Revista ARACÊ
ISSN: 2358-2472

STUDY OF THE FEASIBILITY OF THE AI PLATFORM IN THE PROCESS OF RECALLS IN HEALTHCARE DEVICES

https://doi.org/10.56238/arev6n4-433

Submitted on: 11/26/2024 **Publication date:** 12/26/2024

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ABSTRACT

The main purpose of this article is to study the feasibility of a Health Products Platform, whose purpose is to map and provide information on Recalls and Notifications of medical devices based on the resources of Digital Technology in support of Risk Management in the Health Area.

As a result of this project, a form was created that, after analysis, allowed to have a view of the sector's deficiency and the importance of a Digital Platform to meet the needs of the sector such as: knowledge for professionals in the area; concentrate information and; Automate the process of monitoring medical device alerts.

In addition, an algorithm capable of performing the automatic search considerably reducing the time that Health Care Establishments spend to monitor their Medical Devices was made.

Keywords: Recall. Artificial intelligence. Health Products. Risk Management.

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ISSN: 2358-2472

INTRODUCTION

According to research conducted by Deloitte Consulting (Batra, Betts, and Davis, 2020), health care as we know it today will no longer exist. While disease will never be completely eliminated through science, data, and technology, we will be able to identify it earlier, intervene proactively, and better understand its progression to help consumers more effectively and actively sustain their well-being.

Wamba and Ngai (2013) highlight Health as one of the most complex industries because it includes challenges such as patient safety, the ability to map and track pharmaceutical equipment and products, the flow of products from manufacturers to patients, among other aspects.

Through the innovation that has occurred in the universe of Health Products, its use has led to a significant improvement in the quality of life of the world population, and its contribution is indispensable in the prevention and combat of various pathologies, as well as in the rehabilitation of patients (WHO, 2017).

According to the WHO, the number rises to 1.5 million devices globally (WHO, 2017).

Calculating the success and failure rates of an EMA in different markets is a task made more difficult by the failure of regulatory bodies and manufacturers to identify and connect them in a consistent manner. The absence of a universal numerical registration system with available data is the root of several problems that lead patients in one country to receive implants that have been recalled in another country because of proven health risks. Although some countries have created legislation and advocated for a universal numerical registration system, to date no initiative has been put into practice.

Adverse Event / Technical Complaint - The definition of Adverse Event, according to Anvisa, is any undesired effect in humans resulting from the use of products under health surveillance. The agency also defines a Technical Complaint as a change or irregularity of a product or company related to technical or legal aspects and that may or may not cause damage to individual and collective health. (RDC67, 2009)

Data obtained from the Notivisa of notifications in Technovilância a total of 178,150 from January 1, 2006 to August 31, 2021, with Adverse Event occupying 15.28% of the total notifications and the others by Technical Complaint. In the year 2021 alone, to the present date, 9,907 cases have been reported. With regard to pharmacovigilance, in the VigiMED panel, ANVISA's tool, 42,777 have already been notified by employees,

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industries, patients and EASs. (BRAZIL, 2009)

Through Anvisa's RDC 2/2010, Risk Management became a requirement of this Agency to health establishments, as it requires that it have a system for monitoring and risk management of health technologies, aiming at reducing and minimizing the occurrence of adverse events, in addition, it must notify the National Health Surveillance System of adverse events and technical complaints involving health technologies. (RDC2, 2010).

THEORETICAL FRAMEWORK

WHAT IS MEDICAL EQUIPMENT?

According to ANVISA, medical equipment is included in the category of health products together with materials for use in health and diagnostic products for in vitro use. Thus, medical equipment under the Sanitary Surveillance regime comprises all equipment for use in health for medical, dental, laboratory or physiotherapeutic purposes, used directly or indirectly for diagnosis, therapy, rehabilitation or monitoring of human beings, and also those for beautification and aesthetics.

Health products are classified, according to RDC No. 185/01, into four risk classes, according to the risk associated with their use:

- Class I – baixo risco
- Class II – medium risk
- Class III – high risk
- Class IV – maximum risk.

Within the framework of the rule, it obeys the indication and purpose of use of the material indicated by the manufacturer, the intended function, there is a determination of the rule and the risk class of the product and not the risk class assigned to other similar products, and must comply with the following criteria:

- Non-invasive products: Rules 1, 2, 3 and 4
- Invasive products: Rules 5, 6, 7 and 8
- Active products: Rules 9, 10, 11, 12
- Special Rules: Rules 13, 14, 15, 16, 17 and 18

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MEDICAL DEVICE CERTIFICATION PROCESS

We observed two routes for approval developed by Anvisa: registration and registration. Registration is simpler and faster for lower-risk devices, but both require similar documentation.

Approval may require a Good Manufacturing Practice (GMP) audit on the manufacturer, which must be carried out before submitting the product registration, as certification is a prerequisite in some cases. Products must be classified prior to registration to determine whether a GMP audit will be required according to RDC No. 185, of October 22, 2001, although complementary legislation is also used in this process. For the notification of risk class I health products and the notification of risk class II health products, the resolutions are RDC No. 270/2019, RDC No. 40/2015 and RDC No. 423/2020, respectively.

Registration or notification is requested by means of submission to ANVISA through a petition for registration or notification request, composed of documents and information indicated in the aforementioned RDCs and other relevant legislation to constitute a documentary process, being analyzed by ANVISA's technical staff who will deliberate on the granting of the request, being able to request additional information and documents, when necessary.

The granting of registration or notification is made public through its publication of approval in the Official Gazette of the Union – DOU (registration and notification) and by publication on the ANVISA Portal (notification).

According to the Manual for the Regularization of Medical Equipment at Anvisa version 12/2021, formulated by the Medical Equipment Technology Management – GQUIP, the registration or notification of the product at Anvisa corresponds to a numerical sequence composed of 11 numbers, figure I, of which the first seven correspond to the Company's Operating Authorization number – AFE, and the last four are sequential, obeying the ascending order of registrations and notifications granted to the same company. In this way, each registration or notification granted is represented by a unique numerical sequence generated automatically and electronically.

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Figure I – Formation of the Anvisa Registration number for Medical Equipment

Fonte: GGMON, 2021

JUSTIFICATION

With the innovation that has occurred in the universe of Health Products, its use has led to a significant improvement in the quality of life of the world population, and its contribution is indispensable in the prevention and combat of various pathologies, as well as in the rehabilitation of patients (WHO, 2017).

According to ANVISA, through RDC No. 02, of January 25, 2010, EMA is defined as equipment or system, including its accessories and parts of medical, dental or laboratory use or application, used directly or indirectly for diagnosis, therapy and monitoring in the health care of the population, and which does not use pharmacological means, immunological or metabolic to perform its main function in human beings, but it can, however, be aided in its functions by such means (RDC 02, 2010).

Medical devices are classified into four different risk classes, according to ANVISA, through Resolution RDC No. 185, of 10/22/2001, classifies medical products, in which EMAs are inserted, according to the intrinsic risk they represent to the health of the consumer, patient, operator or third parties involved (RDC 185, 2001).

Through the modernization of EMAs and the technologies associated with their manufacture, professionals are able to have access to more detailed and faster information, increasing the accuracy of the diagnosis and consequently of its treatment. There is a considerable number of Health Products, from the simplest, such as a bandage, a syringe or a pair of latex gloves, to the most complex equipped with the latest technology. This huge variety of devices and supplies is present in our daily lives, from health centers to specialized hospitals.

According to the WHO, the number rises to 1.5 million devices globally (WHO, 2017). The health products industry is globally organized, but governments' enforcement functions end up at borders. For example, the same product may change its name depending on the country and registration numbers, vary, which makes it difficult to track

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recalled devices. There is no international consensus on safety standards that guarantee the commercialization of health products. Nor is there a warning system to propagate alerts and recalls to patients and health operators across national borders.

Calculating the success and failure rates of an EMA in different markets is a task made more difficult by the failure of regulatory bodies and manufacturers to identify and connect them in a consistent manner. The absence of a universal numerical registration system with available data is the root of several problems that lead patients in one country to receive implants that have been recalled in another country because of proven health risks. Although some countries have created legislation and advocated for a universal numerical registration system, to date no initiative has been put into practice.

The motivation arose from the pains reported by professionals in the area and the time spent to carry out an active search for information on a Health Product, being an obstacle to the Risk Management of Health Products. This project is essential and a systematic study of the theme so that these various difficulties encountered - topics mentioned above - and many others not mentioned here are gradually solved and that the feasibility and understanding of the need for an integrated platform are taken into account for future studies in the health sector.

OBJECTIVES

Feasibility study of the Risk Management Platform for Health Products. Focusing on mapping and providing information on Recalls and Notifications.

Examine the databases made available by Competent Health Agencies; Understanding of the health sector through field research; Creation of Dashboard for publication of the applied form; Creation of an algorithm as an MVP for automating the monitoring of Recall, alerts and notifications of Medical Devices; Study of the method for the preparation of a Digital Platform.

METHODOLOGY

For the development of this project, quantitative and qualitative methodology was used. In this study, a systematic research was carried out by consulting the library collection; consultation of specialized magazines and periodicals, scientific articles, monographs related to the theme, and books from publishers and entities specialized in the areas of Health as Health Products.

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According to Gil (2008), qualitative research aims to provide greater familiarity with a problem and aims to make it explicit, increase knowledge about the phenomenon and suggest a superior study. Similarly, Andrade (2002) points out that descriptive research is concerned with observing the facts, recording them, analyzing them, classifying them, and interpreting them, and the researcher does not interfere with them.

What corresponds to the approach, we can classify it as quantitative research, since, through questionnaires, a research was carried out to help understand the problem with professionals in the area. Quantitative research is appropriate for measuring opinions, attitudes, and preferences as behaviors. It is also used to measure the target audience, estimate potential and validate a hypothesis, and to measure size and importance. For the success of an innovation, it is necessary to establish goals, where it must be verified if the project will meet the proposed objectives; if it will be well accepted by users; if it will have an affordable cost (BAXTER, 2005).

RESULTS AND DISCUSSIONS

FORMULATION OF THE QUESTIONNAIRE

The form made with the help of the Professor and reference in the area of Clinical Engineering in Brazil, Prof. Lúcio Flávio de Magalhães Brito, consists of 20 questions to understand how professionals in the sector deal with the topics of Recall, Notifications and Alerts and the degree of knowledge and importance in a subjective way that each respondent has about Health Products.

When starting the form, there will be a title and a description with the purpose of guiding, explaining the questionnaire to the respondent, as we observed in figure II.

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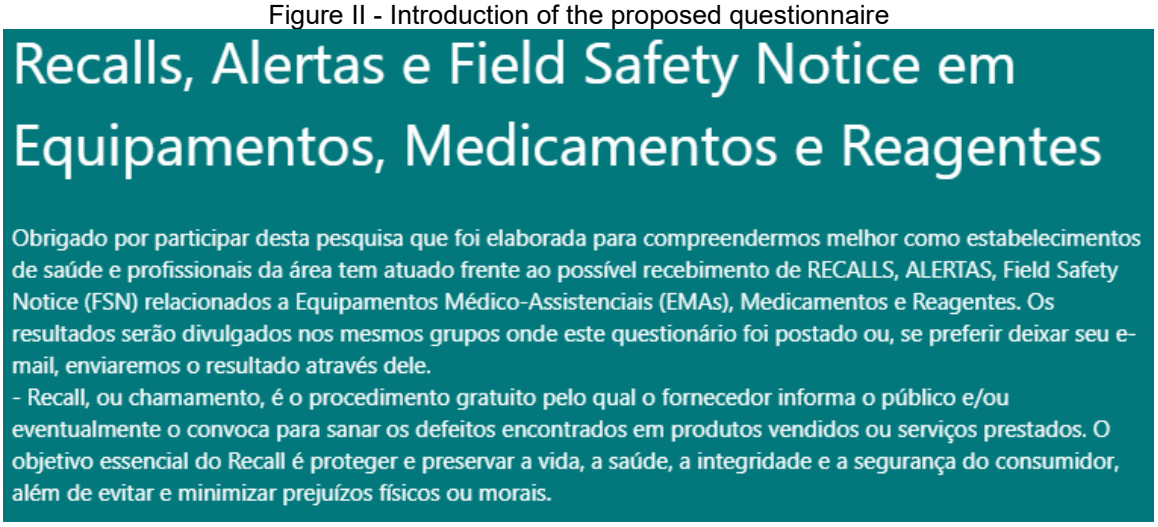
Figure II - Introduction of the proposed questionnaire



The questionnaire, Annex 3, consists of 20 questions, each with the settings and options pertinent to what was analyzed with a competent professional.

The link to the questionnaire was made available in WhatsApp groups, Facebook and LinkedIn communication channels and groups focused on the subject of Biomedical and Clinical Engineering.

Subsequently, a simple statistical analysis was performed, using percentage calculations. The data obtained in the questionnaire underwent a treatment with the Excel tool, later we will use the Power BI tool.

RECALL DATA, NOTIFICATIONS AND ALERTS

Data were collected on the absolute number of notifications made through NOTIVISA, with data from all the circumstances notifiable possible by the system available on its website.

In addition, ANVISA, in order to make the information available, figure III, with an analytical intelligence were able to transform the raw data of medical devices into intelligible data with visual interfaces to give users the ability to perform the most diverse types of analysis for decision making and subsequent action that allowed them to glimpse the proportion of Complaints and Alerts of medical equipment for this study (https://www.gov.br/anvisa/pt-br/acessoainformacao/dadosabertos/informacoes-analiticas/tecnovigilancia).

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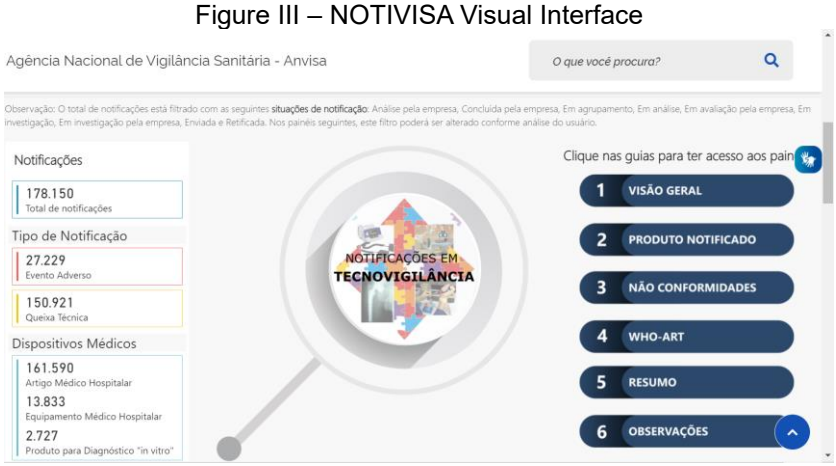
Figure III – NOTIVISA Visual Interface



Source: Technovigilance, 2021

There is a database, made available by ANVISA, which provides information on regularized medical devices with valid registration with the Agency in the format . CSV (https://dados.anvisa.gov.br/dados/TA_PRODUTO_SAUDE_SITE.csv) populated with basic data such as: product name, registration or cadastral number, registration or cadastral holder, manufacturer's name and country of manufacture.

The data is updated daily, on the business day prior to the date of access (D-1), always considering the products that have expired or have been canceled and the new products regularized in accordance with the Access to Information Law.

In this way, the project had access to the current and regularized registrations of all medical devices sold in Brazil.

OBTAINING RECALL INFORMATION AND ACTIVE SEARCH

In the studies carried out for this scientific initiation, it was observed that there are three ways to obtain information on Recall, Alerts and notifications.

The first would be by registering on the website to receive emails from regulatory agencies such as FDA and ANVISA. However, this method, even if it is an advance in the support for Risk Management in EAs, is not effective. The fact that this method is also linked to a recurring and periodic e-mail search, and this information can also be allocated in the SPAM box, makes the monitoring subject to deficiencies.

The second consists of Active Search, where the person responsible for the EMAs of EASs searches for information about medical devices on the websites of regulatory entities and manufacturers. This form becomes unfeasible because the time spent for it would not allow him to perform other activities.

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The third would be for the manufacturer, legally responsible for notifying Recalls, Alerts and Notifications, to have control of the location of its marketed products. For a few categories this form is applied, but in its summary the manufacturer does not have control and knowledge of the final destination of the commercialized Medical Devices.

In this way, we highlight the need for a digital platform capable of effectively and efficiently handling the information of post-market medical devices.

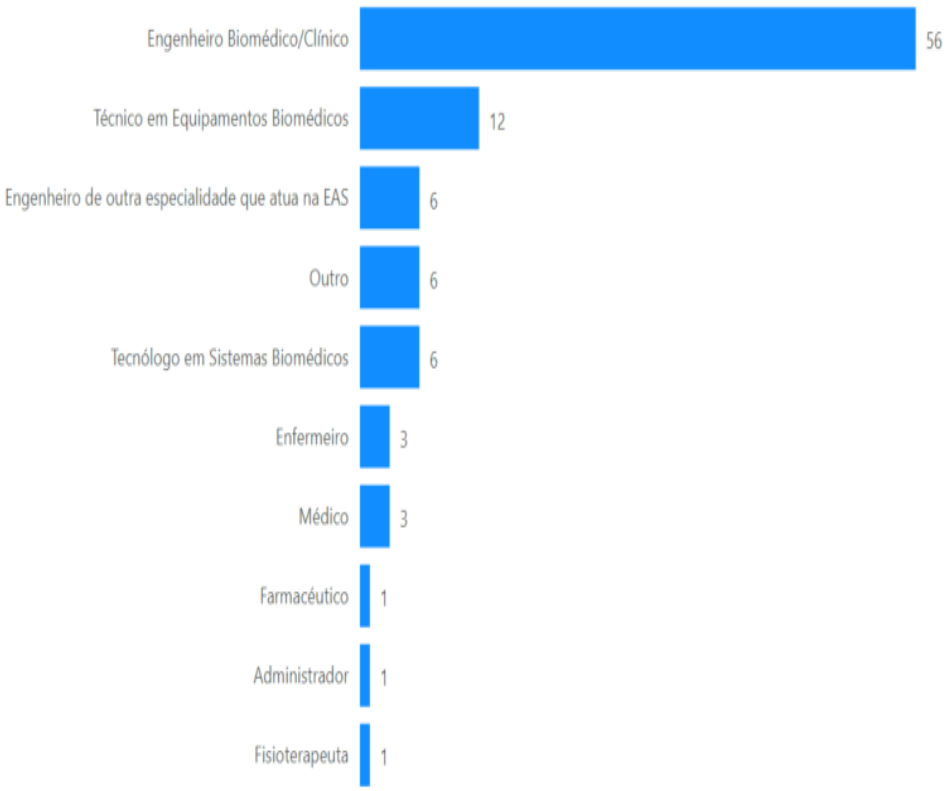
RESULTS

ANALYSIS OF THE DATA COLLECTED IN THE FORM

A total of 112 responses were obtained, and when processing the data, we obtained 17 inconsistencies that could be purged, totaling 95 valid responses. The average time for participants to answer the questionnaire was approximately 9 minutes. Valid participants represented a universe of 122 AESs with an approximate amount of 206,482 medical devices represented in this universe.

The participation in this form was by health professionals, graph I, and 58.95% were Biomedical or Clinical Engineers.

Graph I – What is your Function/Profession at EAS?



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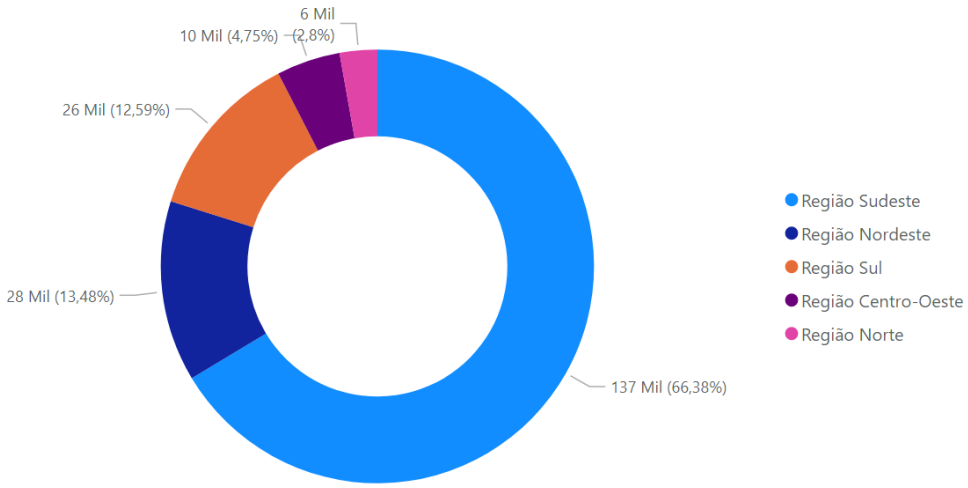
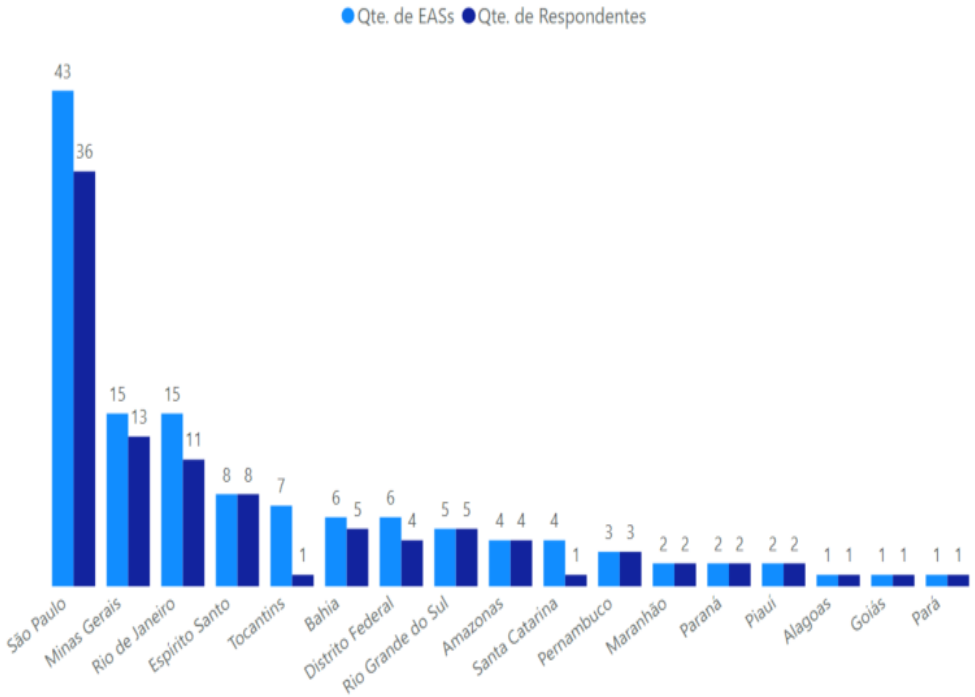
There was participation in all regions of the country, as we can see in graph II, and the three states with the highest representativeness were São Paulo, Minas Gerais and Rio de Janeiro, respectively, graph III.

Graph II – Distribution by Region of the EASs



Graph III – Which federative state finds its EAS?



We observed that the EASs that had the highest representation in the form were hospitals. Having a distribution of 34.43% for medium-sized hospitals, 24.59% for high-capacity hospitals and 4.12% for small hospitals, which totals approximately 63.14%.

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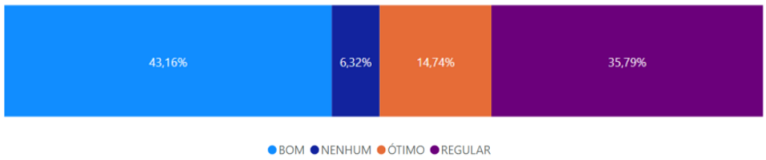
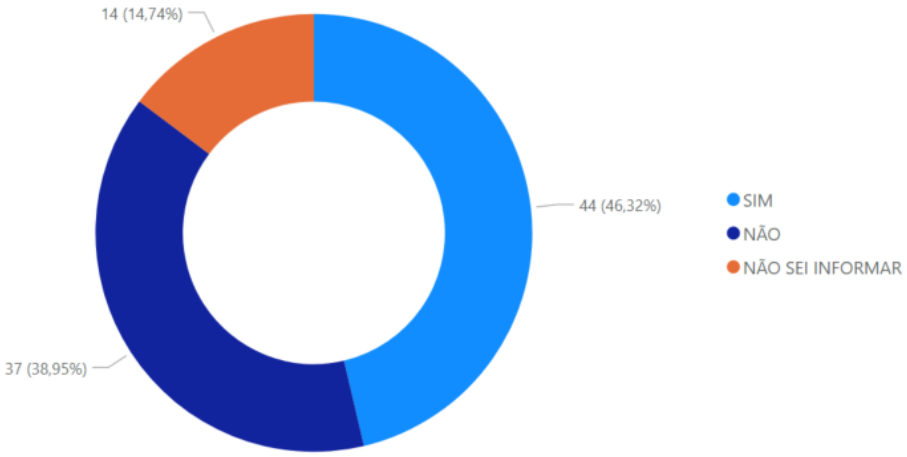
DESCRIPTION OF THE FORM APPLIED

Question 4, "How do you consider your degree of knowledge about *RECALL* or FSN of Medical Assistance Equipment (EMA) and/or Medications?"



Question 8, "In your view, who should be responsible for notifications of *RECALLS and FSN?"*

Question 9," Is there a formal process in the health facility to seek, process, and use information from a *RECALL, ALERT,* or FSN?"



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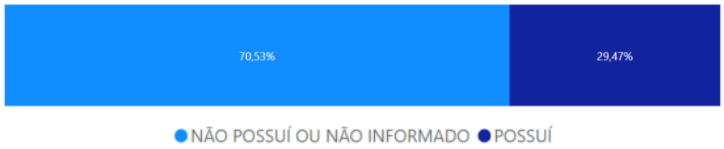
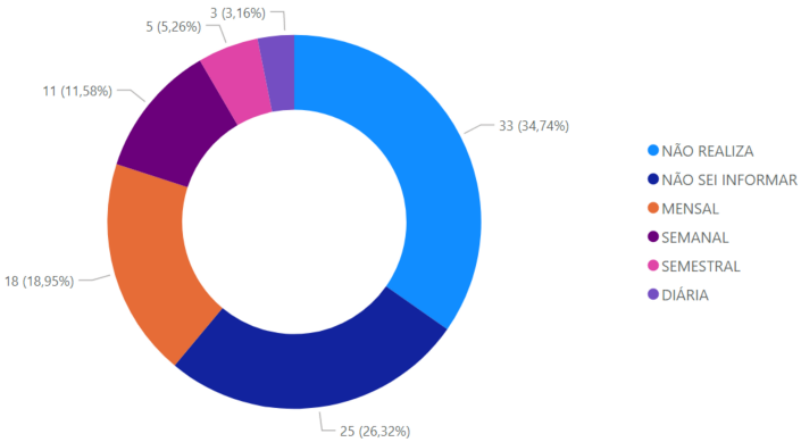
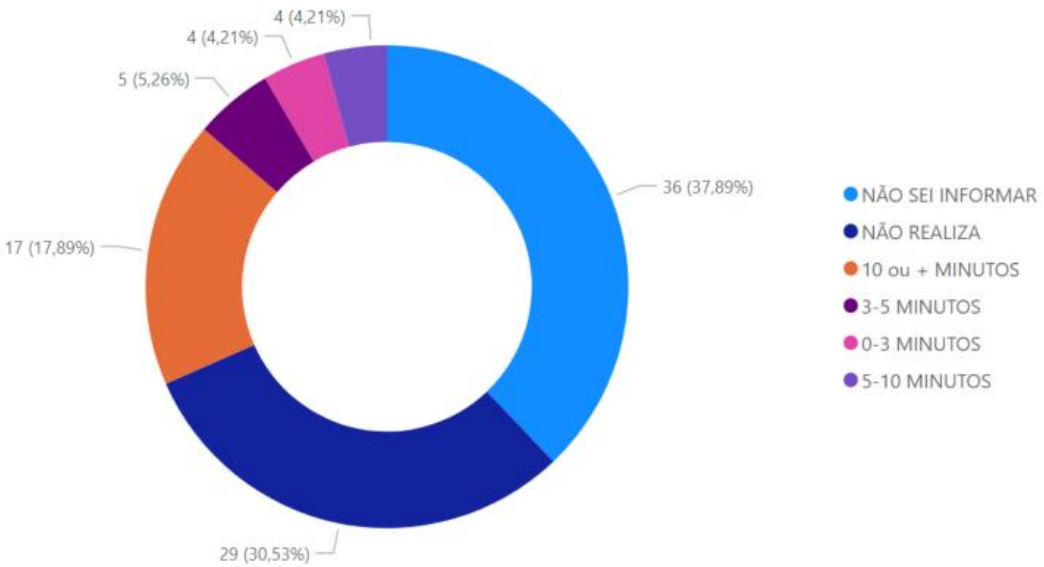
Question 10," Does the establishment have any process to perform ACTIVE *RECALL SEARCH*."



Question 11, "How often does your organization actively search for *RECALL* or FSN?"



Question 12, "How much time, on average, does the EAS team spend for each active *RECALL* or FSN search for each EMA and/or Medications?"



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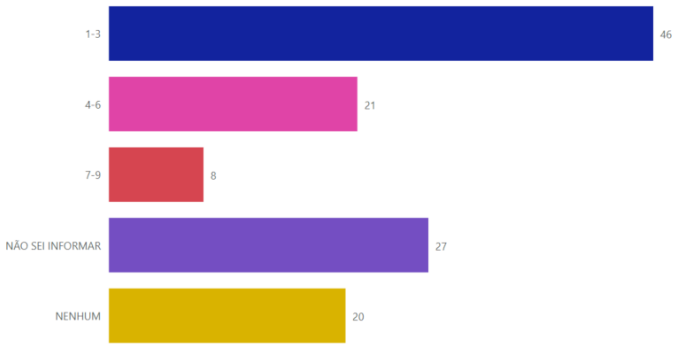
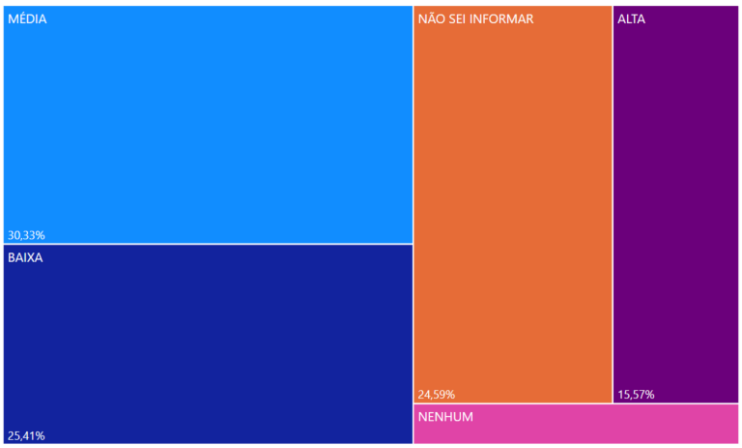
Question 13, "Is the EAS registered in any information system of official agencies such as ANVISA, FDA or MHRA?"

Question 15, "Are you aware of any *RECALL*, ALERTS, or (FSN) notifications related to any medical equipment, medication, or reagent in your organization in the last 2 years?"



Question 16, "If there has been a notification in your hospital, how, in your conception, would you rate the severity of the call?"



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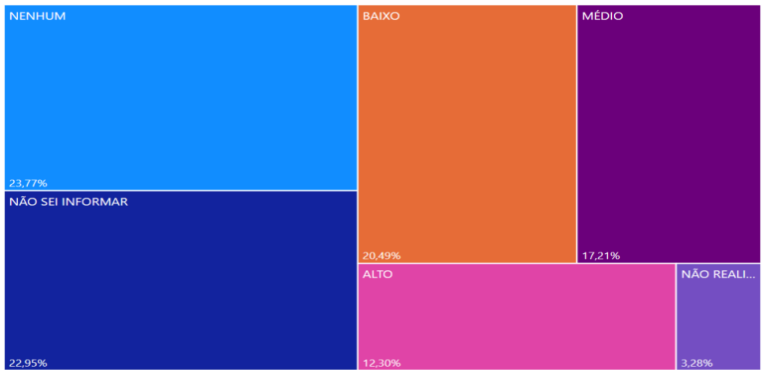
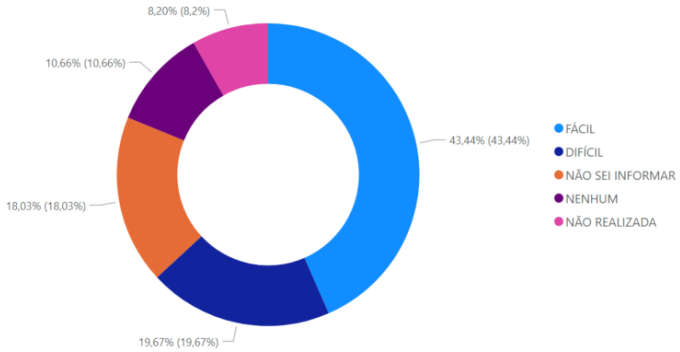
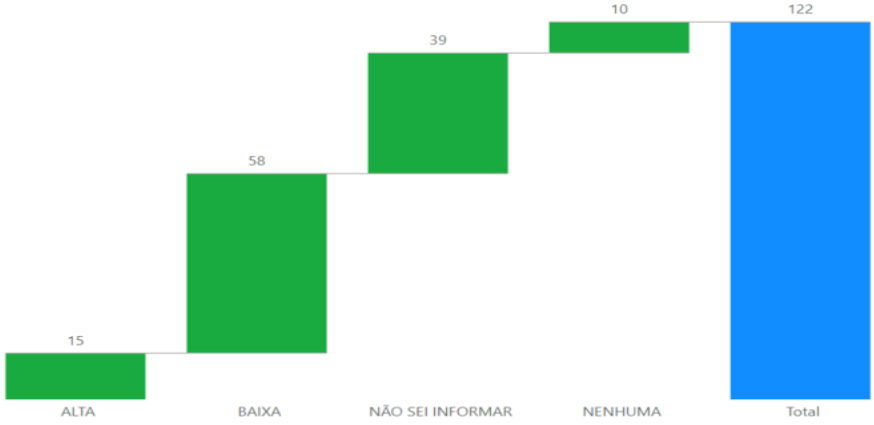
Question 17, "If your organization has received *RECALL,* ALERTS, or FSN, how difficult did the establishment find in implementing the manufacturer's guidelines?"



Question 18," If your organization has received *RECALL,* ALERTS, or FSN, how easy is it to access the Manufacturer?"



Question 19, "In your opinion, how would you rate the overall efficiency of the *RECALL*, ALERTS, and FSN communication system currently employed by your organization?"



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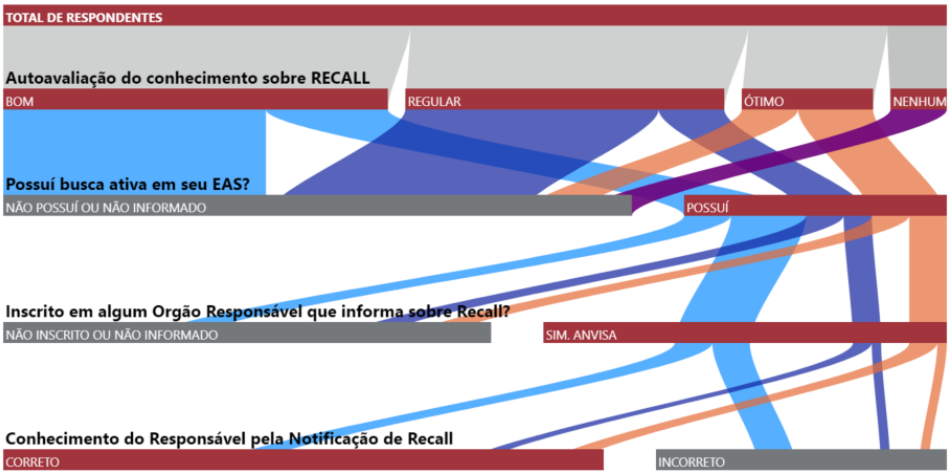
ANALYSIS OF THE FORM DATA

We observed, in the analysis of figure IV, that only 9 participants correctly answered the steps where the individual should say that his EAS has an Active search in the monitoring of Recall, alerts and notifications, and the participants' self-assessment on the knowledge of the theme were: 3 excellent, 4 good and 2 regular. The sum of the EASs represented by them totaled 15 units with an amount of 139,185 of the total EMAs. This leads us to conclude that approximately 32.59% of the EMAs distributed in 107 AESs under the supervision of 86 participants have some deficiency in the monitoring of Recall, Alerts and Notifications.

Figure IV – Real Effectiveness Analysis of Recall Monitoring, Alerts and Notifications



When analyzing the influencers for Effectiveness of monitoring Recall, Alerts and Notifications on Medical Devices in EASs, we observed that when the search frequency is weekly, the probability of high effectiveness increases to 4.76x, on the other hand, when the frequency is monthly, the probability of low effectiveness increases to 1.93x. When the frequency is not realized, the probability of it being no efficacy is 5.16x higher than the other frequency options. With this, we observe that the factor of monitoring recalls, alerts and notifications is directly proportional to the frequency of search the establishment performs.

When analyzing the influencers "contact with the Manufacturer" being easy or none, the effectiveness of monitoring tends to be 3.58x more likely compared to the other options. In addition, an influencer with low or no "manufacturer orientation difficulty" is 2.59x more likely to have a high efficacy. We can conclude that communication between the end user

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and the manufacturer is of paramount importance to maintain the effective monitoring system.

Now, when analyzing the influencers on the "function/profession" of the participants, we observed that the participants who declared to be Biomedical/Clinical Engineers, 58.95% of the participants, obtained the following probabilities:

- 1.66x higher than other professions for active search in their EAS.
- 1.77x higher the frequency of active search is carried out monthly.
- 1.59x longer than the average time per active search for each medical device to be longer than 10 minutes.
- 1.52x greater than the number of Medical Devices in your EAS is greater than 1500.

By verifying the general context of the results obtained, we can assess that those responsible for handling Medical Devices in the EASs have, in the vast majority, a lack of clarity of the processes and a deficiency in knowledge on the topic addressed, directly affecting the level of effectiveness of the monitoring of Recall, Alerts and Notifications of the EASs.

The importance of a digital platform capable of serving this sector not only with the automatic and intelligent monitoring tool, but also the importance of generating information and clarifications for the population in a centralized and easy-to-understand way is necessary.

BUILDING AN MVP WITH PYTHON PROGRAMMING

During the course of the project, the dynamics for carrying out the monitoring of medical devices were clarified, as well as the difficulty encountered in the technological field to carry out this activity within the EASs effectively by professionals in the area.

From this context, the project carried out through Python programming the search for notifications in an automatic, simple and effective way in the monitoring of Recall, Alerts and Notifications on the ANVISA platform where there is centralization and availability of information relevant to the topic.

The construction of the MVP followed with following steps to achieve the algorithm's goal. They are:

1. Obtaining consistent and unique data from medical devices.

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As noted in item 4.2 of this report, ANVISA makes available in an updated form the data of the Recall, Alerts and Notifications records. As noted in item 1.2.6, medical devices that can be marketed and registered with ANVISA have a unique 11-digit numbering that makes it the key to our search algorithm.

2. Source of Recall Information, Alerts and Notifications.

Tecnovigilância, on December 21, 2020, made available the sharing of information for the Alerts as follows:

- With the possibility of access chronologically and subject to the application of filters in its active search with all attachments and pertinent information accessed by consulting the Alert on the Portal ("http://antigo.anvisa.gov.br/alertas").
- With the possibility of performing an active search through a history made available by the National Information System for Professional and Technological Education - SISTEC - as of 03/02/2020, it was integrated with the Gov.br portal ("http://www.anvisa.gov.br/sistec/alerta/consultaralerta.asp")

The latter was used for the verification of Recall, Alerts and Notifications through the algorithm developed in this Scientific Initiation because it presents a simple access that concerns the development approach. In addition, little difficulty was found in authentication and HTTP protocols and HTPPs.

3. Processes and procedures performed by the algorithm.

The Python programming language (.py) was used to carry out this algorithm due to the familiarity that the student has with the tool and the ability of the programming language to spend several libraries (set of modules – they are files with instructions and definitions in Python) capable of assisting in the structuring and functionality of the algorithm. The libraries used were:

- Pandas (https://pandas.pydata.org) - fast, powerful, flexible and easy-to-use open-source data analysis and manipulation tool built on top of the Python programming language .
- Rrequests (https://docs.python-requests.org) – tool that allows you to send HTTP requests with extreme ease. There's no need to manually add query strings to your

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URLs or form-encode your POST data.

- Grequests (https://pypi.org/project/grequests/) – tool that allows you to use Requests with Gevent to make asynchronous HTTP requests easily.
- urllib3 – allows the *Keep-alive and HTTP* connection pooling *to be 100% automatic.*
- Wget (https://pypi.org/project/wget/) - tool that allows you to download unicode urls with Python 3 in addition to downloading and saving in some formats.

The development environment was Visual Studio Code (VS Code) a source code editor developed by Microsoft – figure V, free and open source software, allowing the user several customizations.

Figure V – Project Development Environment VS code

READY-MADE CODE

```
import pandas as pd
import grequests as gr
import requests
import time
import wget
from requests.sessions import session
from requests.packages.urllib3.exceptions import InsecureRequestWarning
requests.packages.urllib3.disable_warnings(InsecureRequestWarning)
url = 'https://dados.anvisa.gov.br/dados/TA_PRODUTO_SAUDE_SITE.csv'
wget.download(url,'TA_PRODUTO_SAUDE_SITE.csv')
```

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```
inventory = pd.read_csv('TA_PRODUTO_SAUDE_SITE.csv', sep = ';')

conjunto_registro = set(inventory['NUMERO_REGISTRO_CADASTRO'])
def houve_recall(resposta_anvisa):
if('There are no alerts with this information!' in resposta_anvisa):
return False
else:
return True
def construir_urls(url_base, parameters):
return [url_base + str(parametro) for parametro in parametros]
def exception_handler(request, exception):
return f"Request failed: {exception}"
urls =
    construir_urls(url_base='https://www.anvisa.gov.br/sistec/alerta/RelatorioAlerta.a
    sp? ColumnName=Ds_Produto&Parameter=',
parametros=conjunto_registro)
sessao = requests. Session()
requisicoes = (gr.get(url,verify=False,session=sessao) for url in urls)
num_req = len(urls)
answers=[]
t0 = time.time()
for i,r in enumerate(gr.imap(requisicoes,exception_handler=exception_handler,size=
    25)):
print(str(round((i+1)/num_req*100,2))+'%',end='\r')
respostas.append({'recall':houve_recall(r.text),'url':r.url})
run_time = time.time() - t0
print('\n')
print('Runtime: ' + str(run_time))
respostas_df = pd. DataFrame(answers)
respostas_df = respostas_df[respostas_df['recall']==True]
respostas_df.to_csv("recalls_econtrados.csv")
```

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By using this algorithm, we were able to enter the ANVISA website, download the updated file ("TA_PRODUTO_SAUDE_SITE.csv"), totaling an amount of 93,942 Medical Device registrations until August 31, 2021.

Subsequently, we used the "NUMERO_REGISTRO_CADASTRO" column of this file where the Registration Number is located and did an asynchronous search with 25 independent channels of access to the SISTEC server jointly.

In short, when it is observed that there is some record in the historical basis of Technovigilance, a new file named "recalls_econtrados.csv" stores the following information:

- the index position of the location of the record number in the original file;
- the validation of the finding as *TRUE and* the *match* between TA_PRODUTO_SAUDE_SITE.csv and the SISTEC database;
- the address at which the user can locate the pertinent information about that alert regarding the Medical Device.

As shown in Figure VI, 1,735 alerts of these registered medical devices were found.

Figure VI – Image from File "recalls_econtrados.csv"

	A
1	,recall,url
2	11,True,https://www.anvisa.gov.br/sistec/alerta/RelatorioAlerta.asp?NomeColuna=Ds_Produto&Parametro=10407379016
3	58,True,https://www.anvisa.gov.br/sistec/alerta/RelatorioAlerta.asp?NomeColuna=Ds_Produto&Parametro=80495510001
4	213,True,https://www.anvisa.gov.br/sistec/alerta/RelatorioAlerta.asp?NomeColuna=Ds_Produto&Parametro=80753460023
5	236,True,https://www.anvisa.gov.br/sistec/alerta/RelatorioAlerta.asp?NomeColuna=Ds_Produto&Parametro=80753460047
1724	77997,True,https://www.anvisa.gov.br/sistec/alerta/RelatorioAlerta.asp?NomeColuna=Ds_Produto&Parametro=80371250016
1725	78096,True,https://www.anvisa.gov.br/sistec/alerta/RelatorioAlerta.asp?NomeColuna=Ds_Produto&Parametro=80804050023
1726	78109,True,https://www.anvisa.gov.br/sistec/alerta/RelatorioAlerta.asp?NomeColuna=Ds_Produto&Parametro=80804050045
1727	78176,True,https://www.anvisa.gov.br/sistec/alerta/RelatorioAlerta.asp?NomeColuna=Ds_Produto&Parametro=80804050103
1728	78193,True,https://www.anvisa.gov.br/sistec/alerta/RelatorioAlerta.asp?NomeColuna=Ds_Produto&Parametro=80804050121
1729	78202,True,https://www.anvisa.gov.br/sistec/alerta/RelatorioAlerta.asp?NomeColuna=Ds_Produto&Parametro=80804050138
1730	78218,True,https://www.anvisa.gov.br/sistec/alerta/RelatorioAlerta.asp?NomeColuna=Ds_Produto&Parametro=80804050154
1731	78265,True,https://www.anvisa.gov.br/sistec/alerta/RelatorioAlerta.asp?NomeColuna=Ds_Produto&Parametro=80804050202
1732	78314,True,https://www.anvisa.gov.br/sistec/alerta/RelatorioAlerta.asp?NomeColuna=Ds_Produto&Parametro=80804050250
1733	78430,True,https://www.anvisa.gov.br/sistec/alerta/RelatorioAlerta.asp?NomeColuna=Ds_Produto&Parametro=80256170001
1734	78431,True,https://www.anvisa.gov.br/sistec/alerta/RelatorioAlerta.asp?NomeColuna=Ds_Produto&Parametro=80256170002
1735	78536,True,https://www.anvisa.gov.br/sistec/alerta/RelatorioAlerta.asp?NomeColuna=Ds_Produto&Parametro=80312270010
1736	

The time it took for this algorithm to check the entire universe registered with ANVISA was approximately 21.64 minutes, as shown in figure VII with the following configurations: a 300 Mb internet in optical fiber; a notebook with 127 SSD memory; 8G RAM and memory; 64-bit Python version 3.9.4.

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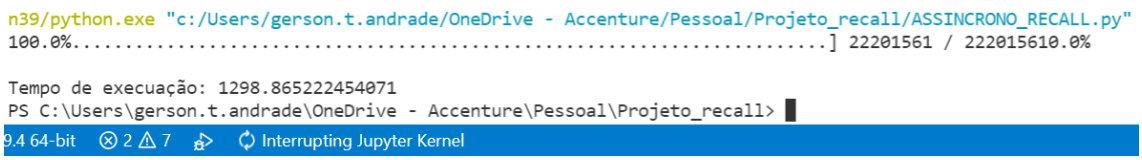
Figure VII – Algorithm processing time in the Total Universe of Medical Device Registration at ANVISA on the SISTEC server in search of alerts generated by Technovigilance



We know that an EAS has only a fraction of the Medical Devices registered with ANVISA and that in Brazil the only standard that enables the tracking of Medical Devices in a unified and efficient way is the Registration Number that is already available to the user when making the purchase.

CONCLUSION

The healthcare industry has many organizations that have developed specifications and standards to support health informatics, information exchange, systems integration, and a broad spectrum of healthcare applications.

Due to the sensitivity of information in health systems, a huge collection of terms and concepts to achieve interoperability between health systems is the great challenge in most domains. In addition, the rising cost of healthcare has been the driving force to put a lot of efforts in this domain to define standardization processes.

The bibliographic searches indicated important issues about the development of a resilient ecosystem aiming at the clear visibility of information on recall of products, inputs and services in health that can affect business and community behavior in terms of risk reduction.

It was observed the availability of a large volume of raw data available about the recall of various Health Products in the competent bodies, which makes the proposal of the platform in question feasible and, with an initial focus only on the data obtained by ANVISA, we could carry out such a platform. This data is easily accessible through scanning and data transformation algorithms to support decision-making with various sectors in health risk management.

The availability of information via a platform accessible to the community in real time will allow agility, flexibility and innovation for the health sector, which is the main purpose of this project.

For in the healthcare domain, most project integrations aim to use healthcare standards to achieve interoperability.

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In the search for understanding with professionals in the area, it will be through the questionnaire that was applied resulted in real identification of the need and feasibility of the Risk Management platform in Health Products.

A larger part of this process requires understanding the legacy system of data and services and which services and terms can be mapped to. This opens up a new avenue for researchers in the reverse engineering community to develop the processes and workflows to address the problems of migrating to new platforms and reengineering legacy systems in the context of standard concepts and operations.

Therefore, any new attempt at interoperability between legacy healthcare systems must conform to standards to ensure their compatibility and maintenance and evolution in the future.

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ISSN: 2358-2472

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