Global Journal of Computer Sciences: Theory and Research

Volume 13, Issue 1, (2023) 34-45 www.gjcs.eu

Regulating and testing normative structures for Artificial Intelligence: the possibilities of the Regulatory Living Lab

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Suggested Citation:
Engelmann, W. & Silva, S., B. (2023). Regulating and testing normative structures for Artificial Intelligence: the possibilities of the Regulatory Living Lab. *Global Journal of Computer Sciences: Theory and Research*. *13*(1), 34-45. https://doi.org/10.18844/gjcs.v13i1.8482

Received from; October 24, 2022, revised from; December 25, 2022 and accepted from February 01.
Selection and peer review under responsibility of Assoc. Prof. Dr. Ezgi Pelin YILDIZ, Kafkas University, Turkey.

Abstract
This qualitative and exploratory study sought to understand how the Living Lab approach can serve as an innovative alternative to test a regulatory structure organized by principles for Artificial Intelligence (AI). The main research problem is: what would be the structuring elements of a non-legislative regulatory model that could standardize the advances in Artificial Intelligence? The units of analysis were the developments and commercialized innovative AI applications of startups from an incubator that integrates an internationally renowned technological park in Brazil. Entrepreneur perceptions of the dimensions of the Living Lab approach are described, analyzed, and compared (i.e. the interaction between multiple stakeholders, co-creation of value, user-centered research, solving real-world problems, and adopting multiple methodologies). The findings suggest that the Living Lab approach is an alternative for creating and developing innovations and applications in AI, with the active involvement of end-users while facing existing regulations and testing environments for new regulations - principles published by the European Union and OECD. An important observation that emerged from the study: the advances in Artificial Intelligence have occurred on an increasing scale, very close to exponentiality. For this reason, the need and importance of spreading the regulatory importance of these "what should be" principles, is very similar to those of the rules produced by state legislative action. In this exploratory study, it became evident that entrepreneurs feel there is a lack of clear regulatory mechanisms. The role of the Law in the creative proposition of regulatory models should be based on globally accepted principles, such as those published by the European Union and the OECD.

Keywords: Regulation, Innovation, Artificial Intelligence, Regulatory Living Lab, Startup, Principles.

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Introduction

In recent decades, innovation research has shown businesses how to improve their development practices, as well as enhance the introduction of products to the market and their impact. Advances in the new Information and Communication Technologies (ICTs) include Artificial Intelligence (AI) and robots that can perform social action, as well as other physical and virtual autonomous systems. These have provided methods and innovative procedures for businesses, policymakers, and researchers that were not previously available. They also guide new trajectories for the conception of better practices through innovative research that benefits businesses, consumers, and society in general. (Lee, Moorman, Moreau, Stephen & Lehmann, 2020).

AI is one of the fastest-growing segments of the new ICTs, and it may propel the current economy towards significantly higher efficiency. It also has the potential to remodel the process of innovation, the organization of research and development (R&D), and innovation management. (Cockburn, Henderson & Stern, 2018; Haefner, Wincent, Parida & Gassmann, 2021). AI has been explored on multiple fronts, especially startups that sell to businesses of all sizes and from different sectors and nations. Contrary to what has been popularly expressed, they report more benefits from AI when it is used to enhance human capabilities rather than substitute them. This is because professional, management and marketing jobs have opened up more frequently while the number of manual, administrative, and frontline service jobs has decreased. (Bessen, Impink, Reichensperger & Seamans, 2018).

While the discussion of AI is generally framed in terms of machines versus humans, there is concern about the unpredictability and uncontrollability of AI and the onus for AI companies, policymakers, and researchers to be more transparent (Agrawal, Gans & Goldfarb, 2017). Any requirement for transparency should result in explanations about biases that are understandable to potential recipients, technically feasible for producers, and useful in specific legal contexts (Buiten, 2019; Wischmeyer & Rademacher, 2020).

Artificial intelligence has presented new challenges for several areas of law, since technology advances much faster than regulatory structures (Fenwick, Kaal & Vermeulen, 2016), whether it is patent or criminal law, privacy or antitrust law (Khisamova, Begishev & Gaifutdinov, 2019), or regulations that can affect innovation in general (Aghion, Bergeaud & Van Reenen, 2021).

Discussing the regulation of AI applications and innovations has proven to be a relevant empirical field. Researchers have not thoroughly examined several approaches. These constitute theoretical and empirical gaps, such as the concept of "Living Labs" which, despite having received increased attention in the last decade, is still neglected. It has the potential to be explored in different fields of application (Greve, Vita, Leminen & Westerlund, 2021), such as the role of living labs in extending the limits of innovation. This would be useful for co-developing socially desirable governance structures, in conjunction with real-time emerging technologies (Van Geenhuizen, 2018; Engels, Wentland & Pfotenhauer, 2019).

Therefore, this article aimed to answer the following question: can the Living Lab approach serve as an innovative alternative to test regulatory models of AI innovations and applications? To shed light on this question, we examined evidence from the empirical field, through exploratory research. We assessed the developments and commercialization of AI innovations and applications by startups from an incubator that integrates an internationally renowned technological park in Brazil.

The article is structured as follows: first, the text presents theorizations about Living Labs. Next, the methodological procedures are presented. After, the results of the research are presented, followed by a discussion regarding the results, the findings, and the final considerations. These include theoretical and managerial implications, as well as ramifications for policymakers. We also address the limitations of this study, recommendations for future research, and finally the framework.

2. THEORETICAL REFERENCE

2.1. LIVING LABS

The concept of "Living Labs" was used for the first time in the early 1990s by Bajgier, Maragah, Saccucci, Verzilli & Prybutok (1991, p. 701) to describe students experimenting with solving problems in a neighborhood in Philadelphia. Later, William J. Mitchell from the MIT Media Lab and School of Architecture further developed the concept to define innovative research that aimed to develop and test information and communication technology in homes, neighborhoods, and cities (Mitchell, 2004; Nesti, 2018). In Europe, the concept was adopted in real-life environments and 'real' experimentation around 2005.

Results of a literature review indicated that the term "Living Lab" is also considered a multidisciplinary phenomenon that is widely used in different contexts and encompasses several research domains, despite being typically discussed as a paradigm of open and user-centered innovation (Burbridge, 2017; McLoughlin, Maccani, Prendergast & Donnellan, 2018; Hossain, Leminen & Westerlund, 2019; Leminen, Nyström & Westerlund, 2020). Greve, Vita, Leminen & Westerlund, 2021).

The first publications about Living Labs focused mainly on software development and the use of digital tools and, at that time, identified two categories of Living Labs. The first defined Living Labs as infrastructures for open and user-centered innovation, to support a network of stakeholders in the creation and development of products and services, with the active involvement of end-users. The second type was the Living Lab as a test environment for new applications through their exposure to and validation by end-users. Thus, the Living Lab was initially seen as a type of room, space, or city connected with a user-centered methodology, in which researchers and end-users perceive, innovate, validate and refine complex home technologies in a real-life context (Leminen, Westerlund & Nyström, 2012). Since the concept has interested many disciplines, and the idea of Living Labs has expanded to other fields, it has been adapted for different applications, and a wide range of definitions have been formulated (Dutilleul, Birrer & Mensink, 2010; Van Geenhuizen, 2013).

A broad variety of activities are carried out under the term "Living Labs". When one does an overview of the literature, one sees that they have been described as a methodology, network, system, concept, approach, environment, or ecosystem, depending on the approach or context (Følstad, 2008; Bergvall-Kareborn & Stahlbrost, 2009; Almirall & Wareham, 2011; Dell'Era & Landoni, 2014; Leminen, 2015).

Living Labs have been recognized as an innovative tool for testing, validating, developing, and co-creating in all of the phases of the design and commercialization process (Buhl, von Geibler, Echternacht & Linder, 2017; McLoughlin, Maccani, Prendergast & Donnellan, 2018; Leminen & Westerlund, 2019; Hossain, Leminen& Westerlund, 2019; Greve, Vita, Leminen & Westerlund, 2021).

In Japan, there is already a living laboratory, in which different regulatory structures can be applied in the style of a regulatory Living Lab. It is built on a set of published principles for the safe and healthy use of AI, including robots in general and humanoid robots. It is called the "Tokku" Special Zone for Robotics Empirical Testing and Development (RT special zone). This Special and Experimental Zone started development and implantation in 2003, in the cities of Fukuoka and Kitakyushu. They were initially created to test robot technology, and the structure of the living laboratory has, more recently, also opened spaces to test the normative frameworks applicable to AI and robots, especially humanoid robots (Weng *et al*, 2015).

In summary, as shown in Table I, the Living Lab approach has five dimensions derived from the interpretation of the literature in this section. It is based on a set of specific references. The dimensions represent the diversity among stakeholders involved in a co-creation process to generate user-centered innovations in response to complex real-world problems. Multiple methodologies constitute a viable method for the context in which innovations are developed.

Table I
Dimensions of the Living Lab Approach

Dimensions	**Descriptions**	**References**
Diversity among interested parties	These include all of the actors of the quadruple helix: representatives from the public and private sectors, academia, and civilians.	Almirall, Lee & Wareham, J. (2012); Leminen, Westerlund & Nyström (2012); e Leminen, S. (2015).
Co-creative process	Users become equal contributors and co-creators, instead of study subjects so that mutually valuable results can be obtained; results that come from all interested parties being actively involved in the process, from beginning to end.	Mirijamdotter, Ståhlbröst, Sällström, Niitamo & Kulkki (2006); Schumacher & Feurstein (2007); e Hagy, Morrison & Elfstrand (2017).
User-centered innovations	Any activity that should involve (final) users at the beginning of its process.	Pallot, Trousse, Senach & Scapin (2010); Schuurman, Lievens, De Marez & Ballon (2012); Ballon, Van Hoed & Schuurman (2018).
Answers to the complex problems of the real world	Activities happen in real environments to gain a complete and general understanding of the context.	Feurstein, Hesmer, Hribernik, Thoben & Schumacher (2008); Bergvall-Kåreborn, Eriksson, Ståhlbröst, & Svensson (2009); e Ståhlbröst, A. (2012).
Multiple methodologi	Different user-centered methodologies of co-creation are combined and personalized to	Almirall & Wareham (2009); Leminen & Westerlund (2016); e

es	better meet goals.	Leminen & Westerlund (2017)

Source: original Table.

3. METHODOLOGY

This was a qualitative, exploratory study (Gil, 2002; Collis & Hussey, 2005; Vergara, 2006; Gil, 2008), and the aim was to understand how the Living Lab approach can constitute an innovative alternative to regulate AI innovations and applications. In this sense, it sought to provide greater familiarity with the research problem to construct patterns, ideas, or hypotheses. The idea was not to test or confirm a given hypothesis, but rather to discover. The technique of an exploratory survey was used to collect information (Freitas, Oliveira, Saccol & Moscarola, 2000) to understand what the target population thinks of a certain concept, or what topics are of interest to the target audience or group. Furthermore, the study design is cross-sectional, since the information was collected at a specific time (during January and February 2021). In the search process, objective questions were defined, such as "what?", "why" "when?", "where?" and "how?". The questions explored the five dimensions of the Living Lab approach: a) diversity among stakeholders; b) co-creation process; c) user-centered innovations; d) responding to complex real-world problems; e) multiple methodologies.

The survey instrument was a questionnaire from Google Forms, which is an application that can create forms by using a spreadsheet in Google Drive. Participant feedback was used only for this study and was kept confidential. Per the request of the startup entrepreneurs, their identities were kept confidential as well. Subsequently, there was interaction with the entrepreneurs to understand common aspects among ventures, and specific aspects related to the regulation of AI innovations and applications.

The units of analysis were the developments and commercialized innovative AI applications of seven startup companies from an incubator that integrates an internationally renowned technological park in Brazil. It was created more than 20 years ago and houses companies from the areas of Information Technology, Semiconductors, Automation and Engineering, Communication and Digital Convergence, Health Technologies, Renewable Energies, and Social and Environmental Technologies. Currently, there are 96 national and international companies, with a turnover of more than R$ 2.5 billion, and about 120 intellectual property registrations. It is a member of the International Association of Technology Parks (IASP) and was chosen twice as the best Technology Park in Brazil. Additionally, the incubator has received a Global Award for Best Incubator, from the Technopolicy Network. The target population was made up of entrepreneurs from the surveyed startups, as shown in Table II.

Table II
Resident startups that develop and commercialize AI innovations and applications

Startup	**AI innovations and applications**
A	A restaurant system that helps entrepreneurs from the food sector upgrade their

	business processes by making them simple, agile, and intelligent.
B	A multiplatform health application for the private and public sectors, with the following aggregated functionalities: self-check (COVID-19); online chat online; teleconsultation; medication management; and appointment booking (in-person and remotely).
C	Wearable products, electromyography systems, upper limb prostheses, and high-definition 3D prototypes.
D	Software and application development services, legacy software updates, and consultancy.
E	A cybersecurity system that aims to provide website security and safety.
F	Programming based on ABAP source code (Advanced Business Application Programming) [this is a high-level programming language that was developed by the SAP software company] to enhance processes.
G	The research, development, production, and commercialization of biosensors, to broaden access to laboratory diagnoses and simplifying testing.

Source: original Table.

Regarding the five dimensions of the Living Lab, the perceptions of the startup entrepreneurs were described, analyzed, and compared, according to the theoretical reference mentioned in this article. This information is presented in the results and discussion.

4. RESULTS

The results of our understanding of the developments and commercialized innovative AI applications of the startups demonstrated that the solutions were diverse. They can involve software, such as applied systems, development applications, and services, programming, or a combination of hardware and software with wearable products and biosensors. On the other hand, all solutions were designed to enhance results, increase productivity and save the customer's time. This shows that AI-based decision systems serve as aids to human decision-making.

The development and commercialization of innovative AI applications are the results of recent ventures, with no more than four years of trajectory, based on different business models. Where one enterprise may adopt the Platform strategy, another may use B2B (business-to-business).

Occasionally, there was feedback from the startups about the need to identify unwanted biases in AI innovations and applications, mediated by human supervision. Additionally, there was a unanimous report about attempts to comply with the General Law on Protection of Personal Data (in Brazilian Portuguese: LGPD), and "how" information must be protected. Moreover, one of the

entrepreneurs reported having expectations regarding Bill 5051/2019[*], which is under review in the Federal Senate and aims to provide guidelines for the use of Artificial Intelligence in Brazil.

As for the perception of the startup entrepreneurs regarding the five dimensions of the Living Lab approach, this information is shown in Table III.

Table III
The perceptions of startup entrepreneurs regarding the five dimensions of the Living Lab approach

Dimensions	**Perceptions of the entrepreneurs**
Diversity among interested parties	All businesses (100%) reported that they do not host interactions between the multiple stakeholders (investors, Scientific and Technological Institutions - STIs, regulatory bodies, customers, etc.) to evaluate the regulation of Artificial Intelligence (AI) in their enterprises.
Co-creative process	Some of the enterprises (40%) encourage the co-creation (constructing through conversational exchanges) of solutions with their customers (end users) in the regulation of Artificial Intelligence (AI) in business, especially in the preliminary negotiation phases when the delivery of the contracted solutions and the clauses of their commercial contracts are determined. The other businesses (60%) usually unilaterally establish clauses regarding applicable regulation compliance, with an emphasis on the LGPD, or adjust specific clauses to associate the LGPD with their contracts.
User-centered innovations	The development of user-based (end-user) solutions (innovations and applications) is common for a portion of the businesses (40%). They usually consider their end-users in the development of their business models through interviews and personas (fictitious representations of the ideal client for a business). For the others (60%), end-users are not involved in the development of solutions. They are activated in some representations as testers for developed solutions.
Answers to the complex problems of the real world	The solutions provided by some of the businesses (60%) are developed in response to complex problems in the real world (solutions associated with "customer complaints", a common expression in the construction of the value proposition of enterprises). Regarding the current regulation of AI, while other businesses (40%) conduct their developments in response to complex real-world problems, they do not take into account the current regulation, as it could restrict creative thinking and, consequently, innovations.

[*] Law n° 13709, 14 August 2018, also known as the *Lei Geral de Proteção de Dados Pessoais* (LGPD) in Brazilian Portuguese. Available on: http://www.planalto.gov.br/ccivil_03/_ato2015-2018/2018/lei/L13709.htm. Accessed on: 28 February 2021.

Multiple methodologies	The totality of the enterprises adopts multiple methodologies to develop solutions, such as those from the design sector (design thinking), engineering (Minimum Viable Product), administration (the SWOT Matrix), and particularly, lean startups. However, the regulation of Artificial Intelligence (AI) in business is only occasionally considered since it represents a possible restriction for innovations or a risk to the viability of businesses. This perception of risk comes from reflections about strategic threats.

Source: original Table.

None of the startups adopted a Living Lab approach in its entirety. Each one adopted two or even three Living Lab dimensions to develop solutions, according to the particularities of its business model and the specific characteristics of its innovations and AI applications. However, some common principles were adopted by the majority (80%) of entrepreneurs to develop their AI solutions. Namely: the principle of transparency for disclosing all their actions, except for the normative exceptions; the principle of ethics to respect the life, heritage, and well-being of others, and social justice so no one is harmed; and the principle of resolvability to solve or bring about the resolution of an issue. This was a common term in the field of health and among the startups that operate in this field.

Some of the interviewees (40%) expressed difficulties in developing innovative solutions in the face of AI regulations. This is because they are not yet well defined by Brazilian law. These startups understand that there should be more specific sources of funding for AI innovations and applications and that these sources should present standard notions to which all businesses could equally conform. In addition, a portion of the interviewees (20%) did not recognize their solutions like AI, even though they involved several technologies, such as algorithms and learning systems that can simulate the human capacity for intelligence.

Furthermore, the majority of respondents (80%) stated they would be willing to actively participate in the process of building a regulatory model, based on principles developed by international bodies, such as the principles for the development of artificial intelligence (AI) proposed by the OECD (Organization for Economic Cooperation and Development). Forty-two countries are signatories to the document, and Brazil is one of them. The first of these principles, for example, indicates that artificial intelligence should benefit people and the planet for inclusive growth, sustainable development, and well-being, among other principles that can structure a provisional but efficient regulatory framework. This framework should be used by the regulatory Living Lab until state regulation comes into force.

5. DISCUSSION

Having a clear regulatory framework is a factor that may or may not foster innovation in a given sector. In the case of AI, as well as other technologies that belong to the panorama of the Fourth Industrial Revolution (Schwab, 2016; Schwab; Davis, 2018), there is an important obstacle that hinders the development of traditional and legislative regulation: the rapid progress and transformation of these technologies that operate on an exponential scale. Meanwhile, the process of creating a new law is still structured around deadlines and formalities that are around 200 years old. The survey revealed that 40% of respondents pointed out this difficulty. Given the instability of the legal system in force in Brazil, it further highlights this hurdle in the encouragement and advancement of innovation.

Eighty percent of the interviewees reported structuring a regulatory Living Lab and using certain principles to build it. They already use, to some extent, certain principles to guide their activities. Therefore, there is already an implicit recognition of this regulatory framework. This finding shows that a complete regulatory scheme, based on a set of principles, such as that of the OECD, could serve as a path for future research.

Despite this finding, there is still a lack of more detailed and complete knowledge about the structuring elements of a regulatory Living Lab. One hundred percent of the interviewees reported using one or more of Living Lab characteristics, but not a complete model. As such, a Living Lab space has still not been developed. Therefore, there is an important gap that research can help to bridge by encouraging training for all its components, and showing the possibilities of a regulatory model based on globally accepted principles, such as those of the OECD.

It is worth noting that 40% of the respondents construct solutions without worrying about regulatory issues. This is an important finding. As important as regulations are when they are well-specified and of easy access for the user, they are also ignored if they are not developed or non-existent. The entrepreneur is left up to their creativity and their knowledge of certain legal norms, and they use this knowledge to guide their conduct. This behavior should serve as a warning for the Law, as there is evidence that business is well underway, despite the absence of regulation.

6. FINAL CONSIDERATIONS

The findings of our research suggest that the Living Lab approach is an alternative for creating and developing AI innovations and applications, with the active involvement of end-users while facing existing regulations and testing environments for new regulations. At the same time, it is still possible to move forward with the complete knowledge of the characteristics and structures of a regulatory Living Lab.

By cross-referencing the findings in our empirical research, it became clear that structuring a regulatory framework based on research and co-creation with stakeholders may be an innovative and creative alternative for advancing technological innovation. In the case of AI, there may be more efficient legal and factual possibilities than waiting for a law to be changed, however specialized it may be.

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