of regulatory norms created, the discretion of regulatory acts, and the question of popular participation in regulatory activity (JUSTEN FILHO, 2011; GUERRA, 2011).

Because of it, regulation has been criticised as a construct that lacks a theorisation to help establish an optimality criterion about what should be regulated, what the extent of regulation should be, and who controls the regulator.

However, regulation can be viewed as ontologically fluid and relational. It cannot be objectively defined since it results from the association of controversies of interests that

generate and suffer performative effects and reassembles both regulation itself and the subjects and objectives it proposes to regulate.

### **3. The performative paradigm**

Performativity is transdisciplinary and, therefore, also has a heterogeneous trajectory. It is an itinerant concept (CANBATOUS; SERGI, 2018) that covers different areas of knowledge, such as the philosophy of language, French post-structuralism, theorisations about humankind and the theories produced by Science & Technology Studies (STS) of Bruno Latour and Michel Callon.

The first notion of performativity can be linked to the British philosopher John Austin (1962) in the context of theorising about language and in his search for the relation between language and truth and between statements and facts. Austin developed the idea that some statements would not only be suitable to describe a reality but could transform or decree the status of a reality. One could not only affirm the truth or falsity of a proposition since some of these propositions would have a 'performative' or spreading nature of the declared truths. The neologism, "the utterances", which are not limited to verifying a fact, but do execute something, was created from these ideas brought by Austin (1962). According to the example given by Austin (1962), a justice of the peace before a couple that was declared as "husband and wife" not only describes reality but decrees it, thus establishing a new marital status. Statements that are pronounced and cause an action or make the listener react are also performative.

A second perspective on performativity can be found in the works of Judith Butler (1997), that deal with the self-constitution of actors. In this case, the performativity would lead to reflection on how humankind could be an expectation that produces the very phenomenon it anticipated. For Butler (1999a), even the materiality of human bodies could not be elaborated except through discourses, to the point that discourses would shape what we conceive and constitute as a body.

A third perspective on performativity is found in the work of Karen Barad (2003), which derives from the results of Judith Butler but is also influenced by the Actor-Network Theory from Callon and Latour. Performativity goes beyond purely discursive approaches based on the representative power of words to involve the material world of pre-existing things. Performativity would not be an invitation to turn stuff into words but a contestation of the excessive power given to language that gives its place to human and non-human elements in determining the ontologies of reality (BARAD, 2008). The baradian version of performativity incorporates the material and the discursive, the social and the scientific, the human and non-human, and the natural and the cultural. A post-humanist account is based on the flow of practices through which borders are stabilised and destabilised (GOND; CABANTOUS, 2016).

The fourth version of performativity is developed by STS sociologists represented by Callon (1998) and Latour (1996), who embraced Austin's idea and recognised that scientific claims are performative in that they are not outside the worlds they refer to. Michel Callon mainly explored the performative role of scientific theories and models in his work "The Laws of the Markets" (1998) when performing a performative analysis of economics, covering areas related to finance, marketing, and management in general. For Callon (1988, 2007), models and market theorisations would involve not only a pre-existing description, but they would participate in configuring the phenomena they propose to describe, thus constituting them and making them real. Callon's economic thesis of performativity also suggests that the constitution of the realities described by theorisations involves not only the social sciences but also the natural sciences, in an indication that converges with Barak's sociomateriality. Therefore, scientific statements would be associated with the socio-technical arrangements or agencement involved in producing the facts in these statements (CALLON, 2007). It is as if the technical instruction manual of a device. However, a compilation of the description of the device in question ends up participating in its constitution because it is the agencement that makes it work

(CALLON, 2007). Agencements are incorporated into the operating statements of a technical device; capabilities are incorporated into the equipment, into the rules and procedures involved, without distinguishing between statements and materiality in this arrangement. Both constitute the elements of a structure endowed with the agency to give meaning and reality that they propose to describe (CALLON, 2007). Callon (2007) also argues that the theorisations, more than corresponding to the truths they are intended to predict, are fulfilled with the endorsement of social, political and technical elements, thus constituting the foreseen reality from then on. It is, therefore, a constructivist approach to the participation of heterogeneous elements in the constitution and affirmation of scientific fact.

The performative and procedural approaches have some commonalities (CALLON, 2007; CABANTOUS, SERGI, 2018). The first is a methodological commitment to qualitative empirical research, aimed at following and describing the action and everything involved, with a view and scrutinising "what is happening". The second is that reality is procedural in any version of performativity. Whatever our interests, discourses, genres, theories or models, and how such phenomena enact the realities they are involved, something more than temporal stability or a becoming will always be implied.

Despite the commonalities, process theories also have distinctive features with performative approaches. The first one concerns the agency. While process theories can accommodate various agentic approaches, including those centred on human agency, performative studies will always adopt post-human approaches precisely to deconstruct the idea of human intentionality and protagonism to understand reality. The second one is the sociomateriality. The notion of agencement developed by Callon (1998), formed by socio-technical elements, evidence the distinctive feature of the performative vision that is not always present in procedural approaches. The third is that while those who study the process emphasise change and movement, performativity theorists are concerned with durability once the focus is on understanding how phenomena become visible or perceptible. In this aspect, the notion of punctuation, derived from ANT (LAW, 2004; LATOUR, 2007), reflects this subtle difference since the reality constituted by the associations of actors-networks may become recurrences of patterns of movement in networks, reifying in macro-actors or institutional-actors. The inflexion point, however, remains a flow activity, which highlights ANT's performative character, without giving up its procedural and flow ontology. The fourth aspect among studies based on process and performativity approaches is the relational issue. While performative approaches come from a relational ontology, such as Baradian and actor-network theories, in procedural approaches, relationality is only compatible with the so-called 'strong theories' of processes (HERNES, 2014).

The performativity approach can benefit from some procedural aspects incorporated into its research (GARUD, GEHMAN; THARCHEN, 2018). First, avoiding the "ballistic trap" (MUNIESA, 2014) is recommended, which consists of seeking causal connections, excessively linear trajectories, and recursions or circular explanations between the phenomena studied. The performative approach requires a focus on the "becoming," the multi-temporal, and the multispatial, which reveals the triggering of phenomena without the need for clear, defined, or finalised trajectories. Second, it is required to reject the search for classifications or gradations of performativity but to focus on the stabilisation processes rather than the results or effects of those processes. These stabilisations may be partial and incomplete, but a performative process will occur if the process forges connections between abstractions and material things (CABANTOUS; SERGI, 2018). Third, there is no need to constitute "proof" of performativity as it is enough to shed light on the process or reveal the complexity of its becoming. It implies a change of "mindset" in describing phenomena and an ontologically based stance on fluidity. Materiality itself takes on a spectrum, like a rainbow, and performative narratives can describe phenomena with different natures, including a discourse, an idea, a tangible thing, or a hybrid.

Therefore, the development of a performative mentality implies investigating multiple and complex relations between statements and ideas among abstractions and their visible, tangible expressions (or their materialisation), unveiling how phenomena aggregate, disaggregate, stabilise and destabilise amid a fluid process of associations of heterogeneous elements.

#### **4. The ANT as a micro foundation for the performative approach used in this work**

The performativity adopted in a new concept of regulation is based on the foundation of the actor-network theory (ANT), whose approach gained great prominence from the works of Bruno Latour, Michel Callon and John Law, seminal authors who started an alternative movement to try to understand reality from a procedural and heterogeneous view (CAMILLIS; ANTONELLO, 2016). It represents an alternative lens to understand reality based on the lack of interest in an anticipated object definition. It means a relegation of an “a priori” labelling and an emphasis on tracking the propagation and reiteration of relational configurations (LAW, 1992). ANT also rejects collective entities as being conceived as stable and singular and defends that they result from continuously gathered elements (LAW, 1992; LANGLEY AND TSOUKAS, 2016). It is central for ANT the principle of symmetry or the recognition of an ontological status between humanity and objectivity (TONELLI, 2016), the notion of controversy and the concept of translation developed as follows.

##### ***Symmetry principle***

The notion of symmetry originated with David Bloor (1991). It started from the critique that elements of nature and society were not being symmetrically considered to explain between true and false sciences. Bloor (1991) defended the impartiality between true and false, between rational and irrational, and between success and failure, in addition to the need to transfer the right of explanations to the then-neglected pole of society. Callon (1999) developed the notion of generalised symmetry, in which an accurate symmetric description could not start from any of the poles (nature or society). Callon and Latour's concept advanced to refer to symmetry, not only as an equal treatment between truth and falsehood in the history of science but also to establish an ontological symmetry between elements of nature and society and between humans and non-humans for the generation of negotiations and performativities (TONELLI, 2016). Thus, symmetry has become a heuristic tool used to understand the contingent role played by actants within an actor-network (CALLON, 1999) based on the assumption of complete planification between the elements of nature and society (LATOURE, 1994).

From the symmetry principle, any actor can participate in a controversy which involves human beings and non-humans in an integrating “heterogeneous arrangement” (LAW, 1999). ANT does not claim that an object has a volitional capacity like a human but that human action does not result exclusively from the will dissociated from its relationships with objects. Every volition is manifested from symmetrical relationships in which any human or non-human actant is present, which makes them protagonists of controversies that function as a “hybrid forum” (CALLON; RIP, 1992) or a space of conflicts, debates and negotiation in search of stabilisation.

##### ***Controversies***

Controversies are central to ANT (CALLON 1986), as associations between heterogeneous elements occur under friction. The notion that collective life is made up of alliances and their dissolutions also emerges here, thus emphasising the role of controversies in the constitution of society (VENTURINI, 2015).

The controversies are also considered one of the most complex phenomena observed in communal life (VENTURINI, 2010a), although little explored among the authors of ANT. It involves anything that challenges the status quo among actors (HUSSENOT AND MISSIONER, 2010).

To develop controversy studies under ANT, Latour created MACOSPOL (Mapping Controversies on Science for Politics), a project funded by the European Union to develop a

collaborative platform for mapping controversies under the actor-network approach. According to MACOSPOL documents (2007, p. 6), controversy is every piece of science and technology that needs to be stabilised or closed. This definition presents controversy as a state of shared uncertainty about facts of scientific nature.

The controversies are resistant to reduction (VENTURINI, 2010a), which means that everything gives rise to discord as if there were an infinite regression that makes its closure impossible. Volcanic magma, which alternates between its liquid and solid states, is an excellent metaphor to illustrate the dynamics of controversies, which ceaselessly settle down or intensify (VENTURINI, 2010a).

As criteria for choosing a controversy, Venturini (2010a, 2010b) and Hussenot (2014) suggest that it is advisable to investigate where collective life becomes more complex, where the largest and most diverse variety of actants are involved, where alliances and oppositions are transformed more irrationally and inconsistently, where nothing is as simple as it seems, where everyone is screaming and fighting and where conflicts become more severe.

The closure of a dispute constitutes what ANT calls the “black box”, a cybernetic term that means the concealment of the internal systems of a system or the result of an attitude of making opaque the functional processes that transform one data into another (LATOURE, 1999). A black box is formed, or a statement becomes solid as a fact, whenever it is introduced in new formulations as an unquestionable premise, to the point of deducing that the solidity of a fact, or its stabilisation, will always depend on all those who keep it moving, in a work of legions of allied and interconnected networks (LATOURE, 1999). Whenever a fact encounters opposition or obstacles in circulation, it will be pushed towards an assertion of “falsehood” in an environment of controversy in which black boxes will be reopened. When a fact becomes a black box, it creates autonomy and independence. When the black box opens, it means the reinstatement of controversy.

The emergence and the development of controversies co-occur with the production of collective aggregates (or groups) that are placed in opposition to each other, which are accompanied by elements enlisted to support their positions and arguments that delineate these group boundaries, enabling the construction of analysis maps of the established relationships. The controversies will be perceived because of these different senses of belonging of the groups and the translations formed from this work of the actors-networks.

### ***Translation***

Supposing controversies represent disagreement between heterogeneous actors engaged in action (VENTURINI, 2010a), in that case, the translations will seek to establish their contradictory interests (LATOURE, 1999), reshaping network actors and causing them to appear, change or be excluded from reality (HUSSENOT, 2014). The notion of translation was created by Michel Serres, one of the great influencers of Latour's thought. Serres (1996), who also defended a practical impossibility of dualism between the sciences and the outside world, developed the notion of multi-temporality by stating that the phenomena of reality refer at the same time to the past, present and future (TONELLI, 2016).

These ideas outlined what translation consists of in the view of Michel Serres (1996), which are processes of building connections, passages or establishing communications, an act of invention or *bricolage* that emerges from the mixture of heterogeneous multitemporal elements (TONELLI, 2016).

This notion of translation did not only have linguistic or symbolic connotations, but involved acts of displacement or substitution of knowledge, people or things, and fell not only on elements that it translated but also on what was translated in a clear allusion to the performativity of relations (CZARNIAWSKA, 2005).

The notion of translation was incorporated by the seminal authors of ANT, who defined it as an “interpretation given by fact-makers to their interests and those of the people they enlist”

(LATOUR, 1999). It was later conceived as a geometric notion of displacement and transformation, which offers new interpretations of interests, channelling people into different positions (LATOUR, 1999, 2007).

Callon (1986, p. 203) defined translation as a “process during which the identity of the actors, the possibility of interaction and the margins for manoeuvre are negotiated and delimited”. This negotiation process involves problematisation, interlacement, enrolment and mobilisation. In the problematisation movement, the main actors establish their identities and goals to create a crossing point everyone must accept to achieve their interests. It is as if the rules for developing controversies were established. The intersement involves the imposition of other actors of the movements defined in the problematisation, preventing the identities defined in the previous phase from being lost. Enrolment means defining the roles to be played by the actors and how the others will relate within the networks. In the mobilisation phase, there is a coalition in which the main actors borrow the strength of their allies, passive agents, and become their representatives or spokespersons. At this stage, dissenting voices are silenced, and the controversy ends with the commitment to negotiation, the result of which becomes legitimised.

### **5. The Brazilian clinical trial regulation as a performative artefact**

A clinical trial is a step in the R&D pharmaceutical process investigating the effects of treating a group of human beings with a new product. The targets are to prove its safety and efficiency, evaluate the product's recommended dose and check possible adverse effects (GOMES et al., 2012). The ability to develop new drugs can be directly related to the skills to carry out these tests, and this led to high vertical integration of the research and development process in the pharmaceutical industry throughout the 20<sup>th</sup> century. Greater competitiveness led the sector to live with financial pressures due to having less credit for research. Regulatory pressures became a crucial factor for pharmaceutical R&D, which began to live with increasing requirements, resulting in the extension of deadlines for approval of the stages of the process, increased supervision, and expansion of the regulatory scope with implications and ethical questions about conducting research. Focusing on the regulatory issues concerned with the Brazilian clinical trial segment, there is an essential difference between ethical and sanitary regulation. Ethical regulation is present every time research involves human beings, and it aims at protecting the rights, safety and well-being of those participating in the study. In contrast, sanitary regulation regards the control of the research and its registration so that it is introduced in the market.

This work it was studied the dynamic involved in the ethical instance regulation presented by the National Health Council (CNS), which is a deliberative permanent collegiate body of the Unified Health System (SUS) which established a structure and a process for the ethical evaluation of clinical trial, divided into two more stages or approval sub-bodies, whose functions were assigned to two bodies: the National Research Ethics Commission (CONEP) and the Research Ethics Committees (CEPs) that together constitute what is commonly known as the CEP-CONEP System. CONEP is a commission created to implement the standards and regulatory guidelines for research involving human beings. CONEP works with a network of more than 800 Research Ethics Committees (CEP) organised within the institutions where research is conducted. Therefore, any research protocol involving human beings will be submitted to a CEP, which will be responsible for deciding on the ethics of the research to be carried out at the institution.

The controversies raised in a clinical trial involve the interests of patients in search of health treatment, research participants, sponsors, researchers and research proponent centres, besides regulatory agents inserted in the state control structure of this activity. The meta-controversy that guided this work can be summarised by the search for efficiency in conducting



clinical trials, as opposed to safeguarding the control of this process as a guarantee of the rights and protection of research participants.

In recent years, several mobilisations have taken place to reinforce Brazil's clinical trial segment. Among these stand out is the presentation of a Bill of Law before the Brazilian Federal Senate, under number PLS 200/2015, converted into Bill number 7082/2017, pending at the Chamber of Deputies. Its proponents aim to create a law that has as its primary objective the reformulation of the CEP-CONEP System through creating a regulatory framework for clinical trial in Brazil to remove the obstacles that generate slowness in the process and, thus, have an impact. Positive impact on the sector's competitiveness. On the other hand, the reaction to the bill has been strong, and the actions taken by its antagonists have succeeded in casting doubts on whether this bill collides with the stated objectives and if it will be approved.

## 6. Methodological path

When researching based on ANT, Latour (2007, p. 208) reminds us that a painter does not create his art by starting with the frame. It means that the methodological path of mapping controversies requires more than the adoption of known techniques but the creativity of elaborating the very instruments of data collection and analysis that led to the work of following the actors and describing the performative dynamics of the regulatory artefact. In this work, we conducted a documental analysis divided into three paths:

First path: We surveyed data available on websites that were directly or indirectly related to the clinical trial segment and obtained about one hundred research sources by choosing the following indexers: “clinical research”, “clinical trial”, “regulation of clinical research” and the bill “PLS 200/2015” or “PL 7082/2017”. We accessed news, opinion articles, interviews, and lectures in written form, in audio and in videos, whose contents were transcribed, which enabled an "approach" or the phase of the beginning of the recognition of the controversies that took place around the regulatory dynamics of a clinical trial in Brazil.

Second path: We accessed the electronic environments of the Federal Senate and the Chamber of Deputies that record all the legislative activity of PLS 200/2015 and PL 7082/2017, involving the individualised work of each of their thematic commissions and collection of all documents of the process (project proposals, legislative reports, opinions, amendments, requirements, and complementary information). We also accessed the shorthand notes from the work meetings of the Legislative Commissions involved with the bill. Over 200 documents were obtained – around 1500 pages examined –containing transcripts of interviews and lectures on the websites surveyed, documents from legislative processes, shorthand notes from legislative sessions and public hearings, and normative acts produced by CONEP and ANVISA.

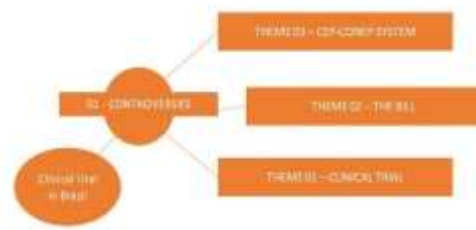
Third path: We adopted the cartography of controversies (VENTURINI, 2010a, 2010b, 2018; HUSSENOT, 2008, 2014; TURETA, CLEGG, 2021) to describe the reassembling of the regulatory artefact of the clinical trial. Tureta and Clegg (2021) developed a cartographic process divided into five relational and non-linear focal points: The "sampling", the "scanning", the "tracing", the "labelling", and the "describing", as follows in Table 1:

Table 1: Cartography of controversies process

Step	Function	Description
<b>Sampling</b>	How to identify controversies	What types of controversies are at stake, and what are their connections?
<b>Scanning</b>	How to map actor-networks	Follow the network of actants formed around controversies, look for those whose participation makes a difference in the actions of others, to map who and what is involved in the controversies.
<b>Tracing</b>	How to design the translation process	Seek how network actants relate, connect, disconnect, and align, generating translations.
<b>Labelling</b>	How to analyse the policies of the actor-networks.	Understand the relations and practices of power involved in the controversies, look for what moves the actants to mobilise other actants and what represses or silences them.
<b>Describing</b>	How to describe multiple realities and power relations	Identify excluded actants, bring up hidden events, and bring out the different possibilities of reality.

Source: Tureta; Clegg, 2021, adapted by the authors

Figure 01: Themes



Source: The Authors

necessary to understand the different hierarchical levels considered in its representation. First, the 'themes/controversies' are established. On the second level, the 'positions' are placed, understood as the convergence of actants on one of the possibilities to solve the controversy. On the third level, the 'arguments' used by the actants during the debates in favour of a given position are presented. The fourth level presents the human and non-human 'actants' involved in each argument (CERRETTO; DOMENICO, 2016).

To build the hierarchical trees, we used the Debategraph software, a web-based collaborative tool for visualising ideas focused on complex issues, enabling the creation and management of mind maps. Guided by the technique of cross coding and categorisation (CORBIN; STRAUSS, 1990), which included both a priori and a posteriori coding, it was possible to carry out the "sampling" through the creation of a hierarchic tree containing the 'controversies', which hierarchically break down into (a) themes, (b) positions (c) favourable arguments and (d) arguments against each identified position, identifying the controversies in their four levels made extracting the explicit and

Figure 03: Position (of controversy 01.03)



Source: The Authors

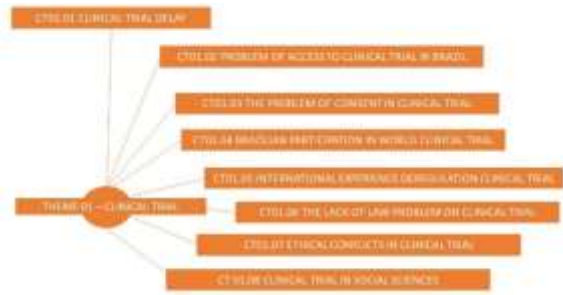
implicit 'interests' possible.

Considering the focal point of sampling or scanning, the networks of actors involved in each of the controversies were identified, distinguishing between 'human actants', 'non-human (objects)', 'non-human (almost-objects)' and the 'institutional actors' or 'macro actors' (LATOUR, 2007).

All "events" that occurred during the processing of the bill "PLS 200/2015" and "PL 7082/2017" were also described in chronological order. In each event, place, date, and a summary of the events and the actants (humans and non-humans) involved were recorded. Through "cross-link", in which each controversy is linked to the actants involved, it was possible to monitor the networks formed around each controversy,

We identified the controversies ("sampling") by reading all collected documents and organising them into "hierarchical trees", which are graphical representations of controversies in which a plurality of issues is presented and makes the debate complex (VENTURINI, 2010b; CERRETTO; DOMENICO, 2016). Considering that "every controversy is always part of other larger meta-controversies and is always composed of several sub-controversies" (VENTURINI et al., 2015, p. 79), it would be

Figure 02: Controversies (of Theme 01)



Source: The Authors

and management of mind maps. Guided by the technique of cross coding and categorisation (CORBIN; STRAUSS, 1990), which included both a priori and a posteriori coding, it was possible to carry out the "sampling" through the creation of a hierarchic tree containing the 'controversies', which hierarchically break down into (a) themes, (b) positions (c) favourable arguments and (d) arguments against each identified position, identifying the controversies in their four levels made extracting the explicit and

Figure 04: Arguments (of controversy 01.01)



Source: The Authors

identifying the actors whose participation made a difference in the action of others, making it possible to map who and what was involved in each controversy (the “scanning” process). Also, through “cross-link”, (a) controversies relate to (b) events and with (c) interests declared or implied by the networks formed by (d) actants, as well as with (e) decisions that are taken along the events, both from the intra-relational (legislative process) and inter-relational (which occurs in the meta-organizational universe) points of view. This seeks to design the translations that culminate in the closing of the black boxes (the “tracing” process).

To fulfil the “tracing” or design stage of the translation process, the ‘decisions’ taken while the process was recorded were mainly represented by legislative deliberations, such as approval of amendments to the project and consolidation of versions of the project as it advanced. At the same time, the normative changes promoted by the CEP-CONEP system were also registered, and reactions expressed by the other actants were from the legislative environment. The “a priori” categories were “controversies” and “actants” (humans, objects, quasi-objects and macro-actors). The “a posteriori” categories were “events”, “decisions”, and “interests”. Abductive reasoning was used in this cartography. It consists in exploring the facts and allowing these facts to suggest a theorisation in back-and-forth movements between existing theoretical knowledge and observed phenomena. Thus, in the “labelling” stage, we sought to abductively understand the power relations and practices involved in controversies through the interactions of the various actants, paying particular attention to the moments and spaces in which these interactions could change the course of action of the legislative process. The intention was to understand the production and maintenance of actor networks and how these actors are tied by common bonds and create or alter the reality in which they participate.

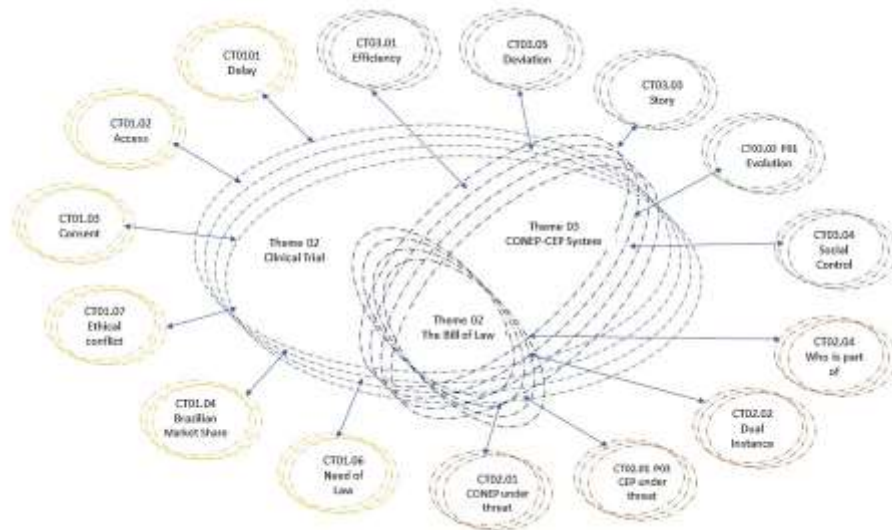
In this “labelling” focus, they were also described as a group of entities acting together and becoming a single voice, or in ANT's terminology, how an actor became scored.

Finally, in “describing”, we reassembled a narrative to tell a story about the regulatory process of the clinical trial, describing the case from a procedural flow ontology, the observer's agnosticism, generalised symmetry, and the possibility of free association.

## 7. Analysis of the results

From the multiple ramifications and different traceable paths, we structured the reassembly of the controversy based on three narrative themes that helped us to understand the clinical trial regulatory dynamics: (a) clinical trial, (b) the CEP/CONEP system, and (c) the Bill of Law (PLS 200/2015 – PL 7082/2017) which generated fifteen controversies were mapped.

Figure 5: Controversies founded in the trial clinical regulation



Source: The authors

The narratives were built from the search to understand the relations that described the dynamics regarding (a) the meaning attributed to clinical trial and the regulation involved in it, (b) the controversies surrounding the ethical regulatory function (CEP-CONEP system) and (c) the legislative process that proposes a rearrangement of this regulatory dynamic, but also suffers performative effects in its construction.

To sample the performativity of regulation, we will cut the cartography related to three (of fifteen) controversies: 'the delay of the clinical trial' (CT01.01), 'the consent of trial participants' (CT01.03) and 'the efficiency of the CEP-CONEP system' (CT03.01).

#### ***The delay in the clinical trial (CT01.01)***

The debate on clinical trial regulation starts in the Federal Senate. The networks defended by the Senators are eager to release medications, and cancer is the actant that most afflict them (P01 b4). The delay affects the poorer (P01 b5 b6), scares away the researchers from leaving the country (P01 c) and harms the generation of industrial property (P01 ob002). The reaction to the explosive rhetoric of critics of regulation is parsimonious but blunt: "Any effort to reduce deadlines will have our support" (CT0101 P01 f); however, the actors-networks triggered to flaunt the "hurry" were silenced by the following data: "Response time of CONEP decreased from 10-11 months to 48 days" (CT0101 P01 d). More numbers refuted it: "The response has been coming with numerous pending issues, which means that the delay persists" (CT0101P01 d2). What good is the decrease in time response of CONEP if the levels of demand remain the same, and as a practical result, clinical trial fails to advance? Haste is now associated with bureaucracy.

As a socio-technical artefact, regulation was constituted as a starting point, by relations with slowness and bureaucracy, and with the propagating effect of disease, death generator, injustice promoter, scaring away talent and reducing wealth.

The "hurry" that would justify the deconstruction of the regulation for the fastest clinical trial shifted to the search for the speed of the PLS 200/2015 itself. If data war alone was not enough to contain and deconstruct the regulation, in the case of the search for the speed of PLS 200/2015, new actants proved capable of such purposes: the Internal Regulations of the Federal Senate and the Chamber of Deputies, which provided requests for "views" and caused the suspension of the course of the bill. Several views were granted, and PLS200/2015, converted into PL 7082/2017, has been in process for years with no prospect of completion, which makes us ask where the rush was.

Moreover, suppose the rush did not move parliamentarians to speed up the processing of PLS200/2015. In that case, the same cannot be said of the infra-legal revisions of CONEP itself, as deadlines have gradually been reduced to the point where Brazilian processing times have become shorter than those practised in the United States (CT0101 P01 m).

Finally, the promoters of PLS 200/2015 celebrated the performativity of the initiative by stating that the improvement of regulation has advanced despite all the obstacles to the creation of the legal framework for regulation (CT0206 P01 b).

#### ***Consent of the participants (CT01.03)***

In CT01.02, it was said that clinical trial is favourable to the population, the country and scientific progress, which takes us to why hinder its advancement. Moreover, as an actant, 'trial' is the key to understanding that all these benefits take their toll, as research involves discoveries, experimentation, and the possibility of not finding what one is looking for. There are also unanticipated and uncontrolled adverse effects that must be avoided or mitigated, especially when research participants are human beings.

It expressed the ambivalence of the artefact: On the one hand, regulation, which promoted death, did not fight cancer and was bureaucratic, now saves lives. On the other hand, clinical trial, which until then generated jobs, supported the SUS and was responsible for the progress of science, now produce deaths as well. If both clinical trial and regulation can save and kill,

the benchmark to find a balance in this antagonism becomes the consent of research participants, a new actant, which must be free and clear.

An essential ally of regulation was the Indian case, which followed the same steps (of deregulation) recommended in PLS 200/2015, thus making the rules for controlling clinical trial more flexible. However, the results of the experiment were catastrophic: 370 deaths in clinical studies in 2 years. Between 2005 and 2012, 2600 patients died. The Supreme Court of India then decided to suspend research until the regulation was more adequate (CT0105). An anti-history (“Second World War) was rescued to recall the origins of ethical legislation and its function to protect participants’ freedom of consent in clinical trials (CT0103 P01). As the difference between drug and poison lies in the dose given, the discussion arose about whether the consent of clinical trial is an act of the participant, who expresses himself freely, or whether the vulnerable and unable-to-discern participant has his freedom compromised or suppressed.

The clinical trial of the “cure of diseases” and “progress” combined with the artefact of “regulation that kills” will remain with the consent as an individual act of the participant. Clinical trials regarding the “Indian experience” that took place in the “second world war”, allied to the “regulation that saves lives”, will remain with the mitigated consent, where not even the participant alone can decide. It is the dispute between “freedom” and “security”.

From the view of ‘freedom’, regulation cannot be conceived to protect participants beyond what they wish to be protected. The final word belongs to the one who is protected and not otherwise (CT0107 P02 a). From the point of view of ‘security’, it is precisely despair that suppresses free and informed consent from people, requiring them to be protected even from themselves (CT0107 P01 c).

However, it is not just about mitigating the right to free consent of clinical trial participants but reconciling conflicting interests of those who want a cure and those who want to profit from the cure despite the lives lost (CT0103 P01 c).

The conflict between freedom and security shifts to an apparent dilemma between “protecting the participants” or “caring for the patients”. It is as if we were faced with “Sophie's choice”. Would it be acceptable to sacrifice participants to save patients? Or, to protect participants will we live as much as necessary with the deaths of patients? (CT01.07 P02). The dilemma was rejected. The “hurry” reminds the regulation that the reasonableness of time for the clinical trial is also an ethical precept to be protected, including the very regulation (CT0107 P03 a). The ambivalence of artefacts fighting for a regulation definition seems to recalcitrate. Time and ethics need to agree.

#### ***The CEP/CONEP system and social control (CT03.04)***

Democracy is an underlying actant because it was associated with the networks formed during the deconstruction and reconstruction of clinical trial, its regulation and the CEP-CONEP macro-actors revived throughout the process.

Stylised at first, in the 'opinion+lawyer+Luiz\_Barroso', 'democracy' was an ally in the search for the reconstruction of the system under the aegis of law since regulation being supported by infra-legal norms, democracy would be underrepresented by non-mandatory agents of the popular will. However, it was also enlisted by defenders of the current infra-legal model, who accused PL 200/2015 (PL 7082/2017) of weakening the 'social control' erected under the nomination criteria of CONEP members.

Social control entered relations as the third guiding element of the regulatory model advocated by the actants. It was not just 'efficiency' and 'ethics' that were in dispute, but the power emanating from the so-called 'social control' that was instrumentalised by the right to participate in the production of resolutions issued by CONEP or to limit its prerogative (CT0304 P01 b).

The current system establishes the obligation of 'social control' through the participation of representatives of research users in CEPs (CT0304 P01 a). At CONEP, social control was

established not only through the representation of civil society in general but also by members who have “technical profiles” and are “highly qualified” (CT0304 P01 a1).

The choice of members of these bodies follows criteria considered “objective” by CEPs and by CONEP (CT0301 P01 j).

According to Resolution 446/2012, CONEP was composed of thirty members, twenty-two of whom were appointed by the CEP and eight by the CNS. At least within the CEPs, social control was improved, as verified by the issue of Resolution number 647/2020, which regulated the process of designation and performance of CEP members appointed by social control entities called RPP (Research Participant Representatives), establishing rules on the profile, performance, rite of nominations and relations that the RPP must keep with the CEPs they participate.

The power one tries to build does not involve only the RPP, but science itself and the artefacts that confer legitimacy to the technical and scientific authority, as if socio-political actants were not also present in them (CT0304 P01 d).

The CEP-CONEP system struggled to depoliticise the participatory democracy chosen to legitimise social control in the constitution of its members.

Opposing networks claimed that depoliticisation is impossible and wanted to introduce, under the importance of a law that remodels the system, representative democracy, which is more technical, scientific, and reduced in constructing communication channels between the State and society.

The recommended model denounced the politicisation of the CEP-CONEP system as a driving force behind inefficiency, distortion, and delays in approving research protocols.

The current model denounces the PLS 200/2015 (PL 7082/2017) intention to make the process technical and far from the interests of the clinical trial participants and democratically insufficient.

In the clash and movement of networks, one can see that “science” and “politics”, as well as “participatory” and “representative” forms of democracy, are all being enlisted for the definition of control over-regulation.

It does not matter which institutional actors – CEPs, CONEP, with these or other designations – will constitute the regulatory “agencement”. What matters is to know which relations involved will win the fight.

## **8. Conclusion**

A performative view of the regulation using the ANT allows us to generate theoretical, methodological, and practical contributions.

Theoretically, we observed a new concept of regulation that works performatively with bidirectional movements. The actors-networks related, connected, disconnected, and achieved alignments, generating translations from where some decisions were punctuated in the form of approval of amendments. As a “labelling” of the mapped movement that the relationships arising from the actants who remounted the legislative process acted simultaneously inside and outside the National Congress, it was seen that while a bill struggled to become a law, the regulatory artefact produced its improvement to harden itself and try to prevent the advance of the bill.

Not only did regulation generate and suffer performative effects in its reconstitution, it also promulgated realities to the activities and entities subjected to it, such as the formation and existence of groups articulated around PLS 200/2015. We call such phenomena performative effects that occur intra- and inter-relational and are guided by the three rhetorical questions below (VILLAR, 2019).

‘*What is regulation*’: The socio-material notion derived from ANT allows us to move regulation away from the notion of an institute resulting from deliberate human will and be understood as a negotiated process of heterogeneous interests whose agency is symmetrically

distributed. It is also the effect of an agreement (socio-technical arrangement) whose network actors claim power over the other actants who participate in the network. Finally, it is a negotiating space to distribute power where relations arising from the actants assemble and remount the reach or the extent of the networks configuring the artefact.

The methodological contribution is evidenced by the adoption of the cartography of controversies (VENTURINI, 2010a) as a viable technique to describe processes of constitution of moving realities, with more operable indications on how actors-networks promote translations, moving ontologically procedural realities, although often punctuated by performative effects. ANT research is challenging, and the increasing use of cartography is perhaps the most user-friendly method to generate good descriptions of dynamic and complex processes. It has also allowed a more consistent view of the constitution of reality without the modernising vice of taking what still needs to be understood for granted. This processual-performative stance can reduce the pressure of hasty diagnoses about black boxes that never close, or at least, in which closure is not a definitive process. Such reflections from this view allow us to recognise that the relativisation of human intentionality is also reflected in finding the natural performativity of network actors, also ontologically explained by becoming, although not punctuated under the denomination of social aggregates.

As a practical contribution, we retrieve the debate surrounding the need for a regulation general theory to address the epistemological weakness of its construct. Whether regulation is necessary, we ask what, why, when, where and how to regulate. The antagonism and polarisation of controversies glimpsed in clinical trials demonstrated that regulation is nothing more than an artefact pointing out the power of networks voiced by humans, non-humans and macro actors. The position of an actor network manifested by its interests and by the combat of its opponents is determined by the socio-material relations that support the network with which it is associated. These controversies are functions of sociotechnical networks that mediate these associations. Constituent elements of these networks are positioned “against” or “in favour” of a particular interest depending on the relationships they are involved in within the networks in which they participate, which aggregate and disaggregate, procedurally and performatively.

Controversy and performativity of relational networks, initially antagonistic, generate spaces for negotiation or a zone of translation, through which they pass and establish contacts with new constituent elements of networks. The debate about what levels of regulation are involved in the different regulated activities could be re-signified if we adopt the performative approach. This controversy may become an adiaphoron since ideological, political, economic or social factors no longer serve to justify antagonistic positions but would become integrated into the networks to be also performatively reassembled from the relationships in which they are immersed. In this sense, regulation will always be present in the work of networks, whose power will always be explained by the associations of human and non-human actants attached to it.

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