IDEATION PHASE

Define The Problem Statement

Team Id	NM2023TMID04410
Project name	Project- Drug Traceability

Introduction:

- The development of advanced information technology (IT) solutions has enabled the formation of inter-organizational networks which facilitate the processing and sharing of information in real time, thereby allowing several controls, including traceability in supply chains. As the manufacture, supply, and distribution of drugs becomes more complex, there is an increased need for innovative technology-based solutions to protect patients globally via traceability systems.
- Traceability has become a differentiator in many industries. The pharmaceutical industry, along with the food industry, has been capturing the interest of researchers more than other industries, due to its more stringent regulation by governments and international organizations, while safety and quality in the industry have caught the world's attention
- .However, the implementation of effective drug traceability systems faces many challenges, and it is essential to identify the critical success factors (CSFs) for such systems.
- There are theoretical gaps in the study of the development of traceability in different pharmaceutical supply chains, such as the creation of value by the implementation of traceability systems, as discussed by. In references, the authors argue that the primary reason for adopting traceability may be to respond to legal claims, and that companies that use new technologies do not make the most of the potential operational benefits of traceability.

Pharmaceutical Supply Chain :

- The pharmaceutical sector currently accounts for 8% of Brazil's Gross Domestic Product (GDP), contributing 75,000 direct and 500,000 indirect jobs [9]. By April 2022, all Brazilian drugs will have to comply with the regulations set by the National Agency of Sanitary Vigilance (ANVISA), which enable drug traceability.
- ANVISA, a government agency, is considering a model in which the agency centralizes drug traceability, similar to models which have been adopted in countries recognized for their drug traceability models, such as Turkey and Argentina.

- The value of the global pharmaceutical market is expected to reach around US $ 1.4 trillion by 2020; the value of Brazil's pharmaceutical market currently ranks seventh in the world, and is expected to rise to fifth by 2020.
- In reference [11], the author discusses processes, operations, and organizations involved in the discovery, development, and manufacture of drugs and medications [12]. PSCs are socio-technical systems designed to align firms in order to enable improved health status through the provision of medicines.
- Complementary and alternative products and process technologies may coexist within such a system. A PSC is a five-tier supply chain which includes:
    - Primary manufacturers, who are responsible for the production of required active ingredients (RAI)
    - Secondary manufacturers, who are responsible for further production processes (manufacturing centers)
    - Main distribution centers
    - Local distribution centers
    - Destination zones/demand points

Other authors, such as in [15], define PSCs as organizations acting in different buying and selling capacities, including:

- Manufacturers (sellers)
- Wholesalers (buyers and sellers)
- Hospitals (buyers)

The aforementioned authors [11,12,13,14,15] consider that a PSC is composed of layers, namely a supplier, manufacturer, wholesaler, and pharmacy or hospital. The understanding of the concept of a PSC and the respective actors is an important factor for several research areas, including traceability, inter-organizational systems implementation, anti-counterfeiting strategies, and best practices in the PSC around such sophisticated tools.

PSCs are affected by counterfeiting and theft issues, which not only compromise the profits and reputations of manufacturers, wholesalers, pharmacies, and hospitals, but also compromise public health and consumer safety. In this context, traceability plays a central role, particularly in supply chains where multiple parties are involved and in which rigorous criteria must be fulfilled to lead to a successful outcome .

Critical Success Factors of the Drug Traceability System :

- Critical success factors (CSFs) are not detailed practices for the implementation of a system; rather, they are factors that support the highly successful implementation of systems and help the organization to focus on the most important factors [29,30]. The implementation of an effective traceability system faces many challenges, and it is essential to identify its CSFs [31].

- The implementation of a traceability system requires an appropriate strategy, and the CSFs of systems that have been effectively implemented, and interaction among them, may help to develop an effective strategy for the systems.
- Additionally, the implementation of traceability systems can be seen as the adoption of information systems in enterprises operating in a complex PSC.
- Thus, models of technology adoption as technology–organization–environment (TOE) provided useful guidance for developing this study. IT developers should obtain a better understanding of nontechnological factors in order to better plan their implementation.
- The TOE framework explains that three different contexts influence the decisions to adopt new technologies, namely technological context, organizational context, and environment.
- The TOE framework, as originally presented and later adapted in IT adoption studies, provides a useful analytical framework that can be used to study the adoption and assimilation of different types of IT innovations.
- Ngai et al. (2007) discussed critical factors regarding the use of Radio Frequency Identification (RFID) technology in the aeronautical industry, which they categorized into four categories: raised organizational motivation for improvement; implementation process; cost control; and university–industry interaction.
- Aung and Chang (2014) mention that an efficient traceability system must be characterized by the amplitude (that is, the amount of collected information), the depth (the capacity to track relevant information), and the precision of information, thus allowing the balance of costs and benefits. Duan et al. (2017 established a CSF framework for the implementation of traceability systems based on empirical evidence collected in China.

References [8,31] highlight the following dimensions of critical factors for the implementation of a traceability system:

- Environment (legislation, government support, standards);
- Organizational (involvement of top management, supplier support, effective communication);
- Technology (the quality of the tracked information and the traceability system).

Traceability is essentially a subsystem of quality management. The development of an advanced internal traceability system can also be stimulated by the attempt to improve and increase the efficiency of data collection, plant control, and quality assurance. Additionally, Moe (1998) states that there is a need to create a data model for tracking the variation in the quantity of unit-traceable resources at all times, or tracking the history of process activity.

Traceability systems require the sharing of information and the use of a standardized language, since data flow occurs between different companies. The implementation of a traceability system primarily focuses on rethinking the tasks and objectives of the entire management of the supply chain.

Rotunno et al. (2014) argue that a traceability system for the pharmaceutical industry places additional demands on the architecture of the applications and components of the existing IT architecture of companies.

This raises critical factors, such as the integration between exterior systems (horizontal integration) and the presence of a multi-layer architecture (vertical integration). Canavari et al. (2010) mention internal factors (related to the mission of companies, structure, technology, and removal of limitations), the type of operators involved and their links, as well as the characteristics of the macroenvironment (legislation and competitive environment) and the influence of the internal factors on the choice of the information process

Due to the constraints and factors mentioned above, every company or supply chain has to define which strategies drive its activity and what kind of good or service it will provide to the market.Based on the studies discussed in this article we consolidate the CSFs for the implementation of a traceability system (Table 1).

Table 1

Critical success factors (CSFs) for the development of a drug traceability system.

Critical Success Factors	Authors							
	Ngai et al. (2007) [33]	Alfaro e Rábade (2009) [23]	Canavari et al. (2010) [37]	Miao et al. (2011) [8]	Aung e Chang (2014) [34]	Rotunno et al. (2014) [4]	Duan, et al. (2017) [31]	Theyel (2017) [7]
Legislation	√		√	√	√		√	
Government Support				√			√	
Effective communication		√			√	√		
Top management involvement	√		√	√			√	
Supplier Support	√	√		√			√	
Consumer Knowledge				√			√	
Quality of information and traceability system		√	√	√	√	√	√	
Interação Indústria – Universidade	√							
Interoperabilidade					√			
Traceability data management	√		√		√			
Transparency, authenticity and access					√			
Sharing Information					√	√		
Technological Update/Use of new technologies.	√		√					√
Inter-organizational implementation/Collaboration	√			√	√	√	√	
Adoption of Standards								
Review of tasks and internal operations	√							√
Identification of companies that play a role in traceability								
Cost	√		√					

The Success of the Drug Traceability System—Value Creation :

Simchi-Levi and Fine (2010 suggest that modern supply chains must be seen as value chains or networks of interconnected organizations in a win-win relationship with increasing interdependence. The implementation of a traceability system implies the development of a network; for it to be effective, it is imperative to create value for the actors and for the network as a whole.

Lovis (2008) affirmed that many potential benefits can be expected from a traceability system for the health sector, such as:

- An increase in the efficiency of the supply chain;
- The prevention of errors;

- The protection of public health (to prevent fraud and counterfeit products);
- Medical-legal investigations (the identification of actors and locations on the timeline);
- Clinical research and epidemiological surveillance (data source to leverage the use of clinical data);
- The management of flows and processes;
- Revenues (in the sense of facilitating control;
- Fraud prevention measures;

The values that can be generated by a traceability system have been studied by several authors, such as], who present the impact on an organization's effectiveness while sharing information with customers, suppliers, and regulatory agencies. The authors highlight traceability as a source of competitive advantage.

In this sense, will develop a study and present its impacts, such as the efficiency and efficacy (Table 2) that a traceability system generates for the actors in the network

Table 2

Impacts of a drug traceability system.

Impact on Efficiency-Company's Ability to Manage Its Operating Costs	Impact on Effectiveness-Ability to Affect the Market in Which It Operates
Recall/Withdrawal expenses	Brand Protection
Inventory Costs	Product Quality Management
Acquisition Cost	Reputation Improvement
Sales Costs	Product differentiation
	Notify stakeholders

Narsimhalu et al. (2015 discuss (from the distributors' points of view) the impacts that the deployment of a traceability system can have on safety and quality, in terms of the improvement in supply chain performance, the reduction of the cost of replacement and risk, supply chain sustainability, and effective inventory management.

Canavari et al. (2010) affirm that a traceability system implemented only to answer a legal question should not be seen as a system that creates value for a company.

However, a traceability system can create value by exceeding legal standards. In this sense Dabbene et al. (2014) [36] state that a traceability system involves managerial decisions about the value chain that go beyond product substitution in case of crisis and falsification prevention.

Supply chain actors typically assign different values to traceability, such as increasing the efficiency of management processes and risk management.

For consumers, this represents added value that is mainly related to safety and quality.

For producers, this is a tool to avoid a break in the market supply that can strengthen the brand, in addition to ensuring the compliance with respect to the suppliers.

Table 3

Value creation of a drug traceability system.

Expected Values	Lovis (2008) [39]	Alfaro & Rábade (2009) [23]	Canavari et al. (2010) [37]	Dabbene, Gay e Tortia (2014) [36]	Epelbaum e Martinez (2014) [40]	Narsimhalu, Potdar e Kaur (2015) [41]	Theyel (2017) [7]
Increased Supply Chain Efficiency	√				√	√	
Preventing errors/Reliability/improves accuracy	√	√			√	√	√
Protect public health. (Avoid Fraud and Falsification)	√				√		√
Allow medical-legal investigations	√						
Clinical research and epidemiological surveillance	√						
Improve flow and process management	√	√	√	√	√		√
Increased Profit/Cost/Loss Reduction/Inventory Optimization		√				√	√
Employee Satisfaction/Shared Value			√				√
Fraud Prevention Measures/Patient Safety/	√			√			
Improvement in quality				√	√	√	
Reputation/Brand					√		
Innovation							√
Flexibility							
Differentiation of products/competitive		√			√		

Research Framework Based on the Technology–Organization–Environment (TOE)

Based on the literature review, we obtained a set of CSFs and values, which were defined in the literature as presented in Figure 2

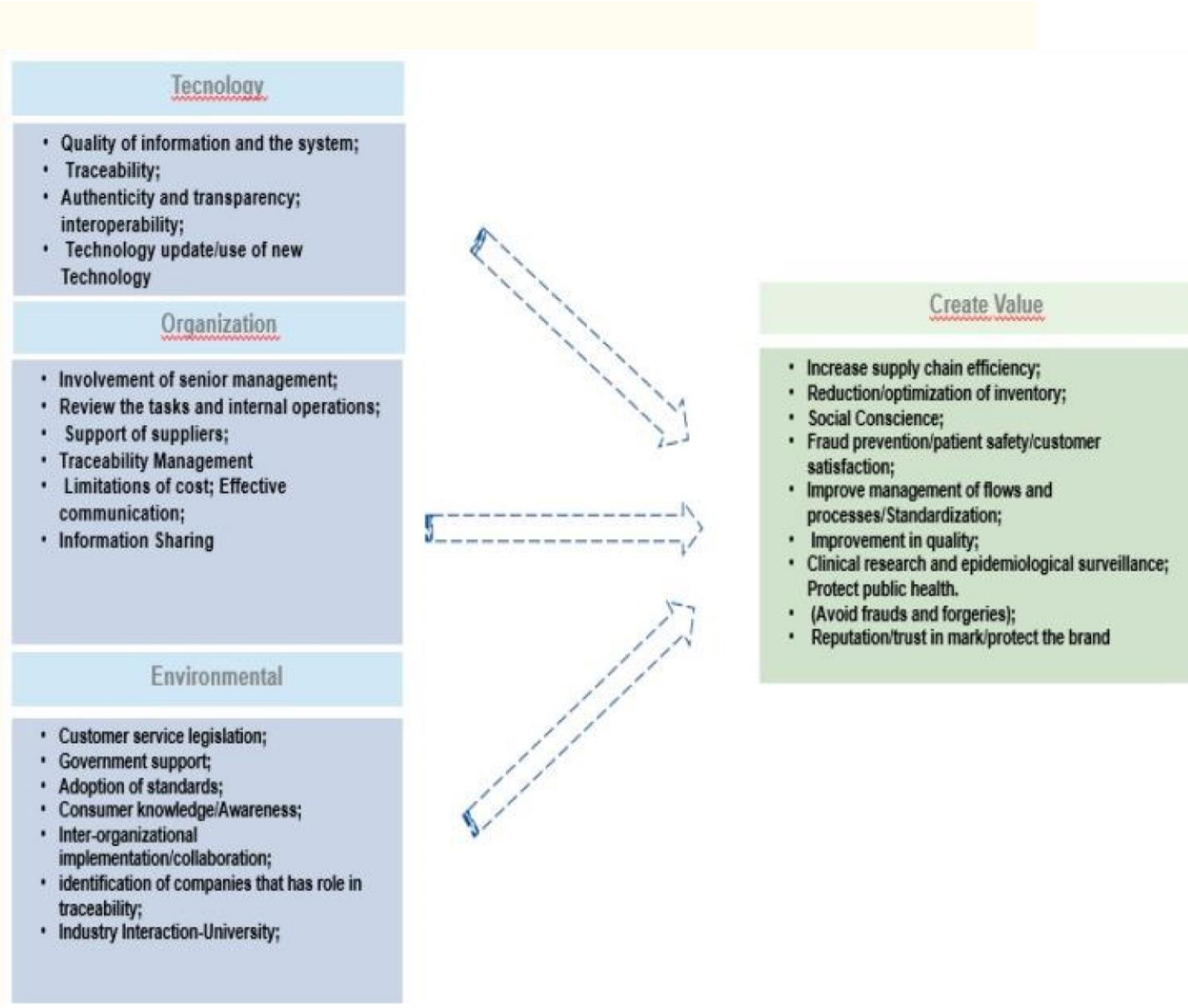

Figure 2

Research framework of the critical success factors for a drug traceability system (adapted from [31]).

Technological factors refer to the characteristics of the technological environment, which can influence the diffusion of the drug traceability systems in an organization. These factors include various dimensions of technology, such as the relative advantage of the quality of information in the system, which increase the diffusion of information technology in the organization. Organizational factors refer to the scope, resources, and size of an organization, and the environmental dimension refers to the context in which the organization develops its industry, competitors, and government. relations. TOE is a well-known and widely used framework in technology adoption and diffusion The TOE framework has been widely used to identify the main drivers of interorganizational innovation for partners [46,47,48].

Analytic Hierarchy PROCESS (AHP) Approach

- The AHP was developed by Thomas L. Saaty in the early 1970s and is a well-known and widely used multicriteria decision-making process to support decision-making in negotiated dispute resolutions.
- The AHP is based on the comparison of criteria pairs followed by the application of a process to calculate the relative importance of each criterion.
- Then, using peer comparison, the alternatives are scored against the criteria to determine the best overall candidate. Saaty (1990, 1994) defined three main operations for the AHP, namely

Construction of hierarchies:

- The problem with AHP is that it is structured in hierarchical levels, as a way of seeking a better understanding and evaluation of the problem being analyzed.
- The construction of hierarchies is a basic stage of the process of human reasoning.
- In this study, we identify the key elements of the decision making and group them in similar sets, which are placed in specific layers;

Definition of priorities:

- Priority setting in AHP is based on human beings' ability to perceive the relationship between observed objects and situations by comparing pairs in the light of a particular focus or criterion (parity judgments)

Logical consistency:

- In the AHP, it is possible to evaluate the consistency of the constructed prioritization model. The AHP begins by decomposing the problem into a hierarchy.
- The scale recommended by, shown in Table 5, ranges from 1 to 9, where 1 means the lack of importance of one criterion to another, and 9 means the extreme importance of one criterion to another, with intermediary stages between 1 and 9.
- Disregarding the comparisons between the criteria themselves, which represent 1 on the scale, only half of the comparisons need to be made, as the other half consists of the reciprocal comparisons in the comparison matrix, which are the already compared reciprocal values.

Table 5

Basic Analytic Hierarchy Process (AHP) scale of Saaty.

Intensity of Importance	Definition	Explanation
1	Equal importance	Both criteria contribute equally to the objective.
3	Moderate importance	The evaluator's experience says that one element has little greater importance than the other for the objective
5	Strong importance	The evaluator's experience says that one element has greater importance than the other for the objective
7	Very strong importance	The evaluator's experience says that one element has relatively greater importance than the other for the objective
9	Extremely important	The evaluator's experience says with a high degree of certainty that one element is of greater importance than the other in relation to the objective
2, 4, 6, 8	Intermediate values	Used when an intermediate index of importance is required

After the matched comparisons are performed through the previously created hierarchy and the fundamental table developed by , a square matrix is created. In this matrix, by convention, the results of the comparisons between the element in the left column in the row with the element that is displayed in the first row of the comparison column are displayed. Table 6 presents an example of a judgment matrix used in the AHP method. In the example, a total of five criteria are compared to pairs.

Table 6

AHP comparison matrix with five criteria.

	A	B	C	D
A	1	2	3	7
B	1/2	1	2	4
C	1/3	1/2	1	3
D	1/7	1/4	1/3	1

The values on the diagonal of the comparison matrix, starting at the comparison between the pair AA, are always equal to one. This is due to the fact that the element has equal importance when compared with itself. The scale presented in Table 1, proposed by [49], is used in order to fill the other comparisons. Judgments are made by comparing the line element to the respective pairs in the columns. Judgments are reciprocal, that is, values are presented inversely to the weight

assigned in the evaluation. Therefore, when criterion “A” is seven times more important than criterion “D”, when compared to criterion “A”, criterion “D” will present one-seventh of its strength.

Consistency Index (*CI*)

Peer judgments must be normalized in order to obtain the Consistency Index (*CI*). According to, the *CI* is obtained by the following equation:

$$CI = (\lambda - n)/n - 1$$

where λ is the largest matrix eigenvector, equivalent to Eigen’s main number, and n is the number of criteria of the matrix

Although the decision is based on the values and preferences of the decision maker, a series of specific criteria or objectives can be used to prioritize the projects and determine the real meaning of the optimal relationship. These criteria must be grouped in sets to be in line with their objectives.

To create the AHP questionnaire, the TOE framework was adopted to group the critical factors validated from the literature and other factors discussed by experts.

Result :

As a result of study, we obtained a set of CSFs, which were determined based on the literature review and validated by the professionals who participated in the study, as presented in Table 7**.**

Table 7

CSFs for the implementation of a drug traceability system.

DIMENSION	**FACTORS**
Technology	Quality of Information and Traceability System
	Interoperability
	Transparency, authenticity, and access
	Technological update/Use of new technologies
Organization	Involvement with senior management

DIMENSION	FACTORS
	Supplier support
	Data governance
	Traceability Management
	Effective communication (training-divulgation)
	Sharing Information
	Revision of internal tasks and operations
	Cost limitations
Environment	Legislation compliance
	Government support
	Knowledge of the consumer/awareness
	Industry-University interaction
	Interorganizacional implementation/Contribution
	Adoption of Standards
	Identification of the companies that have a role in traceability

After the validation of the weights obtained from the application of the method, it was necessary to calculate the consistency ratio (CI) in order to verify the consistency of the responses assigned by the decision maker. The CI found for the responses given by the decision maker was:

$$CI = 0.039$$

that is, below the limit of 0.10.
After calculating and collecting the results according to the steps of the AHP method, the products of the matrices with the parity comparisons between the criteria and the sub-criteria were transferred to a spreadsheet, from which Table 8 was generated.

Table 8

Prioritization of the CSFs.

Criteria	Sub-Criteria	Average	Prioritization
Organization	Involvement with senior management	21.0%	1

Technology	Quality of Information and Traceability System Management	13.1%	2
Organization	Data governance	9.8%	3
Organization	Revision of internal tasks and operations	8.6%	4
Technology	Transparency, authenticity, and access	6.6%	5
Technology	Interoperability	6.5%	6
Organization	Supplier support	6.3%	7
Organization	Cost limitations	6.0%	8
Organization	Effective communication (training-divulgation)	5.5%	9
Organization	Sharing Information	5.2%	10
Technology	Technological update/Use of new technologies	2.5%	11
Environment	Legislation compliance	2.5%	12
Environment	Government support	1.6%	13
Environment	Adoption of Standards	1.3%	14
Environment	Knowledge of the consumer/awareness	1.1%	15
Environment	Interorganizacional implementation/Contribution	1.0%	16
Environment	Identification of the companies that have a role in traceability	0.8%	17
Environment	Industry-University interaction	0.5%	18
Criteria	**Sub-Criteria**	**Average**	**Prioritization**
			100%

- The authors of [8,30] suggest the use of the TOE model to evaluate the adoption of new and innovative technologies and information systems; they indicate that the main factors that should be considered in the implementation of a traceability system are divided into three categories:

- organizational, technological, and environmental. In this context, the results of this study were grouped using these categories.
- In a first comparative analysis, the most important criteria tend to be those linked to organization (62.4%), followed by those linked to technology (28.7%) and environment (8.9%). There is also a tendency for hospitals to share this view with laboratories.
- This is a slightly different view from that proposed by [48], who suggest that technological criteria are more relevant for hospitals for the implementation of a system than organizational ones**.**

Conclusion:

- There are several limiting factors for the development of a drug traceability system in Brazil.

- For example, the drug traceability scenario in Brazil is not consolidated. The study of drug traceability systems in Brazil is at an early stage, and will be the subject of many other discussions.

- The scenario analyzed in the present study, in which there are various interests among the actors, also opens the opportunity for future academic research.

- The results show that data governance is a topic of extreme importance and merits more study. It is necessary to have a data governance structure that works according to data management.

- Data governance has recently evolved to formally provide clarity in policies and standards, data quality measurements, roles and responsibilities, and changes that allow the value of information assets to be maximized. Data governance is important due to the need for lengthy discussions that result in the amendment of the law regarding drug traceability.

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